K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 97th "Institutional Ethics Committee" Meeting was held on 12th July, 2019

K.G's Medical University, U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 97th "Institutional Ethics Committee" Meeting was held on 12th July, 2019

Item no. IA

Action Taken

K.G's Medical University, U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 97th ECM held on 12th July, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

Minutes of the ***"Institutional Ethics Committee"*** Meeting was held on **12th July, 2019 from 2.00 p.m. onwards** in the **'Board Room'**, Office of the Vice Chancellor, Administrative Block of this University.

The following members were present in the Meeting

1- Prof.S.P. S Gaur	*-Chairman*
2- Dr. Surajit Bhattacharya	*-Member*
3- Dr. Vimal Kumar Paliwal	*-Member*
4- Prof. Amita Jain	*-Member*
5- Prof. Rajendra Nath	*-Member*
6- Prof. A.A. Sonkar	*-Member*
7- Prof. Anoop Kumar Verma	*-Member*
8- Prof. Rajeev Garg	*-Member*
9- Prof. Balendra Pratap Singh	*- Member*
10- Prof. R. K. Garg	*-Member-Secretary, Ex-officio*

The following Members were not present:

1- Justice Hin'ble Vishnu Sahai	*- Member*
2- Dr. Manju Agrawal	*-Member*
3- Mr. Ram Niwas Jain	*-Member*
4- Dr. Preeti Agarwal	*-Member*

Chairperson, IEC
King George's Medical University
U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 97th ECM held on 12th July, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

I. (A) Action taken

IA	Action Taken on decisions of previous Ethics Committee Meeting
	Part (a) 91st ECM
a1	Clarification of research proposal entitled ***"Effect of magnesium sulphate as an additive to spinal anaesthesia in pre-eclampsia patients undergoing lower segment caesarean section: A randomized control trial"*** submitted by Dr. Vijay Bahadur JR-II, Department of Anaesthesiology of this University via letter no. nil dated 18-05-18. **EC Comment on 3rd August, 2018:** • This RCT involves intrathecal Mg injection with anesthesia. • Investigatotrs claim no side effect; however a new born and mothers in put eclampsia are the study population. • 70 patients of pre eclampsia will be targeted; through calculated sample size is 60. • CONSORT guidelines are not followed. • Data score sheet for measuring pain is to be provided. • Variable under study need to be listed. **EC Decision on 3rd August, 2018:** Revise & Re-submit ***The above clarification was forwarded to Dr. Amita Jain, reply received from Dr. Jain with following comments:*** • ***Consort is yet not followed. This is RCT should be allow. At one point investigator mention that no harm has been reported by using Mg. while and additive record its efficacy & this is for MD thesis.*** *The above comment send to the P.I. reponse received from P.I. which is again forwarded to you for your kind review, reply received from Dr. Jain & approved.* **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 91stII B-Thesis/P3*** ***(Primary Reviewer : Dr. Amita Jain)***
	Part (b) 92nd ECM
b1	Clarification of research proposal entitled ***"A prospective study of orbital floor reconstruction"*** submitted by Dr. Sneha Gupta, JRI, Department of Oral and Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. nil dated nil.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment on 14th September, 2018: • There too many variable so, sample sizes seem to be low. **EC Decision on 14th September, 2018:** Approval after justification ***The aboe comment forwarded to the P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 92nd ECM II B-Thesis/P9*** ***(Primary Reviewer: Dr. S.P.S. Gaur)***
	Part (c) 93rd ECM
c1	Clarification of research proposal entitled ***"Nanostring nCounter based screening for molecular typing and target based therapeutics of TNBC in the Indian population"*** sponsored by C.S.I.R., New Delhi submitted by Dr. Neetu Singh, Associate Professor, Department of Molecular Biology Unit, Center for Advance Research of this University by via letter no. CFAR/2018/176 dated 30th August, 2018. **EC Comment on 2nd November, 2018:** • Applicant is moving on to next step of validation as if she knows the answer to research question? • Primary objective is not defined. • Was Nano string, Ncounter used in previously studies? • If yes then review of literature is not appended? **EC Decision on 2nd November, 2018:** Provisionally approved ***The above proposal was already Provisionally approved in the last meeting.*** **EC Decision:** Approved ***Ref. code: 93rd ECM II A/P5*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
c2	Clarification of research proposal entitled ***"Comparison of routine versus high dose antisnake venom in critically ill neurotoxic snake bite patients"*** submitted by Prof. Avinash Agrawal, Department of Critical Care Medicine of this University via letter no. nil dated nil. **EC Comment 2nd November, 2018:** • Point No. 8 Interaction is written in past tense as if the study has already been done. • Sample size – 50 disease samples and 50 age sex matched normal control. Was a statistician consulted to arrive at this sample size?

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Data collection chart has not been included. What will be observed, over how long period of time in the two groups? • Have we assured the clinical safety of high dose of anti-snake venom? Where is the background literature and bibliography to support it? • Kindly submit as per CONSORT guidelines **EC Decision 2nd November, 2018:** Approval after justification ***Dr. Anoop Kumar Verma did not take part in the discussion*** ***The above comment forwarded to P.I. reply has given by P.I. which was forwarded to Dr. Surajit Bhattacharya, reply received from Dr. Bhattacharya with following comment.*** ***Comment:-*** ***In the first 6 months all patients will receive low dose ASV and in the next 6 months high dose. This is a bad study model. Snakes are seasonal and different types of snakes come out at different time of the year. Snakes are most active in the spring and autumn. Some snake species are highly seasonal in their activity; others are active all during the warm season, so this study design will not work. Both the limbs of the study have to be started simultaneously.*** ***Reply received from Dr. Avinash Agarwal which was forwarded to Dr. Surajit Bhattacharya, Response has given byDr. Bhattacharya & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 93rdECM II A/P17*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
c3	Clarification of research proposal entitled ***"A study of Paediatric tuberculosis cases in Lucknow"*** submitted by Dr. Ambrish Kumar Rai, JR-II, Department of Community Medicine & Public Health of this University via letter no. nil dated nil. **EC Comment on 10th May, 2019:** • Provide clear aim with objectives • Describe methods clarification on the title. • It is too "non-descriptive" • No CRF attached **EC Decision on 10th May, 2019:** Revise & Re-submit ***The aboe comment forwarded to the P.I. which was forwarded to Dr. Amita Jain, reply has given by Dr. Jain & approved.*** **ActionTaken:** Provisionally approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 93rd ECM II B-Thesis/P38*** ***(Primary Reviewer: Dr. Amita Jain)***
	Part (d) 95th ECM
d1	Clarification of research proposal entitled **"*Prosthetic satisfaction and body image among lower limb amputee of north Indian population*"** submitted by Dr. Sudhir Mishra, Assistant Professor, Department of Physical Medicine & Rehabilitation of this University by via letter no. 1235/18 dated 22nd November, 2018. **EC Comment on 22nd February, 2019:** • Title to be revised. It is Northern India and not North India. North Korea and South Korea, North Sudan and South Sudan are independent countries and hence their name is thus. Northern India is a part of India • The review of literature has no reference from this millennium. In the last two decades lower limb prosthesis have undergone quantum improvement and so a better and more recent literature review is needed • Objective is clear. Inclusion and exclusion criteria are acceptable • Why are patients using their prosthesis intermittently excluded? The prosthesis obviously did not improve their quality of life otherwise they would have used it regularly • It is a cross-sectional study • Sample size is derived statistically • Data collection sheet is very elaborate and thorough–clinic-demographic data, Revised Trinity Amputation and Prosthesis Experience Scale and Amputee Body Image Scale are in it. **EC Decision on 22nd February, 2019:** Approved after justification ***The above comment forwarded to P.I. reply has given by P.I. which was forwarded to Dr. Surajit Bhattacharya, reply received from Dr. Bhattacharya with following comment.*** ***Comment:-*** • ***Medical or surgical problem in the stump needs further clarification. As I understand, once the prosthesis has been fitted and then the amputee stops using it, it is a prosthesis failure. These patients have to be included and labeled failures otherwise we are planning to manufacture favorable results.*** ***The above comment forwarded to P.I. via letter no.843/Ethics/19 dated7th June, 2019,reply has not provided from Dr. Sudhir Mishra. Reply pending from P.I.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	ActionTaken: None **EC Decision:** Pending ***Ref. code: 95th ECM II A/P2*** ***(Primary Reviewer: Dr.Surajit Bhattacharya)***
d2	Clarification of research proposal entitled ***"Success, survival and satisfaction for implant supported prosthesis in anterior region: a retrospective cross-sectional study"*** submitted by Prof. Pooran Chand, Head, Department of Prosthodontics, Faculty of Dental Sciences of this University by via letter no. nil dated. 10th January, 2019. **EC Comment on 22nd February, 2019:** Kindly clarify about study design: • As this the design of study is retrospective, have to taken the data (questionnaire) already with the consent of the patients? • How many years' retrospective data you will include in the study? • Kindly attach complete record sheet which will be used in this study. **EC Decision on 22nd February, 2019:** Approval after justification ***The aboe comment forwarded to the P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 95th ECM II A/P19*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
d3	Clarification of research proposal entitled ***"Demographic profile, etiology, clinical presentation and prognosis in patients with pericardial effusion in a tertiary care centre, north India"*** submitted by Dr. Akshyaya Pradhan. Associate Professor, Department of Cardiology of this University by via letter no. nil dated 12th January, 2019. **EC Comment on 22nd February, 2019:** • The study seems to be already over, if no, please tell when will first patient is this likely to be enrolled? **EC Decision on 22nd February, 2019: Not approved** ***The aboe comment forwarded to the P.I. reply has given by P.I.which was forwarded to Dr. Amita Jain, reply has given by Dr. Jain & approved.*** **ActionTaken:** Provisionally approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 95th ECM II A/P23*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
d4	Clarification of research proposal entitled ***"Urodynamic study in spinal cord injury patients- a cress sectional study"*** submitted by Dr. Chandan Sharma, JR-II, Department of Physical Medicine & Rehabilitation of this University via letter no. nil dated 26th November, 2018. **EC Comment on 22nd February, 2019:** • Study duration is not mentioned • When will first patient be enrolled in your study? **Study Design:-** • It is not a cross sectional study as mentioned in protocol. **Sample size:** • Arbitrary sample size is not acceptable for cross sectional study. • As suggestion is to redescible the protocols disenptive study. A sample size calculation may not be of much importance for descriptive studies. • Lot of data is proposed to be collected. What will be done with data plan for data analyesed is not mentioned, Include **EC Decision on 22nd February, 2019: Revise & Re-submit** ***The aboe comment forwarded to the P.I. reply has given by P.I. which was forwarded to Dr. Amita Jain, reply has given by Dr. Jain with following comment:*** ***Please re-submit the whole revised protocol.*** ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by Dr. R. K. Garg & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 95th ECM II B-Thesis/P2*** ***(Primary Reviewer:Dr. Amita Jain)***
d5	Clarification of research proposal entitled ***"To study prevalence and association of microalbuminuria in chronic obstructive pulmonary disease patients"*** submitted by Dr. Mudit Kotwal, JR-II, Department of Medicine of this University via letter no. nil dated 28th November, 2018. **EC Comment on 22nd February, 2019:** Study duration is not mentioned. • When will first patient be enrolled in your study?

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision on 22nd February, 2019: Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by Dr. R. K. Garg & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 95th ECM II B-Thesis/P9*** ***(Primary Reviewer: Dr. Rajeev Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

d6	Research proposal entitled ***"Prevalence of diabetes in chronic obstructive pulmonary patients"*** submitted by Dr. Ajay Kumar Verma, Associate Professor, Department of Respiratory Medicine of this University by via letter no. nil dated. 22nd November, 2018. **EC Comment:** • People with Diabetes have 22% increase risk of COPD and people with COPD have 40-50% increase incidence of diabetes • The objective is to study the prevalence of Diabetes in patients with COPD and to correlate the diabetes with the severity of COPD. A third objective is to assess the influence of tobacco smoking, solid fuel combustion and air pollution in patients of COPD with diabetes • It is a prospective observational study • Sample size is not mentioned; need to take the help of a statistician to derive the same. • Data collection form and patient questionnaire has not been provided and so we know nothing about the study **EC Decision:** Re-submit ***The aboe comment forwarded to P.I., reply has given by P.I. which was forwarded to Dr. Surajit Bhattacarya, response received from Dr. Bhattacharya with following comment:*** • ***Sample size is not mentioned; need to take the help of a statistician to derive the same.*** • ***Data collection form and patient questionnaire has not been provided and so we know nothing about the study.*** ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by Dr. R. K. Garg & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 95thECM II A/P10*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
d7	Clarification of research proposal entitled ***"Utility of soluble LOX 1 levels in risk assessment of patients of acute coronary syndromes/CAD"*** submitted by Dr. Sandeep Kumar, JR-II, Department of Pathology of this University via letter no. nil dated 21st November, 2018. **EC Comment on 22nd February, 2019:** **Study duration**: September, 2018 till Augsut, 2019

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• When will be first patient enrolled in your study? • PI/Guide should focus on type of study/Methodology. The Hypothesis state "Risk assessment" risk of what? Is not described? • How the risk will be assessed? • Cross sectional design is not used for risk assessment **EC Decision on 22nd February, 2019:** Approval after justification ***The aboe comment forwarded to P.I., reply has given by P.I. which was forwarded to Dr. Amita Jain response received from Dr. Jain with following comment:*** **Comment:** • Subjects are already enrolled, without ethical clearance? • Thesis title and study type, both are changed including aim & objectives. • Revised protocol should be submitted. ***The above comment forwarded to P.I.reply has not given by P.I.*** **Action Taken:** None **EC Decision:** Pending ***Ref. code: 95th ECM II B-Thesis/P13*** ***(Primary Reviewer: Dr. Amita Jain)***
d8	Clarification of research proposal entitled ***"Role of topical corticosteroid in healing of chronic ulcers"*** submitted by Dr. Nikhil, SR-II, Department of Plastic Surgery of this University via letter no. nil dated 14th November, 2018. **EC Comment on 22nd February, 2019:** **Study duration:** October, 2018-November, 2019 • When will first patient be enrolled in your study? • Sample size calculation needed. **EC Decision on 22nd February, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by Dr. R. K. Garg & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 95th ECM II B-Thesis/P31*** ***(Primary Reviewer:Dr. Rajendra Nath)***
d9	Clarification of research proposal entitled ***"A randomized control study to compare the outcomes in the patients of chronic venous insufficiency receiving micronized purified flavonoid fraction (MPFF) before surgical intervention and patients not receiving micronized purified flavonoid fraction (MPFF)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	before surgical intervention" submitted by Dr. Harshal Verma, JR-II, Department of General Surgery of this University via letter no. nil dated 11th December, 2018. **EC Comment on 22nd February, 2019:** • Study duration one & half year. When will first patient beenrolled in your study? **EC Decision on 22nd February, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by Dr. R. K. Garg & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 95th ECM II B-Thesis/P35*** ***(Primary Reviewer:Dr. Balendra Pratap Singh)***
d10	Clarification of research proposal entitled ***"Correlation of statistical performance of colposcopic swede score with histopathological diagnosis of cervical lesions"*** submitted by Dr. Shruti Srivastava, JRII, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 5th January, 2019. **EC Comment on 22nd February, 2019:** **Study duration:** One year • When will first patient be enrolled in your study? **EC Decision on 22nd February, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by Dr. R. K. Garg & approved.*** **ActionTaken:** Provisionally approved EC Decision: Approved ***Ref. code: 95th ECM II B-Thesis/P44*** ***(Primary Reviewer:Dr. Amita Jain)***
d11	Clarification of research proposal entitled ***"Evaluation of the midfacial morphology of cleft palate patients among the Indian population and the effect of palatoplasty at different ages on midface growth"*** submitted by Dr. Harsh Shanishwara, SR-II, Department of Plastic Surgery of this University via letter no. nil dated 14th November, 2018. **EC Comment on 22nd February, 2019:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Study duration not mentioned. • When will first patient be enrolled in your study? **EC Decision on 22nd February, 2019**: Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by Dr. R. K. Garg & approved.*** ActionTaken: Provisionally approved EC Decision: Approved ***Ref. code: 95th ECM II B-Thesis/P46*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
d12	Clarification of research proposal entitled ***"A study of job satisfaction among nurses in a tertiary care government Hospital"*** submitted by Dr. Sandeep Manar, under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/037dated 8th January, 2019. **EC Comment on 10th May, 2019:** • Waiver can not be granted • Kindly submit full proposal **EC Decision on 10th May, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by Dr. R. K. Garg & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 95th ECM IIB MHA/P11*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
	Part (e) 96th ECM
e1	Clarification of research proposal entitled ***"Promoter methylation of DNA repair genes and correlation with treatment outcome in cervical cancer"*** submitted by Prof. Monisha Banerjee, Molecular and Himan Genetics Laboratory, Department of Zoology, Lucknow University, Lucknow sponsored by ICMR, New Delhi through Prof. Kirti Srivastava, Department of Radiotherapy of this University via letter no. nil dated 12th January, 2019. **EC Comment on 10th May, 2019:** • This is no justification to samole size • In consent form at place the potential funding agency is mentioned as ICMR-SRF scheme while at other it is DST. Hindi & English consent

Chairperson IEC
King George's Medical University
U.P., Lucknow

	forms are different. • Budget is not disclosed. **EC Decision on 10th May, 2019:** Approval after justification The aboe comment forwarded to P.I., reply has given by P.I. which was forwarded to Dr. Amita Jain response received from Dr. Jain & approved. **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II A/P1*** ***(Primary Reviewer: Dr. Amita Jain)***
e2	Clarification of research proposal entitled ***"Study of severity of airflow limitation in treated post- TB COPD subjects in India"*** submitted by Prof. Suryakant, Department of Respiratory Medicine of this University via letter no. nil dated 29th January, 2019. **EC Comment on 10th May, 2019:** • Sample size is written as 1000. Is it achievable in the study duration of 6 months? How the sample size calculated? • Methods are not provided. A detailed elaboration of methods needs to be provided. In patient information document, the authors claimed that they will use a questionnaire prepared by RRNI (?). What is RRNI? What is the role of RRNI in this study? No questionnaire is provided for review of ethics committee. • Patient information document in English and Hindi are grossly deficient. The headings like risk from the study, complication, compensation cannot be written as Nil. Things have to be described in some detail. How will the confidentiality be maintained? What are the rights of the patient? What if patients refuse to take part in the study? What are the alternatives? All these headings have to be described as it is an important part of informed consent. **EC Decision on 10th May, 2019:**Approval after justification ***The aboe comment forwarded to P.I., reply has given by P.I. which was forwarded to Dr. Vimla Kumar Paliwal, response has not received from Dr. Paliwal.*** **Action Taken:** • The answer to most of our comments are satisfactory, However, the PI will use a questionnaire provided by RRNI (Respiratory research Network of India) which the PI claims to be non-profit organisation. The participant information sheet and the questionnaire provided by PI has a study code published on the foot note of each page that mentions study number as RRNI/2017/10. Therefore, it is not clear whether it is an

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	investigator initiated study or a study funded by RRNI? Since, it is an observational cross-sectional study, no intervention is likely to be used. In my opinion, the ethical clearance may be granted if the above mentioned information is obtained from the PI. ***The above comment forwarded to P.I. response pending.*** **EC Decision:** Pending ***Ref. code: 96th ECM II A/P3*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
e3	Clarification of research proposal entitled ***"Quantitative analysis of TNF-α and TGF-β in serum and saliva of oral lichen planus patients"*** submitted by Dr. Akhilanand Chaurasia, Assistant Professor, Department of Oral Medicine and Radiology of this University via letter no. 118/OMR/19 dated 18th February, 2019. **EC Comment on 10th May, 2019:** • Primary objectives are not defined. • Self funding- What do you mean by that? **EC Decision on 10th May, 2019:**Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by Dr. R. K. Garg & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II A/P17*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
e4	Clarification of research proposal entitled ***"Identification and validation of gene signature profile to predict the recurrence and progression of urothelial cancer: a cohort study"*** sponsored by ICMR, New Delhi submitted by Prof. Vishwajeet Singh, Department of Urology of this University via letter no. nil dated 25th February, 2019. **EC Comment on 10th May, 2019:** • Kindly submit follow up plan as it is a cohort. It will help in validation of gene signatures to predict recurrence and progress in ***urothelial*** cancers. **EC Decision on 10th May, 2019:**Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was forwarded to Dr. Rajeev Garg, reponse received from Dr. Garg & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II A/P18*** ***(Primary Reviewer:Dr. Rajeev Garg)***

Chairperson IEC
King George's Medical University
U.P., Lucknow

e5	Clarification of research proposal entitled ***"To study epidemiology, clinical parameters, and inflammatory markers- clara cell protein-16, surfactant protein-D and matrix metalloproteinase-9 in chronic obstructive pulmonary disease"*** submitted by Dr. Ajay Kumar Verma, Department of Respiratory Medicine this University via letter no. nil dated 18th February, 2019. **EC Comment on 10th May, 2019:** • Budget is not disclosed: Who is going to fund this study? **EC Decision on 10th May, 2019:** Approval after justification • ***The above comment forwarded to P.I. response has given by P.I.which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II A/P26*** ***(Primary Reviewer:Dr. Amita Jain)***
e6	Clarification of research proposal entitled ***"Retrospective analysis of traumatic cervical spine injury patients: Our experience of last 5 Years"*** submitted by Dr. Amit Kumar Shrivastava, SR-II, Department of Neurosurgery of this University via letter no. nil dated 31st January, 2019. **EC Comment on 10th May, 2019:** • Consent waiver can only be granted if this is only Chart review and patient identity remain concealed. **EC Decision on 10th May, 2019:**Approval after justification ***The above comment send to P.I. reply has given by P.I. which was forwarded to Dr. Vimal Kumar Plaiwal, response received by Dr. Paliwal.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
e7	Clarification of research proposal entitled ***"A Comparative study of pigtail catheter v/s malecot chest tube insertion in the management of empyema thoracis"*** submitted by Dr. Vignesh K, JRII, Department of Respiratory Medicine of this University via letter no. nil dated 11th February, 2019. **EC Comment on 10th May, 2019:** • The study hypothesizes that the pigtail catheter is better than malecot catheter in the management of empyema thoracis in terms of efficacy,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	radiological improvement, duration of hospital stay and patient mobility after tube insertion. • When the title says that the subjects will be those who have Empyema Thoracis, then why do the inclusion criteria include Hydropneumothorax? The effulent in pyothorax and empyema is more viscid and so why add the variable of the the relatively less viscid effluent of hydropneumothorax? The radiological recovery is also different in these two sets of patients. So, either change the title or remove hydropneumothorax from your inclusion criteria. • Sample size is 50 in each group. Was it statistically calculated? Please show the calculations. • What will be studies in these two groups drained by pigtail or malecot is not mentioned. We need a data collection sheet which should have the demographic details, details of his disease, details offered by the physician like ease of insertion / retrieval, time taken etc. and responses obtained from the patient like pain (measured on a pain scale), ease of mobility from 0 to 5, requirement of pain killers, comfort during catheter retrieval. • Radiological improvement and duration of hospitalization too should find a place in the form. • Ideally, it should be in form of RCT **EC Decision on 10th May, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.*** **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P4*** ***(Primary Reviewer: Dr. Surajit Bhattachrya)***
e8	Clarification of research proposal entitled ***"The effect of duration of preoperative biliary stenting on postoperative outcomes after pancreaticoduodenectomy"*** submitted by Dr. Nitin Kumar, SR-II, Department of Surgical Gastroenterology of this University via letter no. nil dated 2nd June, 2018. **EC Comment on 10th May, 2019:** • It is a retrospective study. Please remove the word prospective and retrospective cohort study. • The study duration is written as June 2009 to August 2019. The duration of retrospective study cannot exceed the date of application for ethical clearance. • The methods of collection of retrospective data is not mentioned for example: manual collection from the discharge summaries or by using certain key words in the hospital information system (computerized system)

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	• In the methods section, the "preoperative evaluation and perioperative management", "procedure" is not required. The type of data that the PI intends to collect from the hospital records should be elaborated in this section. The PI should enlist the data that is needed to compare between the pre-operative short-duration and long-duration biliary stent. • The PI should add in the methods that the missing data of the patient in the hospital records will be telephonically enquired from the patients. • Do the PI have records of follow-up stored in the computerized hospital records? How will the follow-up data be collected? • How the PI intends to collect mortality data especially in patients with out-of- hospital mortality? • The project is written in past tense as if the study has already been done. • The patient information document is filled as if it is an interventional prospective study. **EC Decision on 10th May, 2019:** Revise & Re-submit ***The above comment sent to P.I. reply has given by P.I. wich was forwarded to Dr. Vimla Kumar Paliwal, reply received from Dr. Paliwal with following comment:*** • ***The explanations provided by Dr. Nitin Kumar are incomplete. Please provide a point wise "answer to reviewer's comments" with mentionin the page number and paragraph where the PI has made the corrections.*** ***The above comment again send to P.I.reply has provided by P.I. which wa reviewed by Dr. R.K. Garg, Membe-Secretary, IEC.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P8*** ***(Primary Reviewer: Dr.Vimal Kumar Paliwal)***
e9	Clarification of research proposal entitled ***"Comparative study between conventional Vs3 DCRT for early and late toxicities in locally advanced inoperable Head and Neck squamous cell carcinoma"*** submitted by Dr. Surya Kumar Shukla, JR-II, Department of Radiotherapy of this University via letter no. nil dated 6th March, 2019. **EC Comment on 10th May, 2019:** • Study type: Prospective or retrospective study? If prospective, how can a study start in retrospect (1st August 2018 to 31st July 2019)? If retrospective, how can the duration of data collection exceed the date of application for ethical clearance? "Patients enrolled in the study 25th September 2018"- The enrolment of patients into the study cannot be done without taking ethical clearance for the study. • We can only presume that the study is a prospective interventional study with two arms that compares two ways of administering the radiotherapy in head and neck malignancy. This has to be clearly stated in the methods of the study. • In the inclusion criteria please spell out KPS. • Which randomization method will be used to offer either of the radiotherapy method? • Is any of the two radiotherapy methods proposed for this study is a standard of care? If

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	yes, then PI has to give justification of using the other method for the purpose of study. • The sample size estimation appears incorrect. The expected drop out % of study subjects are required to be added to the estimated study population. Here, the PI assumed a dropout rate of 25% which needs to be added to the estimated sample size. In my view, the PI can take the help of a biostatistician for sample size calculation. • The patient information document needs to be filled properly. In the "study procedure" the PI should inform the patient regarding the two methods of radiotherapy. The pros and cons of the either method of radiotherapy should be disclosed to the patient. The patient should be informed why he or she is chosen for the particular radiotherapy method. The complications of the either method should be discussed in the complication method. Compensation should be discussed. • Patient's performa is not provided. **EC Decision on 10th May, 2019:**Re-submit ***The above comment sent to P.I. reply has given by P.I. wich was forwarded to Dr. Vimla Kumar Paliwal, reply received from Dr. Paliwal with following comment:*** **There are following issues:** **1. The answer to first question is not clear.** **2. Simple randomisation 1;1 will not achieve randomisation. How will 1:1 randomisation be achieved. For example by flipping the coin, by computer-generated randomisation chart, or any other method?** **3. Are both methods of delivering radiotherapy namely - conventional method and 3DCRT method standard of care?** **4. Are there no complications known secondary to either of the radiotherapy method? Is Cisplatin entirely safe? The possible complications of the treatments have to be discussed.** **5. PI should discuss the compensation if any patient in the study becomes sick secondary to study treatments and chose to go to court for compensation for physical and psychological harm. These points should not be ignored and they are meant to safeguard the PI.** ***The above comment sent to P.I. reply has given by P.I.*** **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P10*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
e10	Research proposal entitled ***"Treatment outcome in patients of head and neck cancer who are poor metaboliser of cytochrome P450 0A6 enzyme"*** submitted by Dr. Deepa Aggarwal, JR-II, Department of Radiotherapy of this University via letter no. nil dated 1st January, 2019. **EC Comment on 10th May, 2019:** • How will the treatment outcome be measured? **EC Decision on 10th May, 2019:**Re-submit ***The above comment send to P.I. reply has given by P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved

Chairperson IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 96th ECM II B-Thesis/P11*** ***(Primary Reviewer: Dr. Amita Jain)***
e11	Clarification of research proposal entitled ***"Comparative study between conventional fractionated radiotherapy versus hypofractionated radiotherapy in carcinoma breast patients undergoing mastectomy"*** submitted by Dr. Vijay Arora, JR-II, Department of Radiotherapy of this University via letter no. nil dated 6th January, 2019. **EC Comment on 10th May, 2019:** • It should be in form of CONSORT guidelines **EC Decision on 10th May, 2019:** Approval afer justification ***The above comment send to P.I. reply has given by P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P12*** ***(Primary Reviewer: Dr. Rajeev Garg)***
e12	Clarification of research proposal entitled ***"Association of uric acid with anthropometric parameters and insulin resistance I prediabetics and diabetics"*** submitted by Dr. Shivam Verma, JR-I, Department of Physiology of this University via letter no. nil dated 3rd April, 2019. **EC Comment on 10th May, 2019:** • Case and control group inclusion & exclusion Criteria not difined. • Prediabetic & Diabetic must be defined in mathodology **EC Decision on 10th May, 2019:** Revise and Re-submit ***The above comment send to P.I. reply has given by P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P19*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
e13	Clarification of research proposal entitled ***"Analysis of CSF diversion in management of pediatric TBM hydrocephalus: A prospective and retrospective study"*** submitted by Dr. Anoop Kumar Jaiswal, SR-II, Department of Neurosurgery of this University via letter no. nil dated nil. **EC Comment on 10th May, 2019:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

- This is a retrospective study and not a prospective study. So, kindly change the title to retrospective study.
- The AIM no. 3 is self sufficient and will also cover the AIM 1 and 2. So, to compare the outcome of patients undergoing ETV versus shunt will include the demographic and clinical profile of these patients and also the complications of shunt and ETV.
- Rest all other points written in the "aims and objectives" should be written in the "methods" section.
- The PI had written that the study duration will be from July 2011 to November 2019. A retrospective study duration cannot exceed the date of application for ethical approval. The PI also writes that the duration of prospective study will be from December 2016 to November 2019. A prospective study cannot enroll any patient before the date of ethical approval. Therefore, it is advisable to keep this study retrospective and keep the duration from any date till April 2019 and not beyond.
- Study design says that once the patient's parameters are collected, the patients will be randomized to either of the procedures. This is not possible for a retrospective study. So, the PI needs to rewrite the methods.
- The follow-up is written in future tense. Follow-up details of the patients in a retrospective study has to be gathered from the patient's registry if that was maintained by the concerned department.
- If the PI plans a prospective study, then it can only be a randomized open-label study to compare the outcome in TBM patients undergoing ETV versus shunt for the treatment of hydrocephalus.
- Patient information document has to be re written in detail regarding the study procedure, type of study, benefits from the study, complications and compensation after the PI decide which type of study they plan to do.
- Patient's performa is required to be submitted with the study proposal.

EC Decision on 10th May, 2019: Re-submit

The above comment forwarded to the Principal-Investigator of the proposal, reply has given by the P.I.which was forwarded to Dr. Vimal Kumar Paliwal, after review Dr. Paliwal he has given following comments:-

- The aims have not been modified,
- 2. Will the css examination be done prospectively?
- 3. Will the follow-up of patients be done prospectively or the follow-up details will be collected from the old records like case files etc?

Reply has not given by P.I.

EC Decision: Pending

Ref. code: 96th ECM II B-Thesis/P20

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Vimal Kumar Paliwal)
e14	Clarification of research proposal entitled ***"Assessment of sleep quality in patients with Gastroesophageal reflux disease"*** submitted by Dr. Umesh Kumar Mishra, JR-I, Department of Physiology of this University via letter no. nil dated nil. **EC Comment on 10th May, 2019:** • Methodology should be explained in detail **EC Decision on 10th May, 2019**: Re-submit ***The above comment send to P.I. reply has given by P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P22*** ***(Primary Reviewer: Dr. Rajendra Nath)***
e15	Clarification of research proposal entitled ***"Heart rate variability in chronic renal failure"*** submitted by Dr. Raveesh Narain Agarwal, JR-I, Department of Physiology of this University via letter no. nil dated 3rd April, 2019. **EC Comment on 10th May, 2019:** • As it is case control study No mention has been made about controls in **Methodology**. • The other issue is, Investigator wants to assess the association of HRV withk mortality in one-year does not seem feasible. **EC Decision on 10th May, 2019:** Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was forwarded to Dr. Rajeev Garg, reponse received from Dr. Garg & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P23*** ***(Primary Reviewer: Dr. Rajeev Agarwal)***
e16	Clarification of research proposal entitled ***"Circadian variation in spirometric parameters and correlation with salivary cortisol level among apparently healthy adults"*** submitted by Dr. Tanuj Mathur, JR-I, Department of Physiology of this University via letter no. nil dated 4th April, 2019. **EC Comment on 10th May, 2019:** • Change study design-from case control to observational study • Define apparently healthy.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision on 10th May, 2019: Approval after justification ***The above comment send to P.I. reply has given by P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P24*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
e17	Clarification of research proposal entitled ***"A comparative study on association of salivary and serum cytokines (IL-1β, IL-4,IL-6, IL-8, TNF-α)in potentially malignant disorders and Oral Cancer Patients"*** submitted by Prof. Shaleen Chandra, Department of Oral Pathology and Microbiology, faculty of Dental Sciences of this University via letter no. 705/Oral/Path/19 dated 2nd February, 2019. **EC Comment on 10th May, 2019:** • They will compare serum & salivary cytokines in potentially naligment disorders and oral cancers patients. • Please clarify define your case i.e. whom would your label as potentially malignment disorders. • Committee is of view that no single person can do so many projects simultaneously. **EC Decision on 10th May, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was forwarded to Dr. Rajeev Garg, reponse received from Dr. Garg & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Committee is of view that no single person can do so many projects simultaneously. ***Ref. code: 96th ECM II A/P28*** ***(Primary Reviewer: Dr. Rajeev Garg)***
e18	Clarification of research proposal entitled ***"Comparison of heart rate variability between women with polycystic ovary syndrome and apparently healthy women"*** submitted by Dr. Ritu Tiwari, JR-I, Department of Physiology of this University via letter no. nil dated 4th April, 2019. **EC Comment on 10th May, 2019:** • Exclusion criteria not written clearly and separately **EC Decision on 10th May, 2019:** Approval after justification

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	The above comment send to P.I. reply has given by P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved. **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P33*** ***(Primary Reviewer: Dr. Rajendra Nath)***
e19	Clarification of research proposal entitled ***"Histopathological examination to assess the sause of death: A forensic boon?"*** submitted by Prof. Shaleen Chandra, Department of Oral Medicine, Faculty of Dental Sciences of this University via letter no. 714/Oral Path/19 dated 6th February, 2019. **EC Comment on 10th May, 2019:** • The objective is to demonstrate the features of decomposition at the cellular level in post mortem gingival tissue and to observe the different cellular changes due to varied causes of death like burns, strangulation, gunshot, poisoning and drowning. • Sample size is 60 – 10 in each category and 10 normal. • What will be done with this tissue – histology, histochemistry, ultrastructure are not clear. • The gingival tissue of a tobacco chewer will be different histologically, so how will the researchers define 'normal'? • The gingival histology will change with age and status of oral hygiene too! • We need a data collection form which should have the demographic details, the history of nature of death / illness or health before death, the examination of the oral cavity, the cause of death and the histological / histochemical / ultrastuuctural findings. • Consent form need to change – signature of patient needs to be omitted, he has already died. • The title needs to change, it does not tell anything about the research hypothesis – it should be 'Histological examination of gingival tissue to assess the cause of death'. • Committee is of view that no single person can do so many projects simultaneously. **EC Decision on 10th May, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was forwarded to Dr. Surajit Bhattacharya, reponse received from Dr. Bhattacharya which was forwarded to P.I. response pending from P.I.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	ActionTaken: None **EC Decision:** Pending , Committee is of view that no single person can do so many projects simultaneously. ***Ref. code: 96th ECM II A/P34*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
e20	Clarification of research proposal entitled ***"Estimation of Immunohistochemical expression and methylation status of USP22 and co expression of miRNA 101 through progression of disease from normal to epithelial dysplasia to malignancy"*** submitted by Prof. Shaleen Chandra, Department of Oral Medicine, Faculty of Dental Sciences this University via letter no. 713/Oral Path/19 dated 6th February, 2019. **EC Comment on 10th May, 2019:** • How will be consent taken? • Committee is of view that no single person can do so many projects simultaneously. **EC Decision on 10th May, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was forwarded to Dr. Rajeev Garg, reponse received from Dr. Garg & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Committee is of view that no single person can do so many projects simultaneously. ***Ref. code: 96th ECM II A/P36*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
e21	Clarification of research proposal entitled ***"Tongue morphology and aid for gender estimation"*** submitted by Prof. Shaleen Chandra, Department of Oral Pathology, Faculty of Dental Sciences this University via letter no. 715/oralpath/19 dated 6th April, 2019. **EC Comment on 10th May, 2019:** • Objective is to examine the uniqueness of tongue morphology and find out parameters to deduce the gender of an individual using the same. • Sample size is 200 – 100 males and 100 females. Only healthy subjects will be chosen. • Examination, photograph, alginate tongue impressions will be collected to create a database of tongue morphology. • A data collection sheet needs to be added which should tell us what

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	all will be observed – surface morphology, shape, presence or absence of fissures, their pattern, their distribution – central / vertical and their numbers – single / multiple / how many, whether deep or shallow. • What are your reference points to consider the shape of the tongue – U or V? I suggest 3 points – with tongue maximally protruded the two points of contact with angle of lips and the tongue tip. • Who all will observe the tongue impressions and the clinical photographs? Will you have a neutral observer, who has not taken the photographs or the impressions? • Why are you restricting yourself to gender estimation only? 200 is a big sample size and if you distribute it in 4 age groups you may find some changes that take place with age? • Committee is of view that no single person can do so many projects simultaneously. **EC Decision on 10th May, 2019:** Re-submit ***The above comment send to P.I. reply has provided by P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Committee is of view that no single person can do so many projects simultaneously. ***Ref. code: 96thECM II A/P41*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
e22	Clarification of research proposal entitled ***"Heart rate variability before and after moderate exercise I different body postures in young healthy adults"*** submitted by Dr. Abhishek Shukla, JR-I Department of Physiology of this University via letter no. nil dated 4th April, 2019. **EC Comment on 10th May, 2019:** • Study will be conducted on 1st year MBBS student, the Investigator did not mention clearly when he will perform study. It should not be conducted during teaching hours. MBBS student should not be pressurized to give consent. **EC Decision on 10th May, 2019:**Approval after justification **EC Decision:** Approved ***Ref. code: 96thECM II B-Thesis/P42*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

e23	Clarification of research proposal entitled ***"Association of sleep pattern with body mass index among young adults"*** submitted by Dr. Preeti Gupta, JR-I, Department of Physiology of this University via letter no. nil dated 4th April, 2019. **EC Comment on 10th May, 2019:** • When will the study/polyimmunography carried out • It is not a cross sectional study • Sample size calculation to be provided • Where patient will be asked to sleep? **EC Decision on 10th May, 2019:** Approval after justification ***The above comment send to P.I. reply has provided by P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P45*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
e24	Clarification of research proposal entitled ***"A study of malnourished Hospitalized children"*** submitted by Dr. Deependra Kumar Verma, JR-II, Department of Community Medicine & Public Health of this University via letter no. nil dated 4th April, 2019. **EC Comment on 10th May, 2019:** • Title is incomplete **EC Decision on 10th May, 2019:** Approval after justification ***The above comment send to P.I. reply has provided by P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **Revised title** ***"A clinic-epidemiological study of Malnourished children admitted in Nutrition Rehabilitation Centers"*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P54*** ***(Primary Reviewer: Dr. Rajeev Garg)***
e25	Clarification of research proposal entitled ***"Assessment of impact of varying the commandments of smile esthetics by q-sort methodology"*** submitted by Dr. Sweta Chaurasia, JR-I, Department of Orthodontics and Dentofacial Orthopaedics, Faculty of Dental Sciences of this University via letter no. 570/Ortho/19 dated 4th April, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment on 10th May, 2019: • Methodology should be explained clearly concerning the participants **EC Decision on 10th May, 2019:**Re-submit ***The above comment send to P.I. reply has provided by P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96thECM II B-Thesis/P57*** ***(Primary Reviewer: Dr. Rajendra Nath)***
e26	Clarification of research proposal entitled ***"CBCT evaluation of incisive canal and its relation to maxillary central incisors in different malocclusions"*** submitted by Dr. Lobsang Chhodon, JR-I, Department of Orthodontics and Dentofacial Orthopaedics, Faculty of Dental Sciences of this University via letter no. 571/Ortho/19 dated 4th April, 2019. **EC Comment on 10th May, 2019:** • CRF is not provided. How will you evaluate patient for inclusion in the study? **EC Decision on 10th May, 2019:**Approval after justification ***The above comment send to P.I. reply has provided by P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P59*** ***(Primary Reviewer: Dr. Amita Jain)***
e27	Clarification of research proposal entitled ***"Ultrasound as a tool for predicting mode of delivery after induction of labour in third trimester primigravida"*** submitted by Dr. Rupa Kumari, JR-I, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 5th April, 2019. **EC Comment on 10th May, 2019:** • The aims of the study say that the ultrasound will be used to predict the mode of delivery in primigravida. The expected modes of delivery are not discussed in the methods • Patient's performa needs to be submitted **EC Decision on 10th May, 2019:** Approval after justification ***The above comments send to P.I. response recieved from P.I. which was***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	forwarded to Dr. Vimal Kumar Paliwal reply recived by Dr. Paliwal & approved. **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P60*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
e28	Clarification of research proposal entitled ***"Validation of sepsis in obstetrics score (SOS) in obstetrics sepsis and its role in evaluation of morbidity and mortality"*** submitted by Dr. Nisha Rani Dwivedi, JR-I, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 5th April, 2019. **EC Comment on 10th May, 2019:** • Carelessely filled up Annexure 7 • Missing page of Annexure-1 • Sample size calculation not provided **EC Decision on 10th May, 2019:** Approval after justification ***The above comment send to P.I. reply has provided by P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96thECM II B-Thesis/P69*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
e29	Clarification of research proposal ***"Association of uric acid with anthropometric parameters and insulin resistance I prediabetics and diabetics"*** submitted by Dr. Shivam Verma, JR-I, Department of Physiology of this University. **EC Comment on 10th May, 2019:** Case and control group inclusion & exclusion Criteria not difined. Prediabetic & Diabetic must be defined in mathodology **EC Decision on 10th May, 2019:** Revise and Re-submit ***The above comment forwarded to P.I. response received from P.I. which was reviewed by Dr.R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P19*** ***(Primary Reviewer: Dr. Preeti Agarwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 97th "Institutional Ethics Committee" Meeting was held on 12th July, 2019

Item no. IIA

New Proposal

K.G's Medical University, U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 97th ECM held on 12th July, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

II-(A)	New Proposal
1-	Research proposal entitled "***To study the anatomy and function of left atrial appendage and its correlation with the incidence of left atrial and appendage thrombus formation in patients with rheumatic mitral stenosis***" submitted by Dr. Monika Bhandari, Associate Professor, Department of Cardiology of this University via letter no. 202/Cardio/Res/19 dated 30th January, 2019. **EC Comment :** 1. Sample size is calculated as 350. The formula used for sample size estimation does not mention how the figure of 350 is achieved. Kindly consult a statistician for calculation of sample size. Is it possible to include 350 patients with rheumatic MS in one year? 2. Patient information document is to be filled in detail. For example: complications of TEE have to be detailed to the patient. Risks from the study have to be outlined. Compensation has to be addressed. **EC Decision :** Approval after justification ***Ref. code: 97th ECM II A/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled "***Pediatric asthma presentations and risk factors in India***" sponsored by Cipla Foundation submitted by Dr. Sarika Gupta, Assistant Professor, Department of Pediatrics of this University via letter no. 522/Ped/19 dated 6th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II A/P2*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
3.	Research proposal entitled "***Association of serotonin transporter, RANK & RANKL gene polymorphisms with their circulatory levels, bone mineral density and biochemical markers in Indian postmenopausal women with and without osteoporosis***" sponsored by DHR KGMU & IMR of Era's Lucknow Medical College and Hospital, Lucknow submitted by Dr. Shah Waliullah, Assistant Professor, Department of Orthopaedic of this University via letter no. nil dated 18th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II A/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Research proposal entitled "***A study on evaluating the role of prad1/cyclin D1 as diagnostic and prognostic biomarker in Oral potentially malignant disorders and***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Oral squamous cell carcinoma*"** sponsored by ICMR, DST, CST, BIRAC, DHR submitted by Dr. Priyanka Singh, Assistant Professor, Department of Oral Pathology and Microbiology, Faculty of Dental Sciences of this University via letter no. nil dated 25th January, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II A/P4 ***(Primary Reviewer: Dr. Rajendra Nath)***
5.	**Move in IIB Ph.D./P1**
6.	Research proposal entitled ***"Study of neuronal autoantibody associated/coexisting with acute viral encephalitis in children, its clinical manifestation and outcome"*** sponsored by ICMR, submitted by Prof. Amita Jain, Head, Department of Microbiology of this University by via letter no. nil dated 2th May, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II A/P6*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
7.	Research proposal entitled ***"Impact of locally consumed tobacco products for general and specific carcinogenicity and screening of patients with oral pre cancer and cancer for polymorphism in DNA base excision repair genes"*** sponsored by ICMR, New Delhi submitted by Prof. Shadab Mohammad, Department of Oral and Maxillofacial Surgery, Faculty of D **EC Decision:** Approved ***Ref. code: 97th ECM II A/P7*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
8.	Research proposal entitled ***"To elucidate the role of a set of circulating micro RNAs(miR-23,, miR-133a, miR-27 and miR-30b) as potential biomarkers for osteoporosis"*** sponsored by Indian Council of Medical Research, Delhi, submitted by Prof. //rivastava, Department of Orthopaedic Surgery of this University via letter no. 66/P/OS/19 dated 2th May, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II A/P8*** ***(Primary Reviewer: Dr. Rajeev Garg)***
9.	Research proposal entitled ***"Assessment of oral precancerous lesion awareness among patients: A cross sectional study"*** submitted by Dr. Akhilanand Chaurasia, Assistant Professor, Department of Oral Medicine and Radiology of this University via letter no. nil dated 2th May, 2019. **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 97th ECM II A/P9
	(Primary Reviewer: Dr. Anoop Kumar Singh)
10.	Research proposal entitled "***A molecular and clinicopathological expression study on USP9X, MLL 4 and ARID 2 genes as markers of progression of oral precancer***" submitted by Prof. Shaleen Chandra, Head, Department of Oral Pathology and Microbiology of this University via letter no. 776/Oral/Path/19 dated 2th May, 2019. **EC Comment:** • How will you perform so many projects? Please explain • Committee is of view that no single person can do so many projects simultaneously. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II A/P10*** ***(Primary Reviewer: Dr. Amita Jain)***
11.	Research proposal entitled "***Isolation of mesenchymal stem cells from human adipose tissue and effect of modulation of the level of different epigenetic regulators on tri- lineage differentiation ex vivo***" sponsored by ICMR New Delhi submitted by Dr. Pramod Kumar Singh, Department of Stem Cell/ Cell Culture Unit Center for Advance Research of this University by via letter no. nil dated 1st May, 2019. **EC Decision:** Refer to **"Stem Cell Committee"** ***Ref. code: 97th ECM II A/P11*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
12.	Research proposal entitled "***Cascade screening of type2 diabetes mellitus and establishing genetic prevalence of the disorder in Lucknow (U.P)***"sponsored by U.P NHM submitted by Dr. Wahid Ali, Associate Professor, Department of Pathology of this University via letter no. nil dated 28th May, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II A/P12*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
13.	Research proposal entitled "***To assess the prevalence of vitamin D deficiency in School going children of Uttar Pradesh and to find its association with nutritional status, physical activity and cardiometabolic markers***" sponsored by DST (WOS-B) submitted by Prof. Shalini Gupta, Department of Oral Pathology Faculty of Dental Science of this University via letter no. nil dated 11th June, 2019. **EC Comment:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• How will you complete this large study of 2880 children without any specialist co-guides for nutritional status, physical activity and cardiometabolic markers? It seems to be a non- dental project. • Approval from government agency to visit the Basic Shiksha Parishad schools is necessary. Kindly attach relevant documents for this. **EC Decision:** Resubmit ***Ref. code: 97th ECM II A/P13*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
14.	Research proposal entitled "***CBCT based anthropometric measurements and cluster analysis of temporomandibular joints in North Indian population***" submitted by Dr. Vikram Khanna, Associate Professor, Department of Oral Medicine & Radiology Faculty of Dental Science of this University via letter no. 417/OM&R/19 dated 11th June, 2019. **EC Comment:** • Consent from Waiver can not be granted **EC Decision:** Approval after justification ***Ref. code: 97th ECM II A/P14*** ***(Primary Reviewer: Dr. Rajendra Nath)***
15.	Research proposal entitled "***Study of dental procedures as a risk factor for Hepatitis C virus transmission in our community***" submitted by Dr.Vikram Khanna, Associate Professor, Department of Oral Medicine & Radiology, Faculty of Dental Science of this University via letter no. 416/OM&R/19 dated 11th June, 2019. **EC Comment:** • Methodology did not cover the objectives to be achieved. Kindly explain in detail. • How do you evaluate dental procedure as risk factors for transmission of hepatitis C? • Kindly mention the NABL certified lab to test hepatitis C in your proposal. **EC Decision:** Resubmit ***Ref. code: 97th ECM II A/P15*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
16.	Research proposal entitled "***Association of methylenetetrahydrofolate reductase (MTHFR) C677T polymorphism in isolated hypospadias in eastern Uttar Pradesh population***" submitted by Dr. Archika Gupta, Associate Professor, Department of

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Pediatric Surgery of this University via letter no. 212/19/Pedsy dated 7th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II A/P16*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
17.	Research proposal entitled "***Effect of educational program on nurses' knowledge and skills about oral care in respiratory intensive care & critical care unit***" submitted by Dr. Ved Prakash, Associate Professor, Head, Department of Pulmonary & Critical Care Medicine of this University via letter no. nil dated 14th June, 2019. **EC Comment:** • Since the study will be performed on the Nurses posted on the respiratory ICU, the patient information document is not required. A participant information document (PID) is required that is meant to inform the participating nurses before obtaining their consent. Kindly fill the PID appropriately and submit. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II A/P17*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
18.	Research proposal entitled "***A study on association of exposure to particulate matter and susceptibility to cardiovascular diseases in North Indian population***" sponsored by CSIR-IITR, Lucknow submitted by Prof. S.K. Dwivedi, Department of Cardiology of this University via letter no. 461/Cardio/Res/19 dated 13th June, 2019 **EC Decision:** Approved ***Ref. code: 97th ECM II A/P18*** ***(Primary Reviewer: Dr. Amita Jain)***
19.	Research proposal entitled "***Oral care in respiratory intensive care unit & critical care unit to prevent the consequence of venitilator associated pneumonia and infection related deaths and to assess the status of nosocomial infection: A randomized, double blind, placebo controlled study***" submitted by Dr. Ved Prakash, Associate Professor, Department of Pulmonary & Critical Care Medicine of this University via letter no. nil dated 14th June, 2019. **EC Comment:** • How will the patients be randomized? • Is denying oral care to patients on ventilator, who comprise the Control group ethical? • Data collection sheet not provided • Consort guidelines not provided

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Ref. code: 97th ECM II A/P19*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
20.	Research proposal entitled "***Awareness of oral cancer: A questionnaire based study***" sponsored by DST, New Delhi submitted by Prof. Shaleen Chandra, Haed, Department of Oral Pathology, Faculty of Dental Sciences of this University via letter no. 830/Ordpth/19 dated 15th June, 2019. **EC Comment:** • Committee is of view that no single person can do so many projects simultaneously. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II A/P20*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
21.	Research proposal entitled "***Correlation of serum and salivary TPS with CK 18m RNA load in Oral squamous cell carcinoma***" sponsored by DST submitted by Prof. Shaleen Chandra, Head, Department of Oral Pathology, Faculty of Dental Sciences of this University via letter no. 831/Ordpth/19 dated 15th June, 2019. **EC Comment:** • There is doubt on study design. Is it cross sectiona/case-control/descriptive? It can not be cross sectional as memtioned. • Sample size is not calculated. A cross-sectional study can not be done without pre decided statistics. What is significant sample size? **Please clarifiy.** • Committee is of view that no single person can do so many projects simultaneously. **EC Decision:** Resubmit ***Ref. code: 97th ECM II A/P21*** ***(Primary Reviewer: Dr. Amita Jain)***
22.	Research proposal entitled "***Pattern of global DNA and histone methylation in normal, dysplastic and oral squamous cell carcinoma- An immunohistochemical study***" sponsored by DHR-MRU submitted by Prof. Shaleen Chandra, Haed, Department of Oral Pathology, Faculty of Dental Sciences of this University via letter no. 834/Ordpth/19 dated 15th June, 2019. **EC Comment:** • Committee is of view that no single person can do so many projects simultaneously. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II A/P22***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Balendra Pratap Singh)
23.	Research proposal entitled **"*Expression of cox-2,IL-10, TGF beta, smad4 in non-syndromic cleft lip and palate: an immunohistochemical study*"** sponsored by UP-CST, Lucknow submitted by Prof. Shaleen Chandra, Department of Oral Pathology, Faculty of Dental Sciences of this University via letter no. 835/Ordpth/19 dated 15th June, 2019. **EC Comment:** • Committee is of view that no single person can do so many projects simultaneously. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II A/P23*** ***(Primary Reviewer: Dr. Rajendra Nath)***
24.	Research proposal entitled **"*Comparison of tetrachromic VOF stain with routine H&E staining techniques for characterizingstromal soft and hard tissue components*"** submitted by Prof. Shaleen Chandra, Department of Oral Pathology, Faculty of Dental Sciences of this University via letter no. 833/Ordpth/19 dated 15th June, 2019. **EC Comment:** • The Members of the Ethics Committee of King Georg's Medical University, U.P., Lucknow **have expressed their concern about the number of proposals** submitted by you in the last two meetings. • Committee is of view that no single person can do so many projects simultaneously. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II A/P24*** ***(Primary Reviewer: Dr. Rajeev Garg)***
25.	Research proposal entitled **"*Dental age estimation by Radiographic methods: comparison of different proposed methods*"** submitted by Prof. Shaleen Chandra, Haed, Department of Oral Pathology, Faculty of Dental Sciences of this University via letter no. 832/Ordpth/19 dated 15th June, 2019. **EC Comment:** • The Members of the Ethics Committee of King Georg's Medical University, U.P., Lucknow **have expressed their concern about the number of proposals** submitted by you in the last two meetings. • Committee is of view that no single person can do so many projects simultaneously. • ***Besides the general comment these two comments pertaining to this propposal must be sent.*** We need a data collection sheet to understand what all will be observed and compared.

Chairperson, IEC
King George's Medical University

	It seems the patient will never be observed. So how do the researchers propose to know the actual date of birth? And if the patient is being observed then the sample comprises of 100 patients and not 100 OPGs. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II A/P25*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
26.	Research proposal entitled "***Detection of antibiotic resistance and virulence genes in isolates form ICU's***" submitted by Prof. Vimala Venkatesh, Department of Microbiology of this University via letter no. nil dated 14th June, 2019. **EC Decision:** Waiver from consent granted. ***Ref. code: 97th ECM II A/P26*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
27.	Research proposal entitled "***Accessing childhood cancer services in India (ACCESS INDIA) study***" submitted by Prof. Nishant Verma, Associate Professor, Department of Pediatrics of this University via letter no. nil dated 8th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II A/P27*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
28.	Research proposal entitled "***To study causes and clinical outcome of new onset renal failure in post- partum period: A prospective observational study***" sponsored by ICMR submitted by Dr. Medhavi Gautam, Assistant Professor, Department of Medicine of this University via letter no. nil dated 12th June, 2019. **EC Comment:** • Where investigators want to study this courses and clinical outcomes new onset renal failure in post partum period and also want to study the clinical criteria to predict the out come. For this only observational study, will not be sufficient, a control arm is also needed which will strengthen this study, so it requests change in study design rest is ok. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II A/P28*** ***(Primary Reviewer: Dr. Rajeev Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

29.	Research proposal entitled ***"Prospective injury surveillance of trauma admissions in largest North Indian teaching Hospital-A cross- sectional descriptive study"*** submitted by Prof. Haider Abbas, Head, Department of Emergency Medicine Trauma Centre of this University via letter no. nil dated 16th June, 2019. **EC Comment:** a. Standardized injury surveillance form is not attached. b. If the PI chose to follow the patients till they are discharged from the trauma center, then the study design will be prospective cohort study and not a cross-sectional study. c. Inclusion criteria say that patients with injury within 24-48 hours of presenting in emergency dept. will be included. The phrase does not make sense. It can either be 24 hours or 48 hours. d. Will the PI include all the consecutive patients that will fulfill the inclusion criteria? If yes, this needs to be clearly stated in the inclusion criteria. **EC Decision:** Resubmit ***Ref. code: 97th ECM II A/P29*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
30.	Research proposal entitled ***"Role of different triggers in precipitation of first ST segment elevation myocardial infarction: A case-crossover study"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology of this University via letter no. 468/Cardio/Res/19 dated 17th June, 2019. **EC Comment:** • Cross-over study design should be described in detail under methodology section. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II A/P30*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
31.	Research proposal entitled ***"Development and evaluation of artificial interlligence (AI) algorithms to interpret chest X-rays for presence of Pulmonary Tuberculosis"*** submitted by Prof. Rajiv Garg, Department of Respiratory Medicine of this University via letter no. 468/Cardio/Res/19 dated 17th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II A/P31*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

II-B	New Thesis-Resident
1.	Research proposal entitled ***"Study of surface area of exstrophy bladder plate in relation to surface area of anterior abdominal wall below the transtubercular line"*** submitted by Dr. Rahul Kumar Rai, SR-I, Department of Pediatric Surgery of this University via **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P1*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
2.	Research proposal entitled ***"Study on association of genetic mutations with resistance level of fluoroquinolones in multi- drug resistant mycobacterial tuberculosis"*** submitted by Dr. Deepti Jaiswar, JR-I, Department of Microbiology of this University **EC Decision:** Approved ***Dr. Amita Jain did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P2*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
3.	Research proposal entitled***"Multimodality imaging in mesenteric lymphadenopathy - in patients UPT 18 years of age"*** submitted by Dr. Naba Kumar Barman, JR-II, Department of Radiodiangosis of this University via letter no. nil dated 16th April, 2019. **EC Comment:** • The aims of the study do not match with the topic of the study. The incidence of mesenteric lymphadenopathy cannot be determined unless it is a population-based study. • When all consecutive patients with mesenteric lymphadenopathy on 64-slice CT are planned to be included, then the purpose of doing a multi-modality imaging in these patients is not justified. One can perform a study to compare the sensitivity/specificity of a particular diagnostic modality to determine the mesenteric lymphadenopathy but then, the project has to be re-written with specific aims and objectives to achieve so. • Sample size estimation needs to be done after finalizing the aims and methods of the study. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P3*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

4.	Research proposal entitled ***"Etiological spectrum of noncompressive cervical myeloradiculopathy"*** submitted by Dr. Nitesh Agarwal, JR-II, Department of Radiodiangosis of this University via letter no. nil dated 10th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P4*** ***(Primary Reviewer: Dr. Rajeev Garg)***
5.	Research proposal entitled ***"Renal neoplasm: A study of the diagnostic Implications of ultrastucture"*** submitted by Dr. Meha Gupta, JRI, Department of Pathology of this University via letter no. nil dated 9th April, 2019. **EC Comment:** • How the researcher will obtain ethical approval for old samples? • On page no 4 she has typed yes for point no 1. which should be NO **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P5*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
6.	Research proposal entitled ***"Biochemical modulator of endothelial cell function with special interest to nitric oxide (NO) and HDL associated pon-1, srb-1 level : a prospective case control study in coronary artery disease"*** submitted by Dr. Manish Kumar, JR-I, Department of Pathology of this University via letter no. nil dated 8th April, 2019. **EC Comment:** • For this thesis there are too many objectives. The aim is not clerly defined. • Thesis case control study does not difine cases & controles clearly. • Why control are included is not justified? • Sample size is not calculated. **EC Decision:** Revise-Resubmit ***Ref. code: 97th ECM II B-Thesis/P6*** ***(Primary Reviewer: Dr. Amita Jain)***
7.	Research proposal entitled ***"Validity of clinical tests and magnetic resonance imaging in ACL,PCL and meniscus injuries of knee"*** submitted by Dr. Atul Kumar Saroj, JR-I, Department of Orthopaedic Surgery of this University via letter no. nil dated 11th April, 2019. **EC Decision:** Approved ***Dr. Amita Jain & Dr. RK Garg did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P7*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

8.	Research proposal entitled ***"Evaluation of functional outcome of total hip replacement in tubercular arthritis hip"*** submitted by Dr. Ravindra Kumar Gupta, JR-I, Department of Orthopaedic Surgery of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • Objective is to evaluate the functional outcome of Tubercular arthritis of hip managed by THR in terms of Harris Hip Score, ESR and CRP levels at 6 weeks, 3, 6 and 9 months and to look for disease reactivation, loosening of implant and osteolysis in post operative phase. • Sample size is not mentioned. It is important to make the results statistically significant. • If your last follow up is at 9 months then the study duration cannot be 9 months. If you operate the last patient at 9 months then the study has to go on for 18 months at least! • A comprehensive data collection sheet is provided • Inclusion and exclusion criteria are satisfactory. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P8*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
9.	Research proposal entitled ***"A prospective and retrospective study for assessment of treatment outcome of ovarian cancer cases"*** submitted by Dr. Abhilasha Srivastava, JRI, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 10th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P9*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
10.	Research proposal entitled ***"Correlation of menstrual abnormalities (FIGO 2011) with endometrial pathology"*** submitted by Dr. Shefali Aggarwal, JR-I, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 9th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P10*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
11.	Research proposal entitled ***"Cytogenetic study in children with acute leukemia and its correlation with clinical presentation"*** submitted by Dr. Surendra Kumar

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Yadav, JR-I, Department of Anatomy of this University via letter no. nil dated 10th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P11*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
12.	Research proposal entitled ***"Serum cortisol and prolactin as biomarkers for severity of diabetic retinopathy at a tertiary care centre in K.G.M.U, U.P, Lucknow"*** submitted by Dr. Akshay Mohan, JR-I, Department of Ophthalmology of this University via letter no. nil dated 9th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P12*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
13.	Research proposal entitled ***"Central corneal thickness measurement for evaluation of outcome of optical penetrating keratoplasty at a tertiary care centre in northern India"*** submitted by Dr. Nayani Amrin Fatema Afzal Hussain, JR-I, Department of Ophthalmology of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • Kindly provide Patient's data sheet (performa). **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P13*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
14.	Research proposal entitled ***"Endothelial cell loss analysis in phacoemulsification versus small incision cataract surgery: A randomized study"*** submitted by Dr. Ritu Singh, JR-I, Department of Ophthalmology of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • Is this a surgical randomized double blind parallel group cataract surgery study? • How randomization will be done? • Is there any difference in the indications for both the methods, to be used? • How will you blind the doctor & the patient? • Both will know what is happening? • Follow Consort guidelines. **EC Decision:** Revised & Re-submit ***Ref. code: 97th ECM II B-Thesis/P14***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Amita Jain)
15.	Research proposal entitled ***"Effect of oral L-Arginine administration on menopausal problems"*** submitted by Dr. Monica Biakthanmawii, JR-I, Department of Physiology of this University via letter no. nil dated 10th April, 2019. **EC Comment:** It should be done accordance with CONSORT guidelines in guidance of a physician/ Gynecologist. **EC Decision:** Resubmit ***Ref. code: 97th ECM II B-Thesis/P15*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
16.	Research proposal entitled ***"Association of heart rate variability and C-reactive protein in patients with depression"*** submitted by Dr. Soni Singh, JR-I, Department of Physiology of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • The amount of blood to be drawn from the ante-cubital vein has to be informed to patients in patient information document. • The patient's data sheet is not attached. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P16*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
17.	Research proposal entitled ***"Impact of central obesity on ischemic heart disease"*** submitted by Dr. Mohd Rafiq, JR-I, Department of Physiology of this University via letter no. nil dated 15th April, 2019. **EC Comment:** • Kindly provide the Sample size **EC Decision:** Provisionally approved ***Ref. code: 97th ECM II B-Thesis/P17*** ***(Primary Reviewer: Dr. Rajendra Nath)***
18.	Research proposal entitled ***"Co-relation of hs- creactive protein levels with anthropometric parameters in obese/overweight adults"*** submitted by Dr. Neeraja Shukla, JR-I, Department of Physiology of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • No issues as far as methodology/Study design/Sample size is concerned, but it is not clear from where they will recruit patients. They have no collaborators in the Clinical department.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Ref. code: 97th ECM II B-Thesis/P18*** ***(Primary Reviewer: Dr. Rajeev Garg)***
19.	Research proposal entitled ***"Prospective interventional study of neoadjuvent temozolomide inpatients of inoperable supratentorial malignant gliomas"*** submitted by Dr. Suresh Kumar Jaiswal, SR-I, Department of Neurosurgery of this University via letter no. nil dated 10th March, 2019. **EC Comment:** • The objective is to analyze the improvement in patients of supra-tentorial glioma in terms of resectability, morbidity and mortality after neo-adjuvant chemotherapy with temozolomide • Sample size not provided • Data recording sheet not provided. We do not know what will be observed and when • How much drug will be given? When will it be given? What effects will be observed, when and how? • What side effects of this drug will be observed? • You will be comparing your results with which group of patients? Will you have a control group of patients who will not be receiving neo adjuvant chemotherapy? **EC Decision:** Re-submit ***Ref. code: 97th ECM II B-Thesis/P19*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
20.	Research proposal entitled ***"Neuropsychological and clinico- radiological analysis of children treated by CSF diversion for congenital hydrocephalus"*** submitted by Dr. Navneet Kala, SR-I, Department of Neurosurgery of this University via letter no. nil dated 11th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P20*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
21.	Research proposal entitled ***"A prospective study of four quadrant ostoplastic decompressive craniotomy vs conventional decompressive craniectomynfor traumatic brain injury"*** submitted by Dr. Yashpal Jaware, SR-I, Department of Neurosurgery of this University via letter no. nil dated 12th April, 2019. **EC Comment:** • Title should mention "RCT".

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• How randomization will be done • CONSORT guidelines should be followed. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P21*** ***(Primary Reviewer: Dr. Amita Jain)***
22.	Research proposal entitled ***"Hospital based cross-sectional study to assess the prevalence of vitamin B12 deficiency in breast fed infants and lactating mothers"*** submitted by Dr. Indra Bhushan Jaiswal, JR-I, Department of Paediatrics of this University via letter no. nil dated 11th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P22*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
23.	Research proposal entitled ***"Incidence & predictors of retinopathy of prematurity in preterm newborn infant: A prospective observational study"*** submitted by Dr. Prabhat Kumar, JR-I, Department of Paediatrics of this University via letter no. nil dated 10th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P23*** ***(Primary Reviewer: Dr. Rajeev Garg)***
24.	Research proposal entitled ***"To study premenstrual syndrome (PMS) & premenstrual dysphoric disorder (PMDD) and its effect on quality of life in adolescent and young women"*** submitted by Dr. Swati Vishwakarma, JR-I, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 10th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P24*** ***(Primary Reviewer: Dr. Rajendra Nath)***
25.	Research proposal entitled ***"Estimation of 25 OH vitamin D level in pregnant women with gestational diabetes and its comparison with nondiabetic pregnant women"*** submitted by Dr. Nazia Khan, JR-I, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 9th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P25*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
26.	Research proposal entitled ***"Study to evaluate the need of surgical interventions amongst adolescent gynaecological problems"*** submitted by Dr. Vijeta Kumari,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	JR-I, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 9th April, 2019. **EC Comment:** • Adolescent gynaecological problems is an heterogeneous group comprising of too many variables – menstrual irregularity, pain, leucorrhoea, PID, Ovarian masses, urinary problems, injury, sexual assault and adolescent pregnancy. So now sample size becomes vital. Please consult a statistician and decide the sample size otherwise your results will become statistically insignificant. • Please spend some time to decide your inclusion and exclusion criteria. Right now you have included all adolescent girls who or whose parents have given consent. • We need a data collection sheet which should have the demographic details, history and examination findings, investigations, interventions, treatment details and outcome • With so many variables you may end up with a very large sample size that may be just too big for your limited duration of study. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P26*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
27.	Research proposal entitled ***"Use of sequential compression device for prevention of hypotension associated with spinal anaesthesia in elective caesarean section"*** submitted by Dr. Aayuhi Agarwal, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 11th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P27*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
28.	Research proposal entitled ***"Comparison of clinical performance of I-GEL™, LMA supreme™ & AMBU® AURAGAIN™ in adult patients during general anaesthesia"*** submitted by Dr. C.L Tejashri, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • Kindly provide CONSORT guidelines • Kindly submit Conflict of interest form **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P28***

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	(Primary Reviewer: Dr. Anoop Kumar Verma)
29.	Research proposal entitled ***"Ultrasound based diaphragmatic thickness fraction as a weaning predictor in simple weaning patient in ICU"*** submitted by Dr. Asmita Singh, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 10th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P29*** ***(Primary Reviewer: Dr.Rajeev Garg)***
30.	Research proposal entitled ***"A comparative study of bupivacaine Vs ropivacaine for efficacy of bilateral erector spinae block in lumbar spine surgeries"*** submitted by Dr. Nimi Sreedhar, SR-I, Department of Anaesthesiology of this University via letter no. nil dated 10th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P30*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
31.	Research proposal entitled ***"Comparative study between ultrasound guided erector spinae plane block and para vertebral block in thoracic surgeries"*** submitted by Dr. Akanksha Jain, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • The study needs to be written as per CONSORT guidelines. Please provide a CONSORT checklist duly filled along with the revised thesis performa. • The topic of the study should reflect the methods like – randomized controlled blinded/open-label etc. • The name of the drug should also be mentioned in the title of the study. • Which one of the two arms will be a control arm if it is a controlled study? • Which randomization method will be used? • How will the allocation concealment be achieved? • Patient information document (PID) is very important document and it needs to be filled again. Are there any complications of either of the anesthesia methods? These have to be discussed with the patient in the PID. Risks from the study have also to be discussed. Compensation has to be planned. • Patient datasheet not attached. **EC Decision:** Approval after justification

Chairperson IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 97th ECM II B-Thesis/P31
	(Primary Reviewer : Dr. Vimal Kumar Paliwal)
32.	Research proposal entitled ***"Comparison between LMA proseal and I-gel airway in anaesthetized patients on spontaneous ventilation during daycare procedures"*** submitted by Dr. Neha Singh, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 13th April, 2019. **EC Comment:** • Kindly submit Conflict of interest form. It should be done in form of RCT. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P32*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
33.	Research proposal entitled ***"Hypoxia inducible factor 1α expression in urothelal malignancy and correlation with clinicopathological parameters"*** submitted by Dr. Priya Sachan, JR-I, Department of Pathology of this University via letter no. nil dated 10th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P33*** ***(Primary Reviewer: Dr. Rajendra Nath)***
34.	Research proposal entitled ***"Aldh1 cancer stem cell marker expression in oral squamous cell carcinoma"*** submitted by Dr. Vaibhav Gupta, JR-I, Department of Pathology of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • Dr Vaibhav has not submitted the revised project. He has submitted only the answer to the reviewer document. Ethical clearance may be granted if the said corrections are made into the revised performa. • Kindly provide **"Stem Cell committe"** Approval letter **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P34*** ***(Primary Reviewer: Dr. Amita Jain)***
35.	Research proposal entitled ***"Evaluation of serum segfr in ovarian tumors, its comparison with serum cai25, HE4 and correlation with histopathological types"*** submitted by Dr. Manoj Kumar Chaudhary, JR-I, Department of Pathology of this University via letter no. nil dated 10th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P35***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. A.A. Sonkar)
36.	Research proposal entitled ***"Study of aberrant DNA methylation of the transcription factors in acute myeloid leukemia and myelodysplastic syndrome"*** submitted by Dr. Damini Singh, JR-I, Department of Pathology of this University via letter no. nil dated 10th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P36*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
37.	Research proposal entitled ***"Immunohistochemical expression of PD-L1 in malignant soft tissue tumor"*** submitted by Dr. Ashutosh Mishra, JR-I, Department of Pathology of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • The objective is to evaluate the immunohistochemical expression of PD-L1, proliferation index K1-67 and its correlation with clinic-pathological findings of malignant soft tissue tumours • Sample size is 50. Has it been statistically derived? • Active patients as well as paraffin blocks of soft tissue sarcoma from records will form the study group. • Methodology has been elaborately described. • How will the consent be obtained from patients whose paraffin blocks will be used in this study? They may not even be alive. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P37*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
38.	Research proposal entitled ***"Role of TLR-3 polymorphism as predisposing factor to infectionsin patients of acute leukemia on treatment"*** submitted by Dr. Akanksha Sharma, JR-I, Department of Pathology of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • Kindly submit **CONSORT** guidelines as it has control arm. • Kindly submit CTRI registration. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P38*** ***(Primary Reviewer: Dr. Rajeev Garg)***
39.	Research proposal entitled ***"EBV immunohistochemical expression in non-neoplastic and neoplastic gall bladder lesions along with evaluation of tumor***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	infiltrating lymphocytes in neoplastic lesions" submitted by Dr. Prachi Goel JR-I, Department of Pathology of this University via letter no. nil dated 9th April, 2019. **EC Comment:** • The study hypothesizes that EBV infection may be related to Gall Bladder disease and so aims at studying the EBV expression in benign and malignant gall bladed lesions. Additionally it aims at evaluating TIL in CA Gall Bladder. • Both fresh GB specimens as well as archived paraffin embedded biopsy tissue would be used for immune-histochemistry of EBV antibodies. • Sample size is 250. Statistically calculated • We need a data collection sheet to understand what all will be recorded and observed. • How will the consent be obtained from patients whose paraffin blocks will be used in this study? **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P39*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
40.	Research proposal entitled ***"Intraoperative squash smear cytology of central nervous system lesions and its clinic- radiological correlation with histopathology and immunohistochemistry"*** submitted by Dr. Jitendra Kumar Vimal JR-I, Department of Pathology of this University via letter no. nil dated 10th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P40*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
41.	Research proposal entitled ***"Audiological profile of presbycusis with pilot observation on familial age related hearing loss"*** submitted by Dr. Hari Krishn Dwivedi, JRI, Department of Otorhinolaryngology and Head- Neck Surgery of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • Prospective & retrospective study- to see record of the patients then follow up them. • Inform Consent form –Hindi & English first page is photocopied not typed. • Kindly submit the Questionnaire.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Ref. code: 97th ECM II B-Thesis/P41*** ***(Primary Reviewer: Dr. Rajendra Nath)***
42.	Research proposal entitled ***"Clinical and radiological comparison of long- term and short- term outcomes of posterior canal wall reconstruction technique by using composite multifractured osteoperiosteal flap (C.M.O.F) versus conventional canal wall down mastoidectomy"*** submitted by Dr. Monica Patnaik, JRI, Department of Otorhinolaryngology and Head- Neck Surgery of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • The PI wishes to compare the outcome of two surgical methods to treat patients with CSOM. How will the patients be chosen for either of the procedures? Will this be an open-label or blinded study? Which allocation concealment method will be used? The thesis performa needs to be written as per the CONSORT guidelines. Please submit a CONSORT checklist dully filled along with the revised thesis performa. • Including patients retrospectively will dilute the impact of the study. It is advisable to restrict this to a prospective study. • The complications from the either of the surgical procedures, the risks involved have to be discussed with the patient in the patient information documents. • The issue of compensation has to be discussed. Who will pay for compensation in case of litigation? Who will bear the cost of treatment if a patient develops complication of either of the surgical procedure? • How much is the additional cost of obtaining/using CMOF for reconstruction of posterior canal wall? Who will bear the cost of the procedure? • Patient data sheet is not provided. **EC Decision:** Re-submit ***Ref. code: 97th ECM II B-Thesis/P42*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
43.	Research proposal entitled ***"Pilot study on mechanisms influencing clinical expression of thyroid associated Ophthalmopathy at a tertiary care centre in K.G.M.U, U.P, Lucknow"*** submitted by Dr. Stuti Tiwari, JR-I, Department of Ophthalmology of this University via letter no. nil dated 18th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P43***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Amita Jain)
44.	Research proposal entitled ***"Anaesthetic considerations and perioperative complications in endoscopic third ventriculostomy: a prospective observational study"*** submitted by Dr. Akanshita Tewari, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 18th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P44*** ***(Primary Reviewer: Dr. Rajeev Garg)***
45.	Research proposal entitled ***"To study prevalence and etiology of persistent/ recurrent pneumonia in Hospitalized children aged 1 Month-5 years- A prospective Hospital based study"*** submitted by Dr. Akanksha D Srivastava, JR-I, Department of Paediatrics of this University via letter no. nil dated 20th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P45*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
46.	Research proposal entitled ***"Morphological and morphometric study of atrioventricular valves and semilunar valves- A cadaveric study in north Indian population"*** submitted by Dr. Adya Priyadarshini, JR-I, Department of Anatomy of this University via letter no. nil dated 26th April, 2019. **EC Decision:** Approved ***Dr. Anoop Kumar Verma did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P46*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
47.	Research proposal entitled ***"Comparative effectiveness of different concentrations of dextrose prolotherapy in osteoarthritis knee- A prospective study"*** submitted by Dr. Snigdha Mishra, JR-I, Department of PMR of this University via letter no. nil dated 22th April, 2019. **EC Comment:** • Hindi & English Inform Consent form is not similar **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P47*** ***(Primary Reviewer: Dr. Rajendra Nath)***
48.	Research proposal entitled ***"A retrospective study of clinic- radiological profile and outcome correlation in patients of medulloblastomas: A KGMU experience"*** submitted by Dr. Rohan Digarse, SR-I, Department of Neurosurgery of this University via letter no. nil dated 18th April, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment: • A retrospective study--- the validtiy of the consent in questionable. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P48*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)*** ***(SecondaryReviewer: Dr. Amita Jain)***
49.	Research proposal entitled ***"A retrospective study of clinic- radiological profile and outcome correlation in patients of medulloblastomas: A KGMU experience"*** submitted by Dr. Rohan Digarse, SR-I, Department of Neurosurgery of this University via letter no. nil dated 18th April, 2019. **EC Comment:** • A retrospective study--- the validiy of the consent in questionable. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P48*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
50.	Research proposal entitled ***"Signature of the ageing skull: age determination through closure of cranial sutures by 3D computerized tomography"*** submitted by Dr. Rajeev Ranjan, JR-I, Department of Forensic Medicine & Toxicology of this University via letter no. nil dated 22nd April, 2019. **EC Decision:** Approved ***Dr. Anoop Kumar Verma did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P50*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
49.	Research proposal entitled ***"Predictive factors for ETV in congenital infantile hydrocephalus"*** submitted by Dr. Rajat Verma, SR-I, Department of Neurosurgery of this University via letter no. nil dated 18th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P49*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
50.	Research proposal entitled ***"Signature of the ageing skull: age determination through closure of cranial sutures by 3D computerized tomography"*** submitted by Dr. Rajeev Ranjan, JR-I, Department of Forensic Medicine & Toxicology of this University via letter no. nil dated 22th April, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 97th ECM II B-Thesis/P50*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
51.	Research proposal entitled ***"Expression of p53, cyclin d1 and ki-67 markers in premalignant and malignant lesions of oral cavity and oropharynx"*** submitted by Dr. Eshani Dutta, JR-I, Department of Otorhinolaryngology and Head- Neck Surgery of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • Please specify the study type. • Objective is not clear. • What analysis Investigator plans to do is not clear. • Sample size is not calculated **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P51*** ***(Primary Reviewer: Dr. Amita Jain)***
52.	Research proposal entitled ***"Effect of nebulised lidocaine on hemodynamic responses during nasotracheal intubation: A randomized controlled double blind study"*** submitted by Dr. Shivani Gaurav, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 14th April, 2019. **EC Decision:** Resubmit in format of CONSORT GUIDELINES ***Ref. code: 97th ECM II B-Thesis/P52*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
53.	Research proposal entitled ***"Estimation of uncuffed endotracheal tube size in paediatric patient using different variables: A comparative randomized study"*** submitted by Dr. Yatendra Kumar, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 20th April, 2019. **EC Decision:** Resubmit in format of CONSORT GUIDELINES ***Ref. code: 97th ECM II B-Thesis/P53*** ***(Primary Reviewer: Dr. Rajendra Nath)***
54.	Research proposal entitled ***"Comparative evaluation of different concentrations of alcohol in ultrasound guided celiac plexus neurolysis for pain relief in patients with upper abdominal malignancies"*** submitted by Dr. Pragya Verma, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 20th April, 2019. **EC Comment:** • It is a randomized double-blind comparative study needs to be submit on

Chairperson IEC
King George's Medical University
U.P., Lucknow

	CONSORT guidelines and necessary formality for CTRI registry. **EC Decision:** Resubmit in format of CONSORT GUIDELINES ***Ref. code: 97th ECM II B-Thesis/P54*** ***(Primary Reviewer: Dr. Rajeev Garg)***
55.	Research proposal entitled ***"Comparison of dexmedetomidine and fentanyl as an adjuvant to ropivacaine for Surgery of fracture Neck femur under sub-arachnoid block"*** submitted by Dr. Devendra Vikram Singh, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 20th April, 2019. **EC Comment:** • The project needs to be re-written as per CONSORT guidelines. • The methodology should be reflected in the topic of the study like – randomized, open-label or blinded (single or double) etc. • The randomization method and methods of allocation concealment have to be discussed in the methods. • A flow-chart must accompany the revised project. • The complications of the procedure and either of the drugs have to be discussed with the patient in the patient information document in detail. • The issue of compensation needs to be discussed. • Patient's data sheet has to be submitted. • CONSORT check-list duly filled should also accompany the revised project. **EC Decision:** Re-submit ***Ref. code: 97th ECM II B-Thesis/P55*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
56.	Research proposal entitled ***"Randomized control trial of quadrates lumborum block with of without dexmedetomidine as an adjuvant drug in patients undergoing elective renal surgery"*** submitted by Dr. Sumit Kumar Umar, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 20th April, 2019. **EC Comment:** • Kindly submit on CONSORT guidelines. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P56*** ***(Primary Reviewer: Dr. A.A. Sonkar)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

57.	Research proposal entitled ***"A study on effect of early diagnosis and intervention on behavior and development in autistic children"*** submitted by Dr. Madhumathi G.S, JR-I, Department of Community Medicine and Public Health of this University via letter no. 88/cm/19 dated 18th April, 2019. **EC Comment:** • Signature missing of Principal-Investigator in Hindi & English Inform consent Form. • Both ICF are similar, it should be according to SOP. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P57*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
58.	Research proposal entitled ***"Endocrine profile and tissue heparin assay in juvenile nasopharyngeal angiofibroma"*** submitted by Dr. Preetam Pathak, JRI, Department of Otorhinolaryngology and Head- Neck Surgery of this University via letter no. nil dated 10th April, 2019. **EC Comment:** • Signature missing of Principal-Investigator in waiver form.It is old version. Kindly provide new version of Waiver form. **EC Decision:** Provisionally approved ***Ref. code: 97th ECM II B-Thesis/P58*** ***(Primary Reviewer: Dr. Rajeev Garg)***
59.	Research proposal entitled ***"Morphometry of gracilis muscle and its perforators: A cadaveric dye injection study for myocutaneous flap desigh"*** submitted by Dr. Amber Irfan, JR-I, Department of Anatomy of this University via letter no. nil dated 20th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P59*** ***(Primary Reviewer: Dr. Rajendra Nath)***
60.	Research proposal entitled ***"Morphometric analysis of gastrocnemius muscle and it's perforators for designing myocutaneous flap: A cadaveric dye injection study"*** submitted by Dr. Amber Rana, JR-I, Department of Anatomy of this University via letter no. nil dated 20th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P60*** ***(Primary Reviewer:Dr. Vimal Kumar Paliwal)***
61.	Research proposal entitled ***"USG guided prolotherapy versus corticosteroid***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	injections for the treatment of lateral epicondylosis in India: A randomized controlled trial" submitted by Dr. Rahul Singh, JR-I, Department of Physical Medicine and Rehabilitation of this University via letter no. nil dated 23rd April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P61*** ***(Primary Reviewer: Dr. Amita Jain)***
62.	Research proposal entitled ***"Effect of fluoroscopy- guided corticosteroid injection in patients with sacroiliac joint dysfunction- A randomized controlled trial"*** submitted by Dr. Anurag Patel, JRI, Department of Physical Medicine and Rehabilitation of this University via letter no. 1821/19 dated 23rd April, 2019. **EC Decision:** Resubmit in format of CONSORT GUIDELINES ***Ref. code: 97th ECM II B-Thesis/P62*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
63.	Research proposal entitled ***"Comparison of suprascapular nerve block with glenohmeral joint dilatation for the treatment of adhesive capsulitis of shoulder joint –A randomized controlled trial"*** submitted by Dr. Madhumita Singh Roy, JR-I, Department of PMR of this University via letter no. 1825/19 dated 24th April, 2019. **EC Decision:** Resubmit in format of CONSORT GUIDELINES ***Ref. code: 97th ECM II B-Thesis/P63*** ***(Primary Reviewer: Dr. Rajendra Nath)***
64.	Research proposal entitled ***"Breastfeeding trends in very low birth weight infants in a tertiary care centre"*** submitted by Dr. Avantika Chauhan, JR-I, Department of Paediatrics of this University via letter no. nil dated 24th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P64*** ***(Primary Reviewer: Dr. Rajeev Garg)***
65.	Research proposal entitled ***"A study to detect raised ICP in patients admitted in a pediatric ICU by optic nerve sheath diameter measurement method using ultrasonography as compared to computed tomography method"*** submitted by Dr. Sakshi Singh, JR-I, Department of Paediatrics of this University via letter no. nil dated 24th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P65***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr.Surajit Bhattacharya)
66.	Research proposal entitled ***"Retrospective and prospective outcome of duplex-ultrasound guided percutaneous ethanol sclerotherapy of endometrioma"*** submitted by Dr. Nitish Singh, JR-II, Department of Radiodiagnosis of this University via letter no. nil dated 24th April, 2019. **EC Comment:** • Signature missing of Principal-Investigator in Hindi & English Inform consent Form. • Both ICF are not similar, it should be according to SOP. • The term retrospective may be removed from the topic of the study as the methods section and flow-chart provided does not reflect upon any criteria for retrospective chart review. It is also advisable for the PI to keep the study prospective as any intervention study should be. • The outcome measures are not clearly mentioned. • Is duplex-ultrasound guided percutaneous sclerotherapy of endometrioma not a standard of care? If yes, then the outcome of such procedures would be known already. If no, then the justification of not choosing the standard of care has to be given. • Will all consecutive patients be treated with the above said method? If yes, then the patient information document should clearly discuss all possible methods of treatment of ovarian endometrioma including the standard of care treatment and why the PI wishes to offer sclerotherpay to the patient. • Will there be any control arm? • The complications of the procedure and risk in participating in the study have to be discussed in detail in the patient information document. • Who will bear the cost of the procedure? • Please discuss the compensation in detail in the PID. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P66***
	(Primary Reviewer: Dr.Vimal Kumar Paliwal)
67.	Research proposal entitled ***"Karyotyping in congenital and primary open angle glaucoma in tertiary care centre"*** submitted by Dr. Anupriya, JR-II, Department of Ophthalmology of this University via letter no. nil dated 27th April, 2019. **EC Comment:** • Please check the study design. This is not a cross-sectional study. Moreover to define the genetic changes, a control group should always be included (to define normal variations. **EC Decision:** Resubmit

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 97th ECM II B-Thesis/P67
	(Primary Reviewer: Dr. Amita Jain)
68.	Research proposal entitled ***"To study intraocular pressure and retinal nerve fiber layer thickness in patients of vernal keratoconjunctivitis"*** submitted by Dr. Divya Gupta, JR-II, Department of Ophthalmology of this University via letter no. nil dated 27th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P68*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
69.	Research proposal entitled ***"To study the epidemiology and quality of life parameters in patients of lower limb lymphatic filariasis in northern India"*** submitted by Dr. Shahrukh Rauf, JR-I, Department of General Surgery of this University via letter no. nil dated 2th May, 2019. **EC Decision:** Approved ***Dr. A.A. Sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P69*** ***(Primary Reviewer: Dr. Rajendra Nath)***
70.	Research proposal entitled ***"To study the outcome in cases of lumbar degenerative disc disease: A prospective study"*** submitted by Dr. Ashutosh Kumar Roy, SR-I, Department of Neurosurgery of this University via letter no. nil dated 2th May, 2019. **EC Decision:** Approved ***Dr. R.K. Garg did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P70*** ***(Primary Reviewer: Dr. Rajeev Garg)***
71.	Research proposal entitled ***"Expression of SCAMP3 and methylated DNA in circulating cell free nucleic acid in oral cancer patients with special reference to disease prognosis- A pilot study"*** submitted by Dr. Saurabh Kumar Singh, JR-I, Department of General Surgery of this University via letter no. nil dated 9th May, 2019. **EC Comment:** • Secretory Carrier Membrane Protein 3 (SCAMP 3) gene expression will be evaluated in circulating free DNA in patients of Oral SCC of 3 groups N0M0, N +ve M0 and N+ve M+ve • A structured questionnaire will be used to record demographic details, examination findings, investigations but the data collection sheet has

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	not been provided and we do not know what will be observed. • Sample size is not provided • The material and method section only talks about the methodology of gene expression and not about patient interaction. What samples will be collected and when we do not know. • Who is paying for this special investigation? Is there a grant for the same? Patient should not be asked to pay for research. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P71*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
72.	Research proposal entitled ***"To study resistive index in central retinal artery in ischemic and non ischemic central retinal vein occlusion"*** submitted by Dr. Akanksha, JR-I, Department of Ophthalmology of this University via letter no. nil dated 9th May, 2019. **EC Comment:** • Retinal Vein occlusion in Diabetic Retinopathy (DR) often leads to loss of vision – partial or total, depending on the degree of retinal capillary non-perfusion. This study aims to assess the restive index of Central Retinal A. in ischemic and non-ischemic Central Retinal V. occlusion. • Sample size is 40. Statistically calculated • Methodology is clear • Data collection sheet is missing. We need a data sheet which should have the demographic details of the patient, their diabetic status, their ophthalmic status and research observations • The data sheet must mention the status of other target organs – heart, kidneys to understand how sick the patient was. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P72*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
73.	Research proposal entitled ***"Detection of acute and chronic brucellosis by serological and molecular methods at a tertiary care Hospital"*** submitted by Dr. Pratima, JR-I, Department of Microbiology of this University via letter no. nil dated 10th May, 2019. **EC Comment:** • Kindly mention the Objective in the title. **EC Decision:** Approval after justification ***Dr. Amita Jain did not take part in the discussion***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 97th ECM II B-Thesis/P73 ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
74.	Research proposal entitled ***"Infections associated with indwelling CNS devices in neurosurgical patients: A prospective study"*** submitted by Dr. Sheetal Agarwal, JR-I, Department of Microbiology of this University via letter no. nil dated 10th May, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P74*** ***(Primary Reviewer:Dr. A.A. Sonkar)***
75.	Research proposal entitled ***"To study the neurodevelopmental outcomes of very low birth weight neonates in neonatal unit- A longitudinal study"*** submitted by Dr. Ramsha Salimuddin, JR-I, Department of Paediatrics of this University via letter no. nil dated 10th May, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P75*** ***(Primary Reviewer: Dr. Rajeev Garg)***
76.	Research proposal entitled ***"Post diphtheric polyneuropathy in children with diphtheria: A prospective observational study"*** submitted by Dr. Deepa Barla, JR-I, Department of Paediatrics of this University via letter no. nil dated 14th May, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P76*** ***(Primary Reviewer: Dr. Rajendra Nath)***
77.	Research proposal entitled ***"Comparison of endotracheal tube with supraglottic airway device during laparoscopic surgery and its effects on level of inflammatory biomarker"*** submitted by Dr. Prince Kumar, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 14th May, 2019. **EC Comment:** • The study aims to compare the use of supra-glottic airway device and endotracheal tube in terms of ease of insertion, peri-operative complications, peak airway pressure, haemodynamic parameters (HR, SBP, DBP, MAP) and changes in levels of inflammatory blocker IL-6 • This is a RCT so please provide consort guidelines

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Sample size is 60. Was this derived after consulting a statistician? • Please explain your exclusion criteria. Why are obese patients excluded? Why are difficult intubation excluded? They should be included and termed as failures otherwise your study group becomes biased. If the patient has been deemed fit for laparoscopy then why are you excluding him/her from your study just because they are difficult cases? **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P77*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
78.	Research proposal entitled ***"A comparison of nebulized ketamine and dexmedetomidine premedication in preschool children undergoing abdominal surgery"*** submitted by Dr. Prabhat Mishra, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 14th May, 2019. **EC Comment:** • Kindly submit CONSORT on guidelines. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P78*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
79.	Research proposal entitled ***"Retrospective study of endoscopic dacrocystorhinostomy (DCR) at tertiary care center"*** submitted by Dr. Dheerendra Pratap Ahirwar, JR-I, Department of Otorhinolaryngology and Head-Neck Surgery of this University via letter no. nil dated 15th May, 2019. **EC Comment:** • A retrospective study the validity of the consent in questionably. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P79*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
80.	Research proposal entitled ***"A comparison between levobupivacaine with dexmedetomidine versus levobupivacaine with clonidine in labour analgesia"*** submitted by Dr. Shruti Kabi, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 15th May, 2019. **EC Comment:** • Kindly submit as per CONSORT guidelines. **EC Decision:** Approval after justification

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 97th ECM II B-Thesis/P80 ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
81.	Research proposal entitled ***"Safety and efficacy of ketamine- dexmedetomidine versus ketamine- propofol combination for short term sedation in post- operative obstetric patients on mechanical ventilation"*** submitted by Dr. Anchal Raj, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 15th May, 2019. **EC Comment:** • It is a randomized double blind trial, kindly submit as per CONSORT guidelines and get registration. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P81*** ***(Primary Reviewer: Dr. Rajeev Garg)***
82.	Research proposal entitled ***"A Prospective observational study: chronic morbidities in postoperative patient of tubercular empyema thoracis"*** submitted by Dr. Chandrakanta Das, JR-I, Department of General Surgery of this University via letter no. nil dated 16th May, 2019. **EC Decision:** Approved ***Dr. A.A. sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P82*** ***(Primary Reviewer: Dr. Rajendra Nath)***
83.	Research proposal entitled ***"Effect of ramucirumab (VEGF2 inhibitor) on six months progression free surviuval (PFS) and quality of life (QOL) in conventional drug resistant or metastatic nonsquamous variant of nsclc: A pilot study"*** submitted by Dr. Debmoy Ghatak, JR-I, Department of General Surgery of this University via letter no. nil dated 10th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P83*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
84.	Research proposal entitled ***"Dose escalation of short course radiotherapy in locally advanced carcinoma rectum- a pilot study"*** submitted by Dr. Deep Chakrabarti, JR-III, Department of Radiotherapy of this University via letter no. nil dated 16th May, 2019. **EC Comment:** • Please tell us when will first patient be enrolled? **EC Decision:** Approval after justification

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 97th ECM II B-Thesis/P84
	(Primary Reviewer: Dr. Vimal Kumar Paliwal)
85.	Research proposal entitled ***"A study of etiology prognosis and outcome of Hospital acquired acute kidney injury and community acquired acute kidney injury"*** submitted by Dr. Rahul Kumar, JR-II, Department of Medicine of this University via letter no. nil dated 20th May, 2019. **EC Comment:** • Sample size calculation is confusing. Please clarify. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P85*** ***(Primary Reviewer: Dr. Amita Jain)***
86.	Research proposal entitled ***"Comparative short term outcome analysis of endovenous laser treatment and radiofrequency ablation in varicose veins- A randomized study"*** submitted by Dr. Dinesh Kumar Singh, JR-II, Department of General Surgery of this University via letter no. nil dated 20th May, 2019. **EC Comment:** • How can this study be retrospective and prospective? • Kindly provide detail methodology of interventions. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P86*** ***(Primary Reviewer:Dr. Balendra Pratap Singh)***
87.	Research proposal entitled ***"To study the effects of oral gabapentin for post operative analgesia in patient undergoing abdominal surgery under general anaesthesia: A randomized control trial"*** submitted by Dr. Anoop Kumar Singh, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 22nd May, 2019. **EC Comment:** • It is a RCT, needs CTRI registration and also needs submission on the basis of CONSORT guidelines **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P87*** ***(Primary Reviewer: Dr. Rajeev Garg)***
88.	Research proposal entitled ***"Prophylactic placement of permanent synthetic mesh at the time of ostomy closure: An outcome based prospective observational study"*** submitted by Dr. Mayank Tripathi, JR-I, Department of General Surgery of this University via letter no. nil dated 22nd May, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Dr. A.A. Sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P88*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
89.	Research proposal entitled ***"Characterization of metallo - beta lactamase producing gram negative bacteria causing ventilator associated pneumonia (VAP)/ ventilator associated events (VAE) in intensive care unit"*** submitted by Dr. Mithlesh Kumari, JRI, Department of Microbiology of this University via letter no. nil dated 23rd May, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P89*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
90.	Research proposal entitled ***"To assess the efficacy of oral care protocol in prevention of ventilator- associated pneumonia in patients on invasive mechanical ventilation: A randomized controlled trial"*** submitted by Dr. Pallika Singh, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 23rd May, 2019. **EC Comment:** • Kindly provide case record form. • Sample size is calculated to be 60. Does it include the number of cases in both the groups? • CONSORT guidelines have to be followed. **EC Decision:** Revise & Re-submit ***Ref. code: 97th ECM II B-Thesis/P90*** ***(Primary Reviewer: Dr. Amita Jain)***
91.	Research proposal entitled ***"A quantitative analysis of glycoprotein acetyls (GlycA), serum total cholesterol and ratio analysis of cholesterol esters with free cholesterol in serum of gall bladder cancer patients, by proton nuclear magnetic resonance spectroscopy"*** submitted by Dr. Samiksha Singh, JR-I, Department of General Surgery of this University via letter no. nil dated 23rd May, 2019. **EC Decision:** Approved ***Dr. A.A. Sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P91*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
92.	Research proposal entitled ***"Patient perceived quality of life after hip arthroplasty in a tertiary care Hospital in north India"*** submitted by Dr.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Chandrakant Gautam, JR-I, Department of Orthopaedic Surgery of this University via letter no. nil dated 24th May, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P92*** ***(Primary Reviewer: Dr. Rajendra Nath)***
93.	Research proposal entitled ***"A prospective study to compare quality of life and early outcomes between endovenous laser therapy, mechanochemical ablation therapy in patients having chronic venous insufficiency"*** submitted by Dr. Abhishek Mishra, JR-II, Department of General Surgery of this University via letter no. nil dated 24th May, 2019. **EC Comment:** • It is comparative study. • Study involves two groups of PF, Which authors have decided arbitrarily (Saying non-randomized) in one group they will use EVLT machine and author gp-Mechochemical ablaltion. • Which is unethical may involve bias, Design it as RCT & get CTRI registrationon CONSORT guidelines. **EC Decision:** Approval after justification ***Dr. A.A. Sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P93*** ***(Primary Reviewer: Dr. Rajeev Garg)***
94.	Research proposal entitled ***"A study of functional impairment after latissimus dorsi myocutaneous flap in breast cancer patients"*** submitted by Dr. Shariq Ahmad, JR-II, Department of General Surgery of this University via letter no. nil dated 24th May, 2019. **EC Comment:** • The study aims to assess the functional impairment after L.D flap breast reconstruction using the DASH questionnaire of American Association of Orthopaedic Surgeons and Q.O.L questionnaire and a few additional questions from focus group study. • Sample size is 80. Statistically calculated • I believe these patients have already been operated and you will be calling them for follow up. So how far do you intend to go in follow up as the initial functional impairment may improve with time? • Adding the QOL questionnaire is a smart move as disease recurrence may change to total outlook of the patient towards reconstruction.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Ref. code: 97th ECM II B-Thesis/P94*** ***(Primary Reviewer: Dr. Surajit Bhattacrya)***
95.	Research proposal entitled ***"A comparative study of gold therapy for breast cancer patients undergoing chemotherapy as an adjunct with NMR evaluation"*** submitted by Dr. Akash Srivastava, JR-II, Department of General Surgery of this University via letter no. nil dated 25th May, 2019. **EC Comment:** • Please clear the formulation of Gold (Swarna Blasma) • Who will bear the cost of Gold therapy? • Needs to mention reference and literature. **EC Decision:** Re-submit ***Dr. A.A. Sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P95*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
96.	Research proposal entitled ***"A prospective study of combined sphincter preserving procedure (Lift+ Vaaft+ Filac)in complex anal fistula"*** submitted by Dr. Abhishek Kumar, JR-II, Department of General Surgery of this University via letter no. nil dated 25th May, 2019. **EC Comment:** • The researchers wish to study the efficacy of a combination of 3 procedures – ligation of inter-sphincteric fistula tract (LIFT), video assisted anal fistula treatment (VAAFT) and fistula laser closure (FiLaC) in the treatment of anal fistula as they ensure preservation of continence, and result in less pain and early healing. • Sample size is 66. Statistically calculated • Data collection sheet has been provided and evaluation criteria defined. • There is no control group. So what are the results going to be compared with? **EC Decision:** Approval after modifiation ***Dr. A.A. Sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P96*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
97.	Research proposal entitled ***"A prospective study of perioperative outcomes of primary duct closure and internal biliary drainage in laparoscopic common bile***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	duct exploration" submitted by Dr. Ankita Bajpai, JR-I, Department of General Surgery of this University via letter no. nil dated 27th May, 2019. **EC Decision:** Approved ***Dr. A.A. Sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P97*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
98.	Research proposal entitled ***"Expression of scamp3 and methylated DNA in circulating cell free nucleic acid in carcinoma gall bladder patients with special reference to disease prognosis"*** submitted by Dr. Niyatank Tyagi, JR-I, Department of General Surgery of this University via letter no. nil dated 30th May, 2019. **EC Decision:** Approved ***Dr. A.A. Sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P98*** ***(Primary Reviewer: Dr. Amita Jain)***
99.	Research proposal entitled ***"Comparative prospective evaluation of eversion of sac versus aspiration sclerotherapy in management of small to medium volume of hydrocele"*** submitted by Dr. Aditya Dhar Dwivedi, JR-I, Department of General Surgery of this University via letter no. nil dated 29th May, 2019. **EC Decision:** Approved ***Dr. A.A. Sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P99*** ***(Primary Reviewer: Dr.Balendra Pratap Singh)***
100.	Research proposal entitled ***"Prospective comparison of functional outcomes of arthroscopic ACL reconstruction by augmented hamstring graft with platelet rich plasma and hamstring graft alone"*** submitted by Dr. Vivek Gupta, JR-I, Department of Orthopaedic Surgery of this University via letter no. nil dated 30th May, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P100*** ***(Primary Reviewer: Dr. Rajendra Nath)***
101.	Research proposal entitled ***"A prospective observational study of perioperative and quality of liff outcomes after surgery for penile cancer"*** submitted by Dr. Agastya Maria, JR-I, Department of General Surgery of this University via letter no. nil dated 31st May, 2019. **EC Comment:** • Study will be done during hospital stay i.e. for operation to discharge.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Please clear about the assessment of sexual function how it in possible in hospital plan clearity. **EC Decision:** Re-submit ***Dr. A.A. Sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P101*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
102.	Research proposal entitled ***"Study to evaluate the treatment outcomes of bile duct injury"*** submitted by Dr. Ravi Patel, SR-I, Department of Surgical Gastroenterology of this University via letter no. nil dated 31st May, 2019. **EC Comment:** • The aim of this study is to assess the demographic and clinic-pathological profile of patients with bile duct injury, their various treatment modalities and their respective outcomes in terms of liver functions, number of interventions and total hospital stay. • It is a prospective and retrospective study • A data collection Performa is attached which is very elaborate. • Sample size is missing. Please sit with a statistician and discuss your study plan which has far too many variables and come to a sample size which will make your results statistically significant. **EC Decision:** Re-submit ***Ref. code: 97th ECM II B-Thesis/P102*** ***(Primary Reviewer:Dr. Surajit Bhattacharya)***
103.	Research proposal entitled ***"Correlation between the sagittal spinopelvic parameters in subjects without spinal deformity, in subjects with low back pain and in subjects with spondylolisthesis"*** submitted by Dr. Rishabh Agarwal, JR-I, Department of Orthopaedic Surgery of this University via letter no. nil dated 27th May, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P103*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
104.	Research proposal entitled ***"Effect of pancreatic steatosis on postoperative outcomes and pancreatic fistula rates after pancreaticoduodenectomy"*** submitted by Dr. Mahesh R, SR-I, Department of Surgical Gastroenterology of this University via letter no. nil dated 1st June, 2019. **EC Comment:** • The objective is to determine if fatty pancreas is a risk factor for pancreatic

Chairperson, IEC
King George's Medical University

	fistula after pancreato-duodenectomy and whether it correlates with other pancreatic histology parameters • Sample size is 60. Is it statistically derived? • Material & Method is elaborately described • The structure of data collection sheet is presented • Data analysis has no value without a statistically derived sample size **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P104*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
105.	Research proposal entitled ***"Endoscopic rectopexy: feasibility study and early results"*** submitted by Dr. Pritheesh Rajan, SR-I, Department of Surgical Gastroenterology of this University via letter no. nil dated 1st June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P105*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
106.	Research proposal entitled ***"To study sputum bacteriology, antibiotic sensitivity pattern and serum procalcitonin levels in copd patients with acute exacerbation"*** submitted by Dr. Shahnawaz Ali Ansari, JR-I, Department of Medicine of this University via letter no. nil dated 17th June, 2019. **EC Comment:** • The whole project is copied and pasted for some source. • This is a Lab based project & there are no supervisior from Lab. • These are routine investigations done for each case of COPD **EC Decision:** Not approved ***Ref. code: 97th ECM II B-Thesis/P106*** ***(Primary Reviewer: Dr. Amita Jain)***
107.	Research proposal entitled ***"Study of pattern, etiology, risk factors and its outcome on discharge and after 3 months of young stroke in a tertiary care Hospital"*** submitted by Dr. Deepak Sharma, JR-I, Department of Medicine of this University via letter no. nil dated 17th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P107*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
108.	Research proposal entitled ***"To study the virulence factors and phenotypic characterization of candida isolates from blood stream infection"*** submitted by Dr. Anshuman Raj, JR-I, Department of Microbiology of this University via letter

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	no. nil dated 4th June, 2019. **EC Comment:** • A large number of risk factors are mentioned in this study. • How & when the data will be collected. • Case record form is not provided **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P108*** ***(Primary Reviewer: Dr. Amita Jain)***
109.	Research proposal entitled ***"Characterization of coagulase-negative staphylococci (CoNS) in blood stream infections at a university Hospital"*** submitted by Dr. Sanjay Kumar, JR-I, Department of Microbiology of this University via letter no. nil dated 6th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P109*** ***(Primary Reviewer:Dr. Surajit Bhattachrya)***
110.	Research proposal entitled ***"Study of complete revascularization versus treatment of infact related artery only revascularization in patient with acute coronary syndrome with multivessel disease: a single centre prospective and retrospective observational study"*** submitted by Dr. Avanish Shukla, SR-II, Department of Cardiology of this University via letter no. nil dated 10th June, 2019. **EC Comment:** • Kindly submit as per CONSORT guidelines **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P110*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
111.	Research proposal entitled ***"Comparison of external beam Radiotherapy followed by sequential high dose rate intracavitary brachytherapy vs external beam Radiotherapy interdigitated with high dose rate intracavitary brachytherapy for locally advanced carcinoma cervix"*** submitted by Dr. Indrajeet Gupta, JR-II, Department of Radiotherapy of this University via letter no. nil dated 10th June, 2019. **EC Comment:** • Kindly submit as per CONSORT guidelines • Signatures are missing. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P111***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr.A.A. Sonkar)
112.	Research proposal entitled ***"A study to assess the dosimetric impact of the anatomical changes occurring in the parotid glands and tumour volume during 3-D conformal Radiotherapy of inoperable/ locally advanced Head and Neck squamous cell cancers (LAHNSCC)"*** submitted by Dr. Arunima Ghosh, JR-II, Department of Radiotherapy of this University via letter no. nil dated 10th June, 2019. **EC Comment:** • Kindly submit CONSORT guidelines • Patient data sheet is not attached. • Signaturres are missing. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P112*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
113.	Research proposal entitled ***"Comparison of neoadjuvant chemotherapy with neoadjuvant chemoradiotherapy in locally advanced tumours of the esophagus and the gastro- esophageal junction)"*** submitted by Dr. Abigail Veravolu Resu, JR-II, Department of Radiotherapy of this University via letter no. nil dated 11th June, 2019. **EC Comment:** • Signatures are missing. **EC Decision:** Provisionally approved ***Ref. code: 97th ECM II B-Thesis/P113*** ***(Primary Reviewer: Dr. Amita Jain)***
114.	Research proposal entitled ***"A comparative evaluation of palliative radiotherapy regimes in locally advanced inoperable Head & neck squamous cell carcinoma"*** submitted by Dr. Sadanand Prakash, JR-II, Department of Radiotherapy of this University via letter no. nil dated 12th June, 2019. **EC Comment:** • Signatures are missing. **EC Decision:** Provisionally approved ***Ref. code: 97th ECM II B-Thesis/P114*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
115.	Research proposal entitled ***"Treatment compliance among patients of type 2 diabetes mellitus in Lucknow"*** submitted by Dr. Ashish Garg, JR-II, Department of Community Medicine and Public Health of this University via letter no. nil

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	dated 11th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P115*** ***(Primary Reviewer Dr. Rajeev Garg)***
116.	Research proposal entitled ***"A study of 14 hours ambulatory blood pressure monitoring among nursing staff working at a tertiary care Hospital in North India"*** submitted by Dr. Deepak Kumar Verma, JR-II, Department of Medicine of this University via letter no. nil dated 10th June, 2019. **EC Comment:** • Title to be revised. It is Northern India and not North India. North Korea and South Korea, North Sudan and South Sudan are independent countries and hence their name is thus. Northern India is a part of India • The researchers aim to study the Blood Pressure levels and 24 hours variability and any dipping pattern among nursing staff, and compare results in nurses working in Emergency, ICUs and in non-emergency wards • It is a cross sectional study of 100 cases, statistically calculated • The methodology is well defined • Ambulatory BP will be measured by an ABPM machine of Chinese make which will record BP every 30 minutes for 1 day while the nurses are doing their normal activities. Thus they will be classified as normotensives / hypertensives, dippers / non-dippers / reverse dippers. • Data collection sheet is missing. It should have the demographic details, the work place details and all the observational findings. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P116*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
117.	Research proposal entitled ***"To compare in situation versus Manchester triage system based initial case management on Hospital based mortality: A before and after study"*** submitted by Dr. Sweta Singh, JR-II, Department of Paediatrics of this University via letter no. nil dated 12th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P117*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
118.	Research proposal entitled ***"Use of interstitial brachytherapy in recurrent cervical carcinoma in terms of response, progression free survival and toxicity"*** submitted by Dr. Afroz Kahkashan Zaidi, JR-I, Department of Radiotherapy of this University via letter no. nil dated 12th June, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment: • Signatures are missing. **EC Decision:** Provisionally approved ***Ref. code: 97th ECM II B-Thesis/P118*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
119.	Research proposal entitled ***"To study the effects of psychosocial factors on adolescent Health in Lucknow district"*** submitted by Dr. Shambhavee Singh, JR-II, Department of Community Medicine and Public Health of this University via letter no. nil dated 10th June, 2019. **EC Comment:** • Participant data sheet is not provided. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P119*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
120.	Research proposal entitled ***"Association of genetic polymorphism in cytochrome P450 2C9 and glutathione s transferase P1 with treatment outcome in patients of head and neck cancers with concurrent chemoradiotherapy"*** submitted by Dr. Abhay Singh, JR-I, Department of Radiotherapy of this University via letter no. nil dated 13th June, 2019. **EC Comment:** • Signature is missing. **EC Decision:** Provisionally approved ***Ref. code: 97th ECM II B-Thesis/P120*** ***(Primary Reviewer: Dr.Balendra Pratap Singh)***
121.	Research proposal entitled ***"Evaluation of 'ICCMS' outcomes in severe early childhood caries"*** submitted by Dr. Vishesh Singh, JR-I, Department of Paediatric & Preventive Dentistry Faculty of Dental Sciences of this University via letter no. nil dated 12th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P121*** ***(Primary Reviewer: Dr.Rajendra Nath)***
122.	Research proposal entitled ***"Impact of HBA1c level on perioperative hemodynamics, recovery room stay and post operative discharge time in patients undergoing hip arthroplasty"*** submitted by Dr. Anamika Gupta, JR-I, Department

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	of Anaesthesiology of this University via letter no. nil dated 14th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P122*** ***(Primary Reviewer:Dr. Rajeev Garg)***
123.	Research proposal entitled ***"A study of the predictors of in Hospital morbidity and mortality among elderly patients"*** submitted by Dr. Azher Rizvi, JR-II, Department of Medicine of this University via letter no. nil dated 14th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P123*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
124.	Research proposal entitled***"Prevalence of obstructive sleep apnea in hypothyroidism patient"*** submitted by Dr. Chitranshu Pancholi, JR-II, Department of Medicine of this University via letter no. nil dated 14th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P124*** ***(Primary Reviewer: Dr. AnoopKumar Verma)***
125.	Research proposal entitled ***"Clinical and radiographic evaluation of efficacy of MTA, biodentine, & silver diamine fluoride as indirect pulp capping materials in primary molars"*** submitted by Dr. Durga R, JR-I, Department of Paediatric and Preventive Dentistry Faculty of Dental Sciences of this University via letter no. nil dated 15th June, 2019. **EC Comment:** • It an RCT design, methodology is incomplete, and the PI has to register the trial with the trial registry. **EC Decision:** Revise & Re-submit ***Ref. code: 97th ECM II B-Thesis/P125*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
126.	Research proposal entitled ***"To assess the usefulness of peak expiratory flow rate on monitoring the level of control of asthma in children"*** submitted by Dr. Shabnam, JR-I, Department of Paediatrics of this University via letter no. nil dated 15th June, 2019. **EC Comment:** • Number of patients required as per sample size calculation is 250. The duration of study is 1 year. Follow-up will be up to 6 months. It is advised to take a help from a statistician to re-evaluate sample size using different parameters from the past studies.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Children will be divided into two groups; one group followed with symptoms alone and other with PEFR and symptoms. How will the children be divided into two groups? **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P126*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
127.	Research proposal entitled ***"A study of emergency obstetric referred- in cases at tertiary care Hospital of Lucknow"*** submitted by Dr. Arunima Saini, JR-II, Department of Community Medicine and Public Health of this University via letter no. nil dated 13th June, 2019. **EC Comment:** • It is a cross-sectional, hospital based, observational study of 15 independent variables and 4 dependent variables which include both medical reasons and health care logistic reasons. • Sample size is not mentioned but the hint is that it will depend on the maximum number of cases collected in 20 data collecting days • Please consult a statistician and decide on a doable sample size. Right now you are chasing almost 600 cases in 20 days or 30 cases in a day. Filling a 6 page Performa and getting a signed consent will take 30 minutes at least. So you are planning to work for 15 hours every day for 20 days! I feel your plan needs a rethink. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P127*** ***(Primary Reviewer: Dr.Surajit Bhattacharya)***
128.	Research proposal entitled ***"A study on prevalence and risk factor of gestational diabetes mellitus (GDM) in rural Lucknow"*** submitted by Dr. Pradeep Kumar Gautam, JR-II, Department of Community Medicine and Public Health of this University via letter no. nil dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P128*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
129.	Research proposal entitled ***"To evaluate the genetic association of MTR, MTRR, MTHFR in non syndromic cleft lip, cleft palate and cleft lip with palate in paediatric patients in northern India"*** submitted by Dr. Aravindhan A, JR-I, Department of Paediatric and Preventive Dentistry Faculty of Dental Sciences of this University via letter no. nil dated 13th June, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment: • Though the desisn is non-randomised but the PI has callously written RCT in one place only. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P129*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
130.	Research proposal entitled ***"Sociodemographic and clinical profile of subjects with female dhat syndrome"*** submitted by Dr. Shubha Joshi, JR-I, Department of Psychiatry of this University via letter no. nil dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P130*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
131.	Research proposal entitled ***"Comparative evaluation of different play therapies for assessing anxiety levels in pediatric dental patients"*** submitted by Dr. Pallavi Yadav, JR-I, Department of Paediatric and Preventive Dentistry Faculty of Dental Sciences of this University via letter no. nil dated 15th June, 2019. **EC Comment:** • The study procedure is not clear. How these 4 groups (listed in heading procedure) will be treated? • What data will be collected? • How it will be analysed • There is lot of ambiguity • Please provide clarification can not be approved in this form **EC Decision:** Re-write & Re-submit ***Ref. code: 97th ECM II B-Thesis/P131*** ***(Primary Reviewer: Dr. Amita Jain)***
132.	Research proposal entitled ***"A cross sectional study of pattern and correlates of tobacco use in patients with schizophrenia"*** submitted by Dr. Shrikrishna Yadav, JR-I, Department of Psychiatry of this University via letter no. nil dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P132*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
133.	Research proposal entitled ***"A comparative study of sensory processing in children and adolescents with autism spectrum disorder and healthy controls"*** submitted by Dr. Mirza Sarwar Baig, JR-II, Department of Psychiatry of this

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	University via letter no. nil dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P133*** ***(Primary Reviewer: Dr. Rajendra Nath)***
134.	Research proposal entitled ***"A follow up study of children and adolescents with dissociative disorder"*** submitted by Dr. Kopal Rohatgi, JR-I, Department of Psychiatry of this University via letter no. nil dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P134*** ***(Primary Reviewer: Dr. Rajeev Garg)***
135.	Research proposal entitled ***"A study of early augmentation with rTMS in patients of drug naïve obsessive- compulsive disorder"*** submitted by Dr. Mohita Joshi, JR-II, Department of Psychiatry of this University via letter no. nil dated 15th June, 2019. **EC Comment:** • Kindly submit as per CONSORT guidelines **EC Decision:** Re-submit ***Ref. code: 97th ECM II B-Thesis/P135*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
136.	Research proposal entitled ***"A study of psychiatric comorbidity in patients with compensated congestive heart failure"*** submitted by Dr. Mohit Jain, JR-I, Department of Psychiatry of this University via letter no. nil dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P136*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
137.	Research proposal entitled ***"A comparative study of burden of care and quality of life between carecivers of patients of alcohol and opioid dependence"*** submitted by Dr. Jabbar Husain, JR-I, Department of Psychiatry of this University via letter no. nil dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P137*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
138.	Research proposal entitled ***"A comparative study of structural and resting state MRI of adolescent with depression and healthy control"*** submitted by Dr. Vinod Kumar Gupta, JR-II, Department of Psychiatry of this University via letter no. nil dated 15th June, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 97th ECM II B-Thesis/P138*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
139.	Research proposal entitled ***"Quality of life among menopausal women in rural and urban areas of Lucknow"*** submitted by Dr. Ginic Gupta, JR-II, Department of Community Medicine and Public Health of this University via letter no. nil dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P139*** ***(Primary Reviewer: Dr. Amita Jain)***
140.	Research proposal entitled ***"A study on Continuum of care in adult Hypertensive patients in Lucknow"*** submitted by Dr. Laxmi Kant Shukla, JR-II, Department of Community Medicine and Public Health of this University via letter no. nil dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P140*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
141.	Research proposal entitled ***"A clinical study of internet gaming in adolescent with Psychiatric disorders"*** submitted by Dr. Praveen Sachan, JR-II, Department of Psychiatry of this University via letter no. nil dated 15th June, 2019. **EC Comment:** • Methodology is not clear, study design is not given **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P141*** ***(Primary Reviewer: Dr. Rajendra Nath)***
142.	Research proposal entitled ***"A study on utilization of Medical termination of pregnancy (MTP) services and concurrent adoption of contraception in Lucknow"*** submitted by Dr. Shruti Singh, JR-II, Department of Community Medicine and Public Health of this University via letter no. nil dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P142*** ***(Primary Reviewer: Dr. Rajeev Garg)***
143.	Research proposal entitled ***"A study of experience of caregiving and coping in caregivers of patients with major neurocognitive disorder due to alzheimer's disease"*** submitted by Dr. Sankalp Dixit, JR-I, Department of Psychiatry of this

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	University via letter no. nil dated 17th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P143*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
144.	Research proposal entitled ***"Experience of caregiving and coping in caregivers of patients with major depressive disorder"*** submitted by Dr. Ashish Kumar, JR-I, Department of Psychiatry of this University via letter no. nil dated 17th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P144*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
145.	Research proposal entitled ***"A study of perceived stress & psychiatric morbidity among postgraduate Medical Students"*** submitted by Dr. Chhaya Singh, JR-I, Department of Community Medicine and Public Health of this University via letter no. nil dated 17th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P145*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
146.	Research proposal entitled ***"Evaluation of temporomandibular joint changes in oral submucous fibrosis patients- A CBCT study"*** submitted by Dr. Yeguri Hema, JR-I, Department of Oral Medicine and Radiology Faculty of Dental Sciences of this University via letter no. nil dated 8th June, 2019. **EC Comment:** • The consent form and the participant information sheet for healthy controls need to be submitted. • Participants' data sheet is not attached. **EC Decision:** Approval after justificaion ***Ref. code: 97th ECM II B-Thesis/P146*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
147.	Research proposal entitled ***"Assessment of efficacy of low level laser therapy (LLLT) with all trans retinoic acid in comparison to efficacy of steroids in osmf patients"*** submitted by Dr. Nahid Hasan, JR-I, Department of Oral Medicine and Radiology Faculty of Dental Sciences of this University via letter no. nil dated 8th June, 2019. **EC Comment:** • Kindly provide Case record form • Sample size is not calculated

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Sample size is 30 – 15 diabetic and 15 non-diabetic. Was this figure statistically derived? • Samples will be obtained in fasting condition in the morning but no data collection sheet is provided and so we do not know what will be observed. • We need a data collection sheet which should have the demographic details, the diabetic status, their oral hygiene, their tobacco / paan / betel nut habit as these people have not been excluded in your study. • Signature missing of Dr. A.B.Pant. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P150*** ***(Primary Reviewer: Dr. Surajit Bhattachrya)***
151.	Research proposal entitled ***"Role of amniotic membrane and platelet rich fibrin in bone healing post endodontic Surgery: A color Doppler sonography study"*** submitted by Dr. Saumya Johri, JR-I, Department of Conservative Dentistry & Endodontics Faculty of Dental Sciences of this University via letter no. nil dated 17th June, 2019. **EC Comment:** • Methodology is not clear **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P151*** ***(Primary Reviewer:Dr. Anoop Kumar Verma)***
152.	Research proposal entitled ***"Comparative evaluation of different irrigating system in removal of gutta-percha/ sealer during retreatment: An in vitro micro-ct study"*** submitted by Dr. Jyoti, JR-II, Department of Conservative Dentistry & Endodontics Faculty of Dental Sciences of this University via letter no. nil dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P152*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
153	Research proposal entitled ***"3D micro-ct analysis of porosity, dissolution and apical extrusion of different root canal sealers: An in vitro study"*** submitted by Dr. Neha Jasrasria, JR-II, Department of Conservative Dentistry & Endodontics Faculty of Dental Sciences of this University via letter no. nil dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P153***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• How & what mentioned is planned? **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P147*** ***(Primary Reviewer: Dr. Amita Jain)***
148.	Research proposal entitled ***"Comparative evaluation of placement of zygomatic implant through extrasinus approach vs. intrasinus approach"*** submitted by Dr. Deepika Kumari Jain, JR-I, Department of Oral Medicine and Radiology Faculty of Dental Sciences of this University via letter no. nil dated 17th June, 2019. **EC Comment:** • Signatures are missing. • Who will bear the cost of implant? Patients can not be asked to bear it. • Kindly clear if any 'conflict of interest is present. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Thesis/P148*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
149.	Research proposal entitled ***"A study of clinic radiological profile and biomarker estimation in smoker and non smoker COPD patient at tertiary care centre"*** submitted by Dr. Mohd Tariq, JR-II, Department of Respiratory Medicine of this University via letter no. nil dated 17th June, 2019. **EC Comment:** • Methodology is not clear • Inform Consent forms are different **EC Decision:** Approval after justification ***Dr. Rajeev Garg did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P149*** ***(Primary Reviewer: Dr. Rajendra Nath)***
150.	Research proposal entitled ***"Metagenomic analysis of salivary and plaque microbiota in diabetic and non-diabetic individuals"*** submitted by Dr. Jyotsana Agarwal, JR-II, Department of Conservative Dentistry & Endodontics Faculty of Dental Sciences of this University via letter no. nil dated 17th June, 2019. **EC Comment:** • Diabetes is associated with higher incidence of root caries and their plaque has a different and aggressive bacterial flora. Bacteria from caries and plaque spill into the saliva. • This is a cross-sectional study in adults between 30 to 60 years of age

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Vimal Kumar Paliwal)
154.	Research proposal entitled ***"Referral of women with post caesarean complication and its outcome in a tertiary care centre: A retrospective study"*** submitted by Dr. Vartika Tripathi, SR, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 17th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P154*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
155.	Research proposal entitled ***"Acute undifferentiated febrile illness-a study of clinical profile and comparative analysis of different diagnositic scores and estimation of cost of treatment at a major tertiary care Institution in Nortern India"*** submitted by Dr. Saurabh Pandey, SR, Department of Medicine of this University via letter no. nil dated 17th June, 2019. **EC Comment:** Signatures are missing. **EC Decision:** Provisionally approved ***Ref code: 97th ECM II B-Thesis/P155*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 97th "Institutional Ethics Committee" Meeting was held on 12th July, 2019

Item no. IIB

Ph.D. Scholar

K.G's Medical University, U.P., Lucknow

IIB	Ph. D. Scholar
1-	Research proposal entitled "***Correlation between cervico- vaginal microbes with HPV persistence, cervical cancer and its recurrence after treatment***" submitted by Dr. Shuchi Shukla under the guidance of Prof. Uma Singh, Department of Obstetrics & Gynaecology this University via letter no. nil dated 4th May, 2019. **EC Comment:** • Who will perform the molecular tests to determine cervico-vaginal microbes? Where will these tests be done? • Who will perform the histopathology for staging of cervical dysplasia and cervical cancer? • The inclusion criteria does not mention about the inclusion of patients undergoing treatment for recurrence of cervical cancer but the topic of the study does mention that cervico-vaginal microbes will be studied in patients with recurrence of cervical cancer. • Is HPV persistence equivalent to dysplasia of cervix? • A flow-chart is required to understand the study methodology. • Consent form for healthy controls is not submitted. • Patient's and participant data sheet is not submitted. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Ph.D./P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled "***Comparision of 18-F NaF bone scan fusion image and high resolution CT to predict recurrence of temporamandibular joint ankylosis***" sponsored by ICMR, New Delhi submitted by Dr. Tasveer Fatima under the guidance of Prof. Shadab Mohammad, Head, Department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences this University via letter no. OMSD/371/19 dated 22nd May, 2019. **EC Comment:** • This proposal is for 3 years period with aim for Ph.D. thesis • Sample size calculation is needed. • Methodology is sketchy is not clear • Case record form is not attached **EC Decision:** Re-write & Re-submit ***Ref. code: 97th ECM II B-Ph.D./P2*** ***(Primary Reviewer: Dr. Amita Jain)***
3.	Research proposal entitled "***A study on staphylococcus aureus bacteraemia in adults and children admitted in a tertiary care centre***" sponsored by ICMR

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	submitted by Dr. Aditi Garg, under the guidance of Prof. Vimala Venkatesh, Department of Microbiology this University via letter no. nil dated 12th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B-Ph.D./P3*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
4	Research proposal entitled ***"A study of brucella species causing unexplained arthritis with or without fever"*** submitted by Dr. Renu Kumari, under the guidance of Prof. Raj Kumar Kalyan, Department of Microbiology this University via letter no. nil dated 13th June, 2019. **EC Decision:** Approved ***Dr. Amita Jain did not take part in the discussion*** ***Ref. code: 97th ECM II B-Ph.D. /P4*** ***(Primary Reviewer: Dr. Rajendra Nath)***
1.	Research proposal entitled ***"A comparative study on hyponatremia in CMS versus non-CNS tuberculosis patients: A correlation with activation of rennin-angiotensin system and stress biomarkers"*** sponsored by ICMR, New Delhi submitted by Ms. Abhilasha Tripathi under the guidance of Prof. Surya Kant, Head, Department of Respiratory Medicine of this University via letter no. nil dated 23rd April, 2019. **EC Comment:** a. The diagnosis of hyponatremia will be considered by two subsequent reports of serum sodium level of <135 meq/l done 24 hours apart. Will a symptomatic patient with hyponatremia not be treated after the first report of serum sodium level of <135 meq/l? If yes, then the serum level is expected to normalize after 24 hours. b. Where will the tests (ANP, BNP, ADH receptor and cytokines) be done? Who will perform the tests? Have you included the concerned lab experts in the study as co-PI? c. The amount of blood sample that is required for the purpose of the study has to be informed to the patient in the patient information document. How many times the blood sample will be taken? Who will pay the cost of tests? Every such information has to be detailed in the patient information document. d. Patient's data sheet (performa) is not attached. **EC Decision:** Approval after justification ***Ref. code: 97th ECM II B-Ph.D/P5*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 97th "Institutional Ethics Committee" Meeting was held on 12th July, 2019

Item no. IIB

Fellowship

K.G's Medical University, U.P., Lucknow

	Fellowship
1-	Research proposal entitled ***"Role of gut microbiome in chronic neuroinflammation followed by young and aged traumatic brain injury"*** sponsored by ICMR New Delhi submitted by Dr. Devlina Ghosh under the guidance Dr. Somil Jaiswal, Associate Professor, Department of Neurosurgery this University via letter no. nil dated 23rd May, 2019. **EC Comment:** • The topic of the study is not clear. Kindly rephrase the topic. • The aim of the study does not matches with the research hypothesis. The aim of the study is to "develop the molecular markers in young and aged TBI patient". What these molecular markers are meant for? Are these molecular markers already proven for neuroinflammation? If yes, then what is the purpose of the study? If no, then the study should be aimed to determine the role of some of the chosen molecular markers in the chronic neuroinflammation post-TBI. The second aim should be determine the dynamic changes in the gut microbiota and how it changes the peripheral microphage activation. Aim of the study does not talk about any dietery intervention but the research hypothesis does, which further brings confusion. • The first blood sample will be taken at < 1 hour. Is it < 1 hour post-head trauma or <1 hour after admission. Is it possible to get TBI patients at < 1 hour after the TBI? • Who will perform the micro RNA, cytokines, MMPs, MBP, NSE, S100 and M1, M2 activation phenotypes? Is that nodal person a part of this study? Who will pay for the tests? Please provide the name of the center where these tests are to be done and also provide a list of all the equipment that are available at the center where these tests are to be done. • Kindly describe in details the methods of performing all these tests • How will the changes in the gut microbiome be detected. What do you expect to happen to gut microbiome over time? How will you relate the gut microbiome changes to ongoing neuroinflammation? • Macrophage activation will be done ex-vivo by exposing them to probiotics. Who will pay for the probiotics? • Why are you choosing both young and old patients with TBI? Nowhere in your methods have you discussed the implications of choosing patients with two distinct age groups. • Please provide a flow-chart of the methods. • The study is not written properly. It has too many variables to study. Ethics committee suggests you to kindly make a more simplified study design with

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	very clearly written objectives and aims of study and clear and crisp methodology. • Patient's data sheet is not provided. • Poorly written **EC Decision:** Approval after justification ***Ref. code: 97th ECM IIB FS/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 97th "Institutional Ethics Committee" Meeting was held on 12th July, 2019

Item no. IIB

Intra Mural Research
Faculty, Resident & Student

K.G's Medical University, U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 97th ECM held on 12th July, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

IIB	IMR-Faculty
1.	Research proposal entitled "***Anatomical aspects of rectus abdominis muscle flaps used in plastic and reconstructive surgeries: A radiographic cadaveric dye injection study in North India***" sponsored by Research Cell KGMU Lucknow submitted by Dr. Sushma Tomar, Assistant Professr, Department of Anatomy this University via letter no. 113/ANA/19 dated 7th June, 2019. **EC Decision:** Approved ***Dr. Anoop Kumar Verma did not take part in the discussion.*** ***Ref. code: 97th ECM II B IMR-F/P1*** ***(Primary Reviewer: Dr. Rajendra Nath)***
Sl no.	**IMR (Resident)**
1-	Research proposal entitled "***Expression of SOX2 and OCT 4 in colorectal adenocarcinomas, and their correlation with clinic- pathological parameters and treatment outcomes***" sponsored by of Research Cell KGMU submitted by Dr. Abigail Veravolu Resu, JR-II under the guidance Prof. Rajeev Gupta, Head, Department of Radiotherapy this University via letter no. nil dated 17th May, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II B IMR-R/P1*** ***(Primary Reviewer: Dr. Rajeev Garg)***
	IMR- Student
1.	Research proposal entitled ***"Diagnostic comparison between liquid based cytology (LBC) and visual inspection of acetowhite areas (VIA) in pre invasive cervical lesions"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Ms. Anshika, BDS III under the guidance Prof. Rekha Sachan, Department of Obstetrics & Gynaecology via letter no. nil dated nil. **EC Comment:** • Signatures are missing. **EC Decision:** Provissionally approved ***Ref. code: 97th ECM IIB IMR-S/P1*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 97th "Institutional Ethics Committee" Meeting was held on 12th July, 2019

Item no. IIB

MBBS

K.G's Medical University, U.P., Lucknow

	MBBS- Student
1.	Research proposal entitled ***"A retrospective comparative study to assess the outcome of two anti- tubercular regimens in previously treated patients of tuberculosis"A retrospective comparative study to assess the outcome of two anti- tubercular regimens in previously treated patients of tuberculosis"*** submitted by Miss. Priya Singh, MBBS under the guidance Prof. Surya Kant, Head, Department of Respiratory Medicine of this University via letter no. nil dated 24th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IIB MBBS/P1*** ***(Primary Reviewer: Dr. Rajeev Garg)***
2.	Research proposal entitled ***"Seasonal Glycemic variability in patient with Type -2 DM during mango season"*** submitted by Mr. Abhishek Singh, MBBS under the guidance Prof. Narsingh Verma, Department of Physiology of this University via letter no. nil dated 17th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IIB MBBS/P2*** ***(Primary Reviewer: Dr. Rajeev Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 97th "Institutional Ethics Committee" Meeting was held on 12th July, 2019

Item no. IIB

Master's in Hospital Administration

K.G's Medical University, U.P., Lucknow

IIB	Master's in Hospital Administration(MHA)
1.	Research proposal entitled ***"A study of eye bank in a tertiary care government Hospital"*** submitted by Dr. Preeti Bharti under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/285 dated 7th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IIB MHA/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Pal)***
2.	Research proposal entitled ***"A study of waste generated of various categories as per Bio- Medical waste rule 2016 in selected areas of a tertiary care government Hospital"*** submitted by Dr. Preeti Bharti under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/303 dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IIB MHA/P2*** ***(Primary Reviewer: Dr. Amita Jain)***
3.	Research proposal entitled ***"A study of biomedical waste generated in selected areas as per biomedical rules 2016 in a tertiary care government teaching Hospital"*** submitted by Dr. Anubha Agrawal under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/309 dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IIB MHA/P3*** ***(Primary Reviewer Dr. Balendra Pratap Singh)***
4.	Research proposal entitled ***"A study of blood safety in blood bank in a tertiary care government Hospital"*** submitted by Dr. Amit kumar, JRII under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/307 dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IIB MHA/P4*** ***(Primary Reviewer: Dr. Rajendra Nath)***
5.	Research proposal entitled ***"A study on utilization pattern of personal protective equipment by bio- medical waste handlers in selected area of tertiary care government Hospital"*** submitted by Dr. Anshuman Shukla under the guidance Prof.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/325 dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IIB MHA/P5*** ***(Primary Reviewer: Dr. Rajeev Garg)***
6.	Research proposal entitled ***"A study on discharge documentation in a tertiary care government Hospital in Lucknow"*** submitted by Dr. Sukriti Shah under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/312 dated 14th June, 2019. **EC Comment:** • The aim is to study the contents of the discharge summary, compare with standard guidelines, and study the policy of discharge documentation in regular discharge, LAMA and DOPR. • Sample size is 100. Statistically derived, • There is a selection bias as critical patients are excluded • Data collection in 2 weeks only. Will there be 100 discharges in 2 weeks from the Unit? • Waiver of consent is sought as the researchers claim that it is collection of data about Units other than individual patients • Data collection form is not provided • This is not true. You cannot see a patient's discharge slip and know about his disease without his/her consent. **EC Decision:** Approval after justification ***Ref. code: 97th ECM IIB MHA/P6*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
7.	Research proposal entitled ***"A study of biomedical waste generated in selected area of a tertiary care government Hospital"*** submitted by Dr. Sukriti Shah under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/308 dated 14th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IIB MHA/P7*** ***(Primary Reviewer: Anoop Kumar Verma)***
8.	Research proposal entitled ***"A study of the biomedical waste generated as per the biomedical medical rule 2016 in selected areas of a tertiary care government Hospital in Lucknow"*** submitted by Dr. Shweta Singh under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/306

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	dated 14th June, 2019. **EC Decision:** No ethical approval needed ***Ref. code: 97th ECM IIB MHA/P8*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
9.	Research proposal entitled ***"A study of operation theatres in the trauma centre of a tertiary care government Hospital"*** submitted by Dr. Shashvat Kshitij Sinha under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/304 dated 14th June, 2019. **EC Decision:** No ethical approval needed ***Ref. code: 97th ECM IIB MHA/P9*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
10.	Research proposal entitled ***"A study on utilization pattern of personal protective equipment's by bio- medical waste handlers in selected area of tertiary care government Hospital"*** submitted by Dr. Naveen Chaturvedi, under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/313 dated 14th June, 2019. **EC Decision:** No ethical approval needed ***Ref. code: 97th ECM IIB MHA/P10*** ***(Primary Reviewer: Dr. Amita Jain)***
11.	Research proposal entitled ***"A study on workload analysis and time taken for lab investigations at trauma centre of tertiary care government Hospital"*** submitted by Dr. Naveen Chaturvedi under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/315 dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IIB MHA/P11*** ***(Primary Reviewer:Dr. Balendra Pratap Singh)***
12.	Research proposal entitled ***"To study cost of handing bio-Medical glass waste in a tertiary care government Hospital"*** submitted by Dr. Shweta Budhiraja, under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/320 dated 15th June, 2019. **EC Decision:** No ethical approval needed ***Ref. code: 97th ECM IIB MHA/P12*** ***(Primary Reviewer: Dr. Rajendra Nath)***
13.	Research proposal entitled ***"A study of gas manifold and liquid gas service in a tertiary care government Hospital at Lucknow"*** submitted by Dr. Shweta Budhiraja, under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	via letter no. HA/2019/321 dated 15th June, 2019. **EC Decision:** No ethical approval needed ***Ref. code: 97th ECM IIB MHA/P13*** ***(Primary Reviewer: Dr. Rajeev Garg)***
14.	Research proposal entitled ***"A study of biomedical waste generated as per bio medical rules 2016 in selected areas of a tertiary care government Hospital at Lucknow"*** submitted by Dr. Prawaal Mehrotra, under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/324 dated 15th June, 2019. **EC Decision:** No ethical approval needed ***Ref. code: 97th ECM IIB MHA/P14*** ***(Primary Reviewer:Dr. Surajit Bhattacharya)***
15.	Research proposal entitled ***"A study of bio- medical waste generated in selected areas of a tertiary care government Hospital"*** submitted by Dr. Shreya Pandey, under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/318 dated 15th June, 2019. **EC Decision:** No ethical approval needed ***Ref. code: 97th ECM IIB MHA/P15*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
16.	Research proposal entitled ***"A study on knowledge, attitude and behavior with respect to fire safety among the employees of the tertiary care government teaching Hospital"*** submitted by Dr. Shreya Pandey, under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/319 dated 15th June, 2019. **EC Comment:** • Kindly provded Questionnaire. • Poorly written **EC Decision:** Re-seubmit ***Ref. code: 97th ECM IIB MHA/P16*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
17.	Research proposal entitled ***"A study of bio- Medical waste generated in selected areas of a tertiary care government Hospital"*** submitted by Dr. Sandhya Yadav, under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/316 dated 15th June, 2019. **EC Decision:** No ethical approval needed

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 97th ECM IIB MHA/P17
	(Primary Reviewer: Dr. Vimal Kumar Paliwal)
18.	Research proposal entitled ***"A study on workload analysis of trauma cases at trauma center of a tertiary care government Hospital"*** submitted by Dr. Sandhya Yadav, under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/317 dated 15th June, 2019. **EC Decision:** No ethical approval needed ***Ref. code: 97th ECM IIB MHA/P18*** ***(Primary Reviewer: Dr. Amita Jain)***
19.	Research proposal entitled ***"A study to compare the red category bio- Medical waste generated with respect to disinfected plastic waste generated in selected tertiary care Hospital"*** submitted by Dr. Shashvat Kshitij Sinha under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/305 dated 14th June, 2019. **EC Decision:** No ethical approval needed ***Ref. code: 97th ECM IIB MHA/P19*** ***(Primary Reviewer: Dr.Balendra Pratap Singh)***
20.	Research proposal entitled ***"A study of Radiotherapy Department in a tertiary care government Hospital"*** submitted by Dr. Anubhuti, under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/314 dated 15th June, 2019. **EC Decision:** No ethical approval needed ***Ref. code: 97th ECM IIB MHA/P20*** ***(Primary Reviewer: Dr. Rajendra Nath)***
21.	Research proposal entitled ***"A study of bio-medical waste generated in selected areas of a tertiary care government Hospital"*** submitted by Dr. Anubhuti, under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/310 dated 15th June, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IIB MHA/P21*** ***(Primary Reviewer: Dr. Rajeev Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 97th "Institutional Ethics Committee" Meeting was held on 12th July, 2019

Item no. IID

Nurses
KGMU

K.G's Medical University, U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 97th ECM held on 12th July, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

II-(C)	**Review of new Drug Trial**
	None
II-D	**Nurses**
1.	Research proposal entitled ***"A descriptive study to assess the effectiveness of structural teaching program on knowledge of menstrual hygiene among adolescent girls selected school of Lucknow"*** submitted by Mrs. Priyanka Singh, KGMU College of Nursing of this University via letter no. dated 16th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IID/P1*** ***(Primary Reviewer: Dr.Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"A descriptive study to assess the level of depression and anxiety among patients having multi drug resistance TB(MDR-TB) taking treatment in KCH, Department of Respiratory Medicine, KGMU, Lucknow, U.P."*** submitted by Mr. G. Srinivasan, KGMU College of Nursing of this University via letter no. dated 16th April, 2019. **EC Decision:** • Methodology & sample size estimation is not provided **EC Decision:** Revise & Re-submit ***Ref. code: 97th ECM IID/P2*** ***(Primary Reviewer: Dr. Amita Jain)***
3.	Research proposal entitled ***"A descriptive study to assess the anxiety among antenatal mothers among queen mary KGMU, Lucknow"*** submitted by Mrs. Suman Lata, KGMU College of Nursing of this University via letter no. nil dated 16th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IID/P3*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
4.	Research proposal entitled ***"A cross sectional descriptive study to assess the emotional intelligence among Nursing Students"*** submitted by Ms. Urvashi Sharma, KGMU College of Nursing of this University via letter no. nil dated 16th April, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM IID/P4*** ***(Primary Reviewer: Dr. Rajendra Nath)***
5.	Research proposal entitled ***"A cross sectional study to assess the co- dependency, anxiety, depression and family burden among the caregivers of patient with opioid***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	dependence syndrome at a tertiary care unit of North India" submitted by Miss. Sanju Pant through Mrs. Sudha Mishra, Assistant Professor, KGMU Institute of Nursing via letter no.475/19 dated 23rd May, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P5*** ***(Primary Reviewer: Dr. Rajeev Garg)***
6.	Research proposal entitled ***"Effectiveness of planned teaching program regarding worm infestation on knowledge among the mothers of under five children in the selected rural areas"*** submitted by Mr. Sandeep Yadav through Mr. Rohitash Kumar, Assistant Professor, KGMU Institute of Nursing via letter no.482/19 dated 23rd May, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P6*** ***(Primary Reviewer: Dr. Surajit Bhattachrya)***
7.	Research proposal entitled ***"Effectiveness of educational intervention regarding foot care on knowledge among diabetes mellitus patients at selected Health Centre"*** submitted by Miss. Anjali Pandey through Mr. Rohitash Kumar, Assistant Professor, KGMU Institute of Nursing via letter no.483/19 dated 23rd May, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P7*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
8.	Research proposal entitled ***"Efficacy of information booklet regarding home care management on knowledge among patients with permanent pacemaker"*** submitted by Miss. Nidhi Tripathi through Mrs. Rashmi P. John, HOD, KGMU Institute of Nursing via letter no.500/19 dated 28th May, 2019. **EC Comment:** • its a study based on new non validated questionnaire **EC Decision:**Re-write & Re-submit ***Ref. code: 91st ECM IID /P8*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
9.	Research proposal entitled ***"Effectiveness of structured teaching program regarding child abuse on knowledge among mothers of School- age children in the selected rural areas"*** submitted by Ms. Sanghpriya through Mr. Rohitash Kumar, Assistant Professor, KGMU Institute of Nursing via letter no.480/19 dated 23rd May, 2019. **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 91st ECM IID /P9 ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
10.	Research proposal entitled ***"Effectiveness of a planned teaching program regarding modified bass brushing technique on knowledge among School children at selected School of rural area"*** submitted by Ms. Shweta Macknight through Mr. Rohitash Kumar, Assistant Professor, KGMU Institute of Nursing via letter no.477/19 dated 23rd May, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P10*** ***(Primary Reviewer: Dr. Amita Jain)***
11.	Research proposal entitled ***"A cross sectional study to assess the relationship between stigma, self- esteem and quality of life among patients with depression at a tertiary care unit of North India"*** submitted by Ms. Jyoti Yadav through Mrs. Sudha Mishra, Assistant Professor, KGMU Institute of Nursing via letter no.473/19 dated 23rd May, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P11*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
12.	Research proposal entitled ***"Effectiveness of informational module regarding polycystic ovarian syndrome on knowledge among young women of selected College at Lucknow"*** submitted by Miss. Rajni through Mrs. Sarita Dubey, Assistant Professor, KGMU Institute of Nursing via letter no.469/19 dated 23rd May, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P12*** ***(Primary Reviewer: Dr. Rajendra Nath)***
13.	Research proposal entitled ***"Impact of early ambulation after femoral approach coronary intervention (FACI) on patient's outcome"*** submitted by Miss. Anchal Gupta, through Dr. Suchana Roy Bhowmik, Assistant Professor, KGMU Institute of Nursing via letter no.476/19 dated 23rd May, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P13*** ***(Primary Reviewer: Dr. Rajeev Garg)***
14.	Research proposal entitled ***"Effectiveness of mirror therapy to improve upper extremity motor function and activity of daily living in stroke patients at Department of Neurology KGMU Lucknow"*** submitted by Ms. Vandana Dwivedi, through Mrs. Kumari Nutan, Assistant Professor, KGMU Institute of Nursing via

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	letter no.498/19 dated 28th May, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P14*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
15.	Research proposal entitled ***"Effectiveness of structured teaching program regarding reproductive Health on knowledge among adolescent Girls in selected School of rural area"*** submitted by Ms. Sarita Singh through Mr. Rohitash Kumar, Assistant Professor, KGMU Institute of Nursing via letter no.481/19 dated 23rd May, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P15*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
16.	Research proposal entitled ***"Effectiveness of an information booklet on the knowledge of caregivers regarding home based management of Children with thalassemia"*** submitted by Ms. Rupali Verma through Mrs. Rina Km, KGMU Institute of Nursing via letter no.484/19 dated 23rd May, 2019. **EC Comment:** • Title does not reflect the the work. Questionnare needs to be validated. **EC Decision:** Revise and resubmit ***Ref. code: 91st ECM IID /P16*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
17.	Research proposal entitled ***"Effectiveness of structured teaching programme regarding prevention of sexually transmitted infections on knowledge among women attending department of Obstetrics and Gynaecology KGMU, Lucknow"*** submitted by Ms. Pooja Baghari through Mrs. Sumamlata, KGMU Institute of Nursing via letter no.499/19 dated 28th April, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P17*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
18.	Research proposal entitled ***"Effectiveness of essential newborn care bundle (ENCB) on knowledge and practice regarding newborn care among primi parous mother's in Department of Obstetrics and Gynecology, KGMU, Lucknow"*** submitted by Ms. Jyoti Verma through Mrs. Sumamlata, KGMU Institute of Nursing via letter no.474/19 dated 23rd April, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P18*** ***(Primary Reviewer: Dr. Amita Jain)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

19.	Research proposal entitled ***"Effectiveness of breathing exercise on dyspnea and quality of sleep among patients with chronic obstructive pulmonary disease at Department of Respiratory Medicine K.G.M.U Lucknow"*** submitted by Mr. Neha Rajput, through Mrs. Rashmi P. John, Head, Department of Medical Surgical KGMU Institute of Nursing via letter no.471/19 dated 23rd April, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P19*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
20.	Research proposal entitled ***"Effect of warm compression on labor pains during active phase of 1st stage of labor in primigravida"*** submitted by Mrs. Archana Chaudhary through Mrs. Sarita Dudey KGMU Institute of Nursing via letter no.472/19 dated 23rd April, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P20*** ***(Primary Reviewer: Dr. Rajendra Nath)***
21.	Research proposal entitled ***"Effectiveness of topical application of mixture of honey and coffee in radiation induced oral mucositis among patients with Head & Neck cancer undergoing radiotherapy at Radiotherapy Department of KGMU, Lucknow"*** submitted by Ms. Anjali Verma through Mrs. Rashmi P John, HOD, Medical Surgicall KGMU Institute of Nursing via letter no.478/19 dated 23rd April, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P21*** ***(Primary Reviewer Dr. Rajeev Garg)***
22.	Research proposal entitled ***"Effectiveness of an instructional module regarding first aid of Pediatric emergencies on knowledge among mothers of 1-6 years children"*** submitted by Ms. Arti through Mrs. Rine Km, KGMU Institute of Nursing via letter no.485/19 dated 23rd April, 2019. **EC Decision:** Approved ***Ref. code: 91st ECM IID /P22*** ***(Primary Reviewer: Dr. Surajit Bhattacrya)***
23.	Research proposal entitled ***"Effectiveness of structured teaching programme regarding post operative care on knowledge and practice among caregivers of the children with anorectal malformation at Department of paediatric"*** submitted by Miss. Monika Pal through Mrs. Rina Raj, KGMU Institute of Nursing via letter no.470/19 dated 23rd April, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 91st ECM IID /P23*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
24.	Research proposal entitled ***"Effectiveness of structured teaching programme regarding optimal feeding practice on knowledge and practices among mothrs of low birth weight newbornms in nicu ward, KGMU"*** submitted by Ms. Payal Saha, through Mrs. Rina Raj, KGMU Institute of Nursing via letter no.479/19 dated 23rd April, 2019. **EC Decision:** • Title is not reflective of the work • very confusing.non validated self made questionnaire **EC Decision:** Re-submit ***Ref. code: 91st ECM IID /P24*** ***(Primary Reviewer : Dr. A.A. Sonkar)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 97th "Institutional Ethics Committee" Meeting was held on 12th July, 2019

Item no. III

Adverse Drug Reaction

K.G's Medical University, U.P., Lucknow

IIIB	Adverse Drug Event
1.	ADE research protocol no. MYL-1402O-3001 entitled "***Multicentre, double-blind, randomization, parallel-group study to assess the efficacy and safety of MYL-14020 compared with Avastin ®, in the first-line treatment of patient with stage IV non-squamous non-samll cell lung cancer***" sponsored by M/s Mylan GmbH by submitted by Dr. Sameer Gupta, Associate Professor, Department of Surgical Oncology of this University via letter no. nil dated 25th April, 2019. **Hospitalization:** **Patient Initial:** P-P **Patient ID: 181011** **Date of Start:** 22nd March, 2018 **Adverse Event:** **SAE:** (181011) **Subject History:** Subject was screened into the study on 22nd March, 2018 with deiagnosis of Stage IV non-squamous non-small cell lung cancer (Adenocarcnoma). Subject had taen two cycles of blinded drug-Bevaciuab and chemotherapy drugs-carboplatin & paclitaxel,3 weekly egimen.Subject had received las dose of Bevacizumab, carboplatin & paclitaxel on 18th April,2018. After dosing subject was discharged form hospital in stable condition. Subject attendant informed the site CRC telephonically around 9 am on 25th April, 2018 that subject was complaining of frequent waterly stools for last 12 hours. CRC informed the P.I. and P.I. suggested that should report in the hospital immediately and also advised to have CBC, KFT and serum electrolytes done at local lab. Subject reported ih ward with hicattendet around 16:05 after getting his blood tests done at local lab. Subject was conscious, oriented but slightly dehydrated. Pulse rate=104,BP=108/70 with sight increased respiratory rate. Subject also complaint of superficial aphthous ulcers causing him difficulty in eating. There was no fever, vomiting, pain abdomen or cough, Immediately subject was started on intravenous fluide, iv. Cipla, Metrogyi, Pantop and Ondansetron and oral Darola and electral powder with input-output charting and oxygen by mask. For oral ulcers, subject was advised to take Folic acid tablets, Boroglycertine mouth paint and Chlorhexidine mouthvash, Subject blood counts revelaed Neutropenia (Hb=15 mg/dl:TLC count= 1600 and Platelet count=76,000/cumon) and Inj G-CSF subcutaneously 12 houtly started along with all aseptic precautions and isolation. Hourly record of vitals was maintanined. by late evening (20:00 pm). Patient started improving wit ear mormal pulse and blood pressure (Pulse=92 and BP=118/70) and diarrhea also improved (3 episodes over last 4 hours). no vever. Subject was taken off ostgen. A subject was tolerating orally well and was advised to avoid mild products. Subject was advised to continue taking his cardiac medications as recommended by physician. Overnight patient improved with only 2 episodes of semi-formed motions, no complaints of fever, vomiting or pain abdomen. Onmorning of 26th April, Inj G-CSF was repeated and repeat complete blood counts (CBS, LFT and KFT) sent at local lab. Patient was taken off i.v. fluids and encouraged to take oral food. Oral uncers also symptomatically improved and subject was tolerating oral diet well, Repeat blood counts revcaled normal blood couts (HB-13.9 mg/dl, TLC=4000 and

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Platelet count= 160.000) and normal KFT and LFT. In view of normal blld counts and no further complaints of ***diarrhea, subject was started on oral antibiotics and probiotics and*** was discharged in stable condition after considering recovered from presenting condition on subject request. This event was considered SAE in view of overninght in-hospital stay. Con-med log for treatment of SAE updated. Updated information: At the time of SAE actually action taken to allIMP and chemotherapy was no action taken but inadvertently was no selected now it has been corrected. **EC Decision:** Re-submit ***Ref. code: 81th ECM IIC/P3*** ***(Primary Reviewer : Dr. Balendra Pratap Singh)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 97th "Institutional Ethics Committee" Meeting was held on 12th July, 2019

Item no. V

Annual Progress Reports

K.G's Medical University, U.P., Lucknow

V-	Annual Progress Reports
1.	Annual Progress Report of research protocol no. entitled*" Histopathology of the jejunoileal atreisa- can we determine the length of adequate resection"* submitted by Dr. Anand Pandey, Associate Professor, Department of Pediatric Surgery of this University via letter no. 131/2019. Dated 5th April, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 87th ECM IIA/ P6*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
2.	Annual Progress Report of research protocol no. KCP-330-009, entitled ***"A phase 2b open-label study of selinexor (KPT-330) in Patients with relapsed/ refractory diffuse large B-cell lymphoma (DLBCL)"*** sponsored by M/s Karyopharm Therapeutics Ltd submitted by Dr. Shailendra Prasad Verma, Principal Investigator & Assistant Professor, Department of Clinical Hematology of this University via letter no. 243/CH/19 Dated 10th April, 2019. **EC Decision:** Kindy provide updated report ***Ref. code: 88th ECM IIC/ P1*** ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Annual Progress Report of research protocol no. entitled ***"Magnesium sulfate (MAGSALF) for fetal neuroprotection given in spontaneous preterm birth versus magnesium sulfate for hypertensive disorder of pregnancy versus preterm newborn not receiving magsalf- A comparative prospective cohort study"*** submitted by Dr. Namrata Kumar, Assistant Professor, Department of Obstetrics and Gynecology of this University via letter no. nil Dated 16th April, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 87th ECM IIA/ P1*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Annual Progress Report of research protocol entitled ***"Gender specific vulnerabilities & socio-psychological factors in tuberculosis female patient population"*** submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine of this University via letter no. nil Dated nil. **EC Decision:** Reviewed & noted ***Ref. code: 87th ECM IIA/ P16*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
5.	Annual Progress Report of research protocol no.I1F-MC-RHCF ***"A 52 Week***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Multicenter, Randomized, Open-Label, Parallel-Group Study Evaluating the Efficacy and Safety of Ixekizumab versus Adalimumab in Patients with Psoriatic Arthritis Who Are Biologic Disease Modifying Anti-Rheumatic Drug naive" sponsored by Eli Lilly and Company (India) Pvt. Ltd. submitted by Prof. Urmila Dhakad, Head, Department of Rheumatology of this University via letter no. 635/2019 Dated 26th April, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 86th ECM IIC/ P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
6.	Annual Progress Report of research proposal entitled ***"Efficacy of Optical Coherence tomography in detection of dysplasia in Oral premalignant disorders"*** submitted by Dr. Ranjitkumar Patil, Department of Oral Medicine & Radiology, Faculty of Dental Sciences this of University via letter no. 280/MSR/19 Dated 22th April, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 87th ECM IIA/ P14*** ***(Primary Reviewer: Dr. Rajeev Garg)***
7.	Annual Progress Report of research protocol entitled ***"Predictive model for oral cancer risk through up - regulation of BC12 oncogene in chronic periodontitis patients"*** submitted by Dr. Rameshwari Singhal, Associate Professor, Department of Periodentology, Faculty of Dental Sciences of this University via letter no. 46/EMP/19 Dated 15th May, 2019. **EC Decision:** Kindly provide updated report ***Ref. code: 89th ECM IIA/ P13*** ***(Primary Reviewer:Dr. A.A. Sonkar)***
8.	Annual Progress Report of research proposal entiltled ***"RAS signaling pathway and EMT (Epithelial to Mesenchymal Transition) in bladder cancer patients"*** submitted by Prof. Apul Goel, Department of Urology of this University via letter no. 46/EMP/19 Dated 15th May, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 89th ECM IIA/ P8*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
9.	Annual Progress Report of research proposal entitled ***"Prevalence of leptospirosis in patient with pyrexia of unknown origin at a tertiary care centre in Northern India"*** submitted by Prof. Raj Kumar Kaylan, Department of Microbiology of this University via letter no. nil Dated nil. **EC Decision:** Reviewed & noted

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 88th ECM IIA/ P4 ***(Primary Reviewer: Dr. Amita Jain)***
10.	Annual Progress Report of research proposal entitled ***"Differential expression of inflammatory responsive genes between chronic Periodontitis and Periodontally affected Bronchiectasis patients"*** submitted by Prof. Umesh Pratap Verma, Department of Periodontology, Faculty of Dental Sciences of this University via letter no. 24/PN/19 Dated 15th May, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 89th ECM II A/P2*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
11.	Annual Progress Report of research protocol no.CLCZ696D2302 entitled ***"A 24 – week, randomized double-blind, multi-center, parallel group, active controlled study to evaluate the effect of LCZ696 on NT-proBNP, symptoms, exercise function and safety compared to individualized medical management of comorbidities in patients with heart failure and preserved ejection fraction"*** sponsored by Eli Lilly and Company (India) Pvt. Ltd. submitted by Dr. Rishi Sethi, Professor, Department of Cardiology this University via letter no. 437/Cardio/Res/2019 Dated 15th May, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 89th ECM II C/P7*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
12.	Annual Progress Report of research protocol no. **CT/REPA+VOGL/DIA/14** entitled ***"Fixed dose combinations (FDC) of repaglinide (0.5mg/1mg) + voglibose (0.2mg/0.3mg) phase III clinical trial"*** sponsored by M/s Torrent Research Centre Ltd, submitted by Prof. Arvind Kumar Mishra, Department of Medicine this University via letter no. nil. Dated 28th May, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 86th ECM II C/P6*** ***(Primary Reviewer: Dr. Amita Jain)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

VI-	**Any Other Matters** *(With the Permission of Chairperson)*
1.	Research proposal entitled ***"A study to assess the effectiveness of planned teachin program on the knowledge and practice regarding dietary pattern amongh mothers of children with tuberculosis admitted in pediatric ward at KGMU hospital, Lucknow"*** submitted by Ms. Anchal Tiwari, Obstetrics and Gynaecology Nursing to ***change the name of Co-guide Mrs. Anugrah Charan in place of Mrs. Fauzia Jawaid Kazi, Assistant Professsor KGMU Institute of Nursing, Lucknow*** of this University of this University via letter no. nil dated 21st June, 2019. **EC Decision:** Permission granted ***Ref. code: 90th ECM IID/P5*** ***(Primary Reviewer : Dr.Anuradha Nischal Previous Primary Reviewer)***
2.	Research proposal entitled ***"Effectiveness of chlorhexidine mouthwash propylaxis for prevention of ventilator-associated pneumonia among children receiving mechanical ventilation in pediatric intensive care unit at KGMU, Lucknow, U.P."*** submitted by Mr. Sanjay Kumar Sahu, Paediatric Nursing to change the name of Co-guide Mrs. Anugrah Charan in place of Mrs. Fauzia Jawaid Kazi, Assistant Professsor KGMU Institute of Nursing, Lucknow of this University of this University via letter no. nil dated 21st June, 2019. **EC Decision:** Permission granted ***Ref. code: 90th ECM IID/P7*** ***(Primary Reviewer : Dr. Surajit Bhattacharya)***
3.	Research proposal entitled ***"A study to assess the effectiveness of the vedio assisted teachin program on knowledge and anxiety regarding colostomy care among the care givers of the childen undergoing colostomy at KGMU, Lucknow"*** submitted by Ms. Kalpana Maurya, Obstetrics and Gynaecology Nursing to change the name of Co-guide Mrs. Anugrah Charan in place of Mrs. Fauzia Jawaid Kazi, Assistant Professsor KGMU Institute of Nursing, Lucknow of this University of this University via letter no. nil dated 21st June, 2019. **EC Decision:** Permission granted ***Ref. code: 90th ECM IID/P6*** ***(Primary Reviewer : Dr. Rajeev Garg)***
4.	Research proposal entitled ***"A study to assess the effectiveness of information brochure on knowledge and practice regarding "home management of side effects of***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	chemotherapy" among primary care givers of pediatrics patients admitted ant department of pediatric oncology KGMU, Lucknow" submitted by Mr. Anil Kumar, Child Health Nursing to change the name of Co-guide Mrs. Anugrah Charan in place of Mrs. Fauzia Jawaid Kazi, Assistant Professsor KGMU Institute of Nursing, Lucknow of this University of this University via letter no. nil dated 21st June, 2019. **EC Decision:** Permission granted ***Ref. code: 90th ECM IID/P10*** ***(Primary Reviewer : Dr. Balendra Pratap Singh)***
5.	Research proposal entitled ***"Early post operative refraction as predictor of bisual and binocular recovery in children undergoing surgery for cataract"*** submitted by Dr. Sajan Dev Kesar, JR-I, Department of Ophthalmology of this University via letter no. nil dated 19th June, 2019. ***The above proposal has already approved in the last EC meeting was held on 10th May, 2019 but the Principal-Investigator has submitted his profarma at the time of his presentation,then the Departmental Committee has suggest that this topic should be revised, so the current title is following:*** ***"Factors affecting vsual outcome in childen undergoing cataract surgery"*** ***The P.I. has requested kindly approve the above topic as per Departmental Committee.*** **EC Decision:** Permission granted ***Ref. code: 96th ECM II B-Thesis/P38*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
6-	Regarding permission to change of tool after Ethical Clearance in conducting a research prject titled as ***'A cross-sectional study to assess psychosocial stressors in elderly with depression"*** at Department of Geriatric Mental Health of this Univeristy submitted by Mr. Shubham Gupta M.Sc (N) II year of this University under the guidance of Mrs. Sudha Mishra, Assistant Proessor, Department of G.M.H. of this University. **EC Decision:** Permission granted

The End

The next meeting date 6th September, 2019

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 98th ECM held on 6th September, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

Minutes of the **"Institutional Ethics Committee"** Meeting to be held on **6th September, 2019 from 2.00 p.m. 4.30 p.m.** in the **'Board Room',** Office of the Vice Chancellor, Administrative Block of this University.

The following members were present in the Meeting

1- Prof.S.P. S Gaur	-Chairman
2- Justice Hin'ble Vishnu Sahai	- Member
3- Dr. Surajit Bhattacharya	-Member
4- Dr. Vimal Kumar Paliwal	-Member
5- Dr. Manju Agrawal	-Member
6- Mr. Ram Niwas Jain	-Member
7- Prof. Amita Jain	-Member
8- Prof. Rajendra Nath	-Member
9- Prof. Anoop Kumar Verma	-Member
10- Prof. Rajeev Garg	-Member
11- Prof. R. K. Garg	-Member-Secretary, Ex-officio

The following Members were not present:

1- Prof. A.A. Sonkar	-Member (send his written comment)
2- Prof. Balendra Pratap Singh	- Member(send his written comment)
3- Dr. Preeti Agarwal	-Member (On maternity leave)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. IA

Action Taken

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 98th ECM held on 6th September, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

I. (A) Action taken

IA	Action Taken on decisions of previous Ethics Committee Meeting
	Part -a- 96th ECM was held on 10th May, 2019
a1	Clarification of research proposal entitled ***"Study of severity of airflow limitation in treated post- TB COPD subjects in India"*** submitted by Prof. Suryakant, Department of Respiratory Medicine of this University via letter no. nil dated 29th January, 2019. **EC Comment on 10th May, 2019:** • Sample size is written as 1000. Is it achievable in the study duration of 6 months? How the sample size calculated? • Methods are not provided. A detailed elaboration of methods needs to be provided. In patient information document, the authors claimed that they will use a questionnaire prepared by RRNI (?). What is RRNI? What is the role of RRNI in this study? No questionnaire is provided for review of ethics committee. • Patient information document in English and Hindi are grossly deficient. The headings like risk from the study, complication, compensation cannot be written as Nil. Things have to be described in some detail. How will the confidentiality be maintained? What are the rights of the patient? What if patients refuse to take part in the study? What are the alternatives? All these headings have to be described as it is an important part of informed consent. **EC Decision on 10th May, 2019:**Approval after justification ***The above comment forwarded to P.I., reply has given by P.I. which was forwarded to the reviewer, response has received from reviewer & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II A/P3*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
a2	Clarification of research proposal entitled ***"To study the adequacy of secondary prevention therapy at discharge in patients with an acute coronary syndrome at a tertiary care centre in North India"*** submitted by Dr. Akshyaya Pradhan, Associate Professor, Department of Cardiology this University via letter no. nil dated 5th January, 2019. **EC Comment on 10th May, 2019:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

		• Title to be revised. It is Northern India and not North India. North Korea and South Korea, North Sudan and South Sudan are independent countries and hence their name is thus. Northern India is a part of India • The objective is to study the adequacy of prevention therapy at discharge in patients with Acute Coronary Syndrome. The lacunae, reasons for not giving the desired drug will be evaluated and the recurrent disease pattern will be studied. • A working proforma is attached. • Sample size is not provided • Inclusion and exclusion criteria are satisfactory **EC Decision on 10th May, 2019:**Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was forwarde to the reviewer, response received from the reviewer & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II A/P12*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
a3	Clarification of research proposal entitled ***"Adherence to guideline directed medical therapy for secondary prevention in ACS patients at a tertiary care center in India"*** submitted by Dr. Pravesh Vishwakarma, Associate Professor, Department of Cardiology this University via letter no. nil dated 5th January, 2019.	**EC Comment on 10th May, 2019:** 1. Methods are deficient. What is the criteria for defining adherence to treatment? Till what time after the discharge from the hospital will the patients be eligible for the inclusion into the study? When will you consider a patient compliant to treatment? The patient's Performa does not contain any of this information. Did the author not think of factors responsible for non-adherence to treatment? If yes, these factors should be enumerated in the patient's Performa to ask from each patient in order not to miss any. 2. What is the sample size? Also provide the basis of calculation of sample size. **EC Decision on 10th May, 2019:** Approval after justification ***The above comment sent to the P.I., response received from P.I., which was forwarded to the reviewer response received from the reviewer with following Comment:*** • ***Kindly submit revised proposal.*** **ActionTaken:** The above comment forwarded to the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Pending ***Ref. code: 96th ECM II A/P13*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
a4	Clarification of research proposal entitled ***"MALDI-Tof based cancer screening panel in a population – based large solid tumor patient's foe predicting prognosis and deciding therapeutics"*** sponsored by ICMR, New Delhi submitted by Dr. Neetu Singh, Associate Professor, Department of Molecular Biology Unit Center for Advance Research of this University by via letter no. CFAR/2019/271 dated 22nd February, 2019. **EC Comment on 10th May, 2019:** • Kindly mention age in Inclusion criteria • Objectives are not spelled out • Consent forms needs to be revised. • It appears copy and paste, many things are enteringled. • Methodology need to be logical and detailed. **EC Decision on 10th May, 2019:** ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II A/P20*** ***(Primary Reviewer:Dr. Anoop Kumar Verma)***
a5	Clarification of research proposal entitled ***"Development and efficacy of intervention programme of 'Cognitive-Metacognitive behaviou therapy' for the management of obsessive compulsive disorder in Indian context"*** submitted by Dr. Shweta Singh, Associate Professor, Department of Psychiatry of this University by via letter no. nil dated 4th April, 2019. **EC Comment on 10th May, 2019:** • Kindly provide sample size. • Questionnaire based study • No budget disclosed **EC Decision on 10th May, 2019:**Approval after justification ***The above comment send to P.I. reply has given by P.I. which was forwarded to the reviewer, response has received from reviewer & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II A/P43***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Amita Jain)
a6	Clarification of research proposal entitled ***"The aim of this study was to investigate central aortic pressure and peripheral vascular hemodynamic variables of arterial stiffness (AS) and their relationship to pulmonary function tests in obstructive (COPD) and Asthma) and restrictive lung disease"*** submitted by Prof. Surya Kant, Department of Respiratory Medicine of this University via letter no. nil dated nil. **EC Comment on 10th May, 2019:** • Kindly review the title. It seems to be cut and paste. **EC Decision on 10th May, 2019:** Approval subject to clarification ***The above comment send to P.I. reply has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **Current title:** ***"To study the central aortic Blood Pressure and arterial stiffness in obstructive lung diseases"*** **ActionTaken :** Provisionally approved **EC Decision:** Approved ***Ref.code: 96th ECM II A/P49*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
a7	Clarification of research proposal entitled ***"To study the dynamic effects of changes in left ventricular end diastolic pressure on instantaneous wave free ratio vs fractional flow reserve"*** submitted by Dr. Prachi Sharma, SR-II, Department of Cardiology of this University via letter no. 3074/Cardio/19 dated 14th March, 2019. **EC Comment on 10th May, 2019:** • When will first patient be enrolled? **EC Decision on 10th May, 2019:** Approval after juistification ***The above comment send to P.I., reply has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P5*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
a8	Clarification of research proposal entitled ***"A study of operative procedure for proximal hypospadias: single stage versus staged repair"*** submitted by Dr. Survesh Kumar Gupta, SR-I, Department of Pediatric Surgery of this University via letter no. nil dated 27th March, 2019. **EC Comment on 10th May, 2019:** • How/which will procedure for surgery be used? • The sample size calculation is wrong.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

		• How will you assess inferior/superior methods? • No CRF is attached, No protocol • It should be in form of CONSORT guidelines **EC Decision on 10th May, 2019:** Approval afer justification ***The above comment send to P.I., reply has given by P.I. which was forwarded to the reviewer, response has received from reviewer & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P13*** ***(Primary Reviewer: Dr. Amita Jain)***
a9	Clarification of research proposal entitled ***"Analysis of CSF diversion in management of pediatric TBM hydrocephalus: A prospective and retrospective study"*** submitted by Dr. Anoop Kumar Jaiswal, SR-II, Department of Neurosurgery of this University via letter no. nil dated nil. **EC Comment on 10th May, 2019:** • This is a retrospective study and not a prospective study. So, kindly change the title to retrospective study. • The AIM no. 3 is self sufficient and will also cover the AIM 1 and 2. So, to compare the outcome of patients undergoing ETV versus shunt will include the demographic and clinical profile of these patients and also the complications of shunt and ETV. • Rest all other points written in the "aims and objectives" should be written in the "methods" section. • The PI had written that the study duration will be from July 2011 to November 2019. Retrospective study duration cannot exceed the date of application for ethical approval. The PI also writes that the duration of prospective study will be from December 2016 to November 2019. A prospective study cannot enroll any patient before the date of ethical approval. Therefore, it is advisable to keep this study retrospective and keep the duration from any date till April 2019 and not beyond. • Study design says that once the patient's parameters are collected, the patients will be randomized to either of the procedures. This is not possible for a retrospective study. So, the PI needs to rewrite the methods. • The follow-up is written in future tense. Follow-up details of the patients in a retrospective study has to be gathered from the patient's registry if that was maintained by the concerned department. • If the PI plans a prospective study, then it can only be a randomized open-label study to compare the outcome in TBM patients undergoing ETV versus

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	shunt for the treatment of hydrocephalus. • Patient information document has to be re written in detail regarding the study procedure, type of study, benefits from the study, complications and compensation after the PI decide which type of study they plan to do. • Patient's performa is required to be submitted with the study proposal. **EC Decision on 10th May, 2019:** Re-submit ***The above comment send to P.I., reply has given by P.I.which was forwarded to the reviewer, response has received from reviewer with following comment:*** • ***Kindly provide revised proposal.*** ***The above comment forwarded to P.I, reply has given by P.I. which was reviewd by the Chairman, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Dr.Amita Jain & Dr. R.K. Garg did not tke part in the discussion.*** ***Ref. code: 96th ECM II B-Thesis/P20*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
a10	Clarification of research proposal entitled ***"Efficacy of tocotrienol and turmeric (Curcuma Longa) in osteoarthritis: A clinical study at a tertiary care centre in KGMU, Lucknow"*** submitted by Dr. Arun Kumar Bharti, JR-I, Department of Pharmacology & Therapeutics of this University via letter no. nil dated nil. **EC Comment on 10th May, 2019:** • Kindly provide the approval of the mentioned drug authority for use in patients • Provide CONSORT guidelines & how will they be followed? **EC Decision on 10th May, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.which was reviwed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P26*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
a11	Clarification of research proposal entitled ***"An observational study predicting the drug resistance of Pulmonary Tuberculosis by microRNA320a and its comparison with CBNAAT at a tertiary care centre"*** submitted by Dr. Arpan Ganguly, JR-I Department of Pharmacology & Therapeutics of this University via letter no. nil dated 4th April, 2019. **EC Comment on 10th May, 2019:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Kindly remove **"KGMU, Lucknow UP"** from title • Where will CBNAAT will be performe, Not mentioned • It is not a cross sectional open labeled not randomized clinical trial the study designe needs to corrected • Title mention Drug reestaver tablet However, the inclusion criteria is not accordingly **EC Decision on 10th May, 2019:** Revised & Re-submit ***The above comment send to P.I., reply has given by P.I.which was reviwed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P35*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
a12	Clarification of research proposal entitled ***"Comparative efficacy of andrographis paniculata and metformin to metformin monotherapy in glycemic control in newly diagnosed, treatment naive type 2 diabetes patients"*** submitted by Dr. Anand Kumar Maurya, JR-I, Department of Pharmacology and Therapeutics of this University via letter no. nil dated 4th April, 2019. **EC Comment on 10th May, 2019:** • Source of herbal drug not mentioned • Plant safety and efficacy and approval of regulation needs to be submitted **EC Decision on 10th May, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.which was forwarded to the reviewer & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P44*** ***(Primary Reviewer: Dr. Rajendra Nath)***
a13	Clarification of research proposal entitled ***"Evaluation of effect of mandibular advancement device on inflammatory marker (TNF-α) in patients with obstructive sleep apnoea: A controlled before and after study"*** submitted by Dr. Neeti Solanki, JR-I, Department of Prosthodontics, Crown & Bridge, Faculty of Dental Sciences of this University via letter no. 16/19 dated 6th April, 2019. **EC Comment on 10th May, 2019:** • Pro inflammatory cytokines like TNF alpha, IL1 beta, IL6 are upregulated in Obstructive Sleep Apnoea (OSA) and their levels come down with continued positive airway pressure (CPAP). In

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	patients who do not tolerate CPAP Mandibular Advancement Devices (MAD) can help. • This study aims to study the effect of MADs TNF alpha levels in patients with OSA. • Sample size is 20 – statistically calculated • Participant selection and Inclusion and exclusion criteria are satisfactory • OSA will be diagnosed by Epsworth Sleepiness Scale, Berlin questionnaire and Updated STOP Bang questionnaire • However, how will the mandibular advancement be done is not clearly defined and a data collection sheet / proforma has not been included. **EC Decision on 10th May, 2019:** Approval after justification ***Dr. Balendra did not take part in the discussion.*** ***The above comment send to P.I., reply has given by P.I.which was forwarded to the reviewer & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P52*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
a14	Clarification of research proposal entitled ***"Misoprostol only Vs. mifepristone plus misoprostol in induction of labour following intrauterine fetal death: an open label randomized controlled trial"*** submitted by Dr. Vejainty Chauhan, JR-I, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 5th April, 2019. **EC Comment on 10th May, 2019:** • Mifepristone is a synthetic steroid with anti progesterone activity and Misoprostol is a PGE1 analogue, a prostaglandin preparation that can be used orally, sublingually, vaginally or rectally. With Mifepristone lower dose of PG is required to induce delivery. • 200 mg of Mifepristone orally plus 50 micrograms of Misoprostol six hourly transvaginally will be used in one group and Misoprostol alone will be used in the other • Sample size is 200 – statistically calculated • Study protocol and outcome measures are defined. • Data collection sheet is not attached. This should have the demographic details, history, examination, details of intervention and what all was observed and when.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

		• If it is a R.C.T, how were the patients randomized and where are the consort guidelines? **EC Decision on 10th May, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.which was forwarded to the reviewer & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P61*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
a15	Clarification of research proposal entitled ***"Correlation of urinary iodine concentration and tear film breakup time with clinical, epidemiological, biochemical, radiological and pathological parameters in patients with goiter"*** submitted by Mr. Sagar Rai, MBBS 2017 Batch under the guidance Dr. Pooja Ramakant, Associate Professor, Department of Endocrine Surgery of this University via letter no. nil dated 28th February, 2019. **EC Comment on 10th May, 2019:** • All the patients enrolled are hospital patients who will undergo thypodictory at endocrine SR department. It is not a cross sectional study • The title is extensive needs to be revised • The methodology must be more elaborate and para '4' of working performa must be attached **EC Decision on 10th May, 2019:** Revise & Re-submit ***The above comment send to P.I., reply has given by P.I.which was reviwed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 96th ECM IIB MBBS/P5*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
a16	Clarification of research proposal entitled ***"Prevalence of radiation caries in head and neck patients undergoing radiotherapy"*** sponsored by Research Cell K.G.M.U U.P. Lucknow submitted by Mr. Vaibhav Amit, BDS III Year through his Mentor Dr. Rhythm, Associate Professor, Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences of this University via letter no. nil dated 15th January, 2019. **EC Comment on 10th May, 2019:** • Please add the term cancer in the title of the project. • It will be in interest of the student to do a sample size calculation done as

Chairperson IEC
King George's Medical University
U.P., Lucknow

	that will help at the time of submission of the study to journals for publication **EC Decision on 10th May, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I. which was forwarded to reviewer response has received from reviewer with following comment:*** • **Kindly provide revised proposal.** ***The aboe comment forwarded to P.I. but response has not given by P.I.*** **ActionTaken :** None **EC Decision:** Pending ***Ref. code: 96th ECM IIB IMR-S/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
	Part b- 97th ECM was held on 12th July, 2019
b1	Clarification of research proposal entitled "***Effect of educational program on nurses' knowledge and skills about oral care in respiratory intensive care & critical care unit***" submitted by Dr. Ved Prakash, Associate Professor, Head, Department of Pulmonary & Critical Care Medicine of this University via letter no. nil dated 14th June, 2019. **EC Comment on 12th July, 2019:** • Since the study will be performed on the Nurses posted on the respiratory ICU, the patient information document is not required. A participant information document (PID) is required that is meant to inform the participating nurses before obtaining their consent. Kindly fill the PID appropriately and submit. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.which was forwarded to the reviewer response has given by reviewer with following comment:*** • **Kindly provide revised proposal** ***The above comment forwarded to P.I. reponse received from P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II A/P17*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
b2	Clarification of research proposal entitled "***Oral care in respiratory intensive care unit & critical care unit to prevent the consequence of venitilator associated pneumonia and infection related deaths and to assess the status of nosocomial infection: A randomized, double blind, placebo controlled study***" submitted by Dr. Ved Prakash, Associate Professor, Head, Department of Pulmonary & Critical Care

Chairperson, IEC
King George's Medical University
U.P., Lucknow

		Medicine of this University via letter no. nil dated 14th June, 2019. **EC Comment n 12th July, 2019:** • How will the patients be randomized? • Is denying oral care to patients on ventilator, who comprise the Control group ethical? • Data collection sheet not provided • Consort guidelines not provided **EC Decision n 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. reponse received from P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II A/P19*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
	b3	Clarification of research proposal entitled "***To study causes and clinical outcome of new onset renal failure in post- partum period: A prospective observational study***" sponsored by ICMR submitted by Dr. Medhavi Gautam, Assistant Professor, Department of Medicine of this University via letter no. nil dated 12th June, 2019. **EC Comment:** • Where investigators want to study this courses and clinical outcomes new onset renal failure in post partum period and also want to study the clinical criteria to predict the out come. For this only observational study, will not be sufficient, a control arm is also needed which will strengthen this study, so it requests change in study design rest is ok. **EC Decision:** Approval after justification ***The above comment forwarded to P.I. reponse received from P.I. which was forwarded to the reviewer.*** **EC Decision:** Approved ***Ref. code: 97th ECM II A/P28*** ***(Primary Reviewer: Dr. Rajeev Garg)***
	b4	Clarification of research proposal entitled "***Role of different triggers in precipitation of first ST segment elevation myocardial infarction: A case-crossover study***" submitted by Prof. S.K. Dwivedi, Department of Cardiology of this University via letter no. 468/Cardio/Res/19 dated 17th June, 2019. **EC Comment on 12th July, 2019:** • Cross-over study design should be described in detail under methodology section.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision on 12th July, 2019: Approval after justification ***The above comment forwarded to P.I. reponse received from P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II A/P30*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
b5	Clarification of research proposal entitled***"Multimodality imaging in mesenteric lymphadenopathy - in patients UPT 18 years of age"*** submitted by Dr. Naba Kumar Barman, JR-II, Department of Radiodiangosis of this University via letter no. nil dated 16th April, 2019. **EC Comment on 12th July, 2019:** • The aims of the study do not match with the topic of the study. The incidence of mesenteric lymphadenopathy cannot be determined unless it is a population-based study. • When all consecutive patients with mesenteric lymphadenopathy on 64-slice CT are planned to be included, then the purpose of doing a multi-modality imaging in these patients is not justified. One can perform a study to compare the sensitivity/specificity of a particular diagnostic modality to determine the mesenteric lymphadenopathy but then, the project has to be re-written with specific aims and objectives to achieve so. • Sample size estimation needs to be done after finalizing the aims and methods of the study. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I. which was forwarded to the reviewer but the reviewer has not given the reply.*** **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P3*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
b6	Clarification of research proposal entitled ***"Biochemical modulator of endothelial cell function with special interest to nitric oxide (NO) and HDL associated pon-1, srb-1 level : a prospective case control study in coronary artery disease"*** submitted by Dr. Manish Kumar, JR-I, Department of Pathology of this University via letter no. nil dated 8th April, 2019. **EC Comment on 12th July, 2019:** • For this thesis there are too many objectives. The aim is not clearly defined. • Thesis case control study does not difine cases & controles clearly. • Why control is included are not justified?

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Sample size is not calculated. **EC Decision on 12th July, 2019:** Revise-Resubmit ***The above comment sent to the P.I. reply has provided by P.I. which was forwarded to the reviewer.Reply received from the Primary Reviewer & approved.*** **ActionTaken :** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P6*** ***(Primary Reviewer: Dr. Amita Jain)***
b7	Clarification of research proposal entitled ***"Evaluation of functional outcome of total hip replacement in tubercular arthritis hip"*** submitted by Dr. Ravindra Kumar Gupta, JR-I, Department of Orthopaedic Surgery of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • Objective is to evaluate the functional outcome of Tubercular arthritis of hip managed by THR in terms of Harris Hip Score, ESR and CRP levels at 6 weeks, 3, 6 and 9 months and to look for disease reactivation, loosening of implant and osteolysis in post operative phase. • Sample size is not mentioned. It is important to make the results statistically significant. • If your last follow up is at 9 months then the study duration cannot be 9 months. If you operate the last patient at 9 months then the study has to go on for 18 months at least! • A comprehensive data collection sheet is provided • Inclusion and exclusion criteria are satisfactory. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment was sent to the P.I. reply has given by the P.I. which was forwarded to the reviewer, response received from reviewer & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P8*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
b8	Clarification of research proposal entitled ***"Central corneal thickness measurement for evaluation of outcome of optical penetrating keratoplasty at a tertiary care centre in northern India"*** submitted by Dr. Nayani Amrin Fatema Afzal Hussain, JR-I, Department of Ophthalmology of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Kindly provide Patient's data sheet (performa). **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I. which was reviewed by the Member-Secreatry, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P13*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
b9	Clarification of research proposal entitled ***"Endothelial cell loss analysis in phacoemulsification versus small incision cataract surgery: A randomized study"*** submitted by Dr. Ritu Singh, JR-I, Department of Ophthalmology of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • Is this a surgical randomized double blind parallel group cataract surgery study? • How randomization will be done? • Is there any difference in the indications for both the methods, to be used? • How will you blind the doctor & the patient? • Both will know what is happening? • Follow Consort guidelines. **EC Decision on 12th July, 2019:** Revised & Re-submit ***The above comment sent to P.I. reply has given by P.I which was forwarded to reviewer response has given by reviewer with following comment:*** • Part-III point-1:- The Prinicpal-Investigator has stated that University wil bear the expences incase f damage How it will be managed & through which source need clarification. • Date is missing in Annexure -7 Part-II ***The above comment sent P.I.reply has given by P.I.which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P14*** ***(Primary Reviewer: Dr. Amita Jain)***
b10	Clarification of research proposal entitled ***"Effect of oral L-Arginine administration on menopausal problems"*** submitted by Dr. Monica Biakthanmawii, JR-I, Department of Physiology of this University via letter no. nil dated 10th April, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment on 12th July, 2019: It should be done accordance with CONSORT guidelines in guidance of a physician/ Gynecologist. **EC Decision on 12th July, 2019:** Resubmit ***The above comment send to P.I., reply has given by P.I.which was reviewed by the Member-Secreatary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P15*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
b11	Clarification of research proposal entitled ***"Association of heart rate variability and C-reactive protein in patients with depression"*** submitted by Dr. Soni Singh, JR-I, Department of Physiology of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • The amount of blood to be drawn from the ante-cubital vein has to be informed to patients in patient information document. • The patient's data sheet is not attached. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I., which was forwarded to the reviewer but reply has not recieved by the reviewer.*** **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P16*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
b12	Clarification of research proposal entitled ***"Impact of central obesity on ischemic heart disease"*** submitted by Dr. Mohd Rafiq, JR-I, Department of Physiology of this University via letter no. nil dated 15th April, 2019. **EC Comment on 12th July, 2019:** • Kindly provide the Sample size **EC Decision :** Provisionally approved ***The above comment sent to P.I. reply has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P17*** ***(Primary Reviewer: Dr. Rajendra Nath)***
b13	Clarification of research proposal entitled ***"CO-RELATION OF hs- CREACTIVE PROTEIN LEVELS WITH ANTHROPOMETRIC PARAMETERS IN OBESE/OVERWEIGHT ADULTS"*** submitted by Dr. Neeraja Shukla, JR-I,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

		Department of Physiology of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • No issues as far as methodology/Study design/Sample size is concerned, but it is not clear from where they will recruit patients. They have no collaborators in the Clinical department. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment sent to P.I., reply has given by P.I. which was forwarded to the reviewer, reply has given by reviewer & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P18*** ***(Primary Reviewer: Dr. Rajeev Garg)***
b14		Research proposal entitled ***"Prospective interventional study of neoadjuvent temozolomide inpatients of inoperable supratentorial malignant gliomas"*** submitted by Dr. Suresh Kumar Jaiswal, SR-I, Department of Neurosurgery of this University via letter no. nil dated 10th March, 2019. **EC Comment on 12th July, 2019:** • The objective is to analyze the improvement in patients of supra-tentorial glioma in terms of resectability, morbidity and mortality after neo-adjuvant chemotherapy with temozolomide • Sample size not provided • Data recording sheet not provided. We do not know what will be observed and when • How much drug will be given? When will it be given? What effects will be observed, when and how? • What side effects of this drug will be observed? • You will be comparing your results with which group of patients? Will you have a control group of patients who will not be receiving neo adjuvant chemotherapy? **EC Decision on 12th July, 2019:** Re-submit ***The above comment send to P.I., reply has given by P.I. which was forwarded to the reviewer reply has given by reviewer with following comment:-*** **Comment:** • Sample size does not depend on patient availability alone. You have to sit with a statistician and discuss your study plan. He/she will ask you what is a doable number of patients and then curtail the number of variables you can chase in this study. This is a good exercise in planning research and this should be done.

Chairperson, IEC
King George's Medical University

		• Since the comparison will be with patients receiving RT alone include them in your study. Now take the number of both the set of patients - your ones and the RT ones to the statistician and ask him to help you to plan your study. • You have the scope of planning a good study as there will surely be enough patients, but if you end up chasing too many variables your results may not be statistically significant. **ActionTaken:** The above comment sent to the P.I. **EC Decision:** Pending ***Ref. code: 97th ECM II B-Thesis/P19*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
	b15	Clarification of research proposal entitled ***"A prospective study of four quadrant ostoplastic decompressive craniotomy vs conventional decompressive craniectomynfor traumatic brain injury"*** submitted by Dr. Yashpal Jaware, SR-I, Department of Neurosurgery of this University via letter no. nil dated 12th April, 2019. **EC Comment on 12th July, 2019:** • Title should mention "RCT". • How randomization will be done • CONSORT guidelines should be followed. **EC Decision on 12th July, 2019:** Approval after justification The above comment sent to P.I., reply has given by P.I. which was forwarded to the reviewer. **ActionTaken:** • Since it is an RCT, it will be deffered to have a look at revised proposal. • Please submit revised proposal with consent checklist **EC Decision:** Pending ***Ref. code: 97th ECM II B-Thesis/P21*** ***(Primary Reviewer: Dr. Amita Jain)***
	b16	Clarification of research proposal entitled ***"Comparison of clinical performance of I-GEL™, LMA supreme™ & AMBU® AURAGAIN™ in adult patients during general anaesthesia"*** submitted by Dr. C.L Tejashri, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • Kindly provide CONSORT guidelines • Kindly submit Conflict of interest form

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision on 12th July, 2019: Approval after justification ***The above comment sent to the P.I. reply has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97thECM II B-Thesis/P28*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
b17	Clarification of research proposal entitled ***"Comparative study between ultrasound guided erector spinae plane block and para vertebral block in thoracic surgeries"*** submitted by Dr. Akanksha Jain, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • The study needs to be written as per CONSORT guidelines. • The topic of the study should reflect the methods like – randomized controlled blinded/open-label etc. • The name of the drug should also be mentioned in the title of the study. • Which one of the two arms will be a control arm if it is a controlled study? • Which randomization method will be used? • How will the allocation concealment be achieved? • Patient information document (PID) is very important document and it needs to be filled again. Are there any complications of either of the anesthesia methods? These have to be discussed with the patient in the PID. Risks from the study have also to be discussed. Compensation has to be planned. • Patient datasheet not attached. • Please provide a CONSORT checklist duly filled along with the revised thesis performa. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment sent to the P.I. reply has given by P.I. which was forwarded to the reviewer response was provided by the reviewer with following comment:*** • The topic of the study may be written as "Randomised open label study to compare the post-operative analgesic effect of ultrasound guided erector spinae plane block and paravertebral block with -----% bupivacaine in thoracic surgeries". • PID needs to be filled properly. Please enumerate all the known drug-related and puncture related adverse effects of the above procedures. Please understand that the PID is for the safeguard of the investigator and therefore, it should be filled in details. Writing NONE and NOT APPLICABLE to the question of "risk from the study" is not acceptable. • Please discuss the "benefits from the study" in some detail. The study will determine whether one method is better than the other or both of them are same. Therefore, the possible benefit will be the attainment of the new knowledge regarding the procedures. Patient under the study may not be the beneficiary.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• PI need to discuss the compensation in case of occurrence of an adverse event secondary to the study method/drug. ***The above comment was again sent to the P.I. reply has not given by the P.I.*** **ActionTaken:** None **EC Decision:** Pending ***Ref. code: 97th ECM II B-Thesis/P31*** ***(Primary Reviewer : Dr. Vimal Kumar Paliwal)***
b18	Clarification of research proposal entitled ***"Audiological profile of presbycusis with pilot observation on familial age-related hearing loss"*** submitted by Dr. Hari Krishn Dwivedi, JRI, Department of Otorhinolaryngology and Head- Neck Surgery of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • Prospective & retrospective study- to see record of the patients then follow up them. • Inform Consent form –Hindi & English first page is photocopied not typed. • Kindly submit the Questionnaire. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision :** Approved ***Ref. code: 97th ECM II B-Thesis/P41*** ***(Primary Reviewer: Dr. Rajendra Nath)***
b19	Clarification of research proposal entitled ***"A retrospective study of clinic-radiological profile and outcome correlation in patients of medulloblastomas: A KGMU experience"*** submitted by Dr. Rohan Digarse, SR-I, Department of Neurosurgery of this University via letter no. nil dated 18th April, 2019. **EC Comment 2th July, 2019:** • A retrospective study--- the validiy of the consent in questionable. **EC Decision 2th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.which was reviewed by the Member-Secretary, IEC.*** **ActionTaken:** Provisionally Approved **EC Decision :** Approved ***Ref. code: 97th ECM II B-Thesis/P48*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)*** ***(Secondray Reviewer: Dr. Amita Jain)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

b20	Clarification of research proposal entitled ***"Effect of nebulised lidocaine on hemodynamic responses during nasotracheal intubation: A randomized controlled double blind study"*** submitted by Dr. Shivani Gaurav, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 14th April, 2019. **EC Comment on 12th July, 2019:** • Kindly provide the CONSORT GUIDELINES **EC Decision on 12th July, 2019:** Resubmit in format of CONSORT GUIDELINES ***The above comment send to P.I., reply has given by P.I.which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision :** Approved ***Ref. code: 97th ECM II B-Thesis/P52*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
b21	Clarification of research proposal entitled ***"Estimation of uncuffed endotracheal tube size in paediatric patient using different variables: A comparative randomized study"*** submitted by Dr. Yatendra Kumar, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 20th April, 2019. **EC Comment on 12th July, 2019:** • Kindly provide the CONSORT GUIDELINES **EC Decision on 12th July, 2019:** Resubmit in format of CONSORT GUIDELINES ***The above comment send to P.I., reply has given by P.I.which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision :** Approved ***Ref. code: 97th ECM II B-Thesis/P53*** ***(Primary Reviewer: Dr. Rajendra Nath)***
b22	Clarification of research proposal entitled ***"Comparative evaluation of different concentrations of alcohol in ultrasound guided celiac plexus neurolysis for pain relief in patients with upper abdominal malignancies"*** submitted by Dr. Pragya Verma, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 20th April, 2019. **EC Comment on 12th July, 2019:** • It is a randomized double-blind comparative study needs to be submit on CONSORT guidelines and necessary formality for CTRI registry. **EC Decision on 12th July, 2019:** Resubmit in format of CONSORT

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	GUIDELINES ***The above comment send to P.I., reply has given by P.I.*** **ActionTaken:** Provisionally Approved with condition to kindly provide CTRI registration. **EC Decision :** CTRI Pending ***Ref. code: 97th ECM II B-Thesis/P54*** ***(Primary Reviewer: Dr. Rajeev Garg)***
b23	Clarification of research proposal entitled ***"Randomized control trial of quadrates lumborum block with of without dexmedetomidine as an adjuvant drug in patients undergoing elective renal surgery"*** submitted by Dr. Sumit Kumar Umar, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 20th April, 2019. **EC Comment on 12th July, 2019:** • Kindly submit on CONSORT guidelines. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment sent to P.I., reply has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P56*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
b24	Clarification of research proposal entitled ***"A study on effect of early diagnosis and intervention on behavior and development in autistic children"*** submitted by Dr. Madhumathi G.S, JR-I, Department of Community Medicine and Public Health of this University via letter no. 88/cm/19 dated 18th April, 2019. **EC Comment on 12th July, 2019:** • Signature missing of Principal-Investigator in Hindi & English Inform consent Form. • Both ICF are similar, it should be according to SOP. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P57*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
b25	Clarification of research proposal entitled ***"Effect of fluoroscopy- guided***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	corticosteroid injection in patients with sacroiliac joint dysfunction- A randomized controlled trial" submitted by Dr. Anurag Patel, JR-I, Department of Physical Medicine and Rehabilitation of this University via letter no. 1821/19 dated 23th April, 2019. **EC Comment on 12th July, 2019:** • Kindly provide the CONSORT GUIDELINES **EC Decision on 12th July, 2019:** Resubmit in format of CONSORT GUIDELINES ***The above comment sent to P.I., reply has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision :** Approved ***Ref. code: 97th ECM II B-Thesis/P62*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
b26	Clarification of research proposal entitled ***"Karyotyping in congenital and primary open angle glaucoma in tertiary care centre"*** submitted by Dr. Anupriya, JR-II, Department of Ophthalmology of this University via letter no. nil dated 27th April, 2019. **EC Comment on 12th July, 2019:** • Please check the study design. This is not a cross-sectional study. Moreover to define the genetic changes, a control group should always be included (to define normal variations. **EC Decision on 12th July, 2019:** Resubmit ***The above comment send to P.I., reply has given by P.I.which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P67*** ***(Primary Reviewer: Dr. Amita Jain)***
b27	Clarification of research proposal entitled ***"To study resistive index in central retinal artery in ischemic and non-ischemic central retinal vein occlusion"*** submitted by Dr. Akanksha, JR-I, Department of Ophthalmology of this University via letter no. nil dated 9th May, 2019. **EC Comment on 12th July, 2019:** • Retinal Vein occlusion in Diabetic Retinopathy (DR) often leads to loss of vision – partial or total, depending on the degree of retinal capillary non-perfusion. This study aims to assess the restive index of Central Retinal A. in ischemic and non-ischemic Central Retinal V. occlusion.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Sample size is 40. Statistically calculated • Methodology is clear • Data collection sheet is missing. We need a data sheet which should have the demographic details of the patient, their diabetic status, their ophthalmic status and research observations • The data sheet must mention the status of other target organs – heart, kidneys to understand how sick the patient was. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I. which was forwarded to the reviewer reply has given by reviewer & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P72*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
b28	Clarification of research proposal entitled ***"Detection of acute and chronic brucellosis by serological and molecular methods at a tertiary care Hospital"*** submitted by Dr. Pratima, JR-I, Department of Microbiology of this University via letter no. nil dated 10th May, 2019. **EC Comment on 12th July, 2019:** • Kindly mention the Objective in the title. **EC Decision on 12th July, 2019:** Approval after justification ***Dr. Amita Jain did not take part in the discussion*** ***The above comment send to P.I., reply has given by P.I.which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P73*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
b29	Clarification of research proposal entitled ***"A comparison of nebulized ketamine and dexmedetomidine premedication in preschool children undergoing abdominal surgery"*** submitted by Dr. Prabhat Mishra, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 14th May, 2019. **EC Comment on 12th July, 2019:** • Kindly submit CONSORT on guidelines. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision : Approved ***Ref. code: 97th ECM II B-Thesis/P78*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
b30	Clarification of research proposal entitled ***"Safety and efficacy of ketamine-dexmedetomidine versus ketamine- propofol combination for short term sedation in post- operative obstetric patients on mechanical ventilation"*** submitted by Dr. Anchal Raj, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 15th May, 2019. **EC Comment on 12th July, 2019:** • It is a randomized double-blind trial, kindly submit as per CONSORT guidelines and get registration. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision :** Approved ***Ref. code: 97th ECM II B-Thesis/P81*** ***(Primary Reviewer: Dr. Rajeev Garg)***
b31	Clarification of research proposal entitled ***"Comparative short term outcome analysis of endovenous laser treatment and radiofrequency ablation in varicose veins- A randomized study"*** submitted by Dr. Dinesh Kumar Singh, JR-II, Department of General Surgery of this University via letter no. nil dated 20th May, 2019. **EC Comment on 12th July, 2019:** • How can this study be retrospective and prospective? • Kindly provide detail methodology of interventions. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision :** Approved ***Ref. code: 97th ECM II B-Thesis/P86*** ***(Primary Reviewer:Dr. Balendra Pratap Singh)***
b32	Clarification of research proposal entitled ***"To study the effects of oral gabapentin for post operative analgesia in patient undergoing abdominal surgery under general anaesthesia: A randomized control trial"*** submitted by Dr. Anoop Kumar Singh, JR-I, Department of Anaesthesiology of this University via letter no. nil

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	dated 22nd May, 2019. **EC Comment on 12th July, 2019:** Approval after justification • It is a RCT, needs CTRI registration and also needs submission on the basis of CONSORT guidelines **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I. which was forwarded to the reviewer, response provided by the reviewer Provisionally approved with condition to kindly submit the CTRI registration.*** **ActionTaken:** The above comments have been forwarded to the P.I. **EC Decision :** Kindly provide CTRI registration ***Ref. code: 97thECM II B-Thesis/P87*** ***(Primary Reviewer: Dr. Rajeev Garg)***
b33	Clarification of research proposal entitled ***"A prospective study to compare quality of life and early outcomes between endovenous laser therapy, mechanochemical ablation therapy in patients having chronic venous insufficiency"*** submitted by Dr. Abhishek Mishra, JR-II, Department of General Surgery of this University via letter no. nil dated 24th May, 2019. **EC Comment on 12th July, 2019:** • It is comparative study. • Study involves two groups of PF, Which authors have decided arbitrarily (Saying non-randomized) in one group they will use EVLT machine and author gp-Mechochemical ablaltion. • Which is unethical may involve bias, design it as RCT & get CTRI registrationon CONSORT guidelines. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.which was forwarded to the reviewer response provided by the reviewer Provisionally approved with condition to kindly submit the CTRI registration.*** **ActionTaken:** The above comment forwarded to the P.I. **EC Decision :** Kindly provide CTRI registration ***Dr. A.A. Sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P93*** ***(Primary Reviewer: Dr. Rajeev Garg)***
b34	Clarification of research proposal entitled ***"A prospective study of combined sphincter preserving procedure (Lift+ Vaaft+ Filac)in complex anal fistula"*** submitted by Dr. Abhishek Kumar, JR-II, Department of General Surgery of this

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	University via letter no. nil dated 25th May, 2019. **EC Comment on 12th July, 2019:** • The researchers wish to study the efficacy of a combination of 3 procedures – ligation of inter-sphincteric fistula tract (LIFT), video assisted anal fistula treatment (VAAFT) and fistula laser closure (FiLaC) in the treatment of anal fistula as they ensure preservation of continence, and result in less pain and early healing. • Sample size is 66. Statistically calculated • Data collection sheet has been provided and evaluation criteria defined. • There is no control group. So, what are the results going to be compared with? **EC Decision on 12th July, 2019:** Approval after modification ***The above comment sent to P.I., reply has given by P.I.which was forwarded to the reviewer, response received from reviewer & approved.*** **ActionTaken:** Provisionally Approved **EC Decision :** Approved ***Dr. A.A. Sonkar did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P96*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
b35	Clarification of research proposal entitled ***"A comparison between levobupivacaine with dexmedetomidine versus levobupivacaine with clonidine in labour analgesia"*** submitted by Dr. Shruti Kabi, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 15th May, 2019. **EC Comment on 12th July, 2019:** • Kindly submit as per CONSORT guidelines. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment sent to P.I. reply has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision :** Approved ***Ref. code: 97th ECM II B-Thesis/P80*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
b36	Clarification of research proposal entitled ***"To study the virulence factors and phenotypic characterization of candida isolates from blood stream infection"*** submitted by Dr. Anshuman Raj, JR-I, Department of Microbiology of this University via letter no. nil dated 4th June, 2019. **EC Comment on 12th July, 2019:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

		• A large number of risk factors are mentioned in this study. • How & when the data will be collected. • Case record form is not provided **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.which was forwarded to the reviewer, response received from reviewer & approved.*** **ActionTaken:** Provisionally Approved **EC Decision :** Approved ***Ref. code: 97th ECM II B-Thesis/P108*** ***(Primary Reviewer: Dr. Amita Jain)***
b37	Clarification of research proposal entitled ***"Comparison of external beam Radiotherapy followed by sequential high dose rate intracavitary brachytherapy vs external beam Radiotherapy interdigitated with high dose rate intracavitary brachytherapy for locally advanced carcinoma cervix"*** submitted by Dr. Indrajeet Gupta, JR-II, Department of Radiotherapy of this University via letter no. nil dated 10th June, 2019.	**EC Comment on 12th July, 2019:** • Kindly submit as per CONSORT guidelines • Signatures are missing. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment sent to P.I. reply has given by P.I. which was reviewed by the Member-Secretary, IEC & noted.*** **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P111*** ***(Primary Reviewer: Dr.A.A. Sonkar)***
b38	Clarification of research proposal entitled ***"A study to assess the dosimetric impact of the anatomical changes occurring in the parotid glands and tumour volume during 3-D conformal Radiotherapy of inoperable/ locally advanced Head and Neck squamous cell cancers (LAHNSCC)"*** submitted by Dr. Arunima Ghosh, JR-II, Department of Radiotherapy of this University via letter no. nil dated 10th June, 2019.	**EC Comment on 12th July, 2019:** • Kindly submit CONSORT guidelines • Patient data sheet is not attached. • Signaturres are missing. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment sent to P.I. reply has given by P.I. which was reviewed by the***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Member-Secretary, IEC & approved. **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P112*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
b39	Clarification of research proposal entitled ***"A comparative evaluation of palliative radiotherapy regimes in locally advanced inoperable Head & neck squamous cell carcinoma"*** submitted by Dr. Sadanand Prakash, JR-II, Department of Radiotherapy of this University via letter no. nil dated 12th June, 2019. **EC Comment on 12th July, 2019:** • Signatures are missing. **EC Decision on 12th July, 2019:** Provisionally approved ***The above comment sent to P.I. reply has given by P.I. which was reviewed by the Member-Secretary, IEC & noted.*** **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P114*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
b40	Clarification of research proposal entitled ***"Use of interstitial brachytherapy in recurrent cervical carcinoma in terms of response, progression free survival and toxicity"*** submitted by Dr. Afroz Kahkashan Zaidi, JR-I, Department of Radiotherapy of this University via letter no. nil dated 12th June, 2019. **EC Comment on 12th July, 2019:** • Signatures are missing. **EC Decision on 12th July, 2019:** Provisionally approved ***The above comment sent to P.I. reply has given by P.I. which was reviewed by the Member-Secretary, IEC & noted.*** **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P118*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
b41	Clarification of research proposal entitled ***"To assess the usefulness of peak expiratory flow rate on monitoring the level of control of asthma in children"*** submitted by Dr. Shabnam, JR-I, Department of Paediatrics of this University via letter no. nil dated 15th June, 2019. **EC Comment on 12th July, 2019:** • Number of patients required as per sample size calculation is 250. The duration of study is 1 year. Follow-up will be up to 6 months. It is advised to take a help from a statistician to re-evaluate sample size using different

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	parameters from the past studies. • Children will be divided into two groups; one group followed with symptoms alone and other with PEFR and symptoms. How will the children be divided into two groups? **EC Decision on 12th July, 2019:** Approval after justification ***The above comment send to P.I., reply has given by P.I.which was forwarded to the reviewer responce has given by reviewer & approved.*** **EC Decision :** Approved ***Ref. code: 97th ECM II B-Thesis/P126*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
b42	Clarification of research proposal entitled ***"A clinical study of internet gaming in adolescent with Psychiatric disorders"*** submitted by Dr. Praveen Sachan, JR-II, Department of Psychiatry of this University via letter no. nil dated 15th June, 2019. **EC Comment on 12th July, 2019:** • Methodology is not clear, study design is not given **EC Decision on 12th July, 2019:** Approval after justification ***The above comment sent to P.I. reply has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P141*** ***(Primary Reviewer: Dr. Rajendra Nath)***
b43	Clarification of research proposal entitled ***"A study of emergency obstetric referred-in cases at tertiary care Hospital of Lucknow"*** submitted by Dr. Arunima Saini, JR-II, Department of Community Medicine and Public Health of this University via letter no. nil dated 13th June, 2019. **EC Comment on 12th July, 2019:** • It is a cross-sectional, hospital based, observational study of 15 independent variables and 4 dependent variables which include both medical reasons and health care logistic reasons. • Sample size is not mentioned but the hint is that it will depend on the maximum number of cases collected in 20 data collecting days • Please consult a statistician and decide on a doable sample size. Right now you are chasing almost 600 cases in 20 days or 30 cases in a day. Filling a 6 page Performa and getting a signed consent will take 30 minutes at least. So you are planning to work for 15 hours every day for 20 days! I feel your plan needs a rethink.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision on 12th July, 2019: Approval after justification ***The above comment sent to theP.I. reply has given by the P.I. which was forwarded to the reviewer, response received from the reviewer with following comment: -*** ***Comment:*** • ***I think I could not convey my concern to the researchers. Considering that they are chasing so many variables they need to sit with the statistician and derive a sample size. The sample size in a research plan is not governed by patient availability alone but by statictics. A statistician willl use formula and conclude a sample size which will make their results statistically singnificant.*** ***The above comment again forwarded to the P.I., response received from P.I. which was forwarded to the reviewer, response received from reviewer & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P127*** ***(Primary Reviewer: Dr.Surajit Bhattacharya)***
b44	Clarification of research proposal entitled ***"Study of complete revascularization versus treatment of infact related artery only revascularization in patient with acute coronary syndrome with multivessel disease: a single centre prospective and retrospective observational study"*** submitted by Dr. Avanish Shukla, SR-II, Department of Cardiology of this University via letter no. nil dated 10th June, 2019. **EC Comment:** • Kindly submit as per CONSORT guidelines **EC Decision:** Approval after justification ***The above comment again forwarded to the P.I., response received from P.I. which was forwarded reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P110*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
d	**Minutes of ADR Sub-Committee was held on 6th September, 2019**
	Non-DCGI
I.	ADE research proposal entitled "***National heart failure registry***" submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 374/CARDIO/RES/19 dated 3rd May, 2019. **Patient ID: 70003**

Chairperson, IEC
King George's Medical University

		Gender: M **Age: 69** **Weight: 58** **Height: 168** **Subject History:** Subject got enrolled in National Heart Failure Registry of India on 11th January, 2019 and today i.e. 3rd May, 2019, P.I. made him a call for 3 month follow up then we come to know that **subject expired** on 12th February, 2019 at around 13:00 pm, Subject is having uneasiness since morning and at around 13:00 pm, He suddenly collapsed and could not survived. He was not taken to any hospital. Hence no documents are available. **ADR Sub-committee Openion:** Since the papers sent by Prof. Rishi Sethi of the Department of Cardiology of K.G.M.U. show that the Department was not responsible for the death of the deceased, no case for compensation is made out. **EC Decision:** Reviewed & noted ***Ref. code: 90th ECM IIA/P25***
II		ADR of research protocol no. ZUV/TOSI/HQ/11/2015 entitled ***"A randomized controlled trial of influenza vaccine to reduce adverse vascular events"*** sponsored by M/s Population Health Research Institute (PHRI) submitted by Prof. Sharad Chandra Department of Cardiology of this University via letter no. 465 & 466/cardio/Res/2019 dated 14th June, 2019.
	a.	**Death:** **Subject ID: # 046052** **Subject initial:** A-A **Gender:** Male **Age:** 58 yrs **Date of Randomization:** 22nd May, 2017 **Patient History:** Perused papers. Since death of the deceased does not appear to be the result of the study drug administered to the deceased, no case for compensation is made out. **ADR Sub-committee Openion:** Perused papers. Since death of the deceased does not appear to be the result of the study drug administered to the deceased, no case for compensation is made out.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

b.	**Death:** **Subject ID: # 046061** **Subject initial:** V-- **Gender:** Female **Age:** 67 yrs **Date of Randomization:** 24th May, 2017 **Patient History:** The P.I. made a call to the patient for 24th month follow up visit and vaccination. Subject's son informed us that she was **expired** on 20th December, 2018 at around 2.00 p.m. and having complain of chest aing and shortness of breath. Patient was not taken to any hospital. A general practitioner declared her death. Autopsy was not done and other documents are not available. **ADR Sub-committee Decision:** Perused papers. Since death of the deceased does not appear to be the result of the study drug administered to the deceased, no case for compensation is made out.
c	**Subject ID: # 046111** **Subject initial:** J-G **Gender:** Male **Age:** 61 yrs **Date of Randomization:** 7th June, 2018 **Patient History:** Patient was called for M-12 follow up visit and 2nd vaccination, his son informed that patient passed away on 30th May, 2019. He was having breathlessness and suddenly he felt on the ground. Local practitioner declared his **death.** Patient was not taken to any hospital, no autopsy was done and no documents provided. **ADR Sub-committee Decision:** Patient was called for M-12 follow up visit and 2nd vaccination, his son informed that patient passed away on 30th May, 2019. He was having breathlessness and suddenly he felt on the ground. Local practitioner declared his **death.** Patient was not taken to any hospital, no autopsy was done and no documents provided.
d	**Death:** **Subject ID: # 046079** **Subject initial:** G-D **Gender:** female **Age:** 44 yrs **Date of Randomization:** 30th May, 2018 **Patient History:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

Patient was called for M-24 follow up visit and 3rd vaccination, her husband informed that patient passed away on 13th May, 2019 at around 05:00 AM. She was having chest pain and vomiting half an hour she **expired** at home. Patient was not taken to any hospital, no autopsy was done and no documents provided.

ADR Sub-committee Decision:

Patient was called for M-24 follow up visit and 3rd vaccination, her husband informed that patient passed away on 13th May, 2019 at around 05:00 AM. She was having chest pain and vomiting half an hour she **expired** at home. Patient was not taken to any hospital, no autopsy was done and no documents provided.

e

Death:

Subject ID: # 046078
Subject initial: P.
Gender: Male
Age: 74 yrs
Date of Randomization: 30th May, 2017
Patient History:

Patient was called for M-24 follow up visit and 3rd vaccination, his son answered the call and informed the call and informed that the subject was expired on 18th December, 2018. He also informed that patient was having breathlessness and edema and was taken to the hospital. Patient's creatinine was increased and at around 08:00 P.M. he expired. No autopsy was done and his son doesn't provide any documents:

ADR Sub-committee Decision:

Perused papers. Since death of the deceased does not appear to be the result of the study drug administered to the deceased, no case for compensation is made out.

f

Death:

Subject ID: # 046116
Subject initial: P.K.S.
Gender: Male
Age: 63 yrs
Date of Randomization: 11th June, 2018
Patient History:

Patient was called for M-12 follow up visit and 2nd vaccination, his son informed us that he was expired on 22nd December, 2018 at around 01.:30 PM. He was not taken to any hospital. Patient was complaining breathlessness and chest pain and suddenly he **expired.** Local medical person confirmed his death. No autopsy was done and no

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	documents are available. **ADR Sub-committee Decision:** Perused papers. Since death of the deceased does not appear to be the result of the study drug administered to the deceased, no case for compensation is made out. ***Ref. code: 82nd ECM IIC/P8***
III	ADR of research protocol entitled ***"A global registry to study the demographics, socioeconomic and clinical factors, etiologies, pathophysiology, management, barriers to outcomes"*** PHRI submitted by Prof. Sharad Chandra, Department of Cardiology of this University via letter no. 497/Cardio/Res/19 dated 03-07-19 with following document:- ***(Registry trial)***
a	**Death:** **Subject ID: # 0653027** **Subject initial:** J-G **Gender:** Male **Age:** 61 yrs **Date of Randomization:** 7th June, 2018 **Patient History:** Patient was called for M-12 follow up visit his son informed that patient passed away on 30th May, 2019. He was having breathlessness and suddenly he felt on the ground. Local practitioner declared his **death**. Patient was not taken to any hospital, no autopsy was done and no documents provided. **ADR Sub-committee Decision:** Perused papers. No case for compensation is made out.
b	**Death:** **Subject ID: # 0653032** **Subject initial:** P-K-S **Gender:** Male **Age:** 63 yrs **Date of Randomization:** 11th June, 2018 **Patient History:** Patient was called for M-12 follow up visit his son informed us that he was expired on 22nd December, 2018 at around 01:30 PM. He was not taken to any hospital. Patient was complaining breathlessness and chest pain and suddenly he **expired.** Local medical person confirmed his death. No autopsy was done and no documents are available. **ADR Sub-committee Decision:** Perused papers. No case for compensation is made out.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 86th ECM IIC/P3
IV.	ADE research proposal entitled ***"ISCHEMIA entitled "International study of comparative health effectiveness with medical and invasive approaches"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology of this University vide letter no. 529/Res/Cardio/2019 dated 25th July, 2019. **Patient ID:** 091019-042 **Patient Initial:** A-P **Gender: M** **Subject History:** This note is based on limited information, available from the report/papers sent by the patient LAR. Patient has been in follow-up at RML hospital for pleural effusion and mediactinal mass (close to hilar vessels). Definitive diagnosis could not be made from pleural effusion examination/cytology. There is no report in available of CT Scan/MRI. The lesion biopsy could not be done. Patient was admitted on 22nd April, 2019 in RML hospital. He was put on ventilat on 29th April, 2019 and **expired** during shifting on the way, from RML hospital to our hospital on 29th April, 2019 at 17:30 hrs. No autopsy was done. **ADR Sub-committee Decision:** Perused papers. No case for compensation is made out. ***Ref. code: 60th ECM IIA/P13***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	DCGI
I-	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no.500/Cardio/Res/2019 dated 10th July, 2019 & 532/Cardio/Res/19 dated 24th July, 2019.
a	**Death** **Subject ID no. 010-0053** **Subject Initial:** S. **SAE term:** Death **Causality:** Could not be ascertain **Event:** Subject develop uneasiness and discomfort. Not taken to any hospital expired at home. **Gender:** M **DOB:** 01-01-1993 **Weight:** 70 KG **Height:** 180 CM **Start Date:** 5th June, 2018 **Subject History:** ***The above subject passed away on 20th May, 2019 at around 11:00 hrs at come. Cause of death is unknown. Subject expired at home, he was not taken to the any hospital.*** ***Call was made him today's morning for 12 month follow up and then site became aware of this event.*** ***ADR-sub-Committee decision:*** Since from a perusal of papers it appears that cause of death was unknown, no case for compensation arises.
b-	**Death** **Subject ID no. 010-0055** **Subject Initial:** P. **SAE term:** Death **Causality:** Cardio Vascular Arrest **Event:** Sudden death. **Gender:** F **Age:** 38 years

Chairperson IEC
King George's Medical University
U.P., Lucknow

		Weight: 30 KG **Height:** 145 CM **Start Date:** 14th July, 2018 **Subject History:** ***The above subject passed away on 1st July, 2019 at around 04:00 hrs at home. Cause of death is unknown. Subject expired at home, she was not taken to the any hospital.*** ***Call was made her yesterday around 15:30 for 12 month follow-up and then site became aware of this event.*** **ADR Sub-committee Decision:** Since from a perusal of papers it appears that cause of death was unknown, no case for compensation arises. ***Ref. code: 83rd ECM IIC/P6***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. IB

Expedited Review

K.G's Medical University U.P., Lucknow

IB	Expedited Review
1-	Research proposal entitled "***An evaluation of efficacy of etanolic extract of Nigella sative L. (Kalonji) on the clinical parameters of moderate-to-severe gingivitis: A split-mouth clinical study***" submitted by Prof. Vibha Singh, Department of Oral &Maxillofacial Surgery, Faculty of Dental Sciences of this University via letter no. nil dated 24th August, 2019. ***The above proposal forwarded to the Prof. Amita Jain, Department of Microbiology & Prof. Balendra Pratap Singh, Department of Prosthodintics, Faculty of Dental Sciences of this University.*** • ***Reply received from both reviewers with following comments:*** ***Comment of Prof. Jain:*** • This is seriously careless effort to draft a proposal: - 1- It appears that the study has already been done & Principal-Investigator has copied & pasted from already existing literature. Kindly refer to page 7,9 & whole methodology (Written in past) • The Principal-Investigator should be aware that plagiarism in any form is not permissible. 2- Backgrounds too brief to understand the subject 3- Hindi consent form is incomplete 4- What parameters will be compared for analysis & how? **"Con not be recommended in the present form"** ***Comment of Prof. Singh:*** • Kindly include one co-guide having expertise of medicinal values and extraction and dose preparation of Nigella Sativa (Kalonji) ***The above comment forwarded to the P.I., response received from P.I. which is forwarded to Prof. Jain for reviewe, which was suggested by her & Which was suggested by Dr. Singh, seen by The Member-Secretary, IEC.*** ***Reply received from Dr. Jain with following comment:-*** • This should be submitted as new proposal & should be considered in full committee. ***The above comment forwarded to the Principal-Investigator.*** **EC Decision:** Kindly submit new proposal. ***Ref. code: 98th ECM IB/P1***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. IIA

New Proposals

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 98th ECM held on 6th September, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

II-A	New Proposal
1.	Research proposal entitled "***Assessment of feasibility, safety, and efficacy of OPN NC super high pressure percutaneous transluminal coronary angioplasty balloon catheter versus rotational atherectomy for plaque modification in severely calcified coronary artery lesions***" submitted by Dr. Akhil Sharma, Associate Professor, Department of Cardiology of this University via letter no. 473/Cardio/Res/19 dated 19th June, 2019. **EC Comment:** • Is this an investigator-initiated trial or a regulatory trial? • Which of the two procedures is standard of care for treatment of calcified plaque? • Are the procedures approved by DCGI for routine use in the said clinical condition? If not, have the authors taken permission form DCGI for using the procedures **EC Decision:** Re-submit ***Ref. code: 98th ECM II A/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled "***Comparative evaluation of Glasgow coma scale with or without assessment aids in emergency Medicine Department- A randomized control study***" submitted by Prof. Haider Abbas, Head, Department of Emergency Medicine Trauma Centre of this University via letter no. nil dated 16th June, 2019. **EC Comment:** • Kindly submit the fresh proposal according to CONSORT Guidelines. **EC Decision:** Re-submit ***Ref. code: 98th ECM II A/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Research proposal entitled "***Comparative evaluation of arterial blood gases with or without assessment aid in an emergency Department- A randomized control trial***" submitted by Prof. Haider Abbas, Head, Department of Emergency Medicine Trauma Centre of this University via letter no. nil dated 16th June, 2019. **EC Comment:** • Who is a participant? • Who will provide consent for participant? • Method of collection is not clear. • Kindly provide the data collection sheet. • Kindly submit proposal according to CONSORT guidelines. • Methodology should be shown in a flow diagram for a better understanding. **EC Decision:** Revise & Re-submit

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 98th ECM II A/P3 ***(Primary Reviewer: Dr. Amita Jain)***
4.	Research proposal entitled ***"CETP and SRBI gene polymorphism on lipid subtypes of LDL and dysfunctional HDL in patient with type II diabetes mellitus"*** sponsored by CST-UP submitted by Dr. Wahid Ali, Associate Professor, Department of Pathology of this University via letter no. nil dated 1st June, 2019. **EC Comment:** • Kindly arrange the serial number of the references in order. • Kindly revise the Hindi consent form. **EC Decision:** Approval after justification ***Ref. code: 98th ECM II A/P4*** ***(Primary Reviewer: Dr. Rajeev Garg)***
5.	**Move in IMR-faculty agenda item no. 98th ECM IIB-IMR-f/P11**
6.	Research proposal entitled ***"To study the range of mean and absolute eosinophil counts in healthy Indian subjects and compare them with asthnatics and COPD patients"*** submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine of this University via letter no. 6258/Res dated 30th May, 2019. **EC Decision:** Provisionally approved with the request to kindly mention the Email address with signature in English ICF ***Ref. code: 98th ECM II A/P6*** ***(Primary Reviewer: Dr. Rajeev Garg)***
7.	Research proposal entitled ***"Follow up of the Lucknow elderly study (LES) in ageing and geriatric mental health as well as development of human resources and service pathways for mentally ill aging population"*** submitted by Dr. Nisha M Pandey, Assistant Professor, Department of Geriatric Mental Health of this University via letter no. 314/GMH dated 20th June, 2019. **EC Comment:** • Kindly clarify the point no. 6 in Annexure 7 in part III **EC Decision:** Approval after justification ***Ref. code: 98th ECM II A/P7*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
8.	Research proposal entitled ***"A two arm control study- Efficacy of automated continuous antiseptic lavage and suctioning of oral, oro-pharyngeal and subglottic secretion in prevention of ventilator associated pneumonia during invasive ventilation of patient"*** submitted by Dr. Zia Arshad, Associate Professor, Department of Anaesthesiology & Critical Care of this University via letter no. nil

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	dated 18th June, 2019. **EC Comment:** • Please inform, if the device is in use already or an entirely new one. DCGI approval needed, if it is a new one. Is it a randomized controlled study? **EC Decision:** Resubmit ***Ref. code: 98th ECM II A/P8*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
9.	Research proposal entitled ***"Validation of Hbchek: smart- point of care-haemoglobin measuring device"*** submitted by Dr. Wahid Ali, Associate Professor, Department of Pathology of this University via letter no. nil dated 15th July, 2019. **EC Comment:** This industry sponsored trial has several limitations:- • All patients enrolled in study should be provided free testing by both the methods at least it not other. • This is a careless effort by P.I. the consent form some other study is attached. Both Hindi & English consent forms are deferent & are signed by different people. • Kindly correct the spelling in Hindi ICF. • Kindly submit the data collection questionnaire/form • Kindly provide the **"Conflict of interest"** **EC Decision:** Re-submit ***Ref. code: 98th ECM II A/P9*** ***(Primary Reviewer: Dr. Amita Jain)***
10.	Research proposal entitled ***"National program on prevention and management of burn injuries (NPPMBI) - A situational analysis"*** sponsored by ICMR, New Delhi to AIIMS, New Delhi submitted by Prof. A. K. Singh, Department of Plastic Surgery of this University via letter no. 620/19 dated 8th July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P10*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
11.	Research proposal entitled ***"Clinical phenotypes and genetic regulation of endometriosis in Indian women"*** sponsored by Wellcome Trust DBT India Alliance submitted by Prof. Vinita Das, Head, Department of Obstetrics & Gynecology of this University via letter no. 14/HRRC-Lko/19 dated 22nd July, 2019. **EC Comment:** This is a large multicenteric case control study supported by ICMR welcome trust. Total case & control size is 2000 each:-

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• KGMU is one of the center, which will enrolle 200 cases. Which is the other center? Please clarifiy. • Total budget is 66 cases. KGMU fund is not visible or is this KGMU fund? • There is no mony allocated to support subjects in case of injurty as (Mentioned in form). Please clarify. • On MOU is already signed with KGMU. Does KGMU take responsibility to support? **EC Decision:** Approval after justification ***Ref. code: 98th ECM II A/P11*** ***(Primary Reviewer: Dr. Amita Jain)***
12.	Research proposal entitled "***Critical analysis of low vs high dose anti snake venom regimen in neuroparalytic snake bite patients***" submitted by Prof. Avinash Agrawal, Head, Department of Critical Care Medicine of this University via letter no. CCM/19/254 dated 16th July, 2019. **EC Comment:** • Low dose and high dose is not defined by the PI. • Is there any existing protocol for deciding the low versus high dose in these patients? Will these factors that determines low or high dose not act as confounders in the study? • Patient's performa is not attached. **EC Decision:** Approval after justification ***Ref. code: 98th ECM II A/P12*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
13.	Research proposal entitled "***Study on economic impact of Heart Failure in India***" sponsored by ICMR submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 515/Cardio/Res/19 dated 23rd July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P13*** ***(Primary Reviewer: Dr. Rajendra Nath)***
14.	Research proposal entitled "***Assisted vaginal delivery (AVD) and caesarean section at full dilatation at tertiary level Hospitals: incidence, impact and current management***" sponsored by Indian Council of Medical Research submitted by Prof. Vinita Das, Head, Department of Obstetrics & Gynecology of this University via letter no. 15/HRRC/19 dated 29th July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P14***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Surajit Bhattacharya)
15.	Research proposal entitled "***A study on microbiological and susceptibility pattern of isolates of pus samples from patients of infected pleural space: A step towards developing antibiotic policy of the Department***" submitted by Dr. Darshan Kumar Bajaj, Associate Professor, Department of Respiratory Medicine of this University via letter no. nil dated 3rd August, 2019. **EC Comment:** Ethically not approved as no collaborator from microbiology and the study involves the microbiological aspect: - • The title is mentioned differently at different plans • The sample size of 400 in 4 months is not possible. **EC Decision:** Revise & Re-submit ***Ref. code: 98th ECM II A/P15*** ***(Primary Reviewer: Dr. Rajeev Garg)***
16.	Research proposal entitled "***Deciphering the role of different isoforms of galectin-9 during HIV infection***" sponsored by DBT submitted by Dr. D. Himanshu, Associate Professor, Department of Medicine of this University via letter no. nil dated 17th July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P16*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
17.	Research proposal entitled "***National environmental Health profile: 20 city multi-site study***" sponsored by Ministry of Environment, Forest & Climate Change, Government of India, New Delhi submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine of this University via letter no. nil dated 6th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P17*** ***(Primary Reviewer: Dr. Rajeev Garg)***
18.	Research proposal entitled "***Genomics, proteomics and lipidomics analysis of exosome secreted from gastric epithelial cell during Helicobacter pylori pathogenesis***" sponsored by UPOE-II and DST New Delhi submitted by Dr. D. Himanshu, Associate Professor, Department of Medicine of this University via letter no. nil dated 17th July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P18*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
19.	Research proposal entitled "***Retrospective analysis of intracranial meningioma at***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	KGMU: 10 years institutional experience" submitted by Dr. Somil Jaiswal, Associate Professor, Department of Neurosurgery of this University via letter no. 1038/19 dated 5th August, 2019. **EC Comment:** • The objective is to assess the demographic and clinical profile of Intra cranial meningiomas and to analyze the treatment outcome in terms of mortality, morbidity, improvement, complications and recurrence. • An outline of data collection sheet has been provided • Inclusion and exclusion criteria are satisfactory • Sample size is not provided. As it is a retrospective study they can easily decide the sample size after discussing with a statistician depending upon the number of variables they are chasing. • As it is a chart analysis consent waiver is sought. **EC Decision:** Permission granted for Waiver from consent ***Ref. code: 98th ECM II A/P19*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
20.	Research proposal entitled **"*Retrospective analysis of occipital encephalocele at KGMU: 10 years institutional experience*"** submitted by Dr. Somil Jaiswal, Associate Professor, Department of Neurosurgery of this University via letter no. 1039/19 dated 5th August, 2019. **EC Comment:** • Approval for waiver form as it is retrospective data analysis. **EC Decision:** Permission granted for Waiver from consent ***Ref. code: 98th ECM II A/P20*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
21.	Research proposal entitled **"*Decrease in corneal hysteresis is a biomarker for severity of diabetic retinopathy*"** submitted by Prof. Sandeep Saxena, Department of Ophthalmology of this University via letter no. 1220/OPH/19 dated 7th August, 2019. **EC Comment:** • Wrong tense is used in statistical analysis. Kindly tell when first patient be enrolled in the study? **EC Decision:** Approval after modification ***Ref. code: 98th ECM II A/P21*** ***(Primary Reviewer: Dr. A.A. Sonkar)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

22.	Research proposal entitled "***A descriptive study on comprehensive profile of lung cancer in young population at a tertiary care centre***" submitted by Dr. Darshan Kumar Bajaj, Associate Professor, Department of Respiratory Medicine of this University via letter no. nil dated 8th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P22*** ***(Primary Reviewer: Dr. Rajendra Nath)***
23.	Research proposal entitled "***Host determinants of hepatitis E disease severity***" submitted by Dr. Manju Lata Verma, Assistant Professor, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 26th July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P23*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
24.	Research proposal entitled "***Meta genomics of Dental plaque associated micro biome to influence of Oral Health, age group, gender and differential food habit in North Indians***" submitted by Prof. Pooran Chand, Head, Department of Prosthodontics, Faculty of Dental Sciences of this University via letter no. nil dated 7th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P24*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
25.	Research proposal entitled "***Diagnostic accuracy of bedside transthoracic cardiopulmonary ultrasound in the diagnosis of acute respiratory failure in critically ill obstetric patients***" submitted by Prof. Avinash Agrawal, Head, Department of Critical Care Medicine of this University via letter no. CCM/2019/303 dated 8th August, 2019. **EC Comment:** • The study aims to prospectively evaluate the accuracy of cardiopulmonary ultrasound for etiologic diagnosis of acute respiratory failure in pregnant and post-partum patients. • The USG findings will be compared with the final diagnosis established by the ICU team • Inclusion and exclusion criteria are satisfactory • Lung ultrasound and trans thoracic echo-cardiography will be done and pneumonia, acute pulmonary oedema, pneumothorax, decompensated COPD and pulmonary embolism will be diagnosed and their diagnostic indicators provided • Data collection sheet needs to be more elaborate. What all will be noted in

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	History and Clinical Examination and when and how frequently will the 2 investigations be repeated? • Sample size is missing. Please consult a statistician and confirm a doable sample size. • I find no collaborators from the Department of Radio-diagnosis **EC Decision:** Approval after justification ***Ref. code: 98th ECM II A/P25*** ***(Primary Reviewer: Dr. Surajit Bhattaharya)***
26.	Research proposal entitled "***Epidemiology of tuberculosis patients admitted to medical/surgical ICU of a tertiary care center***" submitted by Dr. Sulekha Saxena, Assistant Professor, Department of Critical Care Medicine of this University via letter no. CCM/2019/306 dated 8th August, 2019. **EC Comment:** • When will first patient be enrolled in the study? • How the diagnosis of TB will be made? • What epidemiological parameters will be collected? **EC Decision:** Approval after justification ***Ref. code: 98th ECM II A/P26*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
27.	Research proposal entitled "***Antibiogram of ventilator associated pneumonia (VAP) in teritiary care Hospital in North India***" submitted by Dr. Sulekha Saxena, Assistant Professor, Department of Critical Care Medicine of this University via letter no. CCM/2019/304 dated 8th August, 2019. **EC Comment:** This is a study on antibiogram of patients admitted from 1st January, 2018 to 31st December, 2018:- • When will first patient be enrolled in the study? • Is it a retrospective study? • If ***yes*** how will you take consent from patients? • Kindly provide the CRF. Needs clarify. • This is a study on antibiogram & no laboratory person is involved? **EC Decision:** Revised & Re-submit ***Ref. code: 98th ECM II A/P27*** ***(Primary Reviewer: Dr. Amita Jain)***
28.	Research proposal entitled "***To determine the role of acetate, acetone and glutamine metabolites in serum as a prognostic indicator of neurological recovery in acute spinal cord injury (ASCI)***" sponsored by. Health and Research (DHR),

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	New Delhi submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 123/P/OS/19 dated 7th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P28*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
29.	Research proposal entitled "***Study to identify barriers to organ donation among brainstem dead donors in ICU***" submitted by Dr. Suhail Sarwar Siddiqui, Assistant Professor, Department of Critical Care Medicine of this University via letter no. CCM/2019/307 dated 8th August, 2019. **EC Comment:** • At page no. 7 and point no.13, data collection, the method should be non elaborate the questionnaire preferably be added. **EC Decision:** Re-submit ***Ref. code: 98th ECM II A/P29*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
30.	Research proposal entitled "***Barriers and facilitators to timely timely transfer of obstetric critically ill patients to intensive care unit of a tertiary care teaching Hospital***" submitted by Dr. Armin Ahmed, Assistant Professor, Department of Critical Care Medicine of this University via letter no. CCM/2019/308 dated 8th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P30*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
31.	Research proposal entitled "***Hemodynamic resuscitation and monitoring in early sepsis (HERMES Study) an ISCCM research project***" submitted by Prof. Avinash Agrawal, Head, Department of Critical Care Medicine of this University via letter no. CCM/2019/309 dated 8th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P31*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
32.	Research proposal entitled "***Clinical profile and outcome of patients with acute kidney injury in critically ill obstetrics patients***" submitted by Prof. Avinash Agrawal, Head, Department of Critical Care Medicine of this University via letter no. CCM/2019/310 dated 8th August, 2019. **EC Comment:** • Kindly calculate the sample size & provide the require budget. **EC Decision:** Approval after justification

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 98th ECM II A/P32 ***(Primary Reviewer: Dr. Rajendra Nath)***
33.	Research proposal entitled "***Differential microbial profiling and genotyping of dominant resistant strains in sepsis and septic shock patients***" sponsored by. ICMR- DHR submitted by Dr. Neetu Singh, Associate Professor, Department of Molecular Biology Unit Center for Advance Research of this University via letter no. CFAR/2019/405 dated 8th August, 2019. **EC Comment:** • Need to mention the type of study. **EC Decision:** Approval after justification ***Ref. code: 98th ECM II A/P33*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
34.	Research proposal entitled "***Incidence and risk factors for post-dural puncture headache following subarachnoid block in obstetric patients: A prospective observational study***" submitted by Dr. Hemlata, Assistant Professor, Department of Anaesthesiology of this University via letter no. nil dated 8th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P34*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
35.	Research proposal entitled "***Incidence and risk factors for postdural puncture headache in nonobstetric patients after spinal anaesthesia-A prospective observational study***" submitted by Dr. Reetu Verma, Associate Professor, Department of Anaesthesiology of this University via letter no. nil dated 8th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II A/P35***
36.	Research proposal entitled "***Aripiprazole as first line antidepressant inlate life-case not review***" submitted by Dr. Shrikant Srivastava, Head, Department of G.M.H. of this University via letter no. 372/DGMH dated 6th August, 2019. **EC Decision:** Waiver can be granted ***Ref. code: 98th ECM II A/P36***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. IIB

New Thesis

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 98th ECM held on 6th September, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

II-B	New Thesis-Resident
1.	Research proposal entitled ***"Comparative evaluation of usage of bicortical and unicortical anchorage of dental implants in posterior atrophic maxilla, A split mouth study"*** submitted by Dr. Sujay Bhave, JR-I, Department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences of this University via letter no. nil dated 4th June, 2019. **EC Comment:** • Investigator need to explain measurement technique of bone formation in mm per implant area. Kindly clarify. • Study procedure should be same in English and Hindi consent form. • Apart from implant stability, which other stability you will measure as mentioned under heading clinical evaluation. Kindly clarify. **EC Decision:** Approval after justification ***Ref. code: 98th ECM II B-Thesis/P1*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
2.	Research proposal entitled ***"A study to determine the prevalence of katG and inhA gene mutation in microbiologically confirmed isoniazid resistance patients at tertiary care centre"*** submitted by Dr. Amit Raj, JR-II, Department of Respiratory Medicine of this University via letter no. nil dated 19th June, 2019. **EC Decision:** Approved ***Dr. Rajeev Garg & Dr. Amita Jain did not take part in the discussion.*** ***Ref. code: 98th ECM II B-Thesis/P2*** ***(Primary Reviewer:Dr. Anoop Kumar Verma)***
3.	Research proposal entitled ***"Correlation between serum quantitative HBsAg titre and HBV DNA in chronic hepatitis B patients"*** submitted by Dr. Kuldeep Singh, JR-II, Department of Medicine of this University via letter no. nil dated 17th June, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B-Thesis/P3*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
4.	Research proposal entitled ***"Psychiatric morbidity and burden in caregivers of patients admitted in high dependency unit (HDU)"*** submitted by Dr. Soumyajit Sanyal, SR-II, Department of Geriatric Mental Health of this University via letter no. 290/DGMH dated 31st May, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B-Thesis/P4*** ***(Primary Reviewer: Dr. Rajeev Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

5.	Research proposal entitled ***"A correlation of HAMD and GDS in geriatric depression"*** submitted by Dr. Soumyajit Sanyal, SR-II, Department of Geriatric Mental Health of this University via letter no. 308/DGMH dated 13th June, 2019. **EC Comment:** • From the available patient records in the department severe psychological and medical co-morbidities in geriatric patients will be rated by 2 scales – Geriatric Depression Scale (GDS) and Hamilton Rating Scale of Depression (HAMD) • GDS scores have been found to correlate with changes of HAMD score in adults but not in geriatric population • Sample size is not given • Consent waiver is requested as patients are not being questioned. **EC Decision:** Waiver cannot be granted, kindly submit fresh proposal ***Ref. code: 98th ECM II B-Thesis/P5*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
6.	Research proposal entitled ***"Anthropometric measurement of upper end of tibia in north Indian population with its clinical significance: A cadaveric and dry bone study"*** submitted by Dr. Arun Kumar, JR-II, Department of Anatomy of this University via letter no. nil dated 3rd August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B-Thesis/P6*** ***(Primary Reviewer: Dr. Vimla Kumar Paliwal)***
7.	Research proposal entitled ***"Analysis of 3rd delay in women with severe acute maternal morbidity requiring ventilator support"*** submitted by Dr. Vartika Tripathi, SR, Department of Obstetrics & Gynecology of this University via letter no. nil dated 29th July, 2019. **EC Comment:** • Kindly provide the details of objective, inclusion & exclusion criteria, sample size. **EC Decision:** Approval after justification ***Ref. code: 98th ECM II B-Thesis/P7*** ***(Primary Reviewer: Dr. Rajendra Nath)***
8.	Research proposal entitled ***"Prevalence of dyslipidemia in nonobese obstructive sleep apnea (OSA)"*** submitted by Dr. Jyoti Bajpai, SR-III, Department of Respiratory Medicine of this University via letter no. nil dated 6th August, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment: • Your proposal mentined study design at two places on page no. 10, which needs to be corrected. • More over according to the objective mentioned, it has to be simple observational study. So why authors do mentioned case control needs tobe clarified? • Sample size not mentioned please • This proposal needs re-submission with propoer study design and sample size. **EC Decision:** Re-submit ***Ref. code: 98th ECM II B-Thesis/P8*** ***(Primary Reviewer: Dr. Rajeev Garg)***
9.	Research proposal entitled ***"Role of VITAMIN D and calcium in thyroid Ophthalmopathy"*** submitted by Dr. Ashutosh Maharana, JR-I, Department of Ophthalmoology of this University via letter no. nil dated 7th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B-Thesis/P9*** ***(Primary Reviewer: Dr. Amita Jain)***
10.	Research proposal entitled ***"Cathepsin S as an early biomarker for cardio vascular disease in patients of chronic kidney disease"*** submitted by Dr. Prashant Kumar Singh, JR-II, Department of Medicine of this University via letter no. nil dated 8th August, 2019. **EC Comment:** • Kindly attach case sheet **EC Decision:** Approval after justification ***Ref. code: 98th ECM II B-Thesis/P10*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
11.	Research proposal entitled ***"Corneal hysteresis in central serous chorioretinopathy"*** submitted by Dr. Malvika Singh, JR-I, Department of Ophthalmology of this University via letter no. nil dated 8th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B-Thesis/P11*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

IIB.	Ph.D.
1-	Research proposal entitled "***To assess the association of NFKBIZ and IL-1RA gene polymorphisms in community acquired pneumonia patients under the age of 5 years: A case-control study***" submitted by Ms. Neha Verma under the guidance of Prof. Shally Awasthi, Department of Pediatrics of this University via letter no. nil dated 22nd June, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B-Ph.D/P1*** ***(Primary Reviewer: Dr. Amita Jain)***
2.	Research proposal entitled "***To study the relationship between serum leptin and gene expression of jak/stat in pregnancy induced diabetes mellitus***" submitted by Ms. Neha Srivastava under the guidance of Dr. Kalpana Singh, Associate Professor, Department of Biochemistry of this University via letter no. nil dated 1st August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B-Ph.D/P2*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
3.	Research proposal entitled "***Evaluation of matrix metalloproteinases and selenium associated proteins in patients with dengue viral infection in accordance of severity***" submitted by Dr. Debadyuti Sahu under the guidance of Prof. Abbas Ali Mahdi, Department of Biochemistry of this University via letter no. nil dated 1st August, 2019. **EC Decision:** Approved ***Dr. Amita Jain did not take part in the discussion.*** ***Ref. code: 98th ECM II B-Ph.D/P3*** ***(Primary Reviewer: Dr. Rajeev Garg)***
4.	Research proposal entitled "***Enumeration and clinic- pathological correlation of T-regulatory cells in Hodgkin and NonHodgkin lymphomas***" sponsored by ICMR. submitted by Dr. Nishant Taur under the guidance of Prof. Ashutosh Kumar, Head, Department of Pathology of this University via letter no. nil dated 8th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B-Ph.D/P4*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. IIB

Intramural-Faculties

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 98th ECM held on 6th September, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

IIB.	IMR-Faculty
1.	Research proposal entitled ***"16s microbial profiling of gall bladder cancer"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Shiv Rajan, Assistant Professor, Department of Surgical Oncology of this University via letter no. nil dated 1st July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B IMR-F/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"Analysis of miRNA signatures in human cardiac tissue and its applicability in determination of post mortem interval"*** sponsored by. Research Cell KGMU Lucknow submitted by Dr. Sangeeta Kumari, Assistant Professor, Department of Forensic Medicine and Toxicology of this University via letter no. nil dated 20th July, 2019. **EC Decision:** Approved ***Dr. Anoop K. Verma & Dr. R.K.Garg did not take part in the discussion.*** ***Ref. code: 98th ECM II B IMR-F/P2*** ***(Primary Reviewer: Dr. Amita Jain)***
3.	Research proposal entitled ***"Evaluation and creation of an electronic database of the burden of maxillofacial injuries sustained during trauma"*** sponsored by. Research Cell KGMU Lucknow submitted by Dr. Arunesh Kumar Tiwari, Assistant Professor, Department of Oral and Maxillofacial Surgery Trauma of this University via letter no. OMS/509/19 dated 18th July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B IMR-F/P3*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
4.	Research proposal entitled ***"Trauma shock, the psychological perspective of maxillofacial & non-maxillofacial Trauma: A cross sectional triple arm comparative analytical cohort study"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Amiya Agrawal, Assistant Professor, Department of Oral and Maxillofacial Surgery Trauma of this University via letter no. OMS/508/19 dated 18th July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B IMR-F/P4*** ***(Primary Reviewer: Dr. Rajendra Nath)***
5.	Research proposal entitled ***"Serum bilirubin measurement in neonates using traditional wet chemistry method versus dry chemistry method"*** sponsored by. Research Cell KGMU Lucknow submitted by Dr. Kalpana Singh, Associate Professor, Department of Biochemistry of this University via letter no. nil dated 25th

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B IMR-F/P5*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
6.	Research proposal entitled "***To analyze the role of bisphosphonate on clinic radiological shortterm outcome of Legg CALVE's PERTHES disease: A pilot study***" sponsored by Research Cell KGMU Lucknow submitted by Dr. Mayank Mahendra, Assistant Professor, Department of Orthopaedic Surgery of this University via letter no. 220/OS/19 dated 7th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B IMR-F/P6*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
7.	Research proposal entitled "***Delineating the role of WWOX gene expression in the patients of osteosarcoma***" sponsored by Research Cell KGMU Lucknow submitted by Dr. Dharmendra Kumar, Assistant Professor, Department of Orthopaedic Surgery of this University via letter no. 122/P/OS/19 dated 7th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B IMR-F/P7*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
8.	Research proposal entitled "***Prospective randomised study to evaluate the therapeutic effect of high-volume V/S low volume caudal epidural injections in lumber PIVD***" sponsored by Research Cell KGMU Lucknow submitted by Dr. Sanjiv Kumar, Assistant Professor, Department of Orthopaedic Surgery of this University via letter no. 229/OS/19 dated 7th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B IMR-F/P8*** ***(Primary Reviewer: Dr. Rajeev Garg)***
9.	Research proposal entitled "***Developing pshchological resilience applying strategies of psycho-spiritual maturation amongst care givers of older adults consulting tertiary care hospital-a preliminary study***" sponsored by Research Cell KGMU Lucknow submitted by Dr. Nisha M Pandey, Assistant Professor, Department of G.M.H. of this University via letter no. 158/DGMH dated 26th March, 2019. **EC Comment:** • The objective is to explore the indices of spirituality, confidence in life and confidence in self amongst caregivers of mentally ill elderly and to study the impact of 'know yourself curriculum' in developing psychological resilience amongst them.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• The study is in 7 sections. In section 1 in a taped interview the caregiver will be asked about problems they face in rendering care, his/her behavioral anomalies will be mapped and behavioral change setting goals will be set. In section 2 participant's psycho-spiritual development will be explored. Section 3, 4 and 5 will be for contemplation self enquiry through meditation. Session 6 will engage the participants to develop inclusive person-centered community and session 7 will be about outcome assessment by 3 standardized scales SCL-90-R, INSPIRIT-R and IPPA, which have been attached. • 7 sessions will be spread in 30 days • The researchers do not tell us how at the end of the study the audio tapes will be disposed / destroyed. There may be sensitive information in them which the participants may not like to share with anyone else. • Sample size is not provided. **EC Decision:** Approval after justification ***Ref. code: 98th ECM II B IMR-F/P9*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
10.	Research proposal entitled "***To search novel mocroRNAs in serum as a noninvasive biomarker in prostate cancer***" sponsored by Research Cell KGMU Lucknow submitted by Dr. Shweta Kumari, Assistant Professor, Department of Biochemistry of this University via letter no. nil dated nil. **EC Decision:** Approved ***Ref. code: 98th ECM II B IMR-F/P10*** ***(Primary Reviewer: Dr. Rajeev Garg)***
11.	Research proposal entitled "***Prevalence of vitamin D deficiency in HIV disease and its correlation with disease severity: An observational study***" submitted by Dr. Sudhir Kumar Verma, Assistant Professor, Department of Medicine of this University via letter no. 1167/Med/19 dated 14th June, 2019. **EC Comment:** • Please modify the 1st. objective. To study the prevalence of Vitamin D in HIV disease means nothing • Hypothesis is Vitamin D deficiency is common in HIV patients and its levels correlate with the severity of the disease • 8 ml blood will be drawn once for CBC, LFT, RFT, CD4 counts, Serum Calcium – total and ionic, phosphate, 25(OH) Vitamin D, Parathormone • Vitamin D 10-20 ng/ml will be considered as insufficiency and <10 ng/ml will be taken as deficiency • Sample size 60. Was it statistically derived? • Inclusion and exclusion criteria are satisfactory

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Ref. code: 98th ECM II B IMR-F/P11*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P. Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. IIB

Intramural-Residents

K.G's Medical University U.P., Lucknow

IIB	IMR-Resident
1-	Research proposal entitled "***Analysis of immunohistochemical expression and immunomodulatory effects in classical Hodgkin lymphoma***" sponsored by of Research Cell KGMU submitted by Dr. Shalini Rawat, JR-II through her mentor Dr. Mili Jain, Assistant Professor, Department of Pathology of this University via letter no. nil dated 26th July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM II B IMR-R/P1*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
2.	Research proposal entitled "***Age determination through closure of sagittal suture in adult Humans: 3D computerized tomography study in North Indian population***" sponsored by of Research Cell KGMU submitted by Dr. Rajeev Ranjan, JR-II through his mentor Dr. Mousami Singh, Associate Professor, Department of Forensic Medicine of this University. **EC Decision:** Approved ***Dr. Anoop K. Verma & Dr. R.K. Garg did not take part in the discussion.*** ***Ref. code: 98th ECM II B IMR-R/P2*** ***(Primary Reviewer: Dr. Amita Jain)***
3.	Research proposal entitled "***The role of MTR, MTRR, MTHFR gene association in non syndromic cleft LIP, cleft palate and cleft LIP with palate in north Indian children***" sponsored by of Research Cell KGMU submitted by Dr. Aravindhan A, JR-I through his mentor Prof. Rakesh Kumar Chak, Head, Department of Paediatric and Preventive Dentistry of this University via letter no. nil dated 8th August, 2019. **EC Comment:** • Signature of Dr. Nitu Nigam is missing. **EC Decision:** Provisionally approved ***Ref. code: 98th ECM II B IMR-R/P3*** ***(Primary Reviewer: Dr. Rajeev Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. IIB

Intramural-Students

K.G's Medical University U.P., Lucknow

IIB	IMR- Student
1.	Research proposal entitled ***"To study the prevalence of latent tuberculosis infection among medical students"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Mr. Prateek Kumar Dinkar, Batch 2016 through her Mentor Prof. Santosh Kumar, Department of Respiratory Medicine of this University via letter no. nil dated 31st July,2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIB IMR-S/P1*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
2.	Research proposal entitled ***"Review of therapy following burns in patients presenting with post burn contracture in tertiary Hospital"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Mr. Vishal Lodhi, Batch 2017 through her Mentor Prof. Brijesh Mishra, Department of Plastic Surgery of this University via letter no. nil dated 1st August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIB IMR-S/P2*** ***(Primary Reviewer: Dr. Rajeev Garg)***
3.	Research proposal entitled ***"A comparative study on estimation of serum creatinine by different methods with reference to bilirubin interference"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Ms. Zareena Akhtar, Batch 2018, through her Mentor Prof. Dilutpal Sharma, Head, Department of Biochemistry of this University via letter no. nil dated 5th August,2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIB IMR-S/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Research proposal entitled ***"Co-expression of Epstein Barr virus and human papilloma virus in oral and breast cancers and their association with epithelial mesenchymal transition markers"*** sponsored by Indian Council of Medical Research (ICMR) submitted by Dr. Vanshika Shahi through her Mentor Prof. M.M Goel, Head, Department of Pathology of this University via letter no. nil dated 25th July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIB IMR-S/P4*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
5.	Research proposal entitled ***"Prevalence and association of enamel defects and dental caries in 13-15 year old School going Children in Lucknow"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Mr. Moulik Singh Through her Mentor Dr. Pragya Pandey, Assistant Professor, Department of Conservative

Chairperson, IEC
King George's Medical University
U.P., Lucknow

		Dentistry & Endodontics Faculty of Dental Sciences of this University via letter no. nil dated 7th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIB IMR-S/P5*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
6.		Research proposal entitled ***"Molecular analysis of MTHFR (C677T) gene polymorphism and serum lipid level in gestational diabetes patients"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Mr. Vivek Chaurasiya, MBBS 2018. Through his Mentor, Dr. M. Kaleem Ahmad, Associate Professor, Department of Biochemistry of this University via letter no. Bio/040/19 dated 7th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIB IMR-S/P6*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
7.		Research proposal entitled ***"A cross- sectional study of pattern of antipsychotic side effects and medication adherence in patients with schizophrenia"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Miss. Priya Singh, MBBS Through her Mentor, Dr. S.K.Kar, Associate Professor, Department of Psychiatry of this University via letter no. nil dated 8th August, 2019. **EC Comment:** • Objective is to assess the side effects of anti-psychotic drugs and medication adherence in schizophrenia patients. • Inclusion and exclusion criteria are satisfactory • Tools for measurement of variables defined and a semi-structured proforma attached. • Very poorly typed research proposal **EC Decision:** Approval after justification ***Ref. code: 98th ECM IIB IMR-S/P7*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
8.		Research proposal entitled ***"Factors for delayed presentation of advanced oral and breast malignancy in North Indian population-A study from tertiary care Hospital"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Miss. Pooja Saroj & Mr. Devesh Prasad, MBBS II Year Through their Mentor, Prof. Vinod Jain, Department of Surgery (General) of this University via letter no. nil dated 8th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIB IMR-S/P8*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	9.	Research proposal entitled ***"Psychological assessment of pre-operative cancer patients"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Ms. Payal & Ms. Kanika Singh, MBBS Through their Mentor Prof. Vinod Jain, Department of Surgery (General) of this University via letter no. nil dated 7th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIB IMR-S/P9*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. IIC

Registry Trial

K.G's Medical University U.P., Lucknow

II-C	Registry Trial
1-	Research Protocol no. entitled ***"European prospective registry on sirolimus drug coated balloon (thE All- comers Sirolimus- coaTed BallOan eURopeaN rEgistry: the EASTBOURNE REGISTRY)"*** sponsored by Concept Medical submitted by Prof. Sharad Chandra, Department of Cardiology of this University via letter no.543/cardio/Res/19 dated 6th August, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIC/P1*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. IID

Nurses

K.G's Medical University U.P., Lucknow

II-Da	Nurses
1.	Research proposal entitled ***"Effect of pamphlet on knowledge and practice of oralrehydration among mothers of under five children"*** submitted by Mr. Raunak Verma/Ms. Pragati Sharma/Ms. Prerna/Ms. Preeti Nishad/Ms. Priya Singh/Ms. Prashant Pratap/Mr.Prem Kumar/Ms.Pooja Kumari Through Mrs. Rina Raj, KGMU College of Nursing of this University via letter no.nil dated 16th April, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIDa/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"A descriptive study to assess the knowledge regarding blood donation among under graduate students of selected government college of Lucknow with a view to develop information pamphlets"*** submitted by Ms. Meena Devi/Ms.Manswita Bhoop/Ms.Minoo Bhardwaj/Ms. Mansi Verma/Ms.Mandavi Rawat/Ms.Nandini Saxena/Ms.Priya Singh/Ms.Poonam Pal through Mrs. Anugrah Charan & Mr. Sachin Dwivedi, KGMU College of Nursing of this University via letter no.nil dated 16th April, 2019. **EC Comment:** • Kindly provide Questionnaire, Pamphlet sample and calculated sample size of UG students. **EC Decision:** Approval after justification ***Ref. code: 98th ECM IIDa/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Research proposal entitled ***"A descriptive study to assess the knowledge regarding needle stick injury and post exposure prophylaxis among nursing students of KGMU, College of Nursing"*** submitted by Ms. Akanksha Maurya/Ms. Asmita Maurya/ Mr.Akhilesh Kumar through Mr. Bhagwant Singh, KGMU College of Nursing of this University via letter no.nil dated 16th April, 2019. **EC Comment:** • Kindly provide Questionnaire **EC Decision:** Approval after justification ***Ref. code: 98th ECM IIDa/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Research proposal entitled ***"A descriptive study to assess the knowledge of staff nurses regarding management of preeclampsia in selected Hospitals, Lucknow. U.P"*** submitted by Ms. Seema Chaudhary/Mr.Sidrah Javed Rehman/

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Mr.Shivam Kanoujiya/Ms.Shabnam Chishty/Ms.Sapna Verma/Mr.Suhel Khan/Mr. Suvesh Kumar through Ms. Monica Nancy Lal, & Mr. Ankit Raj, KGMU College of Nursing of this University via letter no.nil dated 16th April, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIDa/P4*** ***(Primary Reviewer: Dr. Rajeev Garg)***
5.	Research proposal entitled ***"A descriptive study to assess the awareness of organ donation among the adults visiting Medical OPD of KGMU, Lucknow with a view to increase their awareness about organ donation through informational pamphlets"*** submitted by Ms. Harshita Awasthi/Mr.Himanshi Sahu/Ms.Jyoti Jaiswal/Ms.JyotiYadav/Ms.KirtiKumari/Ms.KajalTripathi/Ms.KusumlataJaiswal/ Ms.KakulKushwaha Through Lalima Gupta & Ms. Manisha Anand KGMU College of Nursing of this University via letter no.nil dated 16th April, 2019. **EC Comment:** • When will first patient be enrolled in the study? **EC Decision:** Approval after justification ***Ref. code: 98th ECM IIDa/P5*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
6.	Research proposal entitled ***"A descriptive study to assess the knowledge and attitude of patients undergoing hemodialysis regarding their dietary management at KGMU, Lucknow with the view to develop an information booklet"*** submitted by Ms. Premsheela Rai/Ms.Priyanka Chaudhary/Ms.Priyanka Verma/Ms.Praveena Singh Deepankar/Ms.Preeti Jaiswar/Mr.Pankaj Jha/Mr. Prabhat Singh under the guidance of Mr.s Roohi Elizabeth Peter KGMU College of Nursing of this University via letter no.nil dated 16th April, 2019. **EC Comment:** • Kindly submit the Methodology. • How to assess the knowledge and attitude of patiens. **EC Decision:** Approval after justification ***Ref. code: 98th ECM IIDa/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
7.	Research proposal entitled ***"A descriptive study to assess the knowledge regarding control of hypertension among the patients of selected ward of K.G.M.U."*** submitted by Ms. Shivani Chauhan/Ms. Shivali Srivastava/ Ms. Smita Prajapati/Mr.Shalu Kashyap/ Ms.Sunita Kumari/Ms.Surabhi Verma/Ms.Supriya Verma/Mr.Shailendra Verma through Mrs. Shikha Malik, KGMU College of Nursing of this University via letter no.nil dated 16th April, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 98th ECM IIDa/P7*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
8.	Research proposal entitled ***"Care burden of caregivers of HEMODIALYSIS patients"*** submitted by Mrs. Roohi Elizabeth Peter, KGMU College of Nursing of this University via letter no.1110/19 dated 27th July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIDa/P8*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
9.	Research proposal entitled ***"A study to assess the effectiveness of structured teaching program on knowledge regarding causes and prevention of cervical cancer among adolescent girls studying in Mount Carmel Inter College, Lucknow"*** submitted by Ms.Arpita Sachan/Ms.Monika Bhatt/Ms.PriyaSingh/Ms.MalayRai/ Ms.GarimaChauhan/Mr.YogendraKumar/Mr.Dhananjay Sahu/Ms. Vandana Maurya/ Ms.Mamta AwasthiMrs. Renuka, KGMU College of Nursing of this University via letter no.728/19 dated 17th July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIDa/P9*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
IID. b	**Vivekananda College of Nursing**
b1.	Research proposal entitled ***"A study to assess the prevalence of common physical health problems among senior citizens at sarojininagar, Lucknow"*** submitted by Ms. Vinita Pandey, under the guidance Mrs. Chandini Tiagi, Principal and Head, Department of Community Health Nursing Vivekananda College of Nursing through Dean, Faculty of Nursing, KGMU UP, Lucknow of this University via letter no. dated 3rd July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIDb/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
B2.	Research proposal entitled ***"Effectiveness of an information booklet on knowledge regarding breastfeeding among mothers of under two year children"*** submitted by Ms. Arpita Nag, under the guidance Mrs. Rina Kumari, Department of Child Health Nursing, Vivekananda College of Nursing through Dean, Faculty of Nursing, Lucknow of this University via letter no. dated 3rd July, 2019. **EC Decision:** Approved ***Ref. code: 98th ECM IIDb/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. III

Adverse Drug Event

K.G's Medical University U.P., Lucknow

IIIB	Adverse Drug Event
1.	**Hospitalization** ADE research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AFTreatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 495/Cardio/Res/19 dated 3rd July, 2019. **Patient ID:010-0026** **EC Decision:** Noted ***Ref. code: 83rd ECM IIC/P6*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. IV

Modification

K.G's Medical University U.P., Lucknow

IV-A	Modification
1-	Modification of Research protocol no. entitled ***"Short period incidence study of severe acute respiratory infection (SPRINT-SARI)"*** submitted by Prof. Shally Awasthi, Department of Pediatrics this University via letter no.nil dated 11th July, 2019. **EC Decision:** Approved ***Ref.code:77th ECM IIA/P8*** ***(Primary Reviewer: Dr. Amita Jain)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. V

Annual Progress Report

K.G's Medical University U.P., Lucknow

V	Annual Progress Report
1-	Annual Progress Report of research proposal entitled ***"Science-Humanities symbiosis: learning tool for effective patient dialogue by dental undergraduates"*** submitted by Dr. Rameshwari Singhal, Associate Professor, Department of Periodentology, Faculty of Dental Sciences of this University via letter dated 14-05-18. **EC Decision:** Reviewed & Noted ***Ref. code: 90th ECM II A/P2*** ***(Primary Reviewer :Dr. Balendra Pratap Singh)***
2-	Annual Progress Report of research proposal entitled ***"Prevalence of Periodontitis in patients with primary oral cancer"*** submitted by Dr. Rameshwari Singhal, Associate Professor, Department of Periodentology, Faculty of Dental Sciences of this University via letter dated 13th August, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 90th ECM II A/P3*** ***(Primary Reviewer :Dr. Amita Jain)***
3-	Annual Progress report of research proposal entitled ***"Predictive model for oral cancer risk through up - regulation of BC12 oncogene in chronic periodontitis patients"*** submitted by Dr. Rameshwari Singhal, Associate Professor, Department of Periodentology, Faculty of Dental Sciences sponsored by U.P.C.S.T. Lucknow of this University via letter no. nil dated 13th August, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 89th ECM II A/P13*** ***(Primary Reviewer :Dr. A.A. Sonkar)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Commiittee

Minutes of 98th Institutional Ethics Committee Meeting held on 6th September, 2019.

Item no. VI

Other Matter with the permission of chair

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 98th ECM held on 6th September, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

VI	Other Matter
1-	As per Doctoral Committe should be revised the topic of research proposal entitled ***"Evalutation of targeted serum biomarkers as A risk factor of Congenital talipes equinovarus and their correlation with its severity: A mother child dyad study"*** **instead of** ***"Evaluation of targeted genes level in blood serum as a risk factor and their correlation with severity of CTEV: a mother child DYAD study"*** submitted by Prof. Ajai Singh, Department of Paediatirc Orthopaedic of this University via letter no. 147/Paedortho/2019 dated 28th July, 2019. **EC Decision:** Permission granted ***Ref. code: 96th ECM II A/P37*** ***(Previous Primary Reviewer: Dr. Preeti Agarwal)***
2-	In accordance with the fact that KGMU is an institute of national stature, I wish to obtain permission from the **"Institutional Etics Committee"** to export biomedical specimen from ear as obtained from 20-25 patients as a part of routie surgery to Stanford University USA under the research proposal entitled ***"To study sleep, nutrition, addictions and physical activity (SNAP) as determinants of occurrence of metabolic syndrome and oral precancerous lesions"*** sponsored by DST, New Delhi submitted by Prof. Anupam Mishra, Department of E.N.T., Head-Neck Surger of this University via letter no. 317/ENT/AM/19 dated 17th July, 2019. **EC Decision:** Permission granted ***Ref. code: 96th ECM II A/P5*** ***(Primary Reviewer: Dr. Surajit Bhattachary)***

The next meeting will be on 18th October, 2019

Thanks

Chairperson, IEC
King George's Medical University
U.P. Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Institutional Ethics committee

Minutes of 99th Institutional Ethics Committee Meeting held on 18th October, 2019.

K.G's Medical University U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Institutional Ethics committee

Minutes of 99th Institutional Ethics Committee Meeting held on 18th October, 2019.

Part IA

Action Taken

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 99th ECM held on 18th October, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

Minutes of the **"Institutional Ethics Committee"** Meeting to be held on **18th October, 2019 from 2.00 p.m. till 3.30 p.m.** in the **'Board Room'**, Office of the Vice Chancellor, Administrative Block of this University.

The following members were present in the Meeting

1- Prof.S.P. S Gaur	*-Chairman*
2- Justice Hon'ble Vishnu Sahai	*- Member*
3- Dr. Surajit Bhattacharya	*-Member*
4- Dr. Vimal Kumar Paliwal	*-Member*
5- Dr. Smriti Bhadauria	*-Member*
6- Prof. Rajeev Garg	*-Member*
7- Dr. Manju Agrawal	*-Member*
8- Prof. Amita Jain	*-Member*
9- Prof. Rajendra Nath	*-Member*
10- Prof. Anoop Kumar Verma	*-Member*
11- Mr. Ram Niwas Jain	*-Member*
12- Prof. R. K. Garg	*-Member-Secretary, Ex-officio*

The following Members were not present:

1- Dr. Preeti Agarwal	*-Member*
2- Prof. A.A. Sonkar	*-Member*

Chairperson, IEC
King George's Medical University
U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 99th ECM held on 18th October, 2019

(Registration No.:ECR/262/Inst/UP/2013/RR-16)

I. (A) Action taken

I	Action Taken on decisions of previous Ethics Committee Meeting
	Part (a) 96th ECM
1	Clarification of research proposal entitled ***"Comparison of acceptability and efficacy of thermocoagulation and cryotherapy in via positive cervical lesions"*** submitted by Dr. Parul Sharma, JR-I, Department of Obstetrics & Gynaecology of this University. **EC Comment on 10th May, 2019:** • Issue is there are two group and involves intervention which will be done after randomization so it requires clinical trial registry as per CONSORT guidelines. **EC Decision on 10th May, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was forwarded to the Primary reviewer & approved.*** **Action Taken :** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P64*** ***(Primary Reviewer: Dr. Rajeev Garg)***
	Part (a) 97th ECM
b1	Clarification of research proposal entitled ***"A prospective study of four quadrant ostoplastic decompressive craniotomy vs conventional decompressive craniectomy for traumatic brain injury"*** submitted by Dr. Yashpal Jaware, SR-I, Department of Neurosurgery of this University via letter no. nil dated 12th April, 2019. **EC Comment on 12th July, 2019:** • Title should mention "RCT". • How randomization will be done • CONSORT guidelines should be followed. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to the Principal-Investigator response has received from P.I. which was forwarded to the Primary reviewer reply has***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	given by reviewer with following comment:- **EC Comment:** • No correction made. • Needed second Review in next meeting. ***Response received from P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **Action Taken :** Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P21*** ***(Primary Reviewer: Dr. Amita Jain)***
b2	Clarification of research proposal entitled ***"Study to evaluate the need of surgical interventions amongst adolescent gynaecological problems"*** submitted by Dr. Vijeta Kumari, JR-I, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 9th April, 2019. **EC Comment on 12th July, 2019:** • Adolescent gynaecological problems is an heterogeneous group comprising of too many variables – menstrual irregularity, pain, leucorrhoea, PID, Ovarian masses, urinary problems, injury, sexual assault and adolescent pregnancy. So now sample size becomes vital. Please consult a statistician and decide the sample size otherwise your results will become statistically insignificant. • Please spend some time to decide your inclusion and exclusion criteria. Right now you have included all adolescent girls who or whose parents have given consent. • We need a data collection sheet which should have the demographic details, history and examination findings, investigations, interventions, treatment details and outcome • With so many variables you may end up with a very large sample size that may be just too big for your limited duration of study. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to Principal-Investigator, response has given by P.I. which was forwarded to the Primary reviewer, reply has given by reviewer & approved.*** **Action Taken :** Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P26*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

b3	Clarification of research proposal entitled ***"Comparative study between ultrasound guided erector spinae plane block and para vertebral block in thoracic surgeries"*** submitted by Dr. Akanksha Jain, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • The study needs to be written as per CONSORT guidelines. • The topic of the study should reflect the methods like – randomized controlled blinded/open-label etc. • The name of the drug should also be mentioned in the title of the study. • Which one of the two arms will be a control arm if it is a controlled study? • Which randomization method will be used? • How will the allocation concealment be achieved? • Patient information document (PID) is very important document and it needs to be filled again. Are there any complications of either of the anesthesia methods? These have to be discussed with the patient in the PID. Risks from the study have also to be discussed. Compensation has to be planned. • Patient datasheet not attached. • Please provide a CONSORT checklist duly filled along with the revised thesis performa. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to Principal-Investigator, response has given by P.I. which was forwarded to the Primary reviewer, reply has given by reviewer with following comment:*** • The CONSORT guideline performa should not show the page and line number where respective change has been made. • Please discuss Randomization method. • How will the allocation be concealed & analysis. • The complications of the Drugs have to be discussed in the PID **Action Taken:** The above comment forwarded to the P.I. via this office letter no. 1416/Ethics/19 dated 24th September, 2019. ***Reply has not given by P.I. by 17th October, 2019.*** **EC Decision:** Pending ***Ref. code: 97th ECM II B-Thesis/P31*** ***(Primary Reviewer : Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

b4	Clarification of research proposal entitled ***"Comparison between LMA proseal and I-gel airway in anaesthetized patients on spontaneous ventilation during daycare procedures"*** submitted by Dr. Neha Singh, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 13th April, 2019. **EC Comment on 12th July, 2019:** • Kindly submit Conflict of interest form. It should be done in form of RCT. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved with condition to kindly submit the CTRI registration. **EC Decision:** Pending because CTRI registration has not submitted by you ***Ref. code: 97th ECM II B-Thesis/P32*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
b5	Clarification of research proposal entitled ***"Immunohistochemical expression of PD-L1 in malignant soft tissue tumor"*** submitted by Dr. Ashutosh Mishra, JR-I, Department of Pathology of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • The objective is to evaluate the immunohistochemical expression of PD-L1, proliferation index K1-67 and its correlation with clinic-pathological findings of malignant soft tissue tumors • Sample size is 50. Has it been statistically derived? • Active patients as well as paraffin blocks of soft tissue sarcoma from records will form the study group. • Methodology has been elaborately described. • How will the consent be obtained from patients whose paraffin blocks will be used in this study? They may not even be alive. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P37*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
b6	Clarification of research proposal entitled ***"Role of TLR-3 polymorphism as predisposing factor to infections in patients of acute leukemia on treatment"***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	submitted by Dr. Akanksha Sharma, JR-I, Department of Pathology of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • Kindly submit **CONSORT** guidelines as it has control arm. • Kindly submit CTRI registration. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was forwarded to the Primary reviewer, response has given by the reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P38*** ***(Primary Reviewer: Dr. Rajeev Garg)***
b7	Clarification of research proposal entitled ***"Clinical and radiological comparison of long- term and short- term outcomes of posterior canal wall reconstruction technique by using composite multifractured osteoperiosteal flap (C.M.O.F) versus conventional canal wall down mastoidectomy"*** submitted by Dr. Monica Patnaik, JRI, Department of Otorhinolaryngology and Head- Neck Surgery of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • The PI wishes to compare the outcome of two surgical methods to treat patients with CSOM. How will the patients be chosen for either of the procedures? Will this be an open-label or blinded study? Which allocation concealment method will be used? The thesis performa needs to be written as per the CONSORT guidelines. • Including patients retrospectively will dilute the impact of the study. It is advisable to restrict this to a prospective study. • The complications from the either of the surgical procedures, the risks involved have to be discussed with the patient in the patient information documents. • The issue of compensation has to be discussed. Who will pay for compensation in case of litigation? Who will bear the cost of treatment if a patient develops complication of either of the surgical procedure? • How much is the additional cost of obtaining/using CMOF for reconstruction of posterior canal wall? Who will bear the cost of the procedure? • Patient data sheet is not provided.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Please submit a CONSORT checklist dully filled along with the revised thesis performa. **EC Decision on 12th July, 2019:** Re-submit ***The above comment send to P.I., reply has given by P.I. but the reviewer has given comment again.*** **Comment:** • Is theirs a retrospective or a prospective study? • CONSORT statement is not required if it is a retrospective study. • A prospective study comparing two surgical procedures will required the project to be re-written as per CONSORT guidelines. **Action Taken:** The above comment was forwarded to the P.I. via this office letter no.1408/Ethics/19 dated 24th September, 2019. ***Reply has not given by P.I. till 17th October, 2019.*** **EC Decision:** Pending ***Ref. code: 97th ECM II B-Thesis/P4*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
b8	Clarification of research proposal entitled ***"Comparative effectiveness of different concentrations of dextrose prolotherapy in osteoarthritis knee- A prospective study"*** submitted by Dr. Snigdha Mishra, JR-I, Department of PMR of this University via letter no. nil dated 22nd April, 2019. **EC Comment on 12th July, 2019:** • Hindi & English Inform Consent form is not similar **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P47*** ***(Primary Reviewer: Dr. Rajendra Nath)***
b9	Research proposal entitled ***"Expression of p53, cyclin d1 and ki-67 markers in premalignant and malignant lesions of oral cavity and oropharynx"*** submitted by Dr. Eshani Dutta, JR-I, Department of Otorhinolaryngology and Head- Neck of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • Please specify the study type. • Objective is not clear.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• What analysis Investigator plans to do is not clear. • Sample size is not calculated **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was forwarded to the Primary reviewer, reply has given by the reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P51*** ***(Primary Reviewer: Dr. Amita Jain)***
b10	Clarification of research proposal entitled ***"Comparison of dexmedetomidine and fentanyl as an adjuvant to ropivacaine for Surgery of fracture Neck femur under sub- arachnoid block"*** submitted by Dr. Devendra Vikram Singh, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 20th April, 2019. **EC Comment on 12th July, 2019:** • The project needs to be re-written as per CONSORT guidelines. • The methodology should be reflected in the topic of the study like – randomized, open-label or blinded (single or double) etc. • The randomization method and methods of allocation concealment have to be discussed in the methods. • A flow-chart must accompany the revised project. • The complications of the procedure and either of the drugs have to be discussed with the patient in the patient information document in detail. • The issue of compensation needs to be discussed. • Patient's data sheet has to be submitted. • CONSORT check-list duly filled should also accompany the revised project. **EC Decision on 12th July, 2019:** Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was forwarded to the Primary reviewer, reply has given by the reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P55*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University

b11	Clarification of research proposal entitled ***"Randomized control trial of quadrates lumborum block with of without Dexmedetomidine as an adjuvant drug in patients undergoing elective renal surgery"*** submitted by Dr. Sumit Kumar Umar, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 20th April, 2019. **EC Comment on 12th July, 2019:** • Kindly submit on CONSORT guidelines. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P56*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
b12	Clarification of research proposal entitled ***"Endocrine profile and tissue heparin assay in juvenile nasopharyngeal angiofibroma"*** submitted by Dr. Preetam Pathak, JR-I, Department of Otorhinolaryngology and Head- Neck Surgery of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019 :** • Signature missing of Principal-Investigator in waiver form. It is old version. Kindly provide new version of Waiver form. **EC Decision on 12th July, 2019:** Provisionally approved ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & noted.*** **Action Taken:** Noted **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P58*** ***(Primary Reviewer: Dr. Rajeev Garg)***
b13	Clarification of research proposal entitled ***"Comparison of suprascapular nerve block with glenohmeral joint dilatation for the treatment of adhesive capsulitis of shoulder joint –A randomized controlled trial"*** submitted by Dr. Madhumita Singh Roy, JR-I, Department of PMR of this University via letter no. 1825/19 dated 24th April, 2019. **EC Comment on 12th July, 2019:** • Signature missing of Principal-Investigator in Hindi & English Inform consent Form.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Both ICF are similar, it should be according to SOP. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P63*** ***(Primary Reviewer: Dr. Rajendra Nath)***
b14	Clarification of research proposal entitled ***"Expression of SCAMP3 and methylated DNA in circulating cell free nucleic acid in oral cancer patients with special reference to disease prognosis- A pilot study"*** submitted by Dr. Saurabh Kumar Singh, JR-I, Department of General Surgery of this University via letter no. nil dated 9th May, 2019. **EC Comment on 12th July, 2019:** • Secretary Carrier Membrane Protein 3 (SCAMP 3) gene expression will be evaluated in circulating free DNA in patients of Oral SCC of 3 groups N0M0, N +ve M0 and N+ve M+ve • A structured questionnaire will be used to record demographic details, examination findings, investigations but the data collection sheet has not been provided and we do not know what will be observed. • Sample size is not provided • The material and method section only talks about the methodology of gene expression and not about patient interaction. What samples will be collected and when we do not know. • Who is paying for this special investigation? Is there a grant for the same? Patient should not be asked to pay for research. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P71*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
b15	Clarification of research proposal entitled ***"Dose escalation of short course radiotherapy in locally advanced carcinoma rectum- a pilot study"*** submitted by Dr. Deep Chakrabarti, JR-III, Department of Radiotherapy of this University via letter no. nil dated 16th May, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment on 12th July, 2019: • Please tell us when will first patient be enrolled? **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P84*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
b16	Clarification of research proposal entitled ***"A study of functional impairment after latissimus dorsi myocutaneous flap in breast cancer patients"*** submitted by Dr. Shariq Ahmad, JR-II, Department of General Surgery of this University via letter no. nil dated 24th May, 2019. **EC Comment on 12th July, 2019:** • The study aims to assess the functional impairment after L.D flap breast reconstruction using the DASH questionnaire of American Association of Orthopaedic Surgeons and Q.O.L questionnaire and a few additional questions from focus group study. • Sample size is 80. Statistically calculated • I believe these patients have already been operated and you will be calling them for follow up. So how far do you intend to go in follow up as the initial functional impairment may improve with time? • Adding the QOL questionnaire is a smart move as disease recurrence may change to total outlook of the patient towards reconstruction. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P94*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
b17	Research proposal entitled ***"A prospective observational study of perioperative and quality of life outcomes after surgery for penile cancer"*** submitted by Dr. Agastya Maria, JR-I, Department of General Surgery of this University via letter no. nil dated 31st May, 2019. **EC Comment on 12th July, 2019:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Study will be done during hospital stay i.e. for operation to discharge. Please clear about the assessment of sexual function how it in possible in hospital plan clarity. **EC Decision on 12th July, 2019:** Re-submit ***Dr. A.A. Sonkar did not take part in the discussion.*** ***The above Comment forwarded to the Primary Reviewer response received from P.R. & approved.*** **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P101*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
b18	Clarification of research proposal entitled ***"To study sputum bacteriology, antibiotic sensitivity pattern and serum procalcitonin levels in COPD patients with acute exacerbation"*** submitted by Dr. Shahnawaz Ali Ansari, JR-I, Department of Medicine of this University via letter no. nil dated 17th June, 2019. **EC Comment on 12th July, 2019:** • The whole project is copied and pasted for some source. • This is a Lab based project & there are no supervisior from Lab. • These are routine investigations done for each case of COPD **EC Decision on 12th July, 2019:** Not approved ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P106*** ***(Primary Reviewer: Dr. Amita Jain)***
b19	Clarification of research proposal entitled ***"A study of early augmentation with rTMS in patients of drug naïve obsessive- compulsive disorder"*** submitted by Dr. Mohita Joshi, JR-II, Department of Psychiatry of this University via letter no. nil dated 15th June, 2019. **EC Comment on 12th July, 2019:** • Kindly submit as per CONSORT guidelines **EC Decision on 12th July, 2019:** Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved

Chairperson, IEC
King George's Medical University

	EC Decision: Approved ***Ref. code: 97th ECM II B-Thesis/P135*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
b20	Clarification of research proposal entitled ***"Evaluation of temporomandibular joint changes in oral submucous fibrosis patients- A CBCT study"*** submitted by Dr. Yeguri Hema, JR-I, Department of Oral Medicine and Radiology Faculty of Dental Sciences of this University via letter no. nil dated 8th June, 2019. **EC Comment on 12th July, 2019:** • The consent form and the participant information sheet for healthy controls need to be submitted. • Participants' data sheet is not attached. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P146*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
b21	Clarification of research proposal entitled ***"A study of clinic radiological profile and biomarker estimation in smoker and non smoker COPD patient at tertiary care centre"*** submitted by Dr. Mohd Tariq, JR-II, Department of Respiratory Medicine of this University via letter no. nil dated 17th June, 2019. **EC Comment on 12th July, 2019** • Methodology is not clear • Inform Consent forms are different **EC Decision on 12th July, 2019:** Approval after justification ***Dr. Rajeev Garg did not take part in the discussion.*** ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P149*** ***(Primary Reviewer: Dr. Rajendra Nath)***
b22	Clarification of research proposal entitled ***"Role of amniotic membrane and platelet rich fibrin in bone healing post endodontic Surgery: A color Doppler sonography study"*** submitted by Dr. Saumya Johri, JR-I, Department of

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Conservative Dentistry & Endodontics Faculty of Dental Sciences of this University via letter no. nil dated 17th June, 2019. **EC Comment on 12th July, 2019:** • Methodology is not clear **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P151*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
b23	Clarification of research proposal entitled ***"A study on discharge documentation in a tertiary care government Hospital in Lucknow"*** submitted by Dr. Sukriti Shah under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/312 dated 14th June, 2019. **EC Comment on 12th July, 2019:** • The aim is to study the contents of the discharge summary, compare with standard guidelines, and study the policy of discharge documentation in regular discharge, LAMA and DOPR. • Sample size is 100. Statistically derived, • There is a selection bias as critical patients are excluded • Data collection in 2 weeks only. Will there be 100 discharges in 2 weeks from the Unit? • Waiver of consent is sought as the researchers claim that it is collection of data about Units other than individual patients • Data collection form is not provided • This is not true. You cannot see a patient's discharge slip and know about his disease without his/her consent. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer with following comment:*** • The data sheet has patients name and unique identification number. • If in a identification his/her by only identification number then you cannot ask for mentioning his/her name. **Action Taken:** The above comments send to the P.I. **EC Decision:** Pending

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	Ref. code: 97th ECM IIB MHA/P6
	(Primary Reviewer: Dr. Surajit Bhattacharya)
b24	Clarification of research proposal entitled ***"A study on knowledge, attitude and behavior with respect to fire safety among the employees of the tertiary care government teaching Hospital"*** submitted by Dr. Shreya Pandey under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/319 dated 15th June, 2019. **EC Comment on 12th July, 2019:** • Kindly provided Questionnaire. • Poorly written **EC Decision on 12th July, 2019:** Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM IIB MHA/P16*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
b25	Clarification of research proposal entitled ***"Comparison of 18-F NaF bone scan fusion image and high resolution CT to predict recurrence of temporamandibular joint ankylosis"*** sponsored by ICMR, New Delhi submitted by Dr. Tasveer Fatima under the guidance of Prof. Shadab Mohammad, Head, Department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences this University via letter no. OMSD/371/19 dated 22nd May, 2019. **EC Comment on 12th July, 2019:** • This proposal is for 3 years period with aim for Ph.D. thesis • Sample size calculation is needed. • Methodology is sketchy is not clear • Case record form is not attached **EC Decision on 12th July, 2019:** Re-write & Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer with following comment:*** • Cannot be approved in the present form. • Sample size calculation appears wrong. • There is not enough plan for 3 yrs/Ph.D. thesis. • Methodology is not clear.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• No patient consent form is attached **Action Taken:** The above comment again forwarded to the P.I. ***Response pending.*** **EC Decision:** Pending ***Ref. code: 97th ECM II B-Ph.D./P2*** ***(Primary Reviewer: Dr. Amita Jain)***
b26.	Clarification of research proposal entitled ***"A comparative study on hyponatremia in CNS versus non-CNS tuberculosis patients: A correlation with activation of rennin- angiotensin system and stress biomarkers"*** sponsored by ICMR, New Delhi submitted by Ms. Abhilasha Tripathi under the guidance of Prof. Surya Kant, Head, Department of Respiratory Medicine of this University via letter no. nil dated 23rd April, 2019. **EC Comment on 12th July, 2019:** a. The diagnosis of hyponatremia will be considered by two subsequent reports of serum sodium level of <135 meq/l done 24 hours apart. Will a symptomatic patient with hyponatremia not be treated after the first report of serum sodium level of <135 meq/l? If yes, then the serum level is expected to normalize after 24 hours. b. Where will the tests (ANP, BNP, ADH receptor and cytokines) be done? Who will perform the tests? Have you included the concerned lab experts in the study as co-PI? c. The amount of blood sample that is required for the purpose of the study has to be informed to the patient in the patient information document. How many times the blood sample will be taken? Who will pay the cost of tests? Every such information has to be detailed in the patient information document. d. Patient's data sheet (performa) is not attached. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment sent to the P.I. reply has given by P.I. which was forwarded to the Primary Reviewer response has provided by P.R. & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Ph.D/P5*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
	Part (c) 98th ECM
c1	Clarification of research proposal entitled ***"Critical analysis of low vs high dose anti***

Chairperson, IEC
King George's Medical University
Lucknow

	snake venom regimen in neuroparalytic snake bite patients*"** submitted by Prof. Avinash Agrawal, Head, Department of Critical Care Medicine of this University via letter no. CCM/19/254 dated 16th July, 2019. **EC Comment on 6th September, 2019:** • Low dose and high dose is not defined by the PI. • Is there any existing protocol for deciding the low versus high dose in these patients? Will these factors that determines low or high dose not act as confounders in the study? • Patient's performa is not attached. **EC Decision on 6th September, 2019:** Approval after justification ***The above comments forwarded to the Principal-Investigator reply have given by P.I. which was reviewed by the Member-Secretary, IEC & approved. **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM II A/P12*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
c2	Clarification of research proposal entitled **"*Study to identify barriers to organ donation among brainstem dead donors in ICU*"** submitted by Dr. Suhail Sarwar Siddiqui, Assistant Professor, Department of Critical Care Medicine of this University via letter no. CCM/2019/307 dated 8th August, 2019. **EC Comment on 6th September, 2019:** • At page no. 7 and point no.13, data collection, the method should be elaborate. The questionnaire should preferably be added. **EC Decision on 6th September, 2019:** Re-submit ***The above comments forwarded to the Principal-Investigator reply have given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM II A/P29*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
c3	Clarification of research proposal entitled **"*Clinical profile and outcome of patients with acute kidney injury in critically ill obstetrics patients*"** submitted by Prof. Avinash Agrawal, Head, Department of Critical Care Medicine of this University via letter no. CCM/2019/310 dated 8th August, 2019. **EC Comment on 6th September, 2019:** • Kindly calculate the sample size & provide the require budget. **EC Decision on 6th September, 2019:** Approval after justification ***The above comments forwarded to the Principal-Investigator reply have given by P.I.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	which was reviewed by the Member-Secretary, IEC & approved. **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM II A/P32*** ***(Primary Reviewer: Dr. Rajendra Nath)***
c4	Clarification of research proposal entitled ***"Comparative evaluation of usage of bicortical and unicortical anchorage of dental implants in posterior atrophic maxilla, A split mouth study"*** submitted by Dr. Sujay Bhave, JR-I, Department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences of this University via letter no. nil dated 4th June, 2019. **EC Comment on 6th September, 2019:** Investigator need to explain measurement technique of bone formation in mm per implant area. Kindly clarify. Study procedure should be same in English and Hindi consent form. Apart from implant stability, which other stability you will measure as mentioned under heading clinical evaluation. Kindly clarify. **EC Decision on 6th September, 2019:** Approval after justification ***The above comments forwarded to the Principal-Investigator reply have given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM II B-Thesis/P1*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
c5	Clarification of research proposal entitled ***"Developing pshchological resilience applying strategies of psycho-spiritual maturation amongst care givers of older adults consulting tertiary care hospital-a preliminary study"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Nisha M Pandey, Assistant Professor, Department of G.M.H. of this University via letter no. 158/DGMH dated 26th March, 2019. **EC Comment on 6th September, 2019:** • The objective is to explore the indices of spirituality, confidence in life and confidence in self amongst caregivers of mentally ill elderly and to study the impact of 'know yourself curriculum' in developing psychological resilience amongst them. • The study is in 7 sections. In section 1 in a taped interview the caregiver will be asked about problems they face in rendering care, his/her behavioral anomalies will be mapped and behavioral change setting goals

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	will be set. In section 2 participant's psycho-spiritual development will be explored. Section 3, 4 and 5 will be for contemplation self enquiry through meditation. Session 6 will engage the participants to develop inclusive person-centered community and session 7 will be about outcome assessment by 3 standardized scales SCL-90-R, INSPIRIT-R and IPPA, which have been attached. • 7 sessions will be spread in 30 days • The researchers do not tell us how at the end of the study the audio tapes will be disposed / destroyed. There may be sensitive information in them which the participants may not like to share with anyone else. • Sample size is not provided. **EC Comment on 6th September, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM II B IMR-F/P9*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Part-d ADR-sub-Committee
	Minutes of "ADR Sub-Committee" of Institutional Ethics Committee Meeting Registered with DCGI vide Registration no. : *ECR/262/Inst/UP/2013/RR-16* The meeting of ADR Sub Committee of Institutional Ethics Committee of King George's Medical University U.P., Lucknow was held on **18th October, 2019** in the Committee room, Administrative Block of this University from 01:30 pm to 02:00 pm. The following members were present:- 1. Hon'ble Justice Vishnu Sahai - Chairperson 2. Dr. Rajendra Nath - Member 3. Dr. Rajeev Gag - Member 4. Dr. Manju Agrawal - Member 5. Mr. Ram Niwas Jain - Member 6. Dr. R. K. Garg - Member Secretary-IEC-ex officio
	DCGI
Sl. no.	**ADR-sub-Committee Meeting**
1	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 623/Cardio/Res/2019 dated 27th September, 2019. **Death** **Subject ID no. 010-0020** **Subject Initial:** K. **Course of event:** Breathlessness, B.P. elevated and vomiting **SAE term:** Death **Causality:** Unknown **DOB:** 01-01-1972 **Weight:** 55KG **Height:** 153 CM **Start Date:** 17th August, 2017 **Subject History:** ***Subject developed breathlessness, B.P. elevated and had vomiting local physician visited at home, but subject could not survive and expired at home. No autopsy done.*** ***ADR-sub-Committee decision:***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Since a perusal of papers does not show that the subject of study died as a result of the study drug (rivaroxaban) administered to her but on the converse shows that the cause of death was unknown and no autopsy was done no question of compensation arises. **EC Decision:** Reviewed

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Institutional Ethics committee

Minutes of 99th Institutional Ethics Committee Meeting held on 18th October, 2019.

Part IIA

New Proposals

K.G's Medical University U.P., Lucknow

II-A	New Proposal
1.	Research proposal ***"A randomized control trial entitled "To study the effectiveness of inhalational anaesthetic as a continuous sedation in intensive care unit, in different groups of patients"*** submitted by Dr. Zia Arshad, Associate Professor, Department of Anaesthesiology & Critical Care of this University via letter no. nil dated 21st August, 2019. **EC Comment:** • Who will bear the cost of anesthetic agent? • How long will the anesthetic agent be required? • Who will deliver the anesthetic agent? • Mode of delivery of anesthetic agent not described-through cylinders or central supply? Is the CCU equipped with the desired equipment to deliver and monitor the anesthetic agent? Please provide with the list of equipment that is required and available at the CCU. • Please enumerate all the known side-effects of the known anesthetic agents. • Please also mention them in the patient information document. • Who will pay the compensation in case of litigation? • Please provide statistically determined sample size. • Please provide the patient information document in Hindi as will. • Please provide patient's Performa that will be used to document patient details **EC Decision:** Revise & Re-submit ***Ref. code: 99th ECM II A/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"Surveillance of scrub typhus infection by serological and molecular testing by DHR- virus diagnostic laboratories across the country"*** sponsored by Health Research, New Delhi submitted by Prof. Amita Jain, Head, Department of Microbiology of this University via letter no. 1582/19 dated 26th August, 2019. **EC Comment:** • Kindly Calculate the sample size (PI-written that Observational study does not need Sample size) • Kindly attached the budget. **EC Decision:** Approval after justification ***Dr. Amita Jain did not take a part in the discussion.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 99th ECM II A/P2 ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Research proposal entitled "***Newborn screening programme***" sponsored by U.P NHM submitted by Dr. Wahid Ali, Associate Professor, Department of Pathology of this University via letter no. nil 28th August, 2019. **EC Comment:** • How many children will be screened? • Cost/analysis? • How results will be communicated to parents? • What is the objective? • Exclusion & inclusion criteria? **EC Decision:** Approval after justification ***Ref. code: 99th ECM II A/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Research proposal entitled "***Comparative study of quality of life and bone mass density among post menopausal females***" submitted by Dr. Dileep Kumar, Associate Professor, Department of Physical Medicine and Rehabilitation of this University via letter no. 2288/19 5th October, 2019. **EC Decision:** Approved ***Ref. code: 99th ECM II A/P4*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
5.	Research proposal entitled "***A study of retinal nerve fiber level (RNLF) changes on optical coherence tomography (OCT) in patients with Alzheimer's dementia (AD)***" sponsored by KGMU UP for CARTS submitted by Dr. Nisha M Pandey, Assistant Professor, Department of Geriatric Mental Health of this University via letter no. nil 9th August, 2019. **EC Decision:** Approved ***Ref. code: 99th ECM II A/P5*** ***(Primary Reviewer: Dr. Rajeev Garg)***
6.	Research proposal entitled "***Status of serum Vitamin D and Calcium levels in Women of reproductive Age group- A cross sectional study***" submitted by Dr. Dileep Kumar, Associate Professor, Department of Medicine and Rehabilitation of this University via letter no. 2317/19 18th September, 2019. **EC Comment:** • Need to mention the lab where level of Vitamin D will be done and who will bear the cost? Kindly clarify how the observations help to make hypothesis.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Ref. code: 99th ECM II A/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Institutional Ethics committee

Minutes of 99th Institutional Ethics Committee Meeting held on 18th October, 2019.

Part IIB

New Thesis

K.G's Medical University U.P., Lucknow

II-B	New Thesis-Resident
1.	Research proposal entitled ***"Predictors of stent malapposition and restenosis in post primary PCI patients- an OCT based study"*** submitted by Dr. Swati Sharma, SR-II, Department of Cardiology of this University via letter no. nil dated 16th August, 2019. **EC Comment:** • Please provide the details of the procedure of OCT, Will the patient be required to get admitted for this procedure? How long will be the hospital stay? • What are the known complications of doing OCT? Please discuss the complications in the patient's documentation Performa. **EC Decision:** Approval after justification ***Ref. code: 99th ECM II B-Thesis/P1*** ***(Primary Reviewer: Dr.Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"Role of flecainide in assessment of ATRIO-ventricular conduction in symptomatic bifascicular block"*** submitted by Dr. Deepak Kumar, SR-II, Department of Cardiology of this University via letter no. nil dated 16th August, 2019. **EC Decision:** Approved ***Ref. code: 99th ECM II B-Thesis/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Research proposal entitled ***"Outcome in acute liver failure and acute on chronic liver failure and their prognostic markers"*** submitted by Dr. Vipin Raj Bharti, JR-II, Department of Medicine of this University via letter no. nil dated 5th September, 2019. **EC Decision:** Approved ***Ref. code: 99th ECM II B-Thesis/P3*** ***(Primary Reviewer: Dr.Amita Jain)***
4.	Research proposal entitled ***"To study the anatomy and function of left atrial appendage and its correlation with the incidence of left atrial appendage thrombus formation in patients with rheumatic mitral stenosis"*** submitted by Dr. Ahmad Tanweer, SR-II, Department of Cardiology of this University via letter no. nil dated 3rd September, 2019. **EC Decision:** Approved ***Ref. code: 99th ECM II B-Thesis/P4*** ***(Primary Reviewer:Dr. Rajeev Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

5.	Research proposal entitled ***"To compare the efficacy and safety of cutting balloon angioplasty versus high- pressure OPN Non-compliant balloon angioplasty before Drug- fluting stent implantation fir the treatment of moderately calcified coronary artery lesions"*** submitted by Dr. Rajeev Krishna Choudhary, SR-II, Department of Cardiology of this University via letter no. nil dated 14th September, 2019. **EC Decision:** Approved ***Ref. code: 99th ECM II B-Thesis/P5*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
6.	Research proposal entitled ***"Novel reticulocyte parameters in thalassemia and iron deficiency anemia"*** submitted by Dr. Kirtijit Chakma, JR-I, Department of Pathology of this University via letter no. nil dated 13th September, 2019. **EC Decision:** Approved ***Ref. code: 99th ECM II B-Thesis/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Institutional Ethics committee

Minutes of 99th Institutional Ethics Committee Meeting held on 18th October, 2019.

Part IIB

Ph.D. Scholars

K.G's Medical University U.P., Lucknow

IIB	Ph. D. Scholar
1-	Research proposal entitled ***"AAS analysis of different base metal alloys and detection of S. mutans and S. sobrinus from dental plaques adhered on dental crown by RT-PCR"*** sponsored by ICMR, New Delhi submitted by Ms. Shikha Gupta under the guidance of Prof. Jitendra Rao, Department of Prosthodontics, Faculty of Dental Sciences of this University via letter no. nil dated 21st August, 2019. **EC Comment:** • Annexure-7, Part III needs to be revised. • Objective of study do not match with the title. • Background information and date are not sufficient. • Methodology should be revised and elaborated in details. • Hindi version of Informed Consent Form is not explicit and should be revised. **EC Decision:** Approval after justification ***Ref. code: 99th ECM II B-Ph.D/P1*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
2.	Research proposal entitled ***"Dose optimization of flaxseed powder and oil in subjects with metabolic syndrome"*** sponsored by CSIR-JRF submitted by Mr. Rahul Kumar Yadav under the guidance of Prof. Narsingh Verma, Department of Physiology of this University via letter no. nil dated 13th August, 2019. **EC Comment:** • Does not involve invasive procedures, though project requires oral administration of Flax seed powder and oil in combination. Flax seed powder being a more of an unprocessed preparation while oil being a concentrated preparation, it is likely that both will have different degree of responses with respect to both efficacy and adverse effect. In case of benefits and/or adverse effect, it will be confounding factor in determining as to which agent is the causative, therefore additional groups being administered either flaxseed powder or oil per se will be desirable • Side effects/adverse effects of flax seed powder/oil have not been presented in the proposal. This is necessary to identify the patient reacting adversely to the treatment which in turn is not very unlikely as the project requires prolonged administration i.e up to 5 months. • PI should provide prior evidence of these agents not being toxic following continuous administration up-to 5 months. • Who will bear the cost? • Kindly provide published authentic documents indicating safety of Flax seed

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	powder and oil in human usage. • Is there any control group? **EC Decision:** Resubmit ***Ref. code: 99th ECM II B-Ph.D/P2*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Institutional Ethics committee

Minutes of 99th Institutional Ethics Committee Meeting held on 18th October, 2019.

Part IIB

New IMR (Resident & Students)

K.G's Medical University U.P., Lucknow

IIB	New IMR-Resident
1-	Research proposal entitled ***"To study the relationship of menstrual cycle dysfunction with stress and its impact on quality of life in adolescent and young female"*** sponsored by of Research Cell KGMU submitted by Dr. Swati Vishwakarma, JR-II through her Mentor Prof. Sujata Deo, Department of Obstetrics & Gynaecology of this University via letter no. nil dated 4th September, 2019. **EC Decision:** Approved ***Ref. code: 99th ECM II B IMR-R/P1*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
IIB	**New IMR-Student**
1.	Research proposal entitled ***"To determine the difference in the heart health status of active and sedentary workers"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Mr. Laksha Maurya, MBBS 2018 through his Mentor Prof. Sunita Tiwari, Department of Physiology of this University via letter no. nil dated 20th August, 2019. **EC Comment:** • Some previous work carried out by other groups with regards to Myths, however, which particular Myths will be studied in proposed study are not clearly stated in the proposal. A list containing Myths to be studied in current study is to be provided. • 6. The 16 point questionnaire mentioned in the proposal is missing in the application **EC Decision:** Approval after justification ***Ref. code: 99th ECM IIB IMR-S/P1*** ***(Primary Reviewer:***
2.	Research proposal entitled ***"Aerobic exercise: effect on memory and cognitive ability"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Mr. Shobhit Singh, MBBS 2018 through his Mentor Prof. Sunita Tiwari, Head, Department of Physiology of this University via letter no. nil dated 22nd August, 2019. **EC Decision:** Approved ***Ref. code: 99th ECM IIB IMR-S/P2*** ***(Primary Reviewer: Rajeev Garg)***
3.	Research proposal entitled ***"Discovering the learning ability of sleeping brain"***

Chairperson, IEC
King George's Medical University

	sponsored by Research Cell K.G.M.U Lucknow submitted by Mr. Arpit Verma, MBBS 2018 through his Mentor, Prof. Sandeep Bhattacharya, Department of Physiology of this University via letter no. nil dated 22nd August, 2019. **EC Comment:** • Kindly attach participant's Performa. **EC Decision:** Provisionally approved ***Ref. code: 99th ECM IIB IMR-S/P3*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
4.	Research proposal entitled ***"The association between sleep spindles and intelligence quotient (IQ) of College Students"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Mr. Raj Vardhan, MBBS 2018 through his Mentor Prof. Archna Ghildiyal, Department of Physiology of this University via letter no. nil dated 7th August, 2019. **EC Decision:** Approved ***Ref. code: 99th ECM IIB IMR-S/P4*** ***(Primary Reviewer: Dr. Rajeev Garg)***
5.	Research proposal entitled ***"To study the effects of binge watching on the sleep wake pattern and the reaction time of the Medical Students"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Mr. Shubham Tripathi, MBBS 2018 through his Mentor Prof. Sunita Tiwari, Head, Department of Physiology of this University via letter no. nil dated 7th August, 2019. **EC Decision:** Approved ***Ref. code: 99th ECM IIB IMR-S/P5*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
6.	Research proposal entitled ***"The correlation of pulse parameters with different anthropometric variations"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Mr. Manjot Kaur Wahlla, MBBS 2018 through his Mentor Prof. Dileep Verma, Department of Physiology of this University via letter no. nil dated 7th August, 2019. **EC Comment:** • Calculated Sample size not given • Exclusion criteria in study is missing • English & Hindi ICFs are different and the name of Mentor (Guide) is missing. **EC Decision:** Approval after justification ***Ref. code: 99th ECM IIB IMR-S/P6***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Rajendra Nath)
7.	Research proposal entitled ***"Enigma of dream: The cohort study"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Ms. Mansi Jaiswal, MBBS 2018, through her Mentor Prof. Jagdish Narayan, Department of Physiology of this University via letter no. nil dated 24th August, 2019. **EC Comment:** • This is a questionnaire-based study. Kindly provide questionnaire. **EC Decision:** Approval after justification ***Ref. code: 99th ECM IIB IMR-S/P7*** ***(Primary Reviewer: Dr. Amita Jain)***
8.	Research proposal entitled ***"A radiological study on patients of osteoarthritis to establish relationship of kellgren-Lawrence grading score with knee range of motion and average pain score"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Mr. Prince Rai, MBBS 2018 through his Mentor Dr. Archana Rani, Department of Anatomy of this University via letter no. nil dated 26th August, 2019. **EC Comment:** • As the study is based on radiographs of patients. Principal-Investigator should involve the treating doctor/any rheumatologist in the study. **EC Decision:** Approval after justification ***Ref. code: 99th ECM IIB IMR-S/P8*** ***(Primary Reviewer: Dr. Anoop Kumar Varma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Institutional Ethics committee

Minutes of 99th Institutional Ethics Committee Meeting held on 18th October, 2019.

Part IIB

Internship-BDS

K.G's Medical University U.P., Lucknow

IIB	BDS- Internship
1.	Research proposal entitled ***"Myths related to dentistry in people of Lucknow"*** submitted by Ms. Shatakshi Tripathi, BDS-Intern through her Mentor Dr. Vinay Kumar Gupta, Associate Professor, Department of Public Health Dentistry Faculty of Dental Sciences of this University this University via letter no. 373/PHO/19 dated 12th September, 2019. **EC Comment:** • Even though Background section does mention some previous work carried out by other groups with regards to Myths, however, which particular Myths will be studied in proposed study are not clearly stated in the proposal. A list containing Myths to be studied in current study is to be provided. • The 16 point questionnaire mentioned in the proposal is missing in the application **EC Decision:** Approval after justification ***Ref. code: 99th ECM IIB BDS-IS/P1*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Institutional Ethics committee

Minutes of 99th Institutional Ethics Committee Meeting held on 18th October, 2019.

Part IIC

Extension study of Drug Trial-Non-DCGI

K.G's Medical University U.P., Lucknow

II-C	Extension study of Drug Trial-Non DCGI
1-	Extension of Research protocol ISCHEMIA entitled ***"International study of comparative health effectiveness with Medical and Invasive approaches"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology of this University via letter nos. 603 & 604/cardio/Res/19 17th September, 2019. **EC Decision:** Approved ***Ref. code: 60th ECM IIA /P13*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Institutional Ethics committee

Minutes of 99th Institutional Ethics Committee Meeting held on 18th October, 2019.

Part III

Adverse Drug Event

K.G's Medical University U.P., Lucknow

III	Adverse Drug Event
1.	ADE research protocol no. ***GS-US-417-0304*** entitled ***"A multicenter, double- blind, long term extension study to assess the safety and efficacy of filgotinib in subjects with rheumatoid arthritis"*** submitted by Dr. Puneet Kumar, Department of Rheumatology of this University via letter no. 62/19 dated 30th August, 2019.
a	**Patient ID: 43979** **Gender: Female** **Age: 56 yrs** **Weight: 45 kg** **Height: 52.0 cm** **Subject History:** Patient has visited site for wk 24 visit on 26th August, 2019 and informed that she has mild pain in abdomen since 19th August, 2019. Pentofer 40 was advised for pain in abdomen. We had completed the Visit procedure. On 29th August 2019, we have received on alert for the subject with high S Amylase and Lypase level G4 toxicity. We have called the patient to visit site immediately Patient has visited site on 29th August, 2019. Retest samples sent for S amylase and S Lypase and patient is hospitalized for close monitoring. Further evaluation and management the event, USG abdomen performed on 30th August, 2019. As per letter no.Rh/Lt/67/19 dated 3rd September, 2019. On 2nd September, 2019, Patient is discharged on 31st August, 2019 as Serum Amylase and S. Lipase level reduced and patient is clinically stable and asymptomatic. Patient is advised to visit site after one week. **EC Decision:** Reviewed & Noted
b	**Patient ID: 44017** **Gender: Female** **Age: 41 yrs** **Weight: 50 kg**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Height: 145.0 cm **Subject History:** Patient has visited site on 28th August, 2019 for wk 24 visit and informed that she has a gland in Neck with fever since 14th August, 2019. Ultrasound was performed on 28th August, 2019 and findings are suggestive of Left supraclavicular Lymphadenopathy infective/inflammatory. Patient is hospitalized for further evaluation and management. **EC Decision:** Reviewed & Noted ***Ref. code: 86th ECM IIE/P1*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Institutional Ethics committee

Minutes of 99th Institutional Ethics Committee Meeting held on 18th October, 2019.

Part V

Annual Progress Reports

K.G's Medical University U.P., Lucknow

IV	Modification
	None
V-	**Annual Progress Reports**
1.	Annual Progress Report of research proposal entitled ***"Establishment of a network of laboratories for managing epidemics and natural calamities"*** submitted by Prof. Amita Jain, Head, Department of Microbiology of this University via letter no. 1581/micro/19. Dated 21st August, 2019. **EC Decision:** Reviewed ***Dr. Amita Jain did not take part in the discussion.*** ***Ref. code: 83rd ECM II A/P9*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Annual Progress Report of research proposal entitled ***"Hospital based cancer registries – data management software"*** submitted by Prof. Arun Chaturvedi, Head, Department of Surgical Oncology of this University via letter no. nil Dated 20th August, 2019. **EC Decision:** Reviewed ***Ref. code: 89th ECM II A/P9*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
3.	Annual Progress Report of research proposal entitled ***"To evaluate AS-6, a clinical trial candidate of CSIR-CIMAP at KGMU against breast cancer tissues of patients through Ex-vivo study"*** submitted by Dr. Satyendra Kumar Singh, Assistant Professor, Department of Stem Cell & Cell Culture (CFAR) of this University via letter no. nil Dated 27th August, 2019. **EC Decision:** Reviewed ***Ref. code: 90th ECM II A/P27*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Annual Progress Report of research proposal entitled ***"Can vitamin A supplementation in early childhood improve adult lung function? Pilot study"*** submitted by Prof. Shally Awasthi, Department of Pediatrics of this University via letter no. nil Dated 3rd September, 2019. **EC Decision:** Reviewed ***Ref. code: 90th ECM II A/P34*** ***(Primary Reviewer: Dr. Rajeev Garg)***

Chairperson, IEC
King George's Medical University
Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Institutional Ethics committee

Minutes of 99th Institutional Ethics Committee Meeting held on 18th October, 2019.

Part VI

Other Matter

K.G's Medical University U.P., Lucknow

VI-	Other Matter
1	In the last Meeting was held on 6th September, 2019, Committee was ask from Prof. Shaleen Chandra, Head, Department of Oral Pathology & Microbiology of this University that ***"Committee is of view that no single person can do so many projects simultaneously"*** reply has received from Prof. Chandra via his letter no. 629/Oral/Path/19 dated 25th September, 2019. **EC Decision:** Decision not taken by the Committee
2	Request to change the topic of the research proposal entitled ***"Prospective interventional study of neoadjuvent temozolomide inpatients of inoperable supratentorial malignant gliomas"*** submitted by Dr. Suresh Kumar Jaiswal, SR-I, Department of Neurosurgery of this University via letter no. nil dated nil. ***The above proposal was put-up in the last Meeting held on 6th September, 2019 with various comment were made by the Dr. Surajit Bhattacharya his Primary Reviewer:-*** **Comment:** • Sample size does not depend on patient availability alone. You have to sit with a statistician and discuss your study plan. He/she will ask you what is a doable number of patients and then curtail the number of variables you can chase in this study. This is a good exercise in planning research and this should be done. • Since the comparison will be with patients receiving RT alone include them in your study. Now take the number of both the set of patients - your ones and the RT ones to the statistician and ask him to help you to plan your study. • You have the scope of planning a good study as there will surely be enough patients, but if you end up chasing too many variables your results may not be statistically significant. ***Reply was not given by the P.I. but due to some technical issue topic has been changed by the Principal-Investigator:-*** ***Current title:- "Traumatic cervical spine injury: A prospective study"***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

100th "Institutional Ethics Committee" Meeting held on 25th January, 2020

K.G's Medical University U.P., Lucknow

K.G's Medical University U.P., Lucknow

100th "Institutional Ethics Committee" Meeting held on 25th January, 2020

Item no. IA

Action Taken

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 100th ECM held on 25th January, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Minutes of the 100th **"Institutional Ethics Committee"** Meeting to be held on 25th January, 2020 **from 12.30 p.m. till 4.00 p.m.** in the **'Board Room'**, Office of the Vice Chancellor, Administrative Block of this University.

The following members were present in the Meeting

1- Prof.S.P. S Gaur	*-Chairman*
2- Justice Hon'ble Vishnu Sahai	*- Member*
3- Dr. Surajit Bhattacharya	*-Member*
4- Dr. Vimal Kumar Paliwal	*-Member*
5- Dr. Manju Agrawal	*-Member*
6- Prof. Rajeev Garg	*-Member*
7- Dr. Preeti Agarwal	*-Member*
8- Prof. Amita Jain	*-Member*
9- Prof. Rajendra Nath	*-Member*
10- Prof. Anoop Kumar Verma	*-Member*
11- Mr. Ram Niwas Jain	*-Member*
12- Prof. R. K. Garg	*-Member-Secretary, Ex-officio*

The following Members were not present:

1- Dr. Smriti Bhadauria	*-Sent her written comment*
2- Prof. A.A. Sonkar	*-Sent his written comment*

I. (A) Action taken

I(A)	Action Taken on decisions of previous Ethics Committee Meeting
	Part (a) 88th ECM was held on 12th July, 2019

Chairperson, IEC
King George's Medical University
U.P., Lucknow

a1-	Clarification of the Annual Progress Report of research protocol no. KCP-330-009 entitled ***"A phase 2b open-label study of selinexor (KPT-330) in Patients with relapsed/ refractory diffuse large B-cell lymphoma (DLBCL)"*** sponsored by M/s Karyopharm Therapeutics Ltd submitted by Dr. Shailendra Prasad Verma, Principal Investigator & Assistant Professor, Department of Clinical Hematology of this University via letter no. 668/CH/19 Dated 9th November, 2019. **EC Decision on 12th July, 2019:** Kindly provide updated report ***The above Decision reviewed by the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 88th ECM IIC/ P1*** ***(Primary Reviewer: Dr. Rajendra Nath)***
	Part (b) 93rd ECM was held on 2nd November, 2018
b1.	Research proposal entitled ***"Nanostring nCounter based screening for molecular typing and target-based therapeutics of TNBC in the Indian population"*** sponsored by C.S.I.R., New Delhi submitted by Dr. Neetu Singh, Associate Professor, Department of Molecular Biology Unit, Center for Advance Research of this University by via letter no. nil dated nil. **EC Comment on 2nd November, 2018:** • Applicant is moving on to next step of validation as if she knows the answer to research question? • Primary objective is not defined. • Was Nano string, Ncounter used in previously studies? • If yes then review of literature is not appended? **EC Decision on 2nd November, 2018:** Provisionally approved ***The above comments were sent to PI. The P.I. has given his reply which was forwarded to the Primary reviewer, response received from Primary reviewer who agreed with her reply.*** **Action taken:** Noted, already Provisionally approved **EC Decision:** Approved ***Ref. code: 93rdECM II A/P5*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
	Part (c) 95th ECM was held on 22nd February, 2019
c1	Clarification of research proposal entitled ***"Prosthetic satisfaction and body image among lower limb amputee of north Indian population"*** submitted by Dr. Sudhir Mishra, Assistant Professor, Department of Physical Medicine & Rehabilitation of

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	this University by via letter no. 2404/19 dated 22nd October, 2019. **EC Comment on 22nd February, 2019:** • Title to be revised. It is Northern India and not North India. North Korea and South Korea, North Sudan and South Sudan are independent countries and hence their name is thus. Northern India is a part of India • The review of literature has no reference from this millennium. In the last two decades lower limb prosthesis have undergone quantum improvement and so a better and more recent literature review is needed • Objective is clear. Inclusion and exclusion criteria are acceptable • Why are patients using their prosthesis intermittently excluded? The prosthesis obviously did not improve their quality of life otherwise they would have used it regularly • It is a cross-sectional study • Sample size is derived statistically • Data collection sheet is very elaborate and thorough – clinic-demographic data, Revised Trinity Amputation and Prosthesis Experience Scale and Amputee Body Image Scale are in it. **EC Decision on 22nd February, 2019:** Approved after justification ***The above comments were sent to PI. The P.I. has given his reply which was forwarded to the Primary reviewer, response received from Primary reviewer with following comment:-*** • ***Reply was not clear.*** **Action taken:** The above comment again forwarded to the Principal-Investigator. ***Reply pending by P.I.*** **EC Decision:** Pending ***Ref. code: 95th ECM II A/P2*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
c2	Clarification of research proposal entitled ***"Study of access site complications in patients undergoing transradial coronary intervention in a north Indian population"*** submitted by Dr. Gyana Ranjan Nayak, SR-II, Department of Cardiology of this University via letter no. nil dated nil. **EC Comment on 22nd February, 2019:** **Study duration:** • October, 18th September, 19

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• When will first patient be enrolled in your study? • Discrepancy in sample size calculation (Which showed sample size of 1500) and quoted sample size (500). • In Objectives it is given that management will be evaluated which is not provided in Methodology. **EC Decision on 22nd February, 2019:** Revise & Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Member-Secretary, IEC & approved*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 95th ECM II B-Thesis/P51*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
c3	Clarification of research proposal entitled ***"Comparison of 'traditional' versus 'artificial intelligence based' coronary artery disease risk prediction scores in young patients with acute coronary syndrome"*** submitted by Dr. Shaweta Vohra, SRII, Department of Cardiology of this University via letter no. nil dated nil. **EC Comment on 22nd February, 2019:** **Study duration:** • 1st Jan, 19- 31st December, 19` • When will be first patient enrolled in your study? • How will they segregate patient in groups? • Methods of Habited not provided, **EC Decision on 22nd February, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Member-Secretary, IEC & approved*** **Action Taken:** Provisionally Approved **EC Comment:** • Methods of Habited not provided **EC Decision:** Kindly clarify the above point ***Ref. code: 95th ECM II B-Thesis/P55***

Chairperson, IEC
King George's Medical University

	(Primary Reviewer: Dr. Preeti Agarwal)
c4	Clarification of research proposal entitled ***"Adherence to guideline directed medical therapy for secondary prevention in ACS patients at a tertiary care center in India"*** submitted by Dr. Pravesh Vishwakarma, Associate Professor, Department of Cardiology this University via letter no. nil dated October, 2019. **EC Comment on 22nd February, 2019:** 1. Methods are deficient. What are the criteria for defining adherence to treatment? Till what time after the discharge from the hospital will the patients be eligible for the inclusion into the study? When will you consider a patient compliant to treatment? The patient's Performa does not contain any of this information. Did the author not think of factors responsible for non-adherence to treatment? If yes, these factors should be enumerated in the patient's Performa to ask from each patient in order not to miss any. 2. What is the sample size? Also provide the basis of calculation of sample size. **EC Decision on 22nd February, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given from the reviewer with following comment:*** • Kindly provide the revised proposal. **Action Taken:** The above comment again forwarded to the P.I. but response is pending till 24th January, 2020. **EC Comment:** • Approval after kindly submit the CTRI registration **EC Decision:** Kindly submit CTRI registration ***Ref. code: 96th ECM II A/P13*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
c5	Clarification of research Protocol no. SCY-078-305 version 1.0 entitled ***"Open-Label to evaluate-the efficacy, safety, tolerability and pharmacokinetics of SCY-078 in patients with candidiasis, including candidemia, caused by candida auris"*** sponsored by M/S SCYNEXIS, INC Hudson street, Suite submitted by Dr. Sulekha Saxena, Assistant Professor, Department of Critical Care Medicine of this University via letter no. nil dated 11th January, 2019. **EC Comment on 22nd February, 2019:** • Insurance must be renewed. **EC Decision on 22nd February, 2019:** Approval after justification

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	The above comment forwarded to the P.I. response received by P.I. which was reviewed by the Member-Secretary, IEC & approved. **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 95th ECM IIC/P7*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
	Part (d) 97th ECM was held on 12th July, 2019
d1	Clarification of research Protocol no.XBR1001 entitled **"*Xplore*: *A phase III* double- *blind, parallel group, multicenter study to compare the efficacy and safety of Xlucane versus lucentis® in patients with neovascular age- related macular degeneration*"** sponsored by M/s Xbrane Biopharma Pvt. Ltd. submitted by Dr. Pramod Kumar, Associate Professor, Department of Ophthalmology of this University via letter no.nil dated 13th March, 2019. **EC Comment on 12th July, 2019:** • Kindly provide DCGI approval **EC Decision on 12th July, 2019:** Not approved ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Withdrawal by P.I.*** ***Ref. code: 96th ECM IIC/Pa1*** ***(Primary Reviewer: Dr. Rajendra Nath)***
	Part (e) 97th ECM was held on 12th July, 2019
e1	Clarification of research proposal entitled **"*CBCT based anthropometric measurements and cluster analysis of temporomandibular joints in North Indian population*"** submitted by Dr. Vikram Khanna, Associate Professor, Department of Oral Medicine & Radiology Faculty of Dental Science of this University via letter no. 524/OMSR/19 dated 4th October, 2019. **EC Comment on 12th July, 2019:** • Consent from Waiver cannot be granted **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally approved

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	EC Decision: Approved ***Ref. code: 97th ECM II A/P14*** ***(Primary Reviewer: Dr. Rajendra Nath)***
e2	Clarification of research proposal entitled ***"Renal neoplasm: A study of the diagnostic Implications of ultra structure"*** submitted by Dr. Meha Gupta, JRI, Department of Pathology of this University via letter no. nil dated nil. **EC Comment on 12th July, 2019:** • How the researcher will obtain ethical approval for old samples? • On page no. 4 she has typed yes for point no 1. Which should be No. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was forwarded to the Primary reviewer, response has received from Primary-Reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P5*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
e3	Clarification of research proposal entitled ***"Comparative study between ultrasound guided erector spinae plane block and paravertebral block in thoracic surgeries"*** submitted by Dr. Akanksha Jain, JR-I, Department of Anaesthesiology of this University via letter no. nil dated nil. **EC Comment on 12th July, 2019:** • The study needs to be written as per CONSORT guidelines. • The topic of the study should reflect the methods like – randomized controlled blinded/open-label etc. • The name of the drug should also be mentioned in the title of the study. • Which one of the two arms will be a control arm if it is a controlled study? • Which randomization method will be used? • How will the allocation concealment be achieved? • Patient information document (PID) is very important document and it needs to be filled again. Are there any complications of either of the anesthesia methods? These have to be discussed with the patient in the PID. Risks from the study have also to be discussed. Compensation has to be planned. • Patient datasheet not attached. • Please provide a CONSORT checklist duly filled along with the revised

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	thesis Performa. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer with following comment:*** • ***The reply submitted is grossly insufficient.*** • ***The consort guideline Performa should show the page and line number where the respective change has been made.*** • ***Randomization methods are not discussed*** • ***How will the allocation be concealed who will do the analysis how will the PI achieved the double blinding the complication has to be provided by the PI in case of any mis-eventuality.*** **EC Decision:** Approved after justification ***Reply has given by the P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P31*** ***(Primary Reviewer : Dr. Vimal Kumar Paliwal)***
e4	Clarification of research proposal entitled ***"Comparison between LMA proseal and I-gel airway in anaesthetized patients on spontaneous ventilation during daycare procedures"*** submitted by Dr. Neha Singh, JR-I, Department of Anesthesiology of this University via letter no. nil dated nil. **EC Comment on 12th July, 2019:** • Kindly submit Conflict of interest form. It should be done in form of RCT. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer & approved*** **Action Taken:** Provisionally Approved with condition to kindly submit the CTRI registration via letter no. 1409/Ethics/19 dated 24th September, 2019. • ***The PI has not given CTRI registration.*** **EC Comment:** Kindly submit the CTRI registration **EC Decision:** Not approved ***Ref. code: 97th ECM II B-Thesis/P32*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
e5	Clarification of research proposal entitled ***"Aldh1 cancer stem cell marker expression in oral squamous cell carcinoma"*** submitted by Dr. Vaibhav Gupta,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	JR-I, Department of Pathology of this University via letter no. nil dated nil. **EC Comment on 12th July, 2019:** • Kindly provide **"Stem Cell committee"** Approval letter **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer with following comment:*** **Comment:** • ***Still the revised proposal has not been provided*** • ***It is not possible to review this document*** **Action Taken:** The above comment forwarded to the P.I. ***Response received from P.I. which was forwarded to the Primary-Reviewer, reply has given by reviewer with following comment:-*** **EC Comment:** • Was clearance taken from **'Stem Cell'** Committee? It not, please justify. • Grossly incomplete form • Except Dr. Malti, none of the supervisor have signed. • Prof. Ashutosh & Prof. Goel has already superannuated. • New format is not used. **EC Decision:** Revised & Re-submit ***Ref. code: 97th ECM II B-Thesis/P34*** ***(Primary Reviewer: Dr. Amita Jain)***
e6	Clarification of research proposal entitled ***"EBV immunohistochemical expression in non- neoplastic and neoplastic gall bladder lesions along with evaluation of tumor infiltrating lymphocytes in neoplastic lesions"*** submitted by Dr. Prachi Goel JR-I, Department of Pathology of this University via letter no. nil dated nil. **EC Comment on 12th July, 2019:** • The study hypothesizes that EBV infection may be related to Gall Bladder disease and so aims at studying the EBV expression in benign and malignant gall bladed lesions. Additionally, it aims at evaluating TIL in CA Gall Bladder. • Both fresh GB specimens as well as archived paraffin embedded biopsy tissue would be used for immune-histochemistry of EBV antibodies. • Sample size is 250. Statistically calculated • We need a data collection sheet to understand what all will be recorded and observed. • How will the consent be obtained from patients whose paraffin blocks

Chairperson, IEC
King George's Medical University
Lucknow

	will be used in this study? **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P39*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
e7	Clarification of research proposal entitled ***"Comparative evaluation of different concentrations of alcohol in ultrasound guided celiac plexus neurolysis for pain relief in patients with upper abdominal malignancies"*** submitted by Dr. Pragya Verma, JR-I, Department of Anesthesiology of this University via letter no. nil dated 20th April, 2019. **EC Comment on 12th July, 2019:** • It is a randomized double-blind comparative study needs to be submitted on CONSORT guidelines and necessary formality for CTRI registry. **EC Decision on 12th July, 2019:** Resubmit in format of CONSORT GUIDELINES ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer & approved*** **Action Taken:** ***CTRI pending*** **EC Decision:** Pending ***Ref. code: 97th ECM II B-Thesis/P54*** ***(Primary Reviewer: Dr. Rajeev Garg)***
e8	Clarification of research proposal entitled ***"Retrospective study of endoscopic dacrocystorhinostomy (DCR) at tertiary care center"*** submitted by Dr. Dheerendra Pratap Ahirwar, JR-I, Department of Otorhinolaryngology and Head-Neck Surgery of this University via letter no. nil dated 15th May, 2019. **EC Comment on 12th July, 2019:** • A retrospective study the validity of the consent is doubtful. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P79***

Chairperson, IEC
King George's Medical University

	(Primary Reviewer: Dr. Anoop Kumar Verma)
e9	Clarification of research proposal entitled ***"A study of etiology, prognosis and outcome of Hospital acquired acute kidney injury and community acquired acute kidney injury"*** submitted by Dr. Rahul Kumar, JR-II, Department of Medicine of this University via letter no. nil dated nil. **EC Comment on 12th July, 2019:** • Sample size calculation is confusing. Please clarify. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P85*** ***(Primary Reviewer: Dr. Amita Jain)***
e10	Clarification of research proposal entitled ***"To assess the efficacy of oral care protocol in prevention of ventilator- associated pneumonia in patients on invasive mechanical ventilation: A randomized controlled trial"*** submitted by Dr. Pallika Singh, JR-I, Department of Anesthesiology of this University via letter no. nil dated 23rd May, 2019. **EC Comment on 12th July, 2019:** • Kindly provide case record form. • Sample size is calculated to be 60. Does it include the number of cases in both the groups? • CONSORT guidelines have to be followed. **EC Decision on 12th July, 2019:** Revise & Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer with following comment:*** **Comment:** • ***This is Randomized control trial.*** • ***The calculated sample size is 215 there is no justification to include only 60 cases against 215*** • ***There are no details provided for control for final comments*** • ***Please revised full proposal*** ***The above comment again forwarded to the Principal-Investigator response received from P.I. This was forwarded to Primary reviewer response received by PR with following comment:-***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• ***Correction as per suggestions is not done.*** • ***CONSORT guidelines have to be followed*** **EC Decision:** Re-submit as new proposal in new format ***Ref. code: 97th ECM II B-Thesis/P90*** ***(Primary Reviewer: Dr. Amita Jain)***
e11	Clarification of research proposal entitled ***"Essentiality of antioxidants in improving the tolerability and quality of life in patient undergoing cancer chemotherapy"*** submitted by Dr. Akash Srivastava, JR-II, Department of General Surgery of this University via letter no. nil dated 25th May, 2019. **EC Comment on 12th July, 2019:** • Please clear the formulation of Gold (Swarna Bhasma) • Who will bear the cost of Gold therapy? • Needs to mention reference and literature. **EC Decision on 12th July, 2019:** Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer with following comment:*** **Comment:** • ***Kindly clarify that the formulation of gold is safe for human use and submit supply date of the compound.*** • ***Kindly incorporate it in the proposal and resubmit complete modified proposal.*** ***The above comment forwarded to the Principal-Investigator response received by reviewer & approved.*** **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P95*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
e12	Clarification of research proposal entitled ***"A study of 24 hours ambulatory blood pressure monitoring among nursing staff working at a tertiary care Hospital in Northern India"*** submitted by Dr. Deepak Kumar Verma, JR-II, Department of Medicine of this University via letter no. nil dated nil. **EC Comment on 12th July, 2019:** • Title to be revised. It is Northern India and not North India. North Korea and South Korea, North Sudan and South Sudan are independent countries and hence their name is thus. Northern India is a part of India • The researchers aim to study the Blood Pressure levels and 24 hours variability and any dipping pattern among nursing staff, and compare results in nurses working in Emergency, ICUs and in non-emergency wards • It is a cross sectional study of 100 cases, statistically calculated

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• The methodology is well defined • Ambulatory BP will be measured by an ABPM machine of Chinese make which will record BP every 30 minutes for 1 day while the nurses are doing their normal activities. Thus they will be classified as normotensives / hypertensives, dippers / non-dippers / reverse dippers. • Data collection sheet is missing. It should have the demographic details, the work place details and all the observational findings. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer & approved*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P116*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
e13	Clarification of research proposal entitled ***"Comparative evaluation of placement of zygomatic implant through extrasinus approach vs. intrasinus approach"*** submitted by Dr. Deepika Kumari Jain, JR-I, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences of this University via letter no. nil dated 17th June, 2019. **EC Comment on 12th July, 2019:** • Signatures are missing. • Who will bear the cost of implant? Patients cannot be asked to bear it. • Kindly clear if any **'Conflict of interest is present'**. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P148*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***
e14	Clarification of research proposal entitled ***"Metagenomic analysis of salivary and plaque microbiota in diabetic and non-diabetic individuals"*** submitted by Dr. Jyotsana Agarwal, JR-II, Department of Conservative Dentistry & Endodontics Faculty of Dental Sciences of this University via letter no. nil dated 17th June, 2019. **EC Comment on 12th July, 2019:** • Diabetes is associated with higher incidence of root caries and their plaque

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	has a different and aggressive bacterial flora. Bacteria from caries and plaque spill into the saliva. • This is a cross-sectional study in adults between 30 to 60 years of age • Sample size is 30 – 15 diabetic and 15 non-diabetic. Was this figure statistically derived? • Samples will be obtained in fasting condition in the morning but no data collection sheet is provided and so we do not know what will be observed. • We need a data collection sheet which should have the demographic details, the diabetic status, their oral hygiene, their tobacco / paan / betel nut habit as these people have not been excluded in your study. • Signature of Dr. A.B. Pant is missing. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer with following comment:*** **Comment:** • ***The data collection sheet still does not include what will be done with the saliva sample?*** • ***What all will be observed in each case abd documented for subsequent analysis?*** **EC Decision:** Pending ***Ref. code: 97th ECM II B-Thesis/P150*** ***(Primary Reviewer: Dr. Surajit Bhattachrya)***
e15	Clarification of research proposal entitled ***"A study on discharge documentation in a tertiary care government Hospital in Lucknow"*** submitted by Dr. Sukriti Shah under the guidance Prof. U.B. Mishra, Head, Department of Hospital Administration via letter no. HA/2019/578 dated 23rd October, 2019. **EC Comment on 12th July, 2019:** • The aim is to study the contents of the discharge summary, compare with standard guidelines, and study the policy of discharge documentation in regular discharge, LAMA and DOPR. • Sample size is 100. Statistically derived, • There is a selection bias as critical patients are excluded • Data collection in 2 weeks only. Will there be 100 discharges in 2 weeks from the Unit? • Waiver of consent is sought as the researchers claim that it is collection of data about Units other than individual patients • Data collection form is not provided

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• This is not true. You cannot see a patient's discharge slip and know about his disease without his/her consent. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM IIB MHA/P6*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
e16	Clarification of research proposal entitled ***"A descriptive study to assess the level of depression and anxiety among patients having multi drug resistance TB(MDR-TB) taking treatment in KCH, Department of Respiratory Medicine, KGMU, Lucknow, U.P."*** submitted by Mr. G. Srinivasan, KGMU College of Nursing of this University via letter no. dated 16th April, 2019. **EC Decision on 12th July, 2019:** • Methodology & sample size estimation is not provided **EC Decision on 12th July, 2019:** Revise & Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer & approved*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM IID/P2*** ***(Primary Reviewer: Dr. Amita Jain)***
e17	Clarification of research proposal entitled ***"Efficacy of information booklet regarding home care management on knowledge among patients with permanent pacemaker"*** submitted by Miss. Nidhi Tripathi through Mrs. Rashmi P. John, HOD, KGMU Institute of Nursing via letter no.1502 dated 12th October, 2019. **EC Comment on 12th July, 2019:** • It's a study based on new non-validated questionnaire **EC Decision on 12th July, 2019:** Re-write & Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM IID /P8***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. A.A. Sonkar)
e18	Clarification of research proposal of research proposal entitled ***"Effectiveness of an information booklet on the knowledge of caregivers regarding home-based management of Children with thalassemia"*** submitted by Ms. Rupali Verma through Mrs. Rina Km, KGMU Institute of Nursing via letter no. 1503 dated 12th October, 2019. **EC Comment on 12th July, 2019:** • Title does not reflect the the work. Questionnaire needs to be validated. **EC Decision on 12th July, 2019:** Revise and resubmit ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Member-Secretary, IEC, & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM IID /P16*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
e19	Clarification of research proposal entitled ***"Effectiveness of structured teaching programme regarding optimal feeding practice on knowledge and practices among mothers of low birth weight new born in NICU Ward, KGMU"*** submitted by Ms. Payal Saha, through Mrs. Rina Raj, KGMU Institute of Nursing via letter no. nil dated nil. **EC Decision on 12th July, 2019:** • Title is not reflective of the work • Very confusing non-validated self-made questionnaire **EC Decision on 12th July, 2019:** Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM IID /P24*** ***(Primary Reviewer : Dr. A.A. Sonkar)***
	Part (f) 98th ECM was held on 6th September, 2019
f1	Clarification of research proposal entitled ***"Assessment of feasibility, safety, and efficacy of OPN NC super high pressure percutaneous transluminal coronary angioplasty balloon catheter versus rotational atherectomy for plaque modification in severely calcified coronary artery lesions"*** submitted by Dr. Akhil Sharma, Associate Professor, Department of Cardiology of this University via letter no. 638/Cardio/Res/19 dated 15th October, 2019.

Chairperson, IEC
King George's Medical University

	EC Comment on 6th September, 2019: • Is this an investigator-initiated trial or a regulatory trial? • Which of the two procedures is standard of care for treatment of calcified plaque? • Are the procedures approved by DCGI for routine use in the said clinical condition? If not, have the authors taken permission form DCGI for using the procedures **EC Decision on 6th September, 2019:** Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer with following comment:*** **Comment:** • ***Kindly Provide the revised proposal*** ***The above Comment forwarded to the Principal-Investigator but response has not been given by P.I.*** **EC Decision:** Pending ***Ref. code: 98th ECM II A/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
f2	Clarification of research proposal entitled "***CETP and SRBI gene polymorphism on lipid subtypes of LDL and dysfunctional HDL in patient with type II diabetes mellitus***" sponsored by CST-UP submitted by Dr. Wahid Ali, Associate Professor, Department of Pathology of this University via letter no. nil dated 16th October, 2019. **EC Comment on 6th September, 2019:** • Kindly arrange the serial number of the references in order. • Kindly revise the Hindi consent form. **EC Decision on 6th September, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer, & approved*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM II A/P4*** ***(Primary Reviewer: Dr. Rajiv Garg)***
f3	Clarification of research proposal entitled "***To study the range of mean and absolute eosinophil counts in healthy Indian subjects and compare them with asthmatics and COPD patients***" submitted by Prof. Surya Kant, Head,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Department of Respiratory Medicine of this University via letter no. nil dated nil. **EC Decision on 6th September, 2019**: Provisionally approved with the request to kindly mention the Email address with signature in English ICF ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Member-Secretary, IEC & notified.*** **Action Taken**: Notified **EC Decision:** Approved ***Ref. code: 98th ECM II A/P6*** ***(Primary Reviewer: Dr. Rajeev Garg)***
f4	Clarification of research proposal entitled "***Follow up of the Lucknow elderly study (LES) in ageing and geriatric mental health as well as development of human resources and service pathways for mentally ill aging population***" submitted by Dr. Nisha M Pandey, Assistant Professor, Department of Geriatric Mental Health of this University via letter no. nil dated 31st October, 2019. **EC Comment on 6th September, 2019:** • Kindly clarify the point no. 6 in Annexure 7 in part III **EC Decision on 6th September, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer, & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM II A/P7*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
f5	Clarification of research proposal entitled "***Clinical phenotypes and genetic regulation of endometriosis in Indian women***" sponsored by Wellcome Trust DBT India Alliance submitted by Prof. Vinita Das, Head, Department of Obstetrics & Gynecology of this University via letter no. 39/HRRC-Lko/19 dated 7th October, 2019. **EC Comment on 6th September, 2019:** • This is a large multicenteric case control study supported by ICMR welcome trust. Total case & control size is 2000 each:- • KGMU is one of the center, which will enrolled 200 cases. Which is the other center? Please clarify. • Total budget is 66 cases. KGMU fund is not visible or is this KGMU fund? • There is no money allocated to support subjects in case of injury as (Mentioned in form). Please clarify. • One MOU is already signed with KGMU. Does KGMU take responsibility

Chairperson, IEC
King George's Medical University

	to support? **EC Decision on 6th September, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM II A/P11*** ***(Primary Reviewer: Dr. Amita Jain)***
f6	Clarification of research proposal entitled ***"A study on microbiological and susceptibility pattern of isolates of ` s from patients of infected pleural space: A step towards developing antibiotic policy of the Department"*** submitted by Dr. Darshan Kumar Bajaj, Associate Professor, Department of Respiratory Medicine of this University via letter no. nil dated nil. **EC Comment on 6th September, 2019:** • Ethically not approved as no collaborator from microbiology and the study involves the microbiological aspect: - • The title is mentioned differently at different plans • The sample size of 400 in 4 months is not possible. **EC Decision on 6th September, 2019**: Revise & Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM II A/P15*** ***Primary Reviewer: Dr. Rajeev Garg)***
f7	Clarification of research proposal entitled ***"Differential microbial profiling and genotyping of dominant resistant strains in sepsis and septic shock patients"*** sponsored by. ICMR- DHR submitted by Dr. Neetu Singh, Associate Professor, Department of Molecular Biology Unit Center for Advance Research of this University via letter no. CFAR/2019/405 dated 8th August, 2019. **EC Comment on 6th September, 2019:** • Need to mention the type of study. **EC Decision on 6th September, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer, & approved.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Action Taken: Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM II A/P33*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
f8	Clarification of research proposal entitled ***"Prevalence of dyslipidemia in non-obese obstructive sleep apnea (OSA)"*** submitted by Dr. Jyoti Bajpai, SR-III, Department of Respiratory Medicine of this University via letter no. nil dated nil. **EC Comment on 6th September, 2019:** • Your proposal mentioned study design at two places on page no. 10, Which needs to be corrected. • More over according to the objective mentioned, it has to be simple observational study. Sample size not mentioned • This proposal needs re-submission with proper study design and sample size. **EC Decision on 6th September, 2019:** Re-submit ***The above comment sent to the Principal-Investigator but response not received till 24th January, 2020.*** **EC Decision:** Pending ***Ref. code: 98th ECM II B-Thesis/P8*** ***(Primary Reviewer: Dr. Rajiv Garg)***

Chairperson, IEC
King George's Medical University

f9	Clarification of research proposal entitled ***"Prevalence of vitamin D deficiency in HIV disease and its correlation with disease severity: An observational study"*** submitted by Dr. Sudhir Kumar Verma, Assistant Professor, Department of Medicine of this University via letter no. 2661/Med/19 dated 29th November, 2019. **EC Comment on 6th September, 2019:** • Please modify the 1st. objective. To study the prevalence of Vitamin D in HIV disease means nothing • Hypothesis is Vitamin D deficiency is common in HIV patients and its levels correlate with the severity of the disease • 8 ml blood will be drawn once for CBC, LFT, RFT, CD4 counts, Serum Calcium – total and ionic, phosphate, 25(OH) Vitamin D, Parathormone • Vitamin D 10-20 ng/ml will be considered as insufficiency and <10 ng/ml will be taken as deficiency • Sample size 60. Was it statistically derived? • Inclusion and exclusion criteria are satisfactory **EC Decision on 6th September, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed the Primary reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM II B IMR-F/P11*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
f10	Research proposal entitled ***"The role of MTR, MTRR, MTHFR gene association in non syndromic cleft LIP, cleft palate and cleft LIP with palate in north Indian children"*** sponsored by of Research Cell KGMU submitted by Dr. Aravindhan A, JR-I through his mentor Prof. Rakesh Kumar Chak, Head, Department of Paediatric and Preventive Dentistry of this University via letter no. nil dated 8th August, 2019. **EC Comment on 6th September, 2019:** • Signature of Dr. Nitu Nigam is missing. **EC Decision on 6th September, 2019:** Provisionally approved ***The above comment sent to the Principal-Investigator reply has given by the P.I. which was seen by the Member-Secretary, IEC & notified.*** **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 98th ECM II B IMR-R/P3
	(Primary Reviewer: Dr. Rajeev Garg)
f11	Clarification of research proposal entitled ***"A descriptive study to assess the knowledge regarding blood donation among under graduate students of selected government college of Lucknow with a view to develop information pamphlets"*** submitted by Ms. Meena Devi/Ms.Manswita Bhoop/Ms.Minoo Bhardwaj/Ms. Mansi Verma/Ms.Mandavi Rawat/Ms.Nandini Saxena/Ms.Priya Singh/Ms.Poonam Pal through Mrs. Anugrah Charan & Mr. Sachin Dwivedi, KGMU College of Nursing of this University via letter no.1580 dated 22nd October, 2019. **EC Comment on 6th September, 2019:** • Kindly provide Questionnaire, Pamphlet sample and calculated sample size of UG students. **EC Decision on 6th September, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM IIDa/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
f12	Clarification of research proposal entitled ***"A descriptive study to assess the knowledge regarding needle stick injury and post exposure prophylaxis among nursing students of KGMU, College of Nursing"*** submitted by Ms. Akanksha Maurya/Ms.Asmita Maurya/Mr.Akhilesh Kumar/Akanksha Patel/AkankshaSingh/Anwar Mansur/Atul Kumar/ through Mr. Bhagwant Singh, KGMU College of Nursing of this University via letter no.nil dated 16th April, 2019. **EC Comment on 6th September, 2019:** • Kindly provide Questionnaire **EC Decision on 6th September, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Member Secretary IEC & approved.*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM IIDa/P3*** ***(Primary Reviewer: Dr. Amita Jain)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

f13	Clarification of research proposal entitled ***"A descriptive study to assess the knowledge and attitude of patients undergoing hemodialysis regarding their dietary management at KGMU, Lucknow with the view to develop an information booklet"*** submitted by Ms. Premsheela Rai/Ms.Priyanka Chaudhary/Ms.Priyanka Verma/Ms.Praveena Singh Deepankar/Ms.Preeti Jaiswar/Mr.Pankaj Jha/Mr. Prabhat Singh under the guidance of Mr.s Roohi Elizabeth Peter KGMU College of Nursing of this University via letter no.nil dated 16th April, 2019. **EC Comment on 6th September, 2019:** • Kindly submit the Methodology. • How to assess the knowledge and attitude of patients. **EC Decision on 6th September, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer & approved.*** **Action Taken:** None **EC Decision:** Approved ***Ref. code: 98th ECM IIDa/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
f14	Clarification of research proposal entitled ***"Clinical and radiological comparison of long- term and short- term outcomes of posterior canal wall reconstruction technique by using composite multifractured osteoperiosteal flap (C.M.O.F) versus conventional canal wall down mastoidectomy"*** submitted by Dr. Monica Patnaik, JRI, Department of Otorhinolaryngology and Head- Neck Surgery of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • The PI wishes to compare the outcome of two surgical methods to treat patients with CSOM. How will the patients be chosen for either of the procedures? Will this be an open-label or blinded study? Which allocation concealment method will be used? The thesis performa needs to be written as per the CONSORT guidelines. Please submit a CONSORT checklist dully filled along with the revised thesis performa. • Including patients retrospectively will dilute the impact of the study. It is advisable to restrict this to a prospective study. • The complications from the either of the surgical procedures, the risks involved have to be discussed with the patient in the patient information documents.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• The issue of compensation has to be discussed. Who will pay for compensation in case of litigation? Who will bear the cost of treatment if a patient develops complication of either of the surgical procedure? • How much is the additional cost of obtaining/using CMOF for reconstruction of posterior canal wall? Who will bear the cost of the procedure? • Patient data sheet is not provided. **EC Decision:** Re-submit ***The above comment forwarded to P.I. response has given by P.I. which was forwarded to Primary Reviewer but response has not given by the reviewer so the Member-Secretary has reviewed the above comment & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P42*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
f15	Research proposal entitled ***"Retrospective and prospective outcome of duplex-ultrasound guided percutaneous ethanol sclerotherapy of endometrioma"*** submitted by Dr. Nitish Singh, JR-II, Department of Radiodiagnosis of this University via letter no. nil dated nil. **EC Comment:** • Signature missing of Principal-Investigator in Hindi & English Inform consent Form. • Both ICF are not similar, it should be according to SOP. • The term retrospective may be removed from the topic of the study as the methods section and flow-chart provided does not reflect upon any criteria for retrospective chart review. It is also advisable for the PI to keep the study prospective as any intervention study should be. • The outcome measures are not clearly mentioned. • Is duplex-ultrasound guided percutaneous sclerotherapy of endometrioma not a standard of care? If yes, then the outcome of such procedures would be known already. If no, then the justification of not choosing the standard of care has to be given. • Will all consecutive patients be treated with the above said method? If yes, then the patient information document should clearly discuss all possible methods of treatment of ovarian endometrioma including the standard of care treatment and why the PI wishes to offer sclerotherpay to the patient. • Will there be any control arm?

Chairperson, IEC
King George's Medical University

	• The complications of the procedure and risk in participating in the study have to be discussed in detail in the patient information document. • Who will bear the cost of the procedure? • Please discuss the compensation in detail in the PID. **EC Decision:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was forwarded to Primary Reviewer but response has not given by the reviewer so the Member-Secretary has reviewed the above comment & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P66*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
	Part-g- 99th ECM was held on 18th October, 2019
g1	Clarification of research proposal entitled "***Surveillance of scrub typhus infection by serological and molecular testing by DHR- virus diagnostic laboratories across the country***" sponsored by Health Research, New Delhi submitted by Prof. Amita Jain, Head, Department of Microbiology of this University via letter no. 1582/19 dated 26th August, 2019. **EC Comment on 18th October, 2019:** • Kindly Calculate the sample size (PI-written that Observational study does not need Sample size) • Kindly attached the budget. **EC Decision on 18th October, 2019:** Approval after justification ***Dr. Amita Jain did not take a part in the discussion.*** ***The above comment sent to the Principal-Investigator, reply has given by the PI which was reviewed by the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Dr. Amita Jain did not take part in the discussion.*** ***Ref. code: 99th ECM II A/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

g2	Clarification of research proposal entitled ***"Newborn screening programme"*** sponsored by U.P NHM submitted by Dr. Wahid Ali, Associate Professor, Department of Pathology of this University via letter no. nil 17th December, 2019. **EC Comment on 18th October, 2019:** • How many children will be screened? • Cost/analysis? • How results will be communicated to parents? • What is the objective? • Exclusion & inclusion criteria? **EC Decision on 18th October, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Primary reviewer, reply has given by the reviewer with following comment:*** **Comment:** • ***Kindly Provide the revised proposal*** • ***Lab protocol: which tests will be used for every child/which test will be offered to selective groups?*** • ***How these groups will be made?*** • ***Copy of parental consent form is not provided*** • ***Since cases will be collected from KGMU as well as outside KGMU how these cases will be collected.*** • ***Is there a supervisor from each contact?*** **Action Taken:** The above comment again forwarded to the Principal-Investigator. ***Response received from P.I. which was forwarded to the Primary reviewer for review.*** ***Reply has given by Primary reviewer & approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 99th ECM II A/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
g3	Clarification of research proposal entitled ***"Status of serum Vitamin D and Calcium levels in Women of reproductive Age group- A cross sectional study"*** submitted by Dr. Dileep Kumar, Associate Professor, Department of Medicine and Rehabilitation of this University via letter no. 2511/19 22nd November, 2019. **EC Comment on 18th October, 2019:**

Chairperson, IEC
King George's Medical University

	• Need to mention the lab where level of Vitamin D will be done and who will bear the cost? Kindly clarify how the observations help to make hypothesis. **EC Decision on 18th October, 2019:** Approval after justification ***The above comment sent to the Principal-Investigator, reply has given by the PI which was forwarded to the Primary reviewer response received from the reviewer & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 99th ECM II A/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
g4	Research proposal entitled ***"Myths related to dentistry in people of Lucknow"*** submitted by Ms. Shatakshi Tripathi, BDS-Intern under the guidance Dr. Vinay Kumar Gupta, Associate Professor, Department of Public Health Dentistry Faculty of Dental Sciences of this University this University via letter no. 373/PHO/19 dated 12th September, 2019. **EC Comment on 18th October, 2019:** • Project is well written and scientific rationale as well as background literature has been adequately cited. • 2. Statistical analysis justifying the sample size has been provided. • 3. Consent form is included • 4. Does not involve invasive procedures • 5. Even though Background section does mention some previous work carried out by other groups with regards to Myths, however, which particular Myths will be studied in proposed study are not clearly stated in the proposal. A list containing Myths to be studied in current study is to be provided. • 6. The 16 point questionnaire mentioned in the proposal is missing in the application **EC Decision on 18th October, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by P.I. which was reviewed by the Member-Secretary, IEC & approved*** **Action Taken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 99th ECM IIB BDS-IS/P1*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

h	Part (h) Decision of ADR Sub Committee Meeting
Sl.	**DCGI**
h1	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 500/Cardio/Res/2019 dated 10th July, 2019 & 532/Cardio/Res/19 dated 24th July, 2019.
a	**Death** **Subject ID no. 010-0053** **Subject Initial:** S. **SAE term:** Death **Causality:** Could not be ascertain **Event:** Subject develop uneasiness and discomfort. Not taken to any hospital expired at home. **Gender:** M **DOB:** 01-01-1993 **Weight:** 70 KG **Height:** 180 CM **Start Date:** 5th June, 2018 **Subject History:** ***The above subject passed away on 20th May, 2019 at around 11:00 hrs at come. Cause of death is unknown. Subject expired at home, he was not taken to the any hospital.*** ***Call was made him today's morning for 12 months follow up and then site became aware of this event.*** ***ADR-sub-Committee decision:*** Since from a perusal of papers it appears that cause of death was unknown, no case for compensation arises. **EC Decision:** Reviewed & noted
b-	**Death** **Subject ID no. 010-0055** **Subject Initial:** P. **SAE term:** Death

Chairperson, IEC
King George's Medical University

	Causality: Cardio Vascular Arrest **Event:** Sudden death. **Gender:** F **Age:** 38 years **Weight:** 30 KG **Height:** 145 CM **Start Date:** 14th July, 2018 **Subject History:** ***The above subject passed away on 1st July, 2019 at around 04:00 hrs at home. Cause of death is unknown. Subject expired at home; she was not taken to the any hospital.*** ***Call was made her yesterday around 15:30 for 12 month follow-up and then site became aware of this event.*** ***ADR-sub-Committee decision:*** Since from a perusal of papers it appears that cause of death was unknown, no case for compensation arises. **EC Decision:** Reviewed & noted ***Ref. code: 83rd ECM IIC/P6***
Sl.	**NON- DCGI**
h1.	**28th December, 2019** The meeting of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** of King George's Medical University U.P was held on 28th December, 2019 at **1.30 p.m. onwards** in the **"Board Room",** Administrative Block of this University. The following members were present in the meeting: 1. Hon'ble Justice Vishnu Sahai - Chairman 2. Dr. Manju Agrawal - Member 3. Sri Ram Niwas Jain - Member 4. Prof. Rajendra Nath - Member 5. Prof. Rajeev Gag - Member

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	6. Prof. R. K. Gag - Member Secretary, Ex-officio
I-	Research entitled ***"ISCHEMIA trial protocol: International study of comparative health effectiveness with medical and invasive approaches"*** submitted by Dr. S.K. Dwivedi, Department of Cardiology of this University vide letter no. 708/Cardio/Res/2019 dated 10th December, 2019 & 709/Cardio/Res/2019 dated 12th December, 2019 respectively.
a-	**Patient ID:** 091019-088 **Subject initial:** R-R **Gender:** M **Age:** 54 yrs old **Event:** Randomized in Conservative arm **Subject History:-** ***The above subject was called by P.I. on 6th December, 2019 for long term Follow-up, LAR answered the call and said that patients developed mild uneasiness in morning at 6:30 AM. He took his scheduled drugs and was alonght by 7 AM. Then he developed suddent severe breathlessness at 8:15 am and expired at 8:30 am. He could not be taken to hospital & no record are available regarding last illness. No autopsy was done.*** ***ADR-sub-Committee decision:*** Since a perusal of papers does not show that there was nexus between the study drug administered to subject and her death and no autopsy was done, no case for compensation is made out. **EC Decision:** Reviewed & noted
b-	**Patient ID:** 091019-068 **Subject initial:** JPS **Gender:** M **Age:** 79 yrs old **Event:** Randomized in Conservative arm **Subject History:-**

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	The above subject was called by P.I. on 6th December, 2019. Subject LAR revealed that subject left all drugs before one week prior and stopped eating. He developed breathlessness, uneasiness and dyspnea at around 3:30 am and he passed away at 4:30 am on 12th August, 2019 before he could not be taken to any hospital. ***ADR-sub-Committee decision:*** Since a perusal of papers shows that cause of death of the subject was unknown (not related to the study drug administered to the subject) and no autopsy was done, no case for compensation is made out. **EC Decision:** Reviewed & noted ***Ref. Code: 60th ECM II-A/P13***
II	Research protocol entitled ***"MyVal-1: A prospective multicenter, single arm, open label study of MyVal TM Transcatheter aortic valve replacement system in the treatment of severe symptomatic native aortic valve stenosis,"*** submitted by Prof. Rishi Sethi, letter no. 74/Cardio/Cardio/18 dated 17th October, 2018 & letter no.805/2018 dated 10th December, 2019 received from Govt. of India, DCGI, CDSCO, New Delhi. **Subject no.**: 001 **Gender:** Male **Subject initial: S-A-S** **SAE Description:** Subject no. 001 under the above study was taken into the study on 5th October, 2017. His TAVI was done on 5th October, 207 procedure was successful and subject was discharged in stable condition. Subject turned up for 12 month follow up on 15th October, 2018. His ECO was done and found that subject is under AF with fast ventricular rate. So, he was hospitalized for the stabilization however a patient is asymptomatic. **EC Decision:** Reviewed & Noted **ADR-sub-Committee decision:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Perused paper no case for compensation is made out. **EC Decision:** Reviewed & noted ***Ref. code: 80th ECM II C/P8***
h2	**DCGI**
I- a	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 667/Cardio/Res/2019 dated 11th November, 2019. 716/Cardio/Res/19 dated 14th December, 2019 respectively. **Death** **Subject ID no. 010-0075** **Subject Initial:** S-D **SAE term:** Death **Causality:** Health failure and Arrhythmia **Event:** Severe dyspnea with Atrial fibrillation with fast Ventricular response. **Gender:** F **Age:** 48 yrs old **Weight:** 70 KG **Height:** 163 CM **Start Date:** 27th September, 2018 **Subject History:** ***The above subject presented to our hospital on 3rd July, 2019 at 6:02 pm and got admitted under another doctor, subject and her LAR did not informed us about the event and did not contacted us during hospitalization.*** ***Today we made a call to subject for 12 month follow-up, and then we came to know that subject expired in the hospital.*** ***His LAR reveled that subject admitted on 3rd July, 2019 and expired on same day. Subject developed breathlessness for which she was admitted. No Autopsy***

Chairperson, IEC
King George's Medical University

	was done. **ADR-sub-Committee decision:** Since a perusal of the papers shows that no records are available regarding the last illness of the deceased subject and no autopsy was done, no case for compensation is made out.
b-	**<u>Death</u>** **Subject ID no. 010-0026** **Subject Initial:** S-S **SAE term:** Death **Causality:** Unknown **Event:** Felt Syncope and fainted. **Gender:** M **Age:** 50 yrs old **Weight:** 52 KG **Height:** 168 CM **Start Date:** 4th October, 2017 **Subject History:** ***The above subject presented to our hospital on 13th October, 2019 at 5:00 pm He did his morning activity and then he felt syncope and fainted. He was taken to the local hospital and there he was declared as brought dead. <u>Cause of death is unknown</u>. No Autopsy was done.*** **ADR-sub-Committee decision:** Since a perusal of the papers shows that the subject left all drugs and stopped eating one week before his death, he died before he could be taken to hospital and no autopsy was done, no case for compensation is made out. ***Ref. code: 83rd ECM IIC/P6***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

100th "Institutional Ethics Committee" Meeting held on 25th January, 2020

Item no. IIA

New Proposals

K.G's Medical University U.P., Lucknow

IIB	Expedited Review
	None
II-A	**New Proposal**
1.	Research proposal entitled ***"Strain parameters at rest and after exercise in symptomatically stable patients with improved heart failure-STRESS-HF"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology of this University via letter no. 628/Cardio/Res/19 dated 3rd September, 2019. **EC Decision:** Approved ***Ref. code: 100th ECM II A/P1*** ***(Primary Reviewer : Dr. Surajit Bhattacharya)***
2.	Research proposal entitled ***"Screening of respiratory disease and lung function profile in the population with respiratory symptoms at Kumbh Mela"*** submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine of this University via letter no. 5807/19 dated 1st February, 2019. **EC Comment:** • It seems work has already been done. **EC Decision:** Not approved ***Ref. code: 100th ECM II A/P2*** ***(Primary Reviewer: Dr. Rajeev Garg)***
3.	Research proposal entitled ***"An evaluation of efficacy of Ethanolic extract of Nigella sativa L. (KALONJI) on the clinical parameters of moderate- to- severe gingivitis: A split-mouth clinical study"*** submitted by Prof. Vibha Singh, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences of this University via letter no. nil dated 30th September, 2019. **EC Decision:** Approved ***Previous Ref.Code: 98th ECMIB/P1*** ***Current Ref. code: 100th ECM II A/P3*** ***(Primary Reviewer: Dr. Rajendra Nath)***
4.	Research proposal entitled ***"Assessment of antigenic targets in membranous nephropathy"*** submitted by Dr. Kiran Preet Malhotra, Department of Pathology, RMLIMS Lucknow of this University via letter no. nil dated 20th September, 2019. **EC Comment:** • Project should be submitted by one of the authors from KGMU **EC Decision:** Approval after justification

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 100th ECM II A/P4 ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
5.	Research proposal entitled "***Elucidate the epigenetic pathways in type 2 diabetes and its associated nephropathy: a case control study***" sponsored by SERB New Delhi submitted by Dr. Gyanendra Kumar Sonkar, Associate Professor, Department of Biochemistry of this University via letter no. Bio/2019/727 dated 11th November, 2019. **EC Decision:** Approved ***Ref. code: 100th ECM II A/P5*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
6.	Research proposal entitled "***Comparison of the efficacy of a 7-day versus a 14-day course of intravenous antibiotics in the treatment of uncomplicated neonatal bacterial sepsis: a randomized controlled non- inferiority trial***" sponsored by Indian Council of Medical Research New Delhi submitted by Prof. Mala Kumar, Department of Pediatrics of this University via letter no. 1717/Ped/19 dated 8th November, 2019. **EC Comment:** • It is not clear from the project when randomization would be starting? • Kindly submit as per CONSORT guidelines **EC Decision:** Approval after justification ***Ref. code: 100th ECM II A/P6*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
7.	Research proposal entitled "***Oral symptoms and oral health related quality of life in people with grisnspan syndromes: A questionnaire based cross- sectional study***" submitted by Dr. Akhilanand Chaurasia, Assistant Professor, Department of Oral Medicine and Radiology, Faculty of Dental Sciences of this University via letter no. nil dated 22nd November, 2019. **EC Decision:** Approved ***Ref. code: 100th ECM II A/P7*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
8.	Research proposal entitled "***Serum vitamin D level estimation and its association with vitamin D receptor (Cdx-2, Apa1 & Taq1) and toll like receptor 2& 8 genetic variants as risk factor for female genital tuberculosis (FGTB) in Northern Indian population***" sponsored by UP-CST submitted by Prof. S.P. Jaiswar, Department of Obstetrics & Gynecology of this University via letter no. nil dated 25th November, 2019. **EC Comment:** • Consent form should be provided in newly approved format

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Dr. Amita Jain did not take part in the discussion.*** ***Ref. code: 100th ECM II A/P8*** ***(Primary Reviewer: Dr. Rajiv Garg)***
9.	Research proposal entitled "***To study the prevalence of MDR and XDR tuberculosis in patients with tubercular pericardial effusion in a tertiary care centre, North India***" submitted by Dr. Akshyaya Pradhan, Associate Professor, Department of Cardiology of this University via letter no. 701/Cardio/Res/19 dated 2nd December, 2019. **EC Comment:** • Where will tuberculosis microbiology be done? • Inform consent form empty, need composition as per revised format. **EC Decision:** Approval after justification ***Ref. code: 100th ECM II A/P9*** ***(Primary Reviewer: Dr. Rajeev Garg)***
10.	Research proposal entitled "***Study of lipid profile in statin naïve Indian patients presenting with acute coronary syndrome: data from high volume tertiary care center in India***" submitted by Dr. Akshyaya Pradhan, Associate Professor, Department of Cardiology of this University via letter no. 700/Cardio/Res/19 dated 2nd December, 2019. **EC Comment:** • What are criteria for high volume? • Methodology should be in greater detail. • Detail of protocol is missing (except the inclusion and exclusion criteria • Calculated sample size is not mentioned. • Budget is not mentioned **EC Decision:** Resubmit ***Ref. code: 100th ECM II A/P10*** ***(Primary Reviewer: Dr. Rajendra Nath)***
11.	Research proposal entitled "***A prospective observation study to evaluate clinical outcomes of perindopril in stable heart failure patients switched from Ramipril***" submitted by Dr. Akshyaya Pradhan, Associate Professor, Department of Cardiology of this University via letter no. 699/Cardio/Res/19 dated 2nd December, 2019. **EC Comment:** • There is no detailed protocol. The consent form is not as per requirement.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Details of methodology is not given. Please disclose any conflict of interest. Who will fund the project? **EC Decision:** Resubmit ***Ref. code: 100th ECM II A/P11*** ***(Primary Reviewer: Dr. Amita Jain)***
12.	Research proposal entitled ***"A study on correlation of Age, gender & body mass index with hematological parameters"*** submitted by Dr. Priyanka Singh, Associate Professor, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences of this University via letter no. nil dated 6th December, 2019. **EC Comment:** • No study proforma given only guidelines for patient information sheet. • No sample calculation provided • Vague study how will they remove confounding factors **EC Decision:** Re-submit ***Ref. code: 100th ECM II A/P12*** ***(Primary Reviewer: Dr. Preeti Agarwal)***

Chairperson, IEC
King George's Medical University

K.G's Medical University U.P., Lucknow

100th "Institutional Ethics Committee" Meeting held on 25th January, 2020

Item no. IIB

New Thesis

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 100th ECM held on 25th January, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

II-B	New Thesis-Resident
1.	Research proposal entitled ***"Etiological, clinical and therapeutic profile of chronic heart failure patients attending out Patient clinic"*** submitted by Dr. Lotos Gailson, SR-II, Department of Cardiology of this University via letter no. nil dated 15th September, 2019. **EC Decision:** Approved ***Ref. code: 100th ECM II B-Thesis/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"Study of coronary culprit lesion characteristics by optical coherence tomography in patients presenting with acute coronary syndrome"*** submitted by Dr. Basant Kumar Gupta, SR-II, Department of Cardiology of this University via letter no. nil dated 20th September, 2019. **EC Decision:** Approved ***Ref. code: 100th ECM II B-Thesis/P2*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
3.	Research proposal entitled ***"Invasive assessment of hemodynamic effect of ivabradine in post ST segment elevation myocardial infarction associated sinus tachycardia"*** submitted by Dr. Amit Kumar Singh, SR-II, Department of Cardiology of this University via letter no. nil dated 20th September, 2019. **EC Comment:** • Please attach the new Performa and patients Information sheet. **EC Decision:** Approval after justification ***Ref. code: 100th ECM II B-Thesis/P3*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
4.	Research proposal entitled ***"The effects of trimetazidine on left ventricular mechanics in chronic stable angina patients"*** submitted by Dr. Varun Sharma, SR-II, Department of Cardiology of this University via letter no. nil dated 20th September, 2019. **EC Comment:** • In chronic angina Trimetazidine increases work capacity and delays appearance of symptoms and ECG changes during exercise. This study aims to evaluate whether this drug, administered as an adjunct to conventional optimal medical treatment in patients of stable angina led to improvement of LV mechanics • LV mechanics includes LVEF, LV global longitudinal strain and radial

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	strain. This will be compared 1, 3 and 6 months after Trimetazidine therapy. • Inclusion and exclusion criteria are satisfactory • Sample size 40 – statistically derived • A study design flow chart and a data collection sheet has been provided • But what are they going to compare their results with? There is no control group which is getting only conventional medical therapy and no Trimetazidine. • Study of design is inappropriate. • RCT would be an appropriate design • Kindly provide as new format **EC Decision:** Resubmit ***Ref. code: 100th ECM II B-Thesis/P4*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
5.	Research proposal entitled ***"Comparative evaluation of gamma H2AX in patients with Oral leukoplakia, Oral submucous fibrosis, Oral squamous cell carcinoma, and tobacco consumers"*** submitted by Dr. Sanad Khandelwal, JR-II, Department of Oral Medicine and Radiology, Faculty of Dental Sciences of this University via letter no. nil dated 8th June, 2019. **EC Comment:** • Please calculate sample size with statistical formula not on the basis of OPD attendance. **EC Decision:** Approval after justification ***Ref. code: 100th ECM II B-Thesis/P5*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
6.	Research proposal entitled ***"Evaluation of clinical and anti-inflammatory effect of tea tree oil used as an adjunctive treatment of chronic periodontitis"*** submitted by Dr. Shubham Sharma, JR-I, Department of Periodontology, Faculty of Dental Sciences of this University via letter no. nil dated 14th September, 2019. **EC Comment:** • Source ad brand/make of tea tree oil may be specified. Furthermore, adverse effect/allergies following oral exposure need to be elaborated in the review section & accordingly measures are to be suggested in case of an episode. **EC Decision:** Approval after justification ***Ref. code: 100th ECM II B-Thesis/P6*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
7.	Research proposal entitled ***"Role of fibroblast growth factor (FGF), epidermal***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	growth factor (EGF) in repair of tympanic membrane perforation" submitted by Dr. Onkar Vedak, SR-I, Department of Otorhinolaryngology and Head- Neck Surgery of this University via letter no. nil dated 24th October, 2019. **EC Comment:** • Kindly calculate the sample size. • Are these two agents approved for human use? • It should be submitted in a RCT format. **EC Decision:** Approval after justification ***Ref. code: 100th ECM II B-Thesis/P7*** ***(Primary Reviewer: Dr. Rajendra Nath)***
8.	Research proposal entitled ***"Volumetric analysis of prefrontal cortex and magnetic resonance spectroscopy in late life psychosis"*** submitted by Dr. Nimitha K.J., SR-I, Department of G.M.H. of this University via letter no. nil dated 9th December, 2019. **EC Comment:** • Kindly provide the consent forms as new format **EC Decision:** Approval after justification ***Ref. code: 100th ECM II B-Thesis/P8*** ***(Primary Reviewer: Dr. Amita Jain)***
9.	Research proposal entitled ***"A clinic-immunological study of Guillain-barre syndrome with special reference to Host TNF- a, CD 14 and CD 1E genetic polymorphism"*** submitted by Dr. Rajarshi Chakraborty, SR-I, Department of Neurology of this University via letter no. nil dated 19th November, 2019. **EC Comment:** • Consent form is blank **EC Decision:** Approval after justification ***Prof. Amita Jain & R. K. Garg did not take part in the discussion.*** ***Ref. code: 100th ECM II B-Thesis/P9*** ***(Primary Reviewer: Dr. Rajiv Garg)***
10.	Research proposal entitled ***"A study of clinical spectrum, risk factors and outcome of drug- induced movement disorders"*** submitted by Dr. Rohit Anand, SR-I, Department of Neurology of this University via letter no. nil dated 23rd November, 2019. **EC Decision:** Approved ***Dr R. K. Garg did not take part in the discussion.*** ***Ref. code: 100th ECM II B-Thesis/P10***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Amita Jain)
11.	Research proposal entitled ***"Evaluation of determinants for rehospitalization in tuberculous meningitis"*** submitted by Dr. Patil Manish Ramesh, SR-I, Department of Neurology of this University via letter no. nil dated 23rd November, 2019. **EC Decision:** Approved ***Prof. Amita Jain & R. K. Garg did not take part in the discussion.*** ***Ref. code: 100th ECM II B-Thesis/P11*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
12.	Research proposal entitled ***"Clinical, laboratory and imaging features of tuberculous myelitis"*** submitted by Dr. Mohd. Imran Khan, SR-I, Department of Neurology of this University via letter no. nil dated 25th November, 2019. **EC Decision:** Approved ***Prof. Amita Jain & R. K. Garg did not take part in the discussion.*** ***Ref. code: 100th ECM II B-Thesis/P12*** ***(Primary Reviewer: Dr. Rajendra Nath)***
13.	Research proposal entitled ***"Primary immune dysregulation in subacute sclerosing panencephalitis: A case control study"*** submitted by Dr. Vijayavarman V, SRI, Department of Neurology of this University via letter no. nil dated 25th November, 2019. **EC Decision:** Approved ***Prof. Amita Jain & R. K. Garg did not take part in the discussion.*** ***Ref. code: 100th ECM II B-Thesis/P13*** ***(Primary Reviewer: Dr. Rajeev Garg)***
14.	Research proposal entitled ***"Lesion reduction on whole body MRI in disseminated cysticercosis after two weeks of albendazole- A pilot study"*** submitted by Dr. Kinzang Wangda, SR-I, Department of Neurology of this University via letter no. nil dated 25th November, 2019. **EC Decision:** Approved ***Prof. Amita Jain & R. K. Garg did not take part in the discussion.*** ***Ref. code: 100th ECM II B-Thesis/P14*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
15.	Research proposal entitled ***"Comparison of clinical characteristics and response to treatment between patients with migraine and migraine with calcified neurocysticercosis"*** submitted by Dr. Kamini Sharma, SR-I, Department of Neurology of this University via letter no. nil dated 22nd November, 2019.

Chairperson, IEC
King George's Medical University

	EC Decision: Approved ***Dr. R. K. Garg did not take part in the discussion.*** ***Ref. code: 100th ECM II B-Thesis/P15*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
16.	Research proposal entitled ***"Study of clinical and temporal profiles in drug resistant epilepsy patients"*** submitted by Dr. Nikhil Kumar Sahu, SR-I, Department of Neurology of this University via letter no. nil dated 19th November, 2019. **EC Comment:** • Sample size is not given **EC Decision:** Approval after justification ***Dr. R. K. Garg did not take part in the discussion.*** ***Ref. code: 100th ECM II B-Thesis/P16*** ***(Primary Reviewer: Dr. Surajit Bhattcharya)***
17.	Research proposal entitled ***"A study of handwriting sample in geriatric population with cognitive impairment"*** submitted by Dr. H.V. Suresh, SR-I, Department of G.M.H. of this University via letter no. nil dated 9th December, 2019. **EC Decision:** Approved ***Ref. code: 100th ECM II B-Thesis/P17*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
18.	Research proposal entitled ***"Study of vitamin B12 supplementation in late life depression"*** submitted by Dr. Pooja Misal, SR-I, Department of G.M.H. of this University via letter no. nil dated 9th December, 2019. **EC Decision:** Approved ***Ref. code: 100th ECM II B-Thesis/P18*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

100th "Institutional Ethics Committee" Meeting held on 25th January, 2020

Item no. IIB

Master's in Hospital Administration (MHA)

K.G's Medical University U.P., Lucknow

IIB	Master's in Hospital Administration(MHA)
1.	Research proposal entitled ***"A study on status of environmental labels and recycling symbols on procured equipment's and surgical consumables in a tertiary care Government Hospital"*** submitted by Dr. Amit Kumar through his Mentor Prof. U.B. Mishra, Head, Department of Hospital Administration of this University via letter no. HA/2019/603 dated 30th September, 2019. **EC Comment:** • Project does not involve the study of human subjects **EC Decision:** Project does not involve the study of human subjects. ***Ref. code: 100th ECM IIB MHA/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"A study of intensive care units in a tertiary care Government Teaching Hospital"*** submitted by Dr. Shweta Budhiraja, Through his Mentor Prof. U.B. Mishra, Head, Department of Hospital Administration of this University via letter no. HA/2019/643 dated 16th September, 2019. **EC Comment:** • Project does not involve the study of human subjects. **EC Decision:** Project does not involve the study of human subjects. ***Ref. code: 100th ECM IIB MHA/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Research proposal entitled ***"A comparative study of central sterile supply Departments (CSSD) in tertiary care Government Teaching Hospitals"*** submitted by Dr. Naveen Chaturvedi, Through his Mentor Prof. U.B. Mishra, Head, Department of Hospital Administration of this University via letter no. HA/2019/679 dated 17th October, 2019. **EC Comment:** • Project does not involve the study of human subjects **EC Decision:** Project does not involve the study of human subjects.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 100th ECM IIB MHA/P3 ***(Primary Reviewer: Dr. Amita Jain)***
4.	Research proposal entitled ***"A study of organ transplant Department in a tertiary care government Hospital"*** submitted by Dr. Sandhya Yadav, through his Mentor Prof. U.B. Mishra, Head, Department of Hospital Administration of this University via letter no. HA/2019/696 dated 14th November, 2019. **EC Comment:** • Project does not involve the study of human subjects **EC Decision:** Project does not involve the study of human subjects. ***Ref. code: 100th ECM IIB MHA/P4*** ***(Primary Reviewer: Dr. Rajeev Garg)***
5.	Research proposal entitled ***"A study on patient satisfaction with dietary services provided in a tertiary care government Hospital"*** submitted by Dr. Preeti Bharti, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Department of Hospital Administration of this University via letter no. HA/2019/695 dated 14th November, 2019. **EC Decision:** Approved ***Ref. code: 100th ECM IIB MHA/P5*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
6.	Research proposal entitled ***"A study of Clientele satisfaction in trauma centre of a tertiary care Government Hospital"*** submitted by Dr. Sukriti Shah, Through his Mentor Prof. U.B. Mishra, Head, Department of Hospital Administration of this University via letter no. HA/2019/733 dated 27th November, 2019. **EC Decision:** Approved ***Ref. code: 100th ECM IIB MHA/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
7.	Research proposal entitled ***"A study of medical store in a tertiary care government Teaching Hospital"*** submitted by Dr. Shreya Pandey, Through his Mentor Prof. U.B. Mishra, Head, Department of Hospital Administration of this University via letter no. HA/2019/731 dated 23rd November, 2019.

Chairperson, IEC
King George's Medical University

	EC Comment: • Project does not involve the study of human subjects. **EC Decision:** Project does not involve the study of human subjects. ***Ref. code: 100th ECM IIB MHA/P7*** ***(Primary Reviewer: Dr.A.A. Sonkar)***
8.	Research proposal entitled ***"A study of OPD services in a tertiary care Government Hospital"*** submitted by Dr. Anubhuti, Through his Mentor Prof. U.B. Mishra, Head, Department of Hospital Administration of this University via letter no. HA/2019/732 dated 24th November, 2019. **EC Comment:** • Project does not involve the study of human subjects **EC Decision:** Project does not involve the study of human subjects. ***Ref. code: 100th ECM IIB MHA/P8*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
9.	Research proposal entitled ***"A study on antibiotic prescribing practicesin a tertiary care government teaching Hospital in Lucknow, India"*** submitted by Dr. Anitta Jose Ellenkil, JRI, Through his Mentor Prof. U.B. Mishra, Head, Department of Hospital Administration of this University via letter no. nil dated 27th November, 2019. **EC Decision:** Approved ***Ref. code: 100th ECM IIB MHA/P9*** ***(Primary Reviewer: Dr. Preeti Agarwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

100th "Institutional Ethics Committee" Meeting held on 25th January, 2020

Item no. IIB

Ph.D

K.G's Medical University U.P., Lucknow

IIB	Ph.D. Scholars
1.	Research proposal entitled ***"To study the validity of foot print analysis in relation to navicular height for diagnosis of paediatric flatfoot"*** submitted by Prof. Ajai Singh under the guidance of Prof. Vineet Sharma, Head, Department of Paediatric Orthopedics of this University via letter no. 294/Paed orth/19 dated 11th December, 2019. **EC Comment:** • Kindly provide **"Conflict of interest"** • Faculty Ph D candidate should not have a topic similar to topic on which his or her student is working. • You cannot enroll a human subject in two referred projects simultaneously. **EC Decision:** Approval after justification ***Ref. code: 100th ECM IIB Ph.D./P1*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
2.	Research proposal entitled ***"To analyse the expression of serum MMP-13 level and correlate it with the severity of Paediatric flat foot"*** submitted by Ms. Aashima Datta, Ph.D. Scholar under the guidance of Prof. Ajai Singh, Department of Paediatric Orthopedics of this University via letter no. 292/Paed orth/19 dated 11th December, 2019. **EC Comment:** • Committee is of view that PhD student and faculty PhD candidate should work on separate subject population. **EC Decision:** Approval after justification ***Ref. code: 100th ECM IIB Ph.D./P2*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
3.	Research proposal entitled ***"Effectiveness of teacher training program (CHAT) for tobacco control in schools of Lucknow"*** submitted by Dr. Nishita Kankane, Ph.D. Scholar under the guidance of Prof. Ajai Singh, Department of Public Health Dentistry, Faculty of Dental Sciences of this University via letter no. nil dated 12th December, 2019. **EC Decision:** Approved ***Ref. code: 100th ECM IIB Ph.D./P3*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

4.	Research proposal entitled ***"To analyse nCD64 and Tioredoxin as Biomarkers for delayed fracture related infection"*** submitted by Ms. Archana Raikwar, Ph.D. Scholar under the guidance of Prof. Ajai Singh, Department of Paediatric Orthopedics of this University via letter no. 293/Paed orth/19 dated 5th December, 2019. **EC Decision:** Approved ***Ref. code: 100th ECM IIB Ph.D./P4*** ***(Primary Reviewer: Dr. Amita Jain)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

100th "Institutional Ethics Committee" Meeting held on 25th January, 2020

Item no. IIC

Re-approval

K.G's Medical University U.P., Lucknow

IIC.	Re- Approval
1.	Research Protocol no. entitled ***"Infant traumatic brain injury: A hidden epidemic in India"*** sponsored by Concept Medical submitted by Prof. Chandrakanta, Department of Paediatrics of this University via letter no.nil dated 14th September, 2019. **EC Decision:** Approved ***Previous Ref. code: 73rd ECM IIA/P10*** ***Current Ref. Code 100 ECM IIE/P1*** ***(Primary Reviewer: Dr. Preeti Agarwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

100th "Institutional Ethics Committee" Meeting held on 25th January, 2020

Item no. III

Adverse Drug Event

K.G's Medical University U.P., Lucknow

III	Adverse Drug Event
1.	ADE research protocol no. ***GS-US-417-0304*** entitled ***"A multicenter, double- blind, long term extension study to assess the safety and efficacy of filgotinib in subjects with rheumatoid arthritis"*** submitted by Dr. Urmila Dhakad, Department of Rheumatology of this University via letter nos. CT/72/19 dated 24th September, 2019 & CT/73/19 dated 24th September, 2019.
a.	**Patient ID:** 44017 **Age:** 41 yrs 8 months **Gender:** Female **Weight:** 50.0 Kg **Height:** 145.0 cm **Patient History:** Patient has visited site for wk 24 visit and informed that she has a gland in Neck with fever since 14th August, 2019. Ultrasound was performed and findings are suggestive of Left supreaclavicular Lymphadenopathy infective/inflammatory. Patient is hospitalized for further evaluation and management. Patient also had C/o decreased Aapette, Nausea, Vomiting, mild Dysphagia, Fever with chills. FNAC was done on 30th Agusut, 2019. Cytomorphology is consistent with Reactiv Lymph Node Hyperplasia. No Granuloma or atypicalcells are seen. Patient was treated with Inj Emset 8 mg IV TDS, Tab Cacium 500mg 1BD, Cap Sompraz D 1OS BBF, Tab Dolo 650mg SOS. Inj Pantocied 40 mg IV OD, Inj Ceftriaxone iG IV BD, Tab Cloze 0.5 mg I OD HS. Treatment advice on 9th September, 2019: Tab Dolo 650 mg SOS, Tab Cefixime 200mg 1 BD, Tab Clozed 0.5 mg 1OD HS, Tab Adirab DSR 1OD BBF. **EC Decision:** Reviewed & noted
	Patient ID: 15876 **Age:** 56 yrs 8 months **Gender:** Female **Weight:** 45.0 Kg **Height:** 152.0 cm **Patient History:** Patient has visited site for wk 24 visit on 26th August, 2019 and infored that she has mild pain inabdomen since 19th August 2019, we have received an alert for the subject with high S Amylase and S Lypase level G4 toxicity. We have called the patient to visit site immediately paient has visied site on 29th August 2019. A retest sample sent for S Amylase and S Lypase and patient is hospitalized for close

Chairperson, IEC
King George's Medical University
U.P., Lucknow

b.	monitoring, further evaluation and management the event. USG abdomen performed on 30th August, 2019. 2nd September, 2019 Patient is discharged on 31st August, 2019 as Serum Amylase and S Lipase level reduced and patients is clinically stable and asymptomatic. Patient is advised to visit site after one week for repeat test. A repeat blood sample was sent to central lab for amylase and Lipase tests on 9th September, 2019. Reports were received on 16th September and were within normal range. Patient was informed to restart IP on 21st September, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 86th ECM IIE/P1*** ***(Primary Reviewer: Dr. Rajendra Nath)***
2.	ADE research protocol no. entitled ***"INVeslgation of rheumatiCAF treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** submitted by Dr. Rishi Sethi, Department of Cardiology of this University via letter no. 647/Cardio/Res/19 dated 18th October, 2019. **Patient ID:** 010-0049 **Subject Initial:** N-D **Age:** 35 yrs **Gender:** Female **Weight:** 155 **Patient History:** Subject 0100049 had symptoms/breathlessness increased and she was hospitalized on 24th May, 2019 in CTVS Department for valve replacement. She was medically established in the ICU and finally taken up for valve surgery on date 12th June, 2019. Her post-operative stay was uneventful and she was discharge on 25th June, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 83rd ECM IIC/P6*** ***(Primary Reviewer: Dr. Rajeev Garg)***
3.	ADE **(Initial)** research protocol no. EGC002 entitled ***"A phase III, Randomized, multicenter, double-blind study to compare efficacy and safety of EG12014 (EirGenix-Trastuzumab) with Herceptin® as Neoadjuvant treatment in combination with anthracycline/Paclitaxel-based systemic therapy in patients with HER2-positive early breast cancer"*** sponsored by M/s Sun Pharma Laboratories Ltd. submitted by Dr. Anand Kumar Mishra, Department of Endocrine Surgery of this University via letter no. nil dated 15th November, 2019.

Chairperson, IEC
King George's Medical University

	Patient ID: 910406 **EC Comment:** • Please provide follow-up report **EC Decision:** Approval after justification ***Ref. code: 92nd ECM IIC/P3*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
4-	ADE of research Protocol No. ALK05-TERI1" entitled ***"A prospective, comparative, active- controlled, randomized, open - label, multicenter study to compare the safety and efficacy of teriparatide of Enzene biosciences Ltd. Versus forteo ® of Eili lilly in the treatment of postmenopausal osteoporosis"*** sponsored by M/s Hetero Drugs Ltd. submitted by Dr. R. N. Srivastava. Professor Department of Orthopedic Surgery of this University via letter No. nil dated 09-06-17. **EC Comment:** • Kindly provide all documents related to the patients. **EC Decision:** Approval after justification ***Ref. code: 86th ECM IIC/P1*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P. Lucknow

K.G's Medical University U.P., Lucknow

100th "Institutional Ethics Committee" Meeting held on 25th January, 2020

Item no. IV

Modification

K.G's Medical University U.P., Lucknow

IV-A	Modification
1-	Modification of Research proposal entitled ***" A study on association of exposure to particulate matter and susceptibility to cardiovascular diseases in North Indian population"*** sponsored by CSIR-IITR, Lucknow submitted by Prof. S.K. Dwivedi, Department of Cardiology this University via letter no.671/Cardio/Res/19 dated 14th November, 2019. **EC Decision:** Approved ***Ref.code:97th ECM IIA/P18*** ***(Primary Reviewer: Dr. Amita Jain)***
2.	Modification of Research proposal entitled ***"Effectiveness of mirror therapy to improve upper extremity motor function and activity of daily living in stroke patients at Department of Neurology KGMU Lucknow"*** submitted by Ms. Vandana Dwivedi, through Mrs. Subin S, Assistant Professor, KGMU Institute of Nursing this University via letter no. nil dated 23rd November, 2019. **EC Decision:** Approved ***Ref.code:97th ECM IID/P14*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
3.	Modification of Research proposal entitled ***"Prospective interventional study of neoadjuvent temozolomide inpatients of inoperable supratentorial malignant gliomas"*** submitted by Dr. Suresh Kumar Jaiswal, SR-I, Department of Neurosurgery of this University via letter no. nil dated 10th March, 2019. **EC Comment on 12th July, 2019:** • The objective is to analyze the improvement in patients of supra-tentorial glioma in terms of resectability, morbidity and mortality after neo-adjuvant chemotherapy with temozolomide • Sample size not provided • Data recording sheet not provided. We do not know what will be observed and when • How much drug will be given? When will it be given? What effects will be observed, when and how? • What side effects of this drug will be observed? • You will be comparing your results with which group of patients? Will you have a control group of patients who will not be receiving neo adjuvant

Chairperson, IEC
King George's Medical University
U.P., Lucknow

chemotherapy?

EC Decision on 12th July, 2019: Re-submit

The above comment send to P.I., reply has given by P.I. which was forwarded to the Previous reviewer r reply has given by reviewer with following comment:-

Comment:

- Sample size does not depend on patient availability alone. You have to sit with a statistician and discuss your study plan. He/she will ask you what a doable number of patients is and then curtail the number of variables you can chase in this study. This is a good exercise in planning research and this should be done.
- Since the comparison will be with patients receiving RT alone include them in your study. Now take the number of both the set of patients - your ones and the RT ones to the statistician and ask him to help you to plan your study.
- You have the scope of planning a good study as there will surely be enough patients, but if you end up chasing too many variables your results may not be statistically significant.

Action Taken: The above comment sent to the P.I.

Reply has not provided by the Principal-Investigator.

EC Decision: Pending

Now, Dr. Jaiswal has changed his title in the research proposal entitled "Traumatic cervical spine injury: A prospective study".

EC Decision: Approved

Ref. code: 97th ECM II B-Thesis/P19

(Primary Reviewer: Dr. Surajit Bhattacharya)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

100th "Institutional Ethics Committee" Meeting held on 25th January, 2020

Item no. IVB

Additional

K.G's Medical University U.P., Lucknow

IVB	Additional Documents
1-	Additional document of research protocol no. entitled ***"Effects of exogenous melatonin on inflammatory protein (S100B) of delirium and its clinical correlation-a case control study"*** submitted by Dr. Mithun Biswas, SR-I, Department of G.M.H. of this University via letter no. 561/DGMH dated 20th November, 2019. **EC Comment:** • modification sought in addition of co-guides, addition of study settings for enrolment of patients from Medical emergency and trauma center, IPD and ICU of cardiology department in addition to previous settings, simple randomization in place of block randomization and modifying age of inclusion criteria from 60 – 75 years to > 60 years **EC Decision:** Approved ***Ref. code: 96th ECM IIB Thesis/ P43*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University

K.G's Medical University U.P., Lucknow

100th "Institutional Ethics Committee" Meeting held on 25th January, 2020

Item no. V

Annual Progress Reports

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 100th ECM held on 25th January, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

V-	Annual Progress Reports
1.	Annual Progress Report of research protocol no. entitled ***"Retrospective descriptive cross-sectional study of epidemiological and clinical features in cutaneous tuberculosis at tertiary care centre in North India"*** submitted by Dr. Parul Verma, Associate Professor, Department of Vnereology and Leprosy of this University via letter no. 189/Sian/19. Dated 13th November, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 86th ECM II A/P18*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Annual Progress Report of research protocol no. entitled ***"Cross sectional prospective study on quality of life in patients with cutaneous dermatophyte infection"*** submitted by Dr. Parul Verma, Associate Professor, Department of Venereology and Leprosy of this University via letter no. 190/Sian/19. Dated 13th November, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 90th ECM II A/P21*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
3.	Annual Progress Report of research protocol entitled ***"National heart failure registry"*** submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 672/Cardio/Res/19. Dated 14th November, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 90th ECM II A/P25*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
4.	Annual Progress Report of research protocol Bio Mime Branch-1 entitled ***"A prospective, active control, open- label, multi- centre, randomized clinical trial comparing BioMime Branch- sirolimus eluting coronary side branch stent system vs. exigence family of everolimus eluting coronary stent system to evaluate safety and performance in patients with de novo coronary bifurcation lesions"*** sponsored by M/s Meril life Sciences Private Ltd. submitted by Dr. Sharad Chandra, Department of Cardiology of this University via letter no. 670/Cardio/Res/19. Dated 14th November, 2019. **EC Comment:** • Please provide reasons for no enrollment of participants **EC Decision:** Approval after justification ***Ref. code: 90th ECM II C/P7*** ***(Primary Reviewer: Dr. Preeti Agarwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

5.	Annual Progress Report of research protocol no. ACT-OCT India entitled ***"A prospective, multi-centric study to investigate the plaque characteristics and natural Historyof lesions in the non-culprit vessels in young Indian patients (<45 yrs) with ACS undergoing PCI by Optical Coherence Tomography (OCT) imaging"*** sponsored by Dr. Batra Hospital & Medical Research Centre, New Delhi submitted by Dr. Rishi Sethi, Department of Cardiology of this University via letter no. 673/Cardio/Res/19. Dated 14th November, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 90th ECM II C/P8*** ***(Primary Reviewer: Dr. Rajeev Garg)***
6.	Annual Progress Report of research protocol no.VCL-HYDRA-01/2014 entitled ***"GENESIS: A clinical evaluation of the HYDRA self expanding transcatheter aortic valve"*** submitted by Dr. Sharad Chandra, Department of Cardiology of this University via letter no. 675/Cardio/Res/19. Dated 14th November, 2019. **EC Comment:** • No patient enrolled. **EC Decision:** Reviewed & Noted ***Ref. code: 79th ECM II C/P9*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
7.	Annual Progress Report of research protocol no. entitled ***" Strengthening laboratory surveillance for pneumococcal meningitis in Indian to understand the impact of pneumococcal conjugate vaccine (PVC) rollout"*** sponsored by Bill & Melinda Gates foundation, Seattle, Washington United states through ICMR, New Delhi submitted by Prof. Amita Jain, Head, Department of Microbiology of this University via letter no. nil. dated nil. **EC Decision:** Reviewed & Noted ***Dr. Amita Jain did not take part in discussion.*** ***Ref. code: 92th ECMIB/P1*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
8.	Annual Progress Report of research protocol no. entitled ***" Nasal changes in different age groups"*** submitted by Dr. Dipti Shastri, Associate Professor, Department of Orthodontics and Dentofacial Orthopaedics, Faculty of Dental Sciences of this University via letter no. nil. Dated nil. **EC Decision:** Reviewed & Noted ***Ref. code: 92th ECMIIA/P14***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. A.A. Sonkar)
9.	Annual Progress Report of research protocol no. entitled ***"B-cell activating factor (BAFF) and osteoprotegerin (OPG) gene expression in dental health status of beta-thalassemia patient "*** submitted by Dr. Dipti Shastri, Associate Professor, Department of Orthodontics and Dentofacial Orthopaedics, Faculty of Dental Sciences of this University via letter no. nil. Dated nil. **EC Decision:** Reviewed & Noted ***Ref. code: 92th ECMIIA/P9*** ***(Primary Reviewer: Dr. Amita Jain)***
10.	Annual Progress Report of research protocol no. ALN-AT3SC-003, entitled ***"Atlas-INH: A phase 3 study to evaluate the efficacy and safety of fitusiran in patients with hemophilia A or B, with inhibitory antibodies to factor VIII or IX"*** sponsored by M/s Bajaj Allianz Generali Insurance Co Ltd. submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology of this University via letter no. nil. Dated 15th November, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 90th ECMIIC/P1*** ***(Primary Reviewer: Dr. Rajendra Nath)***
11.	Annual Progress Report of research protocol no. ALN-AT3SC-004 entitled "***ATLAS-A/B: "A phase 3 study to evaluate the efficacy and safety of fitusiran in patients with hemophilia A or B, without inhibitory antibodies to factor VIII or IX"*** sponsored by M/s Bajaj Allianz General Insurance Co Ltd. Ltd. submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology of this University via letter no. nil. Dated 15th November, 2019 **EC Decision:** Reviewed & Noted ***Ref. code: 90th ECMIIC/P2*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
12.	Annual Progress Report of research proposal entitled ***"Study on child Abuse/Neglect and to Assess Malnutrition to School age children"*** submitted by Prof. Shalini Gupta, Department of Oral Pathology and Microbiology, Faculty of Dental Sciences of this University via letter no. nil. Dated 7th November, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 90th ECMIIA/P14*** ***(Primary Reviewer: Dr. Rajeev Garg)***
13.	Annual Progress Report of research protocol no.**GS-US-419-3895** entitled ***"Combined Phase 3, double-blind, randomized, placebo-controlled studies evaluating the efficacy and safety of filgotinib in the Induction and maintenance of remission in subjects with***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	moderately to severely active Crohn's disease" sponsored by M/s Klinera corporation submitted by Dr. Ajay Kumar, Associate Professor, Department of Medicine of this University via letter no. nil. Dated 18th November, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 89th ECM IIC/P14-a*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
14.	Annual Progress Report of research protocol no. RLS/OST/2016/05 entitled ***"Prospective, multi- center, randomized, double- blind, two- arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of r-TPR-045/Prolia ® in post- menopausal women with osteoporosis"*** sponsored by M/s Reliance Life Sciences Pvt. Ltd submitted by Dr. Deepak Kumar, Principal Investigator, Department of Orthopedic Surgery of this University via letter no. nil. Dated 20th November, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 89th ECM IIC/P12*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
15.	Annual Progress Report of research protocol no. entitled ***"Systematic pulmonary tubetculosis case finding among severely malnourished children admitted to Nutritional Rehabilitation Centers"*** sponsored by Foundation Merieux submitted by Dr. Sarika Gupta, Associate Professor, Department of Pediatrics of this University via letter 1807/Ped/19 nil. Dated 21st November, 2019. **EC Comment:** • Reports seems incomplete, there is mention of only two patients **EC Decision:** Approval after justification ***Ref. code: 91stECM IIA/P8*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
16.	Annual Progress Report of research protocol no. entitled ***"PCR restriction enzyme analysis for diagnosis of candidemia: comparison with automated methods, antigen detection, biochemical methods and virulence factors estimation"*** sponsored by Department of Science and Technology New Delhi submitted by Prof. Gopa Banerjee, Department of Microbiology of this University via letter no. nil. Dated 25th November, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 91stECM IIA/P1*** ***(Primary Reviewer: Dr. Amita Jain)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

17.	Annual Progress Report of research protocol no. entitled ***"Analysis of CCN3 proteins as diagnostic/ prognostic markers and their correlation with primary osteosarcoma patients treatment response"*** sponsored by ICMR New Delhi submitted by Dr. Dilutpal Sharma, Associate Professor, Department of Biochemistry of this University via letter no. nil. Dated 26th November, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 91st ECM IIA/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
18.	Annual Progress Report of research protocol entitled ***"Edentulism and its correlation to sociodemographic profile: A hospital based study in North India"*** submitted by Prof. Pooran Chand, Head, Department of Prosthodontics, Faculty of Dental Sciences of this University via letter no. nil. dated 19th November, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 90th ECM IIA/P6*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

100th "Institutional Ethics Committee" Meeting held on 25th January, 2020

Item no. VI

Any Other Matter

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 100th ECM held on 25th January, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

VI-	**Any Other Matters *(With the Permission of Chairman)***
1-	Due to quorum was not complete of the EC Meeting was held on 10th May, 2019 & after that the EC registration has expired on June, 2019, since then, this modification is pending under the research protocol no. CLCZ696D2302 entitled ***"A 24 – week, randomized double-blind, multi-center, parallel group, active controlled study to evaluate the effect of LCZ696 on NT-proBNP, symptoms, exercise function and safety compared to individualized medical management of comorbidities in patients with heart failure and preserved ejection fraction"*** sponsored by M/s Novartis submitted by Dr. Rishi Sethi, Professor, Department of Cardiology of this University via letter no. 259/Cardio/Res/2019 dated 7th March, 2019 & 657/Cardi/Res/19 dated 23rd October, 2019. **EC Decision:** Approval after fulfillment & Administrative formalities ***Ref. code: 86th ECM IIC/P7***
2-	Due to quorum was not complete of the EC Meeting was held on 10th May, 2019 & after that the EC registration has expired on June, 2019, since then, this Clinical Study Agreement is pending under the research protocol no. C3601002 entitled ***"A Phase 3 Prospective, Randomized, Multicenter, Open Label, Central Assessor Blinded, Parallel Group, Comparative Study To Determine The Efficacy, Safety And Tolerability of Aztreonam Avibactam (ATM AVI) ± Metronidazole (MTZ) Versus Meropenem ± Colistin (MER ± COL) For the Treatment of Serious Infections Due to Gram – Negative Bacteria, Including Metallo B Lactamase (MBL) – Producing Multidrug Resistant Pathogens, For Which There Are Limited Or No Treatment Options"*** M/s Parexel submitted by Dr. Sandeep Tiwari, Department of Trauma Surgery of this University via letter no. nil dated 11th June, 2019. **EC Decision:** Approval after fulfillment & Administrative formalities ***Ref. code: 89th ECM IIC/P9***
3-	Requesting permission to add the Co-Investigator, Prof. Shally Awasthi, Incharge, Asthma Clinic in the project entitled ***"Pediatric asthma presentations and risk factors in India"*** sponsored by Cipla Foundation submitted by Dr. Sarika Gupta, Assistant Professor, Department of Pediatrics of this University via letter no. 1627/Ped/19 dated 23rd October, 2019. **EC Decision:** Approved ***Ref. code: 97th ECM II A/P2***
4-	Requesting permission to change the Guide in the present Dr. Satyendra Kumar Singh in place of Dr. Madhukar Mittal, Ex-Head, Department of Medical Endocrine under the

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	research proposal entitled ***"The mechanisms involved in the action of Furostanolic saponins (Furocyst) in regulating ovarian function in the dehydroepiandrosterone (DHEA) induced polycystic ovary of mouse and its clinical outcomes"*** submitted by Ms. Aparna Shukla, Ph.D. Scholar of this University via letter no. nil dated 29th November, 2019. **EC Decision:** Permission granted ***Ref. code: 95th ECM II B-Ph.D./ P1***
5-	Requesting permission to change the Guide in the present time Mr. Subin S. in place of Mrs. Kumari Nutan Research proposal entitled ***"Effectiveness of mirror therapy to improve upper extremity motor function and activity of daily living in stroke patients at Department of Neurology KGMU Lucknow"*** submitted by Ms. Vandana Dwivedi, M.Sc. Nursing 2nd Year, KGMU College of Nursing via letter no. nil dated 19th October, 2019. **EC Decision:** Permission granted ***Ref. code: Ref. code: 97th ECM IID /P14***
6-	Requesting permission to change the research proposal entitled ***"A study on promoter methylation for gene signature with response to taxane- platinum, and antimetabolites- platinum combination-based chemotherapy in lung cancer"*** sponsored by Indian Council of Medical Research, New Delhi submitted by Prof. Rajiv Garg, Department of Respiratory Medicine of this University via letter no. Bio/2019/92 dated 30th January, 2019. **EC Decision on 10th May, 2019:** Permission granted ***Dr. Rajeev Garg did not take part in the discussion*** **EC Decision:** Permission granted ***Ref. code: 96th ECM II A/P11***
7-	Requesting permission to extend the research proposal which was already approved in the IEC Meeting was held on 7th April, 2017 entitled ***"A study on evaluating the role of HSP27 diagnostic and prognostic biomarker in oral potentially malignant disorder and oral squamous cell carcinoma"*** because it is still in the process of submission submitted by Dr. Priyanka Singh, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences of this University. **EC Decision:** Permission granted ***Ref. code: 84th ECM II B-IMR-F/P1***
8-	As per recommendation of NIRRH IEC, to provide the compensation to study participants (Controls) for the DBT Wellcome trust study entitled ***"Clinical phenotypes***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	and genetic regulation of endometriosis in Indian women". The compensation amount is decided by the IECs of the respective study sites and amount varies from center to center (minimum 200 Rs. to maximum 500 Rs.) In view of this, As requested by the Dr. Vinita Das to kindly communicate with IEC of KGMU to decide the compensation amount for controls. The amount will be paid to study participants (controls) from the contingency grant provided to KGMU, Lucknow via letter no. 74/HRRC-Lko/2019-20 dated 16th January, 2020. **EC Decision:** Approved
9-	Requesting permission to change the Guide Dr. Jamal Masood, Department of Community Medicine in place of Dr. D. Himanshu, Additional Officer, Department of Medicine entitled ***"Orientation of Medical Students in India towards lifeling"*** submitted by Mr. Ahmad Ozair and Ms. Arjumand Faruqi, MBBS student via letter no. nil dated 21st January, 2020. **EC Decision:** Permission granted ***Ref. code: 96th ECM II B MBBS/P2***
10-	Requesting permission to add the following guides in the research proposal which was already approved in the IEC Meeting was held on 6th September, 2019 entitled ***"Correlation of urinary iodine concentration and tear film breakup time with clinical, epidemiological, biochemical, radiological and pathological parameters in patients with goiter"*** submitted by Mr. Sagar Rai, MBBS 2017 Batch under the guidance Dr. Pooja Ramakant, Associate Professor, Department of Endocrine Surgery of this University via letter no. nil dated 10th December, 2019. ***New Co- guides are following:*** ***1- Dr. Wahid Ali, Department of Pathology of this University.*** ***2- Dr. Chanchal Rana, Department of Pathology of this University*** ***3- Dr. Lonew E Enny, Senior Resident, Department of Endocrine Surgery of this University.*** ***4- Dr. Surabhi Garg, Senior Resident, Department of Endocrine Surgery of this University.*** **EC Decision:** Approved ***Ref. code: 96th ECM IIB MBBS/P5***
11-	Requesting permission to change the Principal-Investigator Dr. Shrikant Srivastava, Head, Department of G.M.H. of this University in place of Dr. Nimitha K J, SR-I of the research proposal which was already approved in the IEC Meeting was held on 10th May, 2019 entitled ***"Study of optical coherence tomography and quantitative electroencephalography in late life depression with and without out significant cognitive deficits"*** submitted by Dr. Nimitha K J, SR-I, Department of G.M.H. of this

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	University via letter no. 525/DGMH dated 2nd November, 2019. **EC Decision:** Approved ***Ref. code: 96th ECM IIB Thesis/P32***
12-	As per opinion of the Doctoral Committee to change the title of research proposal entitled ***"Molecular association of subject with metabolic syndrome and effect evaluation of flaxseed powder supplemetaion on certain biocheica parameters"*** in place of ***"Dose optimization of flaxseed powder and oil in subjects with metabolic syndrome"*** submitted by Dr. Rahul Kumar Yadav, Ph.D 2017 under the guidance of Prof. Narsingh Verma Department of Physiology of this University via letter no. nil dated nil & this office letter no. 24/Ethics/2020 dated 23rd January, 2020. **EC Decision:** Permission granted ***Ref. code: 96th ECM IIB Thesis/P32***
14-	Due to quorum was not complete of the EC Meeting was held on 10th May, 2019 & after that the EC registration has expired on June, 2019, since then, this additional is pending under the research protocol no. KCP-330-023 entitled ***"BOSTON- A phase 3 randomized, controlled, open-label study of selinexor, bortezomib and dexamethasone (SVD) versus borterzomib and dexamethasone (Vd) in patients with relaplsed or refractory multiple myeloma (RRMM)"*** sponsored by M/s Excel Life Sciences Pvt. Ltd. submitted by Dr. Shailendra Prasad Verma, Associate Professor, Department of Clinical Hematology of this University via letter no.43/CH/19 dated 15th January, 2019. **EC Decision:** Approved ***Ref. code: 87th ECM IIC/ P4***

Next Meeting date 6th March, 2020

Thanks

Chairperson, IEC
King George's Medical University
U.P. Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 101st Institutional Ethics Committee Meeting held on 9th May, 2020.

K.G's Medical University U.P., Lucknow

Note: The 101st ***"Institutional Ethics Committee"*** meeting which was to be held on 6th March 2020 was held on different dates due to lockdown related to COVID-19.

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 101st Institutional Ethics Committee Meeting held on 9th May, 2020.

Item no. IA

Action taken

K.G's Medical University U.P., Lucknow

Note: The 101st ***"Institutional Ethics Committee"*** meeting which was to be held on 6th March 2020 was held on different dates due to lockdown related to COVID-19.

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 101st ECM held on 9th May, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Minutes of the Institutional Ethics Committee Meeting was held on **9th May, 2020 from 02.00 p.m. till p.m.** in the **'Board Room',** Office of the Vice Chancellor, Administrative Block of this University.

The following members were present in the Meeting

1- **Prof.S.P. S Gaur** -**Chairman**

2- **Justice Hon'ble Vishnu Sahai** - **Member**

3- **Dr. Surajit Bhattacharya** -**Member**

4- **Dr. Manju Agrawal** -**Member**

5- **Mr. Yogesh Mishra** -**Member**

6- **Prof. Rajeev Garg** -**Member**

7- **Prof. R. K. Garg** -**Member-Secretary, Ex-officio**

IA	Action Taken on decisions of previous Ethics Committee Meeting
	Part (a) 97th ECM was held on 12th July, 2019
a1-	Clarification of research proposal entitled ***"Retrospective and prospective outcome of duplex- ultrasound guided percutaneous ethanol sclerotherapy of endometrioma"*** submitted by Dr. Nitish Singh, JR-II, Department of Radiodiagnosis of this University via letter no. nil dated 24th April, 2019. **EC Comment on 12th July, 2019:** • Signature missing of Principal-Investigator in Hindi & English Inform consent Form. • Both ICF are not similar, it should be according to SOP. • The term retrospective may be removed from the topic of the study as the methods section and flow-chart provided does not reflect upon any criteria for retrospective chart review. It is also advisable for the PI to keep the study prospective as any intervention study should be. • The outcome measures are not clearly mentioned. • Is duplex-ultrasound guided percutaneous sclerotherapy of endometrioma not a standard of care? If yes, then the outcome of such procedures would be known already. If no, then the justification of not choosing the standard of care has to be given. • Will all consecutive patients be treated with the above said method? If yes, then the patient information document should clearly discuss all possible methods of treatment of ovarian endometrioma including the standard of care treatment and why the PI

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P. Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	wishes to offer sclerotherpay to the patient. • Will there be any control arm? • The complications of the procedure and risk in participating in the study have to be discussed in detail in the patient information document. • Who will bear the cost of the procedure? • Please discuss the compensation in detail in the PID. **EC Decision on 12th July, 2019:** Approval after justification ***The aboe comment forwarded to the P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P66*** ***(Primary Reviewer: Dr.Vimal Kumar Paliwal)***
a2	Clarification of research proposal entitled ***"Comparison of endotracheal tube with supraglottic airway device during laparoscopic surgery and its effects on level of inflammatory biomarker"*** submitted by Dr. Prince Kumar, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 14th May, 2019. **EC Comment on 12th July, 2019:** • The study aims to compare the use of supra-glottic airway device and endotracheal tube in terms of ease of insertion, peri-operative complications, peak airway pressure, haemodynamic parameters (HR, SBP, DBP, MAP) and changes in levels of inflammatory blocker IL-6 • This is a RCT so please provide consort guidelines • Sample size is 60. Was this derived after consulting a statistician? • Please explain your exclusion criteria. Why are obese patients excluded? Why are difficult intubation excluded? They should be included and termed as failures otherwise your study group becomes biased. If the patient has been deemed fit for laparoscopy then why are you excluding him/her from your study just because they are difficult cases? **EC Decision on 12th July, 2019:** Approval after justification ***The aboe comment forwarded to the P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.***

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P. Lucknow

Chairperson IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 97th ECM II B-Thesis/P77*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
a3	Clarification of research proposal entitled ***"To study the effects of oral gabapentin for post operative analgesia in patient undergoing abdominal surgery under general anaesthesia: A randomized control trial"*** submitted by Dr. Anoop Kumar Singh, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 22nd May, 2019. **EC Comment on 12th July, 2019:** • It is a RCT, needs CTRI registration and also needs submission on the basis of CONSORT guidelines **EC Decision on 12th July, 2019:** Approval after justification ***The aboe comment forwarded to the P.I. which was reviewed by Dr. R.K. Garg, Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P87*** ***(Primary Reviewer: Dr. Rajeev Garg)***
a4	Clarification of research proposal entitled ***"To assess the efficacy of oral care protocol in prevention of ventilator- associated pneumonia in patients on invasive mechanical ventilation: A randomized controlled trial"*** submitted by Dr. Pallika Singh, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 23rd May, 2019. **EC Comment on 12th July, 2019:** • Kindly provide case record form. • Sample size is calculated to be 60. Does it include the number of cases in both the groups? • CONSORT guidelines have to be followed. **EC Decision on 12th July, 2019:** Revise & Re-submit ***The aboe comment forwarded to the P.I., responcegiven by the P.I. which was reviewed by the reviewer with following comments:-*** • ***This is a randomized control trial the calculated sample sizes 215. There is no justification to include only 60 cases against 215. There are no detaisls provided for control for final comments I will tike to see revised full proposal.*** ***The above comment forwarded to P.I. response given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University
U.P. Lucknow

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	ActionTaken: Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P90*** ***(Primary Reviewer: Dr. Amita Jain)***
a5	Clarification of research proposal entitled ***"Study to evaluate the treatment outcomes of bile duct injury"*** submitted by Dr. Ravi Patel, SR-I, Department of Surgical Gastroenterology of this University via letter no. nil dated 31st May, 2019. **EC Comment on 12th July, 2019:** • The aim of this study is to assess the demographic and clinic-pathological profile of patients with bile duct injury, their various treatment modalities and their respective outcomes in terms of liver functions, number of interventions and total hospital stay. • It is a prospective and retrospective study • A data collection Performa is attached which is very elaborate. • Sample size is missing. Please sit with a statistician and discuss your study plan which has far too many variables and come to a sample size which will make your results statistically significant. **EC Decision on 12th July, 2019:** Re-submit ***The aboe comment forwarded to the P.I. which was forwarded to Primary Reviewer, response received from reviewer & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P102*** ***(Primary Reviewer:Dr. Surajit Bhattacharya)***
a6	Clarification of research proposal entitled ***"Effect of pancreatic steatosis on postoperative outcomes and pancreatic fistula rates after pancreaticoduodenectomy"*** submitted by Dr. Mahesh R, SR-I, Department of Surgical Gastroenterology of this University via letter no. nil dated 1st June, 2019. **EC Comment on 12th July, 2019:** • The objective is to determine if fatty pancreas is a risk factor for pancreatic fistula after pancreato-duodenectomy and whether it correlates with other pancreatic histology parameters • Sample size is 60. Is it statistically derived? • Material & Method is elaborately described • The structure of data collection sheet is presented • Data analysis has no value without a statistically derived sample size

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P. Lucknow

Chairperson, IEC
George's Medical University

	EC Decision on 12th July, 2019: Approval after justification ***The aboe comment forwarded to the P.I. which was forwarded to Primary Reviewer, response received from reviewer with following comment:-*** • ***I think the researchers have not understood our point about sample size. It does not matter whether the samplesize is small or big, if their results are not statistically significant then they will find it difficult to publish their data in good journals. They have to take their study plan to a statistician and hr/she will be able to tell them show many variables they can chase with their available sample size in order to get statistically significant results.*** **ActionTaken:** The above comment again forwarded to the P.I. response pending by P.I. **EC Decision:** Defer in next meeting ***Ref. code: 97th ECM II B-Thesis/P104*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
a7	Clarification of research proposal entitled ***"Comparision of 18-F NaF bone scan fusion image and high resolution CT to predict recurrence of temporamandibular joint ankylosis"*** sponsored by ICMR, New Delhi submitted by Dr. Tasveer Fatima under the guidance of Prof. Shadab Mohammad, Head, Department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences this University via letter no. OMSD/371/19 dated 22nd May, 2019. **EC Comment on 12th July, 2019:** • This proposal is for 3 years period with aim for Ph.D. thesis • Sample size calculation is needed. • Methodology is sketchy is not clear • Case record form is not attached **EC Decision on 12th July, 2019:** Re-write & Re-submit ***The aboe comment forwarded to the P.I. which was forwarded to Primary Reviewer, response received from reviewer & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Ph.D./P2*** ***(Primary Reviewer: Dr. Amita Jain)***
	Part (b) 98th ECM was held on 6th September, 2019

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P. Lucknow

Chairperson, IEC
King George's Medical University
U.P. Lucknow

b1	Clarification of research proposal entitled ***"A descriptive study to assess the knowledge and attitude of patients undergoing hemodialysis regarding their dietary management at KGMU, Lucknow with the view to develop an information booklet"*** submitted by Ms. Premsheela Rai/Ms.Priyanka Chaudhary/Ms.Priyanka Verma/Ms.Praveena Singh Deepankar/Ms.Preeti Jaiswar/Mr.Pankaj Jha/Mr. Prabhat Singh under the guidance of Mr.s Roohi Elizabeth Peter KGMU College of Nursing of this University via letter no.nil dated 16th April, 2019. **EC Comment on 6th September, 2019:** • Kindly submit the Methodology. • How to assess the knowledge and attitude of patiens. **EC Decision on 6th September, 2019:** Approval after justification ***The above comment forwarded to P.I. response given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 98th ECM IIDa/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
	Part (c) 100th ECM was held on 25th January, 2020
c1	Clarification of research proposal entitled ***"Serum vitamin D level estimation and its association with vitamin D receptor (Cdx-2, Apa1 & Taq1) and toll like receptor 2& 8 genetic variants as risk factor for female genital tuberculosis (FGTB) in Northern Indian population"*** sponsored by UP-CST submitted by Prof. S.P. Jaiswar, Department of Obstetrics & Gynecology of this University via letter no. nil dated 25th November, 2019. **EC Comment on 25th January, 2020:** • Consent form should be provided in newly approved format **EC Decision on 25th January, 2020:** Approval after justification ***Dr. Amita Jain did not take part in the discussion.*** ***The above comment forwarded to P.I. response given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 100th ECM II A/P8***

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University
U.P., Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Rajiv Garg)
c2	Clarification of research proposal entitled ***"Volumetric analysis of prefrontal cortex and magnetic resonance spectroscopy in late life psychosis"*** submitted by Dr. Nimitha K.J., SR-I, Department of G.M.H. of this University via letter no. nil dated 9th December, 2019. **EC Comment on 25th January, 2020:** • Kindly provide the consent forms as new format **EC Decision on 25th January, 2020:** Approval after justification ***The above comment forwarded to P.I. response given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 100th ECM II B-Thesis/P8*** ***(Primary Reviewer: Dr. Amita Jain)***

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P. Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 101st Institutional Ethics Committee Meeting held on 9th May, 2020.

Item no. IB

Expedited Review

K.G's Medical University U.P., Lucknow

Note: The 101st ***"Institutional Ethics Committee"*** meeting which was to be held on 6th March 2020 was held on different dates due to lockdown related to COVID-19.

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 101st ECM held on 9th May, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Expedited Review

I	Expedited Review
1-	Research proposal entitled ***"Perspectives of medical undergraduate students in a government medical university in north India during the period of national lockdown to combat COVID-19"*** submitted by Dr. Suyog Sindhu, Assistant Professor, Deptt. of Pharmacology of this University. **Action Taken:** The above proposal forwarded to Prof. Rajendra Nath, Deptt. of Pharmacology of this University: The Primary reviewer has been given his reply & **Approved.** **Further Action taken:** Provisionally approved. **Ethics Committee Decision:** Approved ***Ref.Code: 101st ECM IB/P1***
2-	Research proposal entitled ***"Assessment of mental health concerns during COVID-19 pendemic in general population: an online study"*** submitted by Mrs. Sudha Mishra, Assistant Professor, KGMU College of Nursing of this University. **Action Taken:** The above proposal forwarded to Prof. Rajendra Nat, PR, Deptt. of Pharmacology & Prof. Rajeev Garg, Deptt. of Respiratory Medicine both are this University: The Primary reviewer has been given his reply & **Approved.** **Further Action taken:** Provisionally approved **Ethics Committee Decision:** Approved ***Ref.Code: 101st ECM IB/P2***
3-	Research proposal entitled ***"Epidemiology, clinical features and predictors of short-term outcome in COVID-19 critically ill patients in a tertiary care center of North India"*** submitted by Prof. Avinash Agarwal, Deptt. of Critical Care

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University
U.P. Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Medicine of this University. **Action Taken:** Provisionally approved **Ethics Committee Decision:** Approved ***Ref.Code: 101st ECM IB/P3***
4-	Research proposal entitled ***"Short term ICU training and its usefulness in increasing surge capacity during COVID-19 oNDEMIC:A SINGLE CENTRE EXPERIENCE"*** submitted by Dr. Suhail Sarwar Siddiqui, Assistant Professor, Deptt. of Critical Care Medicine of this University. **Action Taken:** The above proposal forwarded to Dr. Surajit Bhattacharya & Dr. Preeti Agarwl, PR, Deptt. of Pathology of this University: Dr. Bhattacharya has been given his reply & **Approved.** **Further Action taken:** Provisionally approved. **Ethics Committee Decision:** Approved ***Ref.Code: 101st ECM IB/P4***
5-	Research proposal entitled ***"Epidemiology,viral shedding,clinical and genetic characterization of SARC-Cov2 and other respiratory viruses from North India"*** submitted by Prof. Amita Jain, Head, Deptt. of Microbiology of this University. **Action Taken:** The above proposal forwarded to Dr. Surajit Bhattacharya, Primary Reviewer. Dr. Bhattacharya has been given his reply with various comment: **Further Action Taken:** Provisionally approved. **Ethics Committee Decision:** Approved ***Ref.Code: 101st ECM IB/P5***
6-	Research proposal entitled ***"A Web based Questionnaire study exploring the working scenario of Doctors during COVID-19 Pandemic in India"*** submitted by

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P. Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Dr. Suyog Sindhu, Assistant Professor, Deptt. of Pharmacology of this University. **Action Taken:** The above proposal forwarded to Prof. Rajendra Nath, Depatt. of Pharmacology of this University. Dr. Nath has been given his reply & **approved.** **Further Action taken:** Provisionally approved **Ethics Committee Decision:** Approved ***Ref.Code: 101st ECM IB/P6***
7-	Research proposal entitled ***"The impact of COVID-19 pandemic led lockdown on the lifestyle of adolescents and young adults"*** submitted by Prof. Sunita Tiwari, Head, Department of Physiology of this University. **Action Taken:** The above proposal forwarded to Dr. Vimal Kumar Paliwal & Dr. Rajeev Garg. **Further Action taken:** Provisionally approved **Ethics Committee Decision:** Approved ***Ref.Code: 101st ECM IB/P7***
8-	Research proposal entitled ***"A multicenter, phase III, double-blind, randomized, placebo controlled study to evaluate the efficacy of Recombinant BCG VPM1002 in reducing infection incidence and disease severity of SARS-COV-2/COVID-19 among high-risk subject"*** submitted by Dr. D. Himanshu, Associate Professor, Department of Medicine of this University. **Action Taken:** The above proposal forwarded to Dr. Rajendra Nath **Ethics Committee Decision:** Approved ***Ref.Code: 101st ECM IB/P8***
9-	Research proposal entitled ***"The effect of COVID 19 pandemic led lockdown on the sleep quality of general population"*** submitted by Dr. Shweta Kanchan, MD

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	PhD Scholar under the guidance of Prof. Sunita Tiwari, Head, Deptt. of Physiology of this University. **Action Taken:** The above proposal forwarded to Dr. Anoop Kumar Verma & Dr. Preeti Agarwal **Further Action taken:** Provisionally approved **Ethics Committee Decision:** Approved ***Ref.Code: 101st ECM IB/P9***
10-	Research proposal entitled ***"Psycho-social well-being during and after State Lockdown due to COVID 19:an online survey"*** submitted by Dr. Nisha Mani Pandey, Associate Professor (Non Medico), Deptt. of G.M.H.of this University. **Action Taken:** The above proposal forwarded to Dr. Anoop Kumar Verma & Dr. Rajeev Agarwal **Further Action taken:** Provisionally approved **Ethics Committee Decision:** Approved ***Ref.Code: 101st ECM IB/P10***
11-	Research proposal entitled ***"Global COVID-19 pandemic crisis and India's response protocol to facilitate services delivery and promote health security:A snapshot of governance during the lockdown"*** submitted by Dr. Smriti Agarwal, Additional Professor, Deptt. of Obst. & Gynaecology of this University. **Action Taken:** The above proposal forwarded to Dr. Vimal Kumar Paliwal & Dr. Preeti Agarwal ***Dr. Paliwal has given his reply with following comments:*** 1-It is important to know that the interviewer does not have a preconceived idea/view of the Govt policy of devising/implementing health-care policy during the time of COVID-related lock-down.

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P., Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	2-The down-side of snowball sampling is that it tends to accumulate bias because one study subject recruits the future study subject. Therefore, a subsequent interviewee may be a friend of the previous interviewee and may have the same opinion. This is important in today's times when people praise or criticize Govt. policies not on the merit of policies but only out of their affiliations to political parties or religion or caste etc. 3-To get away with both the issues, in my view, the PI should define which departments and "who" in those departments will be interviewed. "Who" means at least the "cadre of the interviewee" may be revealed in SOP to the Ethics Committee. A well structured interview questions will also help in reducing the bias of the interviewer and the interviewee. The questionnaire may be provided to the Ethics committee. **Action taken:** The above comment forwarded to P.I. reply pending. **Ethics Committee Decision:** Approved ***Ref.Code: 101st ECM IB/P11***
12-	Research proposal entitled ***"A Phase II, Open label,randomized controlled trial to assess the safety and efficacy of convalescent plasma to limit COVID-19 associated complications in moderate disease"*** submitted by Dr. D. Himanshu, Associate Professor, Deptt. of Medicine of this University sponsored by ICMR, New Delhi. **Action Taken:** The above proposal forwarded to all EC Members **Dr. S.P.S. Gaur, Chairman, IEC has send his reply with following comments:** **Comment:** The consent to be included in the trial should be accorded by the participating patient and only in case of his inability to do so should a family member been titled to give consent for the patient's inclusion in the trial. There is ambiguity in this matter in the ICF document, the issue needs to be clarified before final approval to the research proposal. **Also, Dr. Rajendra Nath has given his reply with following comments:**

Recorded

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University
U.P., Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• DCGI approval, Insurance, CTRI-Pending ***The above comment send to P.I. reply has given by P.I.*** **Ethics Committee Decision:** Approved ***(Medical Insurance for enrolled subjects will be provided by ICMR, New Delhi)*** ***Ref.Code: 101st ECM IB/P11***

Thanks

The next meeting will be held on 16th May, 2020

Note: The 101st ***"Institutional Ethics Committee"*** meeting which was to be held on 6th March 2020 was held on different dates due to lockdown related to COVID-19.

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University
U.P., Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 101st Institutional Ethics Committee Meeting held on 16th May, 2020.

K.G's Medical University U.P., Lucknow

Note:

- The 101st ***"Institutional Ethics Committee"*** meeting which was to be held on 6th March 2020 was held on different dates due to lockdown related to COVID-19.
- Item no. IB-1 & II A5 are wrongly repeated.

K.G's Medical University U.P., Lucknow

101st "Institutional Ethics Committee" Meeting held on 16th May, 2020

Item no. IA

Action Taken

K.G's Medical University U.P., Lucknow

Note: The meeting which was to be held on 6/3/2020 is due to lock down on several dates.

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Minutes of the 101st **"Institutional Ethics Committee"** Meeting held on 16th May, 2020 **(Saturday) from 12.00 noon on wards** in the **'Board Room',** Office of the Vice Chancellor, Administrative Block of this University.

The following members were present in the Meeting

1- **Prof. S.P. S Gaur** **-Chairman**

2- **Justice Hon'ble Vishnu Sahai** **- Member**

3- **Dr. Surajit Bhattacharya** **-Member**

4- **Dr. Manju Agrawal** **-Member**

5- **Mr. Yogesh Mishra** **-Member**

6- **Prof. Rajeev Garg** **-Member**

7- **Prof. R. K. Garg** **-Member-Secretary, Ex-officio**

IA	Action taken
1	Clarification of research proposal entitled ***"Effect of pancreatic steatosis on postoperative outcomes and pancreatic fistula rates after pancreaticoduodenectomy"*** submitted by Dr. Mahesh R, SR-I, Department of Surgical Gastroenterology of this University via letter no. nil dated 1st June, 2019. **EC Comment on 12th July, 2019:** • The objective is to determine if fatty pancreas is a risk factor for pancreatic fistula after pancreato-duodenectomy and whether it correlates with other pancreatic histology parameters • Sample size is 60. Is it statistically derived? • Material & Method is elaborately described • The structure of data collection sheet is presented • Data analysis has no value without a statistically derived sample size **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to the Principal-Investigator, reply has given by PI which was reviewed by the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally approved

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P., Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 97th ECM II B-Thesis/P104*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
2	Clarification of research proposal entitled ***"Comparative evaluation of different play therapies for assessing anxiety levels in pediatric dental patients"*** submitted by Dr. Pallavi Yadav, JR-I, Department of Paediatric and Preventive Dentistry Faculty of Dental Sciences of this University via letter no. nil dated nil. **EC Comment on 12th July, 2019:** • The study procedure is not clear. How these 4 groups (listed in heading procedure) will be treated? • What data will be collected? • How it will be analysed • There is lot of ambiguity • Please provide clarification cannot be approved in this form **EC Decision on 12th July, 2019:** Re-write & Re-submit ***The above comment forwarded to the Principal-Investigator, reply has given by PI which was forwarded to the reviewer, reply has given by reviewer & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P131*** ***(Primary Reviewer: Dr. Amita Jain)***
3-	Clarification of research proposal entitled ***"Comparison of the efficacy of a 7-day versus a 14-day course of intravenous antibiotics in the treatment of uncomplicated neonatal bacterial sepsis: a randomized controlled non-inferiority trial"*** sponsored by Indian Council of Medical Research New Delhi submitted by Prof. Mala Kumar, Department of Pediatrics of this University via letter no. nil dated 24th February, 2020. **EC Comment 25th January, 2020:** • It is not clear from the project when randomization would be starting? • Kindly submit as per CONSORT guidelines **EC Decision 25th January, 2020:** Approval after justification ***The above comment forwarded to the Principal-Investigator, reply has given by PI which was forwarded to the reviewer, reply has given by reviewer & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 100th ECM II A/P6*** ***(Primary Reviewer: Dr. A.A. Sonkar)***

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P., Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

4-	Clarification of research proposal entitled ***"A study on correlation of Age, gender & body mass index with hematological parameters"*** submitted by Dr. Priyanka Singh, Associate Professor, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences of this University via letter no. nil dated 6th December, 2019. **EC Comment 25th January, 2020:** • No study proforma given only guidelines for patient information sheet. • No sample calculation provided • Vague study how will they remove confounding factors **EC Decision 25th January, 2020:** Re-submit ***The above comment forwarded to the Principal-Investigator, reply has given by PI which was forwarded to the reviewer, reply has given by reviewer & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 100th ECM II A/P12*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
5-	Clarification of Annual Progress Report of research protocol no. entitled ***"Systematic pulmonary tubetculosis case finding among severely malnourished children admitted to Nutritional Rehabilitation Centers"*** sponsored by Foundation Merieux submitted by Dr. Sarika Gupta, Associate Professor, Department of Pediatrics of this University via letter no. 1807/Ped/19 nil. Dated 21st November, 2019. **EC Comment 25th January, 2020:** • Reports seems incomplete, there is mention of only two patients **EC Decision 25th January, 2020:** Approval after justification ***The above comment forwarded to the Principal-Investigator, reply has given by PI which was reviewed by the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Reviewed ***Ref. code: 91st ECM IIA/P8*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
6-	Clarification of research proposal entitled ***"The effect of trimetazidine on left ventricular mechanics in chronic stable angina patients"*** submitted by Dr. Varun Sharma, SR-II, Department of Cardiology of this University. **EC Comment 25th January, 2020:**

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University
U.P. Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• In chronic angina Trimetazidine increases work capacity and delays appearance of symptoms and ECG changes during exercise. This study aims to evaluate whether this drug, administered as an adjunct to conventional optimal medical treatment in patients of stable angina led to improvement of LV mechanics • LV mechanics includes LVEF, LV global longitudinal strain and radial strain. This will be compared 1, 3 and 6 months after Trimetazidine therapy. • Inclusion and exclusion criteria are satisfactory • Sample size 40 – statistically derived • A study design flow chart and a data collection sheet has been provided • But what are they going to compare their results with? There is no control group which is getting only conventional medical therapy and no Trimetazidine. • Study of design is inappropriate. • RCT would be an appropriate design • Kindly provide as new format **EC Decision 25th January, 2020:** Resubmit ***The above comment forwarded to the Principal-Investigator, reply has given by PI which was forwarded to the reviewer, reply has given by reviewer & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref.Code: 100th ECM II B-Thesis/P4*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
7-	Clarification of research proposal entitled ***"A clinic-immunological study of Guillain-barre syndrome with special reference to Host TNF- a, CD 14 and CD 1E genetic polymorphism"*** submitted by Dr. Rajarshi Chakraborty, SR-I, Department of Neurology of this University via letter no. nil dated 19th November, 2019. **EC Comment 25th January, 2020:** • Consent form is blank **EC Decision 25th January, 2020:** Approval after justification ***Prof. Amita Jain & R. K. Garg did not take part in the discussion.*** **EC Decision:** Approved ***Ref. code: 100th ECM II B-Thesis/P9***

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University
U.P. Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Rajiv Garg)
8-	Clarification of research proposal entitled ***"Assessment of antigenic targets in membranous nephropathy"*** submitted by Dr. Medhavi Gautam, P.I., Department of Medicine of this University via letter no. nil dated 15th May, 2020. **EC Comment 25th January, 2020:** • Project should be submitted by one of the authors from KGMU **EC Decision 25th January, 2020:** Approval after justification ***The above comment sent to PI, reply has given by the PI which was approved by the Member-Secretary, IEC & approved.*** **EC Decision:** Approved ***Ref. code: 100th ECM II A/P4*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
9	Clarification of research proposal entitled ***"Effect of early application of speech and language therapy to hearing impaired child in reducing parental stress and habilitation of child"*** submitted by Dr. Rina Kumari PhD Scholar through Prof. Sunita Tiwari, Head, Department of Physiology of this University via letter dated 29-06-16. **EC Comment on 19th August, 2016:** • Kindly provide the Patient Information sheet in detail. **EC Decision on 19th August ,2016:** Approval after modification ***The above comment forwarded to P.I. reply has given by P.I. which was approved by the Member-Secretary, IEC .*** **ActionTaken:** Provisionally approved ***Ref. code: 80th ECM II B-Ph.D./P1*** ***(Primary Reviewer : Dr. S.P.S. Gaur)***

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

101st "Institutional Ethics Committee" Meeting held on 16th May, 2020

Item no. IB

Expedited Review

K.G's Medical University U.P., Lucknow

Note: The meeting which was to be held on 6/3/2020 is due to lock down on several dates.

IB	Expedited Review
1-	Expedited review of research proposal entitled ***"Analogue of prothrombin time: identification and assay development of novel non-invasive and surrogate indicator of blood coagulopathy"*** submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter dated 17th March, 2020. ***The above proposal was approved by the Member-Secretary, IEC.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM IB /P1***
IB	**Expedited Review (COVID-19)**
1-	Expedited review of research proposal entitled ***"Clinical profile of SARS-CoV-2 infected patients admitted to a tertiary care centre of Northern India"*** submitted by Dr. Saurabh Pandey, SR, Department of Medicine of this University via letter no. nil dated nil. ***The above proposal forwarded to Dr. Vimal Kumar Paliwal & Dr. Smriti Bhadauria, reply has given by Dr. Paliwal & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IInd ECM COVID-19 IB/P1***
2-	Expedited review of research proposal entitled ***"The extent of authentic information vs rumors prevailing in general population during COVID-19 pandemic"*** submitted by Prof. Sunita Tiwari, Head, Department of Physiology of this University via letter no. nil dated nil. ***The above proposal forwarded to Dr. Rajendra Nath & Dr. Rajeev Garg, reply has given by both reviewers with following comment:*** **Comment of Dr. Nath:-** 1- Sample size calculation not done 2- How PI will take consent online on sent proforma of informed consent form? **Comment of Dr. Rajeev Garg:-** -The only issue is with regard to exclusion criteria where respondents having co morbidity have been excluded. Also the sample size calculation is also not given in detail only number of patient who will be enrolled is given. ***The above comment forwarded to the P.I. reply has given by PI which was reviewed by the Member-Secretary, IEC & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	Ref. code: IInd ECM COVID-19 IB/P2
3-	Expedited review of research proposal entitled ***"Outcomes of elective surgery during COVID-19 pandemic crisis: an international, multicentre, observational cohort study (CovidSurg-Cancer)"*** submitted by Dr. Shiv Rajan, Assistant Professor, Department of Surgical Oncology of this University via letter no. nil dated 5th May, 2020. ***The above proposal forwarded to Dr. Amita Jain & Dr. Preeti Agarwal reply has given by Dr. Jain which was approved by the Member-Secretary, IEC.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IInd ECM COVID-19IB /P3***
4-	Expedited review of research proposal entitled ***"A pilot study of olfactory status in COVID-19 infection"*** submitted by Prof. Anupam Mishra, Head, Department of ENT of this University via letter no. nil dated 5th May, 2020. ***The above proposal forwarded to Dr. Anoop Kumar Verma & Dr. Preeti Agarwal reply has given by Dr. Verma with following comment:-*** ***As per the guidelines approved in the meeting of the committee constituted to promote research activities for Covid-19 dated 21st April, 2020, point no.2 says- "PI/Co-PI must have been posted in isolation ward or triage" the PI or Co-PI did not mention their involvement in above said areas, As per study design, the interview will be carried by telephonic conversation, it would not be appropriate.*** ***The above comment forwarded to P.I. reply has given by PIwhich was reviewed by the reviewer & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IInd ECM COVID-19 IB/P4***
5-	Expedited review of research proposal entitled ***"Knowledge, attitude and practice (KAP) study to evaluate behavior, coping including quality of life of individuals among different sects of society in COVID-19 pandemic"*** submitted by Dr. Rhythm, Professor Jr. Grade, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences of this University via letter no. nil dated 25th April, 2020. ***The above proposal forwarded to Dr. Anoop Kumar Verma & Dr. Vimal Kumar Paliwal reply has given by Dr. Paliwal with following comment:-*** ***Comment:*** ***Kindly submit Hindi Informed Consent Form, Signature of PI is missing on consent form filled by PI in English language.*** ***The above comment forwarded to the P.I., reply has given by PI which was reviewed by the Member-Secretary, IEC & approved.***

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University

Chairperson IEC
King George's Medical University
U.P., Lucknow

	Action Taken: Provisionally approved **EC Decision:** Approved ***Ref. code: IInd ECM COVID-19 IB/P5***
6-	Expedited review of research proposal entitled ***"What do Dental graduates and postgraduates need to know about COVID-19? A multi-Institutional cohort study in Lucknow city"*** submitted by Dr. Pragya Pandey, Assistant Professor, Department of Conservative Dentistry and Endodontics of this University via letter no. 31/2020 dated 28th April, 2020. ***The above proposal forwarded to Dr. Anoop Kumar Verma & Dr. Rajeev Garg reply has given by Dr. Verma with following comment:-*** **-Kindly change the titled where the word cohort is used which gives us the impression that there would like to observe something but there is no such aim or objective of the proponent as it is just a questionnaire based observational study to know the knowledge about SARS nCV among the dental UGs and PGs.** **The above comment forwarded to PI reply has given by P.I. which was approved by the Member-Secretary, IEC.** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IInd ECM COVID-19 IB/P6***
7-	Expedited review of research proposal entitled ***"A study of psychological and behavioural mental health aspects of COVID-19 pandemic"*** submitted by Prof. P.K. Dalal, Head, Department of Psychiatry of this University via letter no. 2502/Psy dated 14th May, 2020. ***The above proposal forwarded to Prof. Amita Jain & Dr. Preeti Agarwal.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IInd ECM COVID-19 IB/P7***
8-	Expedited review of research proposal entitled ***"Chest X-ray image analysis for diagnosis of COVID-19 patients using computer vision and artificial interlligence"*** submitted by Prof. Anit Parihar, Department of Radiodiagnosis of this University via letter no. nil dated 13th May, 2020. ***The above proposal forwarded to Prof. Anoop Kumar Verma & Dr. Preeti Agarwal.*** ***Reply have given both reviewers & approved.*** **EC Decision:** Approved ***Ref. code: IInd ECM COVID-19 IB/P8***

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P., Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

101st "Institutional Ethics Committee" Meeting held on 16th May, 2020

Item no. IIA

New Proposals

K.G's Medical University U.P., Lucknow

Note: The meeting which was to be held on 6/3/2020 is due to lock down on several dates.

II-A	New Proposal
1.	Research proposal entitled ***"Identifying behavioral and psychological symptom clusters of dementia: A multi centric exploratory study"*** sponsored by IPS Secretariat (Indian Psychiatric Society) submitted by Prof. Shrikant Srivastava, Head, Department of Geriatric Mental Health of this University via letter no. 591/DGMH dated 6th December, 2019. **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"Cerebrospinal fluid based therapeutic target identification for JE virus vaccine development"*** sponsored by ICMR New delhi submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine of this University via letter no. MIC/20/39 dated 5th February, 2020. **EC Comment:** • Procedure details are not provided • How the diagnosis of JE will be made? I do not see any are from dxtic lab in the investigator's list • 27.2% prevalence of JE, which is used for sample size calculation, is 10 yrs old date. New rate is ,10% • Consent forms not as per new format. **EC Decision:** Revise & Resubmit ***Ref. code: 101st ECM IIA/P2*** ***(Primary Reviewer: Dr. Amita Jain)***
3.	Research proposal entitled ***"Treatment adherence and spacer compliance in patients with asthma and COPD"*** submitted by Prof. Suryakant, Head, Department of Respiratory Medicine of this University via letter no. nil dated 26th December, 2019. **EC Comment:** • Budget requirement has not been discussed • Questionnaire and case report form not submitted **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P3*** ***(Primary Reviewer: Dr. RajendraNath)***
5.	Research proposal entitled ***"Analogue of prothrombin time: identification and assay development of novel non-invasive and surrogate indicator of blood***

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	coagulopathy" sponsored by ICMR New Delhi submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. CFAR/2020/03 dated 6th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P5*** ***(Primary Reviewer: Dr. Rajeev Garg)***
6.	Research proposal entitled ***"Prostate cancer: probing of comprehensive (cellular and systemic) metabolomics- based biomarker as a surrogate of the histopathology- based gleason score grading"*** sponsored by ICMR New Delhi submitted by Dr. Manoj Kumar, Associate Professor, Department of Urology of this University via letter no. nil dated 6thJanuary, 2020. **EC Comment:** • This study is to explore for surrogate biomarkers for the histo-pathological Gleason's Score of CA Prostate. • Three cohorts will be studied – healthy cohort, B.H.P and CA. Prostate • Study material comprises of clinical information, serum samples and histological specimens from BHP, CA Prostate and adjacent normal tissue • They will study the qualitative and quantitative differences of metabolomics of serum samples and cellular samples in these 3 cohorts. • An attempt will be made to generate comprehensive biomarkers from serum and cellular metabolomics and compare the same with Gleason's score • Sample size is missing • Methodology – what exactly will be done is missing. We know the material but what is the method? • Data collection sheet is missing • No background data or previous published literature provided • Is it ICMR funded? No evidence provided. **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P6*** ***(Primary Reviewer: Dr. Surajit Bhattachrya)***
7.	Research proposal entitled ***"Diagnostic and epidemiological study of brucellosis in northern India and to construct a clinical prediction rule"*** sponsored by ICMR New Delhi submitted by Prof. Raj Kumar Kalyan, Department of Microbiology of this University via letter no. nil dated 7th January, 2020. **EC Comment:** • Objectives are not clear **EC Decision:** Approval after justification

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 101st ECM IIA/P7 ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
10.	Research proposal entitled **"*Effectiveness of intravenous ferric CARBOXY maltose (FCM) in improving hemoglobin levels among pregnant women with moderate to severe anemia- A multi-site study*"** sponsored by UPNHM submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynaecology of this University via letter no. 2803/19 dated 27th December, 2019. **EC Comment:** • Study is funded by UPNHM. • Ethical clearance given by AIIMS which is a coordinating center. • FCM is approved by the DCGI. • There seems to be no provision of insurance of patients. • The patient's case sheet is not attached. **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P10*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
11.	Research proposal entitled **"*Etiology of acute meningoencephalitis in Children less than 5 years of age in North India*"** sponsored by Health Research, New Delhi submitted by Prof. Amita Jain, Head, Department of Microbiology of this University via letter no. 1681/19 dated 28th December, 2019. **EC Comment:** • Budget requirement has not been discussed. **EC Decision:** Approval after justification ***Dr. Amita Jain did not take part in the discussion.*** ***Ref. code: 101st ECM IIA/P11*** ***(Primary Reviewer: Dr. Rajendra Nath)***
12.	Research proposal entitled **"*Volumetric analysis of mastoid air cells in different malocclusions in 3D CBCT*"** submitted by Dr. Akhilanand Chaurasia, Assistant Professor, Department of Oral Medicine and Radiology of this University via letter no. nil dated 16th January, 2020. **EC Comment:** • Consent form is not as per new format • Study plan is not clear • Sample size calculation is also not clear (not at all) inclusion & exclusion criteria are copied & pasted, as such favour some where (in past tense) • Budget & financial support is not mentioned • Cannot be approved in current form

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Re-submit ***Ref. code: 101st ECM IIA/P12*** ***(Primary Reviewer: Dr. Amita Jain)***
13.	Research proposal entitled ***"The morphometric analysis of mandibular condyle and coronoid process in different malocclusion in 3D CBCT"*** submitted by Dr. Akhilanand Chaurasia, Assistant Professor, Department of Oral Medicine and Radiology of this University via letter no. nil dated 16th January, 2020. **EC Comment:** • The study aims to evaluate the volume of mandibular condyle and coronoid process and correlate it with age, sec and skeletal deformities using 3D CBCT • Guidelines for patient information sheet is attached without making any attempt to construct a study specific patient information sheet • Sample size 152, statistically calculated. • Data collection sheet is missing. What exactly will be observed – what dimensions, what volumes? • Will the patient also be physically examined? A big and tall man will have a bigger condyle as compared to a small and short woman! In Coronoid process significant appositional bone growth secondary to abnormal stresses mediated by the tendon of the temporalis muscle does occur so the patients have to be examined and a data collection **EC Decision:** Re-submit ***Ref. code: 101st ECM IIA/P13*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
14.	Research proposal entitled ***"Role of pharmacogenetics in the treatment of type 2 diabetes in Indian population"*** submitted by Prof. Kauser Usman, Department of Medicine of this University via letter no. 172/MED/2020 dated 21st January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P14*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
18.	Research proposal entitled ***"Expression of circular- RNAs in women with gestational diabetes mellitus (GDM)"*** submitted by Prof. Renu Singh, Department of Obstetrics & Gynaecology of this University via letter no. OG/285/2020 dated 27th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P18*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University

Chairperson, IEC
King George's Medical University

19.	Research proposal entitled **"*Study of light pollution ALAN (Artificial light At Night) as a zeitgeber in ECOS (epigenetics, circadian gene expression, oxidative stress and sleep quality) in patients of metabolic syndrome*"** sponsored by Indian Council of Medical Research New Delhi submitted by Prof. Narsingh Verma, Department of Physiology of this University via letter no. nil dated 24th January, 2020. **EC Comment:** • Pt information sheet missing • Study design and methodology not clearly discussed • Sample size not calculated **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P19*** ***(Primary Reviewer: Dr. Rajendra Nath)***
20.	Research proposal entitled **"*Prevalence of germline EGFR T790M mutation in India: A nationwide cross sectional survey of newly diagnosed non-small cell lung carcinoma patients*"** sponsored by Indian Council of Medical Research New Delhi submitted by Prof. Divya Mehrotra, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences of this University via letter no. OMSD/RP/800/19 dated 20th December, 2019. **EC Comment:** • Consent forms are not as per new format, this study is a multicentre study under MRV at KGMU. Prof. Divya is a Dental Surgeon & is In-charge of this Unit. • This proposal is on lung cancer through she has included one person each from Respiratory Medicine & Pathology, is it ethical to have PI from Dentistry? **EC Decision:** Revise ***Ref. code: 101st ECM IIA/P20*** ***(Primary Reviewer: Dr. Amita Jain)***
21.	Research proposal entitled **"*Effect of intracanal cryotherapy on post-operative pain following irrigation with negative pressure and passive sonic irrigation system: A prospective randomized clinical trial*"** submitted by Prof. Anil Chandra, Department of Conservative Dentistry and Endodontics Faculty of Dental Sciences of this University via letter no. nil dated 30th January, 2020. **EC Comment:** • Kindly condition of CTRI number as the study methodology does not have any issues. **EC Decision:** Approval after justification

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 101st ECM IIA/P21 ***(Primary Reviewer: Dr. Rajeev Garg)***
22.	Research proposal entitled ***"Assessment of knowledge, attitudes and perceptions towards contraceptive use and counselling during post-partum period among medical students and paramedical staff"*** submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynaecology of this University via letter no. 283/2020 dated 27th January, 2020. **EC Comment:** • What will be the contribution of the co-investigator, an MBBS student from a different city? • Material comprises of 150 medical students and 20 para-medical staff posted in OBG, KGMU • Consent waiver is requested but how can you interview someone without their consent? People studying or working in the department are even more vulnerable so consent is a must. • How was the sample size derived? • A structured bi-lingual questionnaire is attached. **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P22*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
23.	Research proposal entitled ***"A study on association of diabetes mellitus, Hypertension and Hyperthyroidism with their blood parameters"*** submitted by Dr. Priyanka Singh, Associate Professor, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences of this University via letter no. 823/OP/2020 dated 29th January, 2020. **EC Comment:** • Study designed did not mentioned • Objectives did not match with the material method. **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P23*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
26.	Research proposal entitled ***"Identifying behavioural and psychological symptom clusters of dementia: A multi-centric exploratory study"*** submitted by Dr. Adarsh Tripathi, Additional Professor, Department of Psychiatry of this University via letter no. 1980/Psy dated 28th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P26***

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University
U.P. Lucknow

Chairperson, IEC
King George's Medical University

	(Primary Reviewer: Dr. Preeti Agarwal)
27.	Research proposal entitled **"*Role of acetone, acetate and glutamine metabolites in regulation of bone mineral density in post menopausal osteoporosis: A prospective case-control study*"** submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 09/P/OS/2020 dated 10th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P27*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
28.	Research proposal entitled **"*To elucidate the role of WWOX (WW domain-containing oxidoreductase) gene in osteosarcoma: A prospective case control study*"** sponsored by ICMR, New Delhi submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 14/P/OS/2020 dated 14th January, 2020. **EC Comment:** • Pt. information sheet missing **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P28*** ***(Primary Reviewer: Dr. Rajendra Nath)***
29.	Research proposal entitled **"*Simultaneously targeting of RUNX2/Hippo signaling pathway for enhancing the anti-cancer effect of standard chemotherapeutic drugs in osteosarcoma*"** sponsored by ICMR, New Delhi submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 8/P/OS/2020 dated 10th January, 2020. **EC Comment:** • Consent form is as per old format. New format is required • Study Design says "Case-Control" • Who will be cases & who will be cohort? • Provide Consent form for controls as well if they are normal healthy individuals (Ethically cannot be as open accessional biopsy needed) • There are lot of lacunae in work plan **EC Decision:** Re-submit ***Ref. code: 101st ECM IIA/P29*** ***(Primary Reviewer: Dr. Amita Jain)***
30.	Research proposal entitled **"*Elucidate the role of microRNA122-5p, miRNA93-5p, miRNA21 and miRNA 140 as a common biomarker for osteoarthritis knee and osteoporosis: A case-control study*"** sponsored by ICMR, New Delhi

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University
U.P., Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 10/P/OS/2020 dated 10h January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P30*** ***(Primary Reviewer: Rajeev Garg)***
31.	Research proposal entitled ***"Role of taurine, vitamin C, and vitamin E in neurological recovery of acute spinal cord injury: A prospective case-control study"*** submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 11/P/OS/2020 dated 10h January, 2020. **EC Comment:** • Taurine has a role in axonal regeneration and high dose Vitamin C and E improve neurotrophic state and reduce contents of NSE and S100B which signal neurologic recovery. • 3 ml blood and urine samples will be collected and followed up at 6 weeks, 3 months and 6 months. • Sample size is 54. Statistically calculated • One group will receive Vit. C 4000 mg x BD for 6 months, the second will get an additional Taurine 1 gm x TDS for six months and a third group will get Vitamin E 1000 IU x BD for 6 months • Why is a 4th group comprising all three Taurine, Vitamin c and E not there? • Clinical assessment by ASCI score, ASIA Impairment scale and QOL score • Study sequence clearly stated. • Data collection sheet missing. **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P31*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
32.	Research proposal entitled ***"Identification of candidate miRAs as a potential diagnostic and prognostic markers in body fluid of patients with chronic kidney disease: a longitudinal study"*** sponsored by ICMR, New Delhi submitted by Prof. Satyendra Kumar Sonkar, Department of Medicine of this University via letter no. 362/MED/2020 dated 8th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P32*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
33.	Research proposal entitled ***"Effectiveness of USG-guided obturator nerve block among children with spastic cerebral palsy- A prospective study"*** submitted by

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University
U.P., Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Prof. A.K. Gupta, Head, Department of Physical Medicine and Rehabilitation of this University via letter no. 2770/2020 dated 10th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P33*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
36.	Research proposal entitled ***"A follow up study of cognitive performance among adult survivors of hanging"*** submitted by Dr. S.K. Kar, Associate Professor, Department of Psychiatry of this University via letter no. 2073/Psy dated 8th February, 2020. **EC Comment:** • Duration of study is not mentioned. • No Indian studies on such subjects were reviewed. **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P36*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
37.	Research proposal entitled ***"Role of taurine, supplementation in neurological recovery of acute spinal cord injury (ASCI) subjects: A prospective case- control study"*** submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 969/OS/2019 dated 16th December, 2019. **EC Comment:** • Patient information sheet missing **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P37*** ***(Primary Reviewer: Dr. Rajendra Nath)***
38.	Research proposal entitled ***"The clinical presentation, management & outcomes among patients with chronic obstructive pulmonary disease patients-the COPD registry (INCOR) study"*** sponsored by SRM MCH & RC, Kattankulathur submitted by Dr. Ajay Kumar Verma, Department of Respiratory Medicine of this University via letter no. 146/2019 dated 10th February, 2020. **EC Comment:** • The Multicentric study is a case registry. • The sponsorer & the budget is not disclosed (ticked on private Consent form is on old format). **EC Decision:** Revise ***Ref. code: 101st ECM IIA/P38*** ***(Primary Reviewer: Dr. Amita Jain)***

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University

Chairperson, IEC
King George's Medical University
U.P., Lucknow

39.	Research proposal entitled ***"Soy, Horsetail, and fig nutraceuticals as an alternative for estrogen replacement therapy in post-menopausal osteoporosis"*** sponsored by ICMR New Delhi submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 12/P/OS/2020 dated 13th January, 2020. **EC Comment:** • This is ICMR, sponsored trial involving nutraeuticals of natural origin. If it comes in perview of ICMR then Clinical trial registry number needed. **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P39*** ***(Primary Reviewer: Dr.Rajeev Garg)***
40.	Research proposal entitled ***"Endoscopic colpopexy for grade 3 and 4 urerine proposae and vaginal vault prolapse"*** submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology of this University via letter no. SG 85 dated 10th January, 2020. **EC Comment:** • In this study an endoscopic technique is being offered to patients of Grade 3 and 4 Uterine and vaginal vault prolapse which promises decrease hospital stay and faster relief without an abdominal incision. • Per vaginally the anterior vaginal wall will be tacked to the anterior abdominal wall by a sub-mucosal approach along the anterior vaginal wall. The sub-mucosal tunnel will be closed by metal clips endoscopically. • So this is not a R.C.T and nothing to do with rectal prolapsed as the research proposal title suggests • Sample size is 10, with no statistical backing. So is it a pilot study? • What will be observed? A data collection sheet is required. • When the anterior wall of the vagina is tacked to the anterior abdominal wall, without having a camera in the abdominal cavity, as there are no abdominal incisions, how can we ensure the safety of the bowels and the urinary bladder? **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P40*** ***(Primary Reviewer: Dr.Surajit Bhattacharya)***
42.	Research proposal entitled ***"Assess the barriers for implementing nursing theory-based practices in the clinical among nursing students"*** submitted by Dr. Suchana Roy Bhomik, Assistant Professor, KGMU College of Nursing of this University via letter no. 117/PF dated 7th February, 2020. **EC Comment:**

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University

Chairperson IEC
King George's Medical University
U.P. Lucknow

	• Poorly written • What theory? • Which circumstance or clinical setting? **EC Decision:** Re-write ***Ref. code: 101st ECM IIA/P42*** ***(Primary Reviewer: Dr. A.A. Sonkar)***

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University

Chairperson, IEC
King George's Medical University
Lucknow

K.G's Medical University U.P., Lucknow

101st "Institutional Ethics Committee" Meeting held on 16th May, 2020

Item no. III

Other Matter

K.G's Medical University U.P., Lucknow

Note: The meeting which was to be held on 6/3/2020 is due to lock down on several dates.

III	Other Matter
1-	Reg. A work plan is designed by the Safety of Patient/Attendant/Research Staff and doctors for the purpose of COVID 19 pandemic on the site of the Department of Endocrine Surgery by Prof. Anand Kumar Mishra, Head, Department of Endocrine Surgery of this University under the research protocol entitled ***"A phase III, randomized, multicenter, double-blind study to compare efficacy and safety of EG12014 (EirGenix Trastuzumab) with Herceptin® as Neoadjuvant treatment in combination with Anthracycline/Paclitaxel-based systemic therapy in patients with HER2-positive early Breast Cancer"*** which was approved by sponsor. **EC Decision:** Approved ***Ref. code: 92nd ECM IIC/P3***
2-	Reg. The sponsor M/s AstraZeneca has requested to help patients make travel arrangements to visit the site for all important study visits so long as your hospital is functional during this lock down beginning from 25th March to 16th April, 2020 under the research protocol entitled Protocol no. D169AC00001 entitled ***"A study to evaluate the effect of dapagliflozin on renal on outcomes and cardiovascular mortality"*** Dr. S.K. Sonkar, P.I. of the trial, Department of Medicine via dated 1st May, 2020. **EC Decision:** Approved ***Ref. code: 84th ECM IIC/P7***
3-	Reg. a mitigation plan shared with IEC considering the follow-up visit and resupply of Riveroxaban during lock down due to COVID-19 pandemic under the research protocol INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc Prof. Rishi Sethi, P.I. of the trial, Department of Cardiology of this University via letter no. 888/Cardio/Res/2020 dated 5th May, 2020. **EC Decision:** Approved ***Ref. code: 83rd ECM IIC/P6***

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P., Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

IV	Corrigendum
1	**This proposal was to be kept in the meeting of 9th May 2020, who missed by mistake so this is being held in the meeting of 16th May, 2020:-** Expedited review of research proposal entitled ***"The psychological impact of COVID-19 pandemic in general population in general population"*** submitted by Prof. Sunita Tiwari, Head, Department of Physiology of this University via letter no. nil dated nil. ***The above proposal forwarded to Dr. Preeti Agarwal & Dr. Anoop Kumar Verma, reply has given by Dr. Verma with following comment:-*** • Methodology is not clear • Target group of participants are not mentioned • Does not fall under the guidelines approved by the Committee (point no. 2) ***The above comment forwarded to the P.I. reply has given by P.I. which was reviewed by the Member-Secretary, IEC with his approval.*** **Action taken:** Approved. ***Ref. Code: IInd ECM COVID-19 IB/P8***

Thanks

Next Meeting will be held on 23rd May, 2020

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 23rd May, 2020

K.G's Medical University U.P., Lucknow

Note: Due to COVID-19 pandemic, the meeting of 6th March, 2020 various different dates took place.

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 23rd May, 2020

Minutes Item no. IA
Expedited review (COVID-19)

K.G's Medical University U.P., Lucknow

Note: Due to COVID-19 pandemic, the meeting of 6th March, 2020 various different dates took place.

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Minutes of the 101st **"Institutional Ethics Committee"** Meeting held on 23rd May, 2020 **(Saturday) from 01.00 p.m. on wards** in the **'Board Room',** Office of the Vice Chancellor, Administrative Block of this University.

The following members were present in the Meeting

1-	**Prof. S.P. S Gaur**	**-Chairman**
2-	**Justice Hon'ble Vishnu Sahai**	**- Member**
3-	**Dr. Surajit Bhattacharya**	**-Member**
4-	**Dr. Manju Agrawal**	**-Member**
5-	**Dr. Vimal Kumar Paliwal**	**-Member**
6-	**Prof. R. K. Garg**	**-Member-Secretary, Ex-officio**

IA	**Expedited Review (COVID-19)**
1-	Expedited review of research proposal entitled ***"Interpretation of indenterminate results in real time PCR for SARS CoV-2"*** submitted by Dr. Parul Jain, Assistant Professor, Department of Microbiology of this University via letter no. nil dated nil. ***The above proposal forwarded to Dr. Preeti Agarwal & Dr. Rajeev Agarwal, reply has given by both reviewers & approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IIIrd ECM COVID-19 IB/P1***
2-	Expedited review of research proposal entitled ***"Phase 2, Randomized, Double-blind, Placebo-Controlled trial of Efficacy, Safety and Tolerability of Hesperidin as an adjunct therapy in non-severe COVID-19 patients"*** submitted by Prof. Hardeep Singh Malhotra, Department of Neurology of this University via letter no. nil dated nil. ***The above proposal forwarded to Dr. Surajit Bhattacharya & Dr. Vimal Kumar Paliwal, reply has given by Dr. Bhattacharya with following opinion:-*** **Opinion:-** • Is there no insurance policy covering this study? **Action Taken:** The above opinion forwarded to the Principal-Investigator ***Reply has given by the P.I. which was reviewed in the EC Meeting & Approved.*** **EC Decision:** Provisionally approved subject to insurance for enrolled subjects.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: IIIrd ECM COVID-19 IB/P2
3-	Expedited review of research proposal entitled ***"A study to assess suicidal behavior and religious attribution to cope during COVID-19 pandemic:A Community survey"*** submitted by Mrs. Sudha Mishra, Assistant Professor, KGMU College of Nursing of this University via letter no.622 dated 18th May, 2020. ***The above proposal forwarded to Dr. A.A. Sonkar & Dr. Vimal Kumar Paliwal, reply has given by Dr. Sonkar with following opinion:-*** **Opinion:-** • Why the PI wants to exclude covid positive patients? Can PI use a self made questionnaire? Altogether new questionnaire? **Action Taken:** The above opinion forwarded to the Principal-Investigator ***Reply has given by P.I which was approved by the Member-Secretary.*** **Further Action Taken:** Provisionally approved. **EC Decision:** Approved
	Ref. code: IIIrd ECM COVID-19 IB/P3
4-	Expedited re*-view of research proposal entitled ***"Impact of COVID-19 on quality of life among health care professional of selected hospital in U.P."*** submitted by Mr. Rohitash Kumar, Assistant Professor, KGMU College of Nursing of this University via letter no.627 dated 18th May, 2020. ***The above proposal forwarded to Dr. A.A. Sonkar & Dr. Vimal Kumar Paliwal, reply has given by Dr. Paliwal & approved.*** **Further Action Taken:** Provisionally approved. **EC Decision:** Approved
	Ref. code: IIIrd ECM COVID-19 IB/P4
5-	Expedited review of research proposal entitled ***"Knowledge, Attitude and Practice (KAP) study to evaluate behavior, coping including quality of life of individuals among different sects of society in COVID-19 pandemic"*** submitted by Dr. Sumit Kumar, Research Scientist II, DHR-MRU through Dr. Pooja Mahour, Associate Professor cum child Psychologist, Department of Psychiatry of this University via letter no. nil dated nil ***The above proposal forwarded to Dr. Vimal Kumar Paliwal, reply has given by Dr. Sonkar with following opinion:-*** • The questionnaire needs to be more detailed and must be discussed either with clinical psychologist or a psychiatrist who must be included as co-investigator. • The sample size is too low for any inference. It needs to be revised. The impact of the present disease is widespread and hence larger study population will only provide any valuable output. • The exclusion criteria says that mentally challenges individual with psychiatric ailment will be excluded but study questionnaire does not include any point by

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	which the investigator will infer participant is mentally challenged and which is not. ***The above comment forwarded to P.I., reply has given by P.I. which was reviewed by the Member-Secretary & approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IIIrd ECM COVID-19 IB/P5***
6-	Expedited review of research proposal entitled ***"COVID-19 awareness, concerns and challenges faced by surgical residents-A questionnaire based survey"*** submitted by Prof. Arshad Ahmad, Department of Surgery (Gen.) of this University via letter no. nil dated nil. ***The above proposal forwarded to Dr. Vimal Kumar Paliwal Dr. & Preeti Agarwal, reply has given by Dr. Preeti with following comment:-*** • The authors must use Google forms format/ or online base questionnaire format instead of paper form for the study. ***Reply has given by P.I. which was reviewed by the Member-Secretary, IEC & Approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IIIrd ECM COVID-19 IB/P6***
7-	Expedited review of research proposal entitled ***"Incidence of COVID-19 in unclaimed dead bodies: a case control study (Prospective title)"*** submitted by Dr. Shiuli, Assistant Professor, Department of Neurology of this University via letter no. nil dated nil. ***The above proposal forwarded to Dr. Surajit Bhattacharya & Dr. Rajeev Garg, reply has given by Dr. Bhattacharya has given his reply with following comment:-*** • The study aims to establish the incidence of COVID-19 deaths with homelessness • 2. Samples will be nasal soab and lung biopsy • 3. Control group is comprised of deaths due to other causes brought to mortuary. • 4. Sample size is not provided. By now the trend is obvious and so along with a statistician a doable sample size should be arrived at so that the results are statistically significant. • 5. When the bodies are unclaimed to whom is the patient information sheet addressed? • 6. Again when the bodies are unclaimed who will give consent? ***The above comment forwarded to P.I. reply has given by P.I. which was reviewed by IEC & approved.*** ***The following Members were not take part in the discussion:-*** ***1-Prof. R.K. Garg*** ***2-Prof. Anoop, Kumar Verma*** ***3- Prof. Amita Jain*** ***4- Dr. Preeti Agarwal***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: IIIrd ECM COVID-19 IB/P7***
8-	Expedited review of research proposal entitled ***"Study of COVID-19 awareness, in Radiology technicians and trainees"*** submitted by Dr. Neha Yadu, SR, Department of Radiodiagnosis of this University via letter no. 252/RD/2020 dated 27th April, 2020. ***The above proposal forwarded to Dr. Anoop Kumar Verma & Dr. Rajeev Garg, reply has given by Dr. Garg with following comment:-*** • Attach the questionnaire in the Hindi language also as the study has been planned in the technicians and not all will be comfortable in the English language. In that case a back translation certificate is also needed. ***Reply has given by P.I. which was reviewed by the Member-Secretary, IEC & Approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IIIrd ECM COVID-19 IB/P8***
9-	Expedited review of research proposal entitled ***"A questionnaire based study on the awareness about COVID-19 in Indian population"*** submitted by Dr. Avirup Majumdar through Prof. Virendra Atam, Head, Department of Medicine of this University via letter no. 627 dated 18th May, 2020. ***The above proposal forwarded to Dr. Vimal Kumar Paliwal & Dr.Preeti Agarwal. reply has given by Dr. Paliwal with following opinion:-*** The PI has now included two residents in the study who have done or doing COVID duty at the present time. However, the PI needs to send the first page of the Ethics SOP with names, designation, address and signatures of the residents who are included in the study. ***The above comment forwarded to P.I. reply has given by P.I. which was approved by the Member-Secretary, IEC & approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IIIrd ECM COVID-19 IB/P9***
10-	Expedited review of research proposal entitled ***"Impact of Lockdown on new onset stroke patients amidst corona pandemic"*** submitted by Dr. Neeraj Kumar, Associate Professor, Department of Neurology of this University via letter no. 122/Neuro/20 dated 21st May, 2020. **EC Decision:** Approved ***Dr. R.K. Garg did not take part in the discussion.*** ***Ref. code: IIIrd ECM COVID-19 IB/P10***
11-	Expedited review of research proposal entitled ***"A potential early marker in COVID-***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

19: Taste and smell" submitted by Dr. Shrikant Shrivastava, Additional Officer, Department of G.M.H. of this University via letter no. nil dated nil.

The above proposal forwarded to Dr. Vimal Kumar Paliwal & Dr. Preeti Agarwal, reply has given by Dr. Agarwal with following comment:-

- Title of the project mentions Taste and smell; however in the objectives the investigators are only investigating the taste
- 2. Group I, Point B : Error: The investigators are not even aware that it is the Nasal and Throat swab which is used for COVID 19 testing not the blood sample.
- 3. Please enlist the names of tertiary care hospitals you intend to include in the study. Either an participation letter should be attached or someone involved in patient care at those centers must be included in the study.
- 4. Selection criteria point 3: no chronic illness' Type II DM and Hypertension are also chronic illnesses, generalized terms must be avoided from the section criteria. it needs to robust and well defined.
- 5. The sample size calculation is based on authors previous study on depression which does not stand for present scenario. Study sample size calculation must be provided clearly.
- 6. Study endpoint is not defined and will they monitor the return of the sense of taste when the patient is declared cured of SARS-Cov2 infection.
- Kindly send the point wise reply at the earliest so that may be taken further action.
- The study involves the examination of taste sensation of COVID 19 affected individuals and normal controls. The tests will be self administered by the patients. Audio-visual consent will be taken. The tests will be monitored by research team by tele consultation to prevent exposure to COVID to research team

Reply has given by P.I. which was reviewed by the Member-Secretary, IEC & Approved.

Action taken: Provisionally approved

EC Decision: Approved

Ref. code: IIIrd ECM COVID-19 IB1

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 23rd May, 2020

Minutes Item no. IIA
New proposals

K.G's Medical University U.P., Lucknow

IIA	New Proposals
9-	Research proposal entitled ***"Evaluation of degradation pattern of different RNA types and gene expression (messenger RNA: HIFlaGAPDH, B-ACTIN, micro RNA: MIR 143, MIR125, ribosomal RNA) in human dental pulp tissue under varied temperature & storage time interval: development of an efficient post mortem interval (PMI) estimation method"*** sponsored by ICMR New Delhi submitted by Prof. Shalni Gupta, Department of Oral Pathology and Microbiology of this University via letter no. nil dated 11th January, 2020. **EC Comment:** • Statistical analysis for selecting sample size is needed. Same may be implemented during project tenure. **EC Decision:-** Approval after justification ***Ref. code: 101st ECM IIA/P9*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
16	Research proposal entitled ***"Phytofabricated metallic nanoparticles and their clinical relevance in treatment of oral premalignant lesions"*** sponsored by Indian Council of Medical Research New Delhi submitted by Prof. Rakesh Kumar Yadav, Department of Conservative Dentistry and Endodontics of this University via letter no. 830/2020 dated 24" January, 2020. **EC Comment:** Assessment: • Back ground information on toxicity profile of relevant nanoparticles needs better elaboration. • Comments: • Statistical analysis for selecting sample size is needed. Same may be implemented during project tenure. **EC Decision:-** Approval after justification ***Ref. code: 101st ECM IIA/P16*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
25.	Research proposal entitled ***"Consumer's perspective on referral services for medical co-morbidities in tertiary care setting of North India"*** submitted by Dr. S.K. Kar, Associate Professor, Department of Psychiatry of this University via letter no. 2022/2020 dated 4th February, 2020. **EC Comment:** • Project is well crafted, however statistical analysis justifying sample size is not provided. Please include this during the execution of project.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Ref. code: 101st ECM IIA/P25*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
34.	Research proposal entitled ***"Comparison of tetrachromic VOF stain with routine H&E staining techniques for characterizing stromal soft and hard tissue components"*** submitted by Prof. Shaleen Chandra, Head, Department of Oral Pathology Faculty of Dental Sciences of this University via letter no. 839/OP/2020 dated 6th February, 2020. **EC Comment:** • Project aims to compare the efficiency of two specific techniques in terms of their ability to adequately characterize tissue components. It has significant application. **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIA/P34*** ***(Primary Reviewer: Dr. Smriti Bhadauri)***
41.	Research proposal entitled ***"Per anal endoscopic Rectopexy versus laparoscopic ventral mesh rectopexy for complete rectal prolaps: A randomized control trial"*** submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology of this University via letter no. SG 84 dated 10th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P41*** ***(Primary Reviewer: Dr.Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 23rd May, 2020

Minutes Item no. IIB
Thesis proposals

K.G's Medical University U.P., Lucknow

IIB	New Thesis-Resident
1.	Research proposal entitled ***"Effect of beta-3 agonist (Mirabegron) and alpha blocker (Tamsulosin) on treatment of ureteral stent related symptoms: A randomized controlled trial"*** submitted by Dr. Pavan Kumar S.K, SRII, Department of Urology of this University via letter no. nil dated 20th December, 2019. **EC Comment:** 50 subjects in three arms – placebo, mirabegron and tamsulosin. Randomization by chart. Body pain score and urinary symptom score will be compared. There are several issues: • Who will bear the cost of the medications and investigations? • DCGI approval of the drugs have to be submitted. • Who will bear the cost of insurance/compensation? The required information has to be submitted to ethics committee. • The study is written in past tense with inclusion of patients from Nov 2019. The part need to be re-written. Inclusion of patients can commence only after obtaining ethical clearance. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"Effect of priming on adjunctive repetitive trans cranial magnetic stimulation in the treatment of late life depression, and associated quantitative EEG changes: A prospective randomized sham controlled study"*** submitted by Dr. Vidya K.L, SR, Department of Geriatric Mental Health of this University via letter no. 601/DGMH dated 10th December, 2019. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Research proposal entitled ***"Voiding dysfunction after vesicovaginal fistula repair: prevalence, predictive factors and comparative analysis of functional outcomes between laparoscopic, open transabdominal and transvaginal repair"*** submitted by Dr. Mayank Jain, SRII, Department of Urology of this University via letter no. nil dated 20th December, 2019. **EC Comment:** • Sample size not calculated • How many cases will be subject to each arm of surgical intervention? • Consent form is as per old version

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Ref. code: 101st ECM II B-Thesis/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Research proposal entitled ***"Menstrual hygiene practices among females of reproductive age in rural Lucknow"*** submitted by Dr. Arunima Saini, JRII, Department of Community Medicine & Public Health of this University via letter no. nil dated 20th December, 2019. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P4*** ***(Primary Reviewer: Dr. Rajeev Garg)***
5.	Research proposal entitled ***"A combined retrospective- prospective cohort study for efficacy of internal urethrotomy followed by CIC with and without clobetasol ointment in the management of stricture urethra"*** submitted by Dr. Mukesh Kumar, JRII, Department of Urology of this University via letter no. nil dated 21st December, 2019. **EC Comment:** • Patients who have undergone internal urethrotomy will be followed up to compare the effect of CIC with or without Clobetasol ointment by uroflometry, RGU or MCU • Data collection sheet has been provided • Sample size is missing. We need this for statistical significance of the results • Follow up schedule and outcome criteria defined • Catheterization schedule standardized **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P5*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
6.	Research proposal entitled ***"A prospective observational study of outcomes of various treatment modalities for chyluria and their correlation with urinary triglyceride levels"*** submitted by Dr. Akash Bansal, SRII, Department of Urology of this University via letter no. nil dated 24th December, 2019. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
7.	Research proposal entitled ***"Nocturia in men aged above 50 years with LUTS/BPH: prevalence, its predictive factors and association with nocturnal polyuria and comparative analysis of outcome after tamsulosin or silodosin therapy by doing an open label randomized controlled study"*** submitted by Dr. Gyanendra Singh, SRII, Department of Urology of this University via letter no. nil dated 23rd December, 2019.

Chairperson, IEC
King George's Medical University

	EC Comment: • Sample size calculation not done **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P7*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
8.	Research proposal entitled ***"Metastatic renal cell carcinoma: retrospective and prospective experience of a tertiary care center"*** submitted by Dr. Sanjeev Kumar, SRII, Department of Urology of this University via letter no. nil dated 23rd December, 2019. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P8*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
9.	Research proposal entitled ***"Demographic, psychiatric and molecular profileof extensively drug resistant tuberculosis patients (A Pilot Study)"*** submitted by Dr. Yash Jagdhari, JRI, Department of Respiratory Medicine of this University via letter no. nil dated 26th December, 2019. **EC Comment:** • As Psychiatric evaluation is being also evaluated in the study someone from the Department of Psychiatry is needed. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P9*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
10.	Research proposal entitled ***"A study of mental Health comorbidities in patients with hypertension"*** submitted by Dr. Pooja Misal, SRI, Department of Geriatric Mental Health of this University via letter no. 2927/MED/19 dated 31st December, 2019. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P10*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
11.	Research proposal entitled ***"USG guided dextrose prolotherapy versus platelet-rich plasma injections for the treatment of plantar fasciitis: A randomized controlled trial"*** submitted by Dr. Neelam Kumari, JRI, Department of Physical Medicine & Rehabilitation of this University via letter no. nil dated 3rd January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P11*** ***(Primary Reviewer: Dr. Rajendra Nath)***
12.	Research proposal entitled ***"Intracranial meningiomas: retrospective review of 10 Years"*** submitted by Dr. Aditya Varshney, SRI, Department of Neurosurgery of this

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	University via letter no. nil dated 4th January, 2020. **EC Comment:** • This is a follow-up study of cases who were died as Meningiomas in last 10 years (Not a retrospective study) 1. There is not clause for cases who are not traceable or who died 2. How many cases are actually registered in the department? 3. How consent will be taken because patient may not be physically present. 4. Consent form is on old format. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P12*** ***(Primary Reviewer: Dr. Amita Jain)***
13.	Research proposal entitled ***"Perceptions and practices regarding clinical ethics by postgraduate Medical Students"*** submitted by Dr. Anila Varghese, JRI, Department of Community Medicine & Public Health of this University via letter no. nil dated 20th December, 2019. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P13*** ***(Primary Reviewer: Dr. Rajeev Garg)***
14.	Research proposal entitled ***"A study of various phenotypes in patients of bronchial asthma attending a tertiary care centre in Northern India"*** submitted by Dr. Naveen Kumar, JRI, Department of Respiratory Medicine of this University via letter no. nil dated 9th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P14*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
15.	Research proposal entitled ***"The comparative effects of injecting intra-articular platelet-rich plasma and hypertonic dextrose prolotherapy in osteoarthritis knee- A randomized control trial"*** submitted by Dr. Neeraj Singh, JRI, Department of Physical Medicine & Rehabilitation of this University via letter no. nil dated 9th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P15*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
16.	Research proposal entitled ***"Evaluation of risk of fall in knee osteoarthritis: A cross-sectional study"*** submitted by Dr. Juhika Kaur Nagi, JRI, Department of Physical Medicine & Rehabilitation of this University via letter no. 2665/20 dated 7th January, 2020. **EC Comment:** • Why half of sample size calculated?

Chairperson, IEC
King George's Medical University

	• Topic should be rewritten? • Eg. BSS and TUG in evaluation of risk of fall. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P16*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
17.	Research proposal entitled ***"Effects of BOTULINUM toxin injection with casting in children of spastic cerebral palsy: A randomized controlled trial"*** submitted by Dr. Shivansh Vishwakarma, JRI, Department of Physical Medicine & Rehabilitation of this University via letter no. 2679/20 dated 15th January, 2020. **EC Comment:** • Prekect is well written and problems are defined nicely however, owing to BOTULINUM TOXIN being bio-hazard, its use must have prior approval from Institutional BioSafety Committee. • There is no such certificate in the proposal. • Second opinion from Bio-safety Incharge will be appreciable • Recommended under the conditions that Use, Disposal and Handling of Botulinum toxin are in accordance with Institutional Biosafety Guidelines. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P17*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
18.	Research proposal entitled ***"A study on the assessment of cardiovascular risk and CIMT in systemic sclerosis and correlation of CIMT with disease activity"*** submitted by Dr. Prasanna Kumar, SRI, Department of Rheumatology of this University via letter no. Rh/82/20 dated 16th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P18*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
19.	Research proposal entitled ***"Major salivary gland ultrasound and elastography as a predictor of disease activity in patients of primary sjogren's syndrome"*** submitted by Dr. Chandwar Kunal Ashutosh, SR, Department of Rheumatology of this University via letter no. Rh/80/20 dated 16th January, 2020. **EC Comment:** 30 patients of Sjogren syndrome will be subjected to ultrasound and elastography of submandibular and parotid glands. • Inclusion of patients in the study should start after obtaining the ethical

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	clearance. The study duration cannot start from December 2019. • Please provide a brief CV of the collaborators from outside the institute. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P19*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
20.	Research proposal entitled ***"Clinical, laboratory profile and outcomes of patients presenting with digital gangrene to a rheumatology clinic in a tertiary care Hospital"*** submitted by Dr. Kriti Kishor, SR, Department of Rheumatology of this University via letter no. Rh/79/20 dated 16th January, 2020. **EC Comment:** • English-ICF not complete • Sample size calculation not done **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P20*** ***(Primary Reviewer: Dr. Rajendra Nath)***
21.	Research proposal entitled ***"A comparative study of vortioxetine and escitalopram in depression"*** submitted by Dr. Pragya Jain, JRI, Department of Pharmacology & Therapeutics of this University via letter no. nil dated 18th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P21*** ***(Primary Reviewer: Dr. Amita Jain)***
22.	Research proposal entitled ***"Comparison of acceptance, side effect and continuation of iucd versus non hormonal pills in postnatal women"*** submitted by Dr. Yashashwini Mishra, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/259 dated 24th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P22*** ***(Primary Reviewer: Dr. Rajeev Garg)***
23.	Research proposal entitled ***"Evaluation of efficacy and safety of drugs used for prophylaxis of migraine in a tertiary care teaching Hospital"*** submitted by Dr. Daraksha, JRI, Department of Pharmacology and Therapeutics of this University via letter no. 94/Pharma/2020 dated 29th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P23*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
24.	Research proposal entitled ***"A study of executive functions in type2 diabetes mellitus"***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	submitted by Dr. Pooja Misal, SR, Department of Geriatric Mental Health of this University via letter no. 252/MED/2020 dated 29th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P24*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
25.	Research proposal entitled ***"Assessment of treatment outcomes for germ cell tumor ovary"*** submitted by Dr. Sugandha Arya, SRI, Department of Surgical Oncology of this University via letter no. SONC/114/2020 dated 27th January, 2020. **EC Comment:** • Project is well crafted, however statistical analysis justifying sample size is not provided. Please include this during the execution of project. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P25*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
26.	Research proposal entitled ***"Institutional experience of neoadjuvant and adjuvant chemotherapy for cancer gall bladder"*** submitted by Dr. Shashwat Tiwari, SRI, Department of Surgical Oncology of this University via letter no. SONC/115/2020 dated 27th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P26*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
27.	Research proposal entitled ***"Role of neuropeptide galanin in the pathogenesis of type2 diabetes mellitus"*** submitted by Dr. Rohit Kumar Mishra, JRI, Department of Pharmacology and Therapeutics of this University via letter no. 95/Ohar/2020 dated 29th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P27*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
28.	Research proposal entitled ***"Volume versus pressure controlled ventilation during one lung ventilation in decortication for empyema thoracis"*** submitted by Dr. Deepali Chandra, JRI, Department of Anaesthesiology of this University via letter no. Anaes/121/2020 dated 1st February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P28*** ***(Primary Reviewer Dr. Preeti Agarwal)***
29.	Research proposal entitled ***"A study of urine TCA cycle metabolites as a marker of nephropathy in type2 diabetes mellitus"*** submitted by Dr. Ammar Sabir Siddiqui, JRI,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Department of Medicine of this University via letter no. 285/MED/2020 dated 31st January, 2020. **EC Comment:** • No co-pi from Singapore is included in the study. • Funding of study is not provided, • International transfer of biomedical material should be done with certain safeguards and these were not discussed in the study. • Case report form is not attached. • Conflict of interest has to be declared by PI and co-PIs. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P29*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
30.	Research proposal entitled ***"To report culture positivity by various methods for processing of gastric aspirate collected from pediatric cases of suspected pulmonary tuberculosis"*** submitted by Dr. Rajeev Sharma, JRI, Department of Microbiology of this University via letter no. 752/2020 dated 3rd February, 2020. **EC Comment:** • Kindly provide sample size **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P30*** ***(Primary Reviewer: Dr. Rajendra Nath)***
31.	Research proposal entitled ***"A comparative analysis of the APRI and FIB-4 score for predicting severe fibrosis in chronic liver disease"*** submitted by Dr. David Zothansanga, JR, Department of Medicine of this University via letter no. 284/MED/2020 dated 31st January, 2020. **EC Comment:** • It appears candidate has not understood the proforma which is self explanatory, there are lots of mistakes in that, it is requested to go through it and fill it responsibly. **EC Decision:** Re-submit ***Ref. code: 101st ECM II B-Thesis/P31*** ***(Primary Reviewer: Dr. Rajeev Garg)***
32.	Research proposal entitled ***"Association of APLASTIC anemia with viruses-A case control study"*** submitted by Dr. Gerlin Varghese, JRI, Department of Microbiology of this University via letter no. 753/2020 dated 3rd February, 2020. **EC Comment:** • The objective is to study the association of Apalstic Anaemia with Human

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Parvo virus B19, Cytomegalovirus, Epstin Barr Virus, Adeno virus, Measles virus, Human Herpes virus 6, Hepatitis virus A, B, C and E and Varicella Zoster Virus. It also intends to study the progression of these viruses in patients receiving immune-suppressive therapy • A patient data form has been attached which includes demographic details, clinical examination and laboratory findings • Blood samples will be collected – How much? How many times? When? • Sample size 76. 38 study group and 38 control. Which individuals are in control group? How this sample size was derived, particularly when there are so many variables. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P32*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
33.	Research proposal entitled ***"Spectrum of aspergillus species causing pulmonary aspergillosis in COPD and POST- TB patients-A descriptive study"*** submitted by Dr. Deepika, JRI, Department of Microbiology of this University via letter no. 755/2020 dated 3rd February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P33*** ***(Primary Reviewer : Dr. Anoop Kumar Verma)***
34.	Research proposal entitled ***"Blood culture positive neonatal sepsis in a tertiary care intensive care unit: A descriptive observational study"*** submitted by Dr. Ankit Pachauri, JRI, Department of Pediatrics of this University via letter no. 227/Ped/2020 dated 4th February, 2020. **EC Comment:** • Project aims to compare the efficiency of two specific techniques in terms of their ability to adequately characterize tissue components. It has significant application. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P34*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
35.	Research proposal entitled ***"Cytogenetic abnormalities in adults with acute lymphoblastic leukemia (ALL) in North India"*** submitted by Dr. Anam Ahmad, JRI, Department of Anatomy of this University via letter no. 658/ANAT/2020 dated 4th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P35*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

36.	Research proposal entitled ***"Site specific distribution of CD68 positive microglia in optic pathway of human cadaver"*** submitted by Dr. Chetana Sharma, JRI, Department of Anatomy of this University via letter no. 659/ANAT/2020 dated 4th February, 2020. **EC Comment:** • Exclusion criteria is not provided **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P36*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
37.	Research proposal entitled ***"Evaluation and correlation of different palatal RUGAE pattern, INTERINCISOR width, INTERCANINE width and INTERCANINE width in North Indian population- A comparative study"*** submitted by Dr. Supriya Sharma, SR, Department of Oral Pathology & Microbiology of this University via letter no. 835/OP/2020 dated 4th February, 2020. **EC Comment:** • Poorly written • Waiver may be provided. • Comparing only male and felaled. Hence data is anonymous **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P37*** ***(Primary Reviewer: Dr.Preeti Agarwal)***
38.	Research proposal entitled ***"Effect of phototherapy on serum calcium and zinc levels in full term neonates"*** submitted by Dr. Bindiya Verma, JRI, Department of Physiology of this University via letter no. 1618/PY/2020 dated 5th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P38*** ***(Primary Reviewer: Dr.Vimal Kumar Paliwal)***
39.	Research proposal entitled ***"Clinical study to monitor prescription pattern, clinical outcomes, quality of life, pharmacoeconomic burden and adverse drug reaction among psoriasis patients treated in out patient Department of dermatology in tertiary care center of North India"*** submitted by Dr. Farah Asif, JRI, Department of Pharmacology & Therapeutics of this University via letter no. 110/Pharma/2020 dated 4th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P39*** ***(Primary Reviewer: Dr. Rajendra Nath)***
40.	Research proposal entitled ***"Evaluation of adverse drug reactions in patients of diabetes mellitus on 1st line anti-tubercular treatment"*** submitted by Dr. Abhay

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Verma, JRI, Department of Pharmacology & Therapeutics of this University via letter no. 105/Pharma/2020 dated 3rd February, 2020. **EC Comment:** • This study involves lab dx of TB & diabetes how & who will do this? There are no investigators from lab side. • There is no questionnaire for reporting/recording ADR • What treatment will be given? MDR is common in diabetes. • Side effect & their prevalence are different from drug to drug. • Kindly provide the consent form as new format **EC Decision:** Revise & re-submit ***Ref. code: 101st ECM II B-Thesis/P40*** ***(Primary Reviewer: Dr. Amita Jain)***
41.	Research proposal entitled ***"A clinical study to monitor prescription pattern, clinical outcomes and adverse drug reaction among patients of various interstitial lung diseases attending respiratory Medicine OPD at tertiary care Hospital in Northern India"*** submitted by Dr. Sabahat Hasan, JRI, Department of Pharmacology & Therapeutics of this University via letter no. 106/Pharma/2020 dated 3rd February, 2020. **EC Comment:** • This study involves the other institute then KGMU, so brief CV of collaborator as mentioned in proforma should be submitted with justification of participation of other institute explaining how much and what part of work will be carried out there. **EC Decision:** Revise & Re-submit ***Ref. code: 101st ECM II B-Thesis/P41*** ***(Primary Reviewer: Dr.Rajeev Garg)***
42.	Research proposal entitled ***"Efficacy of high dose Oral prednisolone therapy in Children with west syndrome"*** submitted by Dr. Chandra Prabha, JRI, Department of Paediatrics of this University via letter no. 207/Paed/2020 dated 3rd February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P42*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
43.	Research proposal entitled ***"A comparative study of outcome of tympanoplasty using methylene blue stained and unstained temporalis fascia graft"*** submitted by Dr. Ramesh Kumar, JRI, Department of ENT & Head & Neck Surgery of this University via letter no. 820/ENT//2020 dated 3rd February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P43***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Smriti Bhadouria)
44.	Research proposal entitled ***"Epidemiological features, risk factors and outcome of pneumonia in children with acute lymphoblastic leukemia"*** submitted by Dr. Prachi Singh, JRI, Department of Pediatrics of this University via letter no. 246/Pel/2020 dated 6th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P44*** ***(Primary Reviewer: Dr.A.A. Sonkar)***
45.	Research proposal entitled ***"Soluble P-SELECTIN level in skin diseases and their association with psychosocial impact"*** submitted by Dr. Jeetendra Kumar, JRI, Department of Physiology of this University via letter no. 1622/PHY/2020 dated 6th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P45*** ***(Primary Reviewer: Dr. Smriti Bhdauria)***
46.	Research proposal entitled ***"Incidence and predictors of early onset sepsis in at risk inborn neonates at tertiary care Hospital: A prospective observational study"*** submitted by Dr. Amina Saad, JRI, Department of Paediatrics of this University via letter no. 258/Ped/2020 dated 6th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P46*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
47.	Research proposal entitled ***"Pre-school wheeze: symptom patterns and risk factors in children less than5 years of age: A Hospital based cohort study"*** submitted by Dr. Akshita Khandelwal, JRI, Department of Paediatrics of this University via letter no. 259/Ped/2020 dated 6th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P47*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
48.	Research proposal entitled ***"To study prognostic implications of plasma fibrinogen, D-dimer and various epithelial-to mesenchymal transition markers in patients with non-muscle invasive bladder cancer"*** submitted by Dr. Sahil Singh, SRI, Department of Urology of this University via letter no. nil dated 6th February, 2020. **EC Comment:** • Pt information sheet & calculated sample Size

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Ref. code: 101st ECM II B-Thesis/P48*** ***(Primary Reviewer: Dr. Rajendra Nath)***
49.	Research proposal entitled ***"Sonographic anatomy and topographical variability of sural nerve in the leg"*** submitted by Dr. Untika Singh, JRI, Department of Anatomy of this University via letter no.675/ANAT/2020 dated 8th February, 2020. **EC Comment:** • There are 100 proposed volunteers who will for in study subjects. • Consent form should be for Volunteers. • Variables of analysis should be listed. **EC Decision:** Revise & Re-submit ***Ref. code: 101st ECM II B-Thesis/P49*** ***(Primary Reviewer: Dr. Amita Jain)***
50.	Research proposal entitled ***"Stroke in children with tuberculous meningitis: A prospective observational study"*** submitted by Dr. Niti Prakash, JRI, Department of Paediatrics of this University via letter no.282/Ped/2020 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P50*** ***(Primary Reviewer: Dr. Rajeev Garg)***
51.	Research proposal entitled ***"Efficacy and NSAID sparing effect of conventional synthetic disease modifying anti-rheumatic drugs (DMARD) in patients of spondyloarthritis"*** submitted by Dr. Juhi Dixit, SRI, Department of Rheumatology of this University via letter no. Rh/81/2020 dated 16th January, 2020. **EC Comment:** • The study aims to evaluate the efficacy and NSAID sparing effect of conventional DMARDs in patients of spondiloarthritis • Sample size is 100. How was it derived? • Data collection sheet with History, Clinical Examination, Ankylosing Spondilitis Disease Activity Score (ASDAS), Bath Ankylosing Spondilitis Disease activity Index (BASDAI), Bath Ankylosing Spondilitis Functional Index (BASFI), Maastricht Ankylosing Spondilitis Enthesitis Index (MASES) and laboratory investigations attached • Which DMARD will be used and in what dosage? (Sulphasalazine / MTX) • What will be the follow up schedule? • How will we look for adverse effects and how will we manage them? • Discontinuation and withdrawal criteria should be spelt out. • Methodology not clear. We need a study plan from start to finish.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Ref. code: 101st ECM II B-Thesis/P51*** ***(Primary Reviewer: Dr. Surajit Bhattacarya)***
52.	Research proposal entitled ***"Study of metabolic profile and common carotid intima media thickness in patients with psoriatic arthritis"*** submitted by Dr. Ekbote Digvijay Gajanan, SRI, Department of Rheumatology of this University via letter no. Rh/118/2020 dated 24th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P52*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
53.	Research proposal entitled ***"A study on the self management practices in adult hypertensive population of Lucknow"*** submitted by Dr. Mohit Mishra, JRI, Department of Community Medicine of this University via letter no. 1298/CM/2020 dated 8th February, 2020. **EC Comment:** • What self management practices would be used? Describe? **EC Decision:** Provisionally approved ***Ref. code: 101st ECM II B-Thesis/P53*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
54.	Research proposal entitled ***"Prevalence and socio-demographic profile of adolescents suffering from attention deficit Hyperactivity disorder in Lucknow"*** submitted by Dr. Dinesh Kumae H, JRI, Department of Community Medicine & Public Health of this University via letter no. 1300 CM/2020 dated 10th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P54*** ***(Primary Reviewer: Dr. Smriti Bahdoria)***
55.	Research proposal entitled ***"Utilization of reproductive and Child Health services from urban primary Health centers of Lucknow"*** submitted by Dr. Santosh Kumar, JRI, Department of Community Medicine & Public Health of this University via letter no. 1299/CM/2020 dated 10th February, 2020. **EC Comment:** • Survey questionnaire is not provided **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P55*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
56.	Research proposal entitled ***"To study the risk factors associated with extubation failure in very low birth weight neonates-a prospective observational study"***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	submitted by Dr. Garvita Srivastava, JRI, Department of Paediatrics of this University via letter no. 260/Ped/2020 dated 6th February, 2020. **EC Decision:** Approved. ***Ref. code: 101st ECM II B-Thesis/P56*** ***(Primary Reviewer: Vimal Kumar Paliwal)***
57.	Research proposal entitled ***"A physical and psychosocial assessment of postpartum women in Lucknow District"*** submitted by Dr. Sarrah Maimoon Usmani, JRI, Department of Community Medicine & Public Health of this University via letter no. 1302/CM/2020 dated 10th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P57*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
58.	Research proposal entitled ***"Association of resistin 420 and 62 gene polymorphisms in patients with oral submucous fibrosis (OSMF) and oral cancer patients"*** submitted by Dr. Roop Ganguly, SRI, Department of Oral and Maxillofacial Surgery of this University via letter no. OMS/12/2020 dated 10th February, 2020. **EC Comment:** • Sample size not calculated only number is given • Methodology not given in detail • Related Questionnaire AND Pt information sheet not submitted **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P58*** ***(Primary Reviewer: Dr. Rajendra Nath)***
59.	Research proposal entitled ***"A comparative study on cognitive functions in late life depression"*** submitted by Dr. Ambrish Kumar Mishra, SRII, Department of Geriatric Mental Health of this University via letter no. 95/DGMH/2020 dated 10thFebruary, 2020. **EC Comment:** • Kindly provide the consent form as new format **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P59*** ***(Primary Reviewer : Dr. Amita Jain)***
60.	Research proposal entitled ***"A comparative study of three minute propofol and dexmedetomidine on emergence agitation in Paediatric patients undergoing surgery for hypospadias"*** submitted by Dr. Kriti Nagar, SR, Department of Anaesthesiology of this University via letter no. nil dated 10th February, 2020. **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 101st ECM II B-Thesis/P60
	(Primary Reviewer: Dr. Rajeev Garg)
61.	Research proposal entitled ***"Comparative evaluation of effects of yoga and oral hygiene interventions in asthmatic patients with periodontal diseases: A randomised control trial"*** submitted by Dr. Pooja Garg, JRI, Department of Periodontology Faculty of Dental Sciences of this University via letter no. 1627/P/2020 dated 10th February, 2020. **EC Comment:** • The aim is to estimate the effect of Yoga and Oral Hygiene interventions on spasmodic and periodontal parameters of asthmatics with periodontal disease • Sample size 80, 20 in each group. Statistically calculated. But what are these groups? • Salivary levels of IL1b by ELISA will be used as a parameter for which 5 ml saliva will be collected and compared after 6 months. • Now where is the R.C.T in all this? Please follow the Consort guidelines and redesign the study • How will Yoga be standardized for all patients? Which research contributor is the expert in Yoga and with what qualifications? • Data collection sheet is not provided **EC Decision:** Re-submit ***Ref. code: 101st ECM II B-Thesis/P61*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
62.	Research proposal entitled ***"Prospective and retrospective study for evaluation of pre and post operative staging and need of adjuvant therapy in cervical cancer"*** submitted by Dr. Divya Sharma, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/439/2020 dated 10th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P62*** ***(Primary Reviewer: Dr.Anoop Kumar Verma)***
63.	Research proposal entitled ***"Cognitive status of patients with chronic kidney diseases: an observational study"*** submitted by Dr. Vidya K.L, SRI, Department of Geriatric Mental Health of this University via letter no. 367/MED/2020 dated 10th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P63*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
64.	Research proposal entitled ***"Application of milan system for salivary gland cytology and diagnostic utility of a panel of immunocytochemistry markers in diagnosing***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	salivary gland neoplasms and it's CYTO-histological correlation for it's risk stratification" submitted by Dr. Pooja Dwivedi, JRI, Department of Pathology of this University via letter no. 173/2020 dated 8th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P64*** ***(Primary Reviewer: Dr. Smriti Bhadoria)***
65.	Research proposal entitled ***"Evaluation of CCL28 and CCR10 expression in oral squamous cell carcinoma"*** submitted by Dr. Manjit Kour Mehta, JRI, Department of Oral Pathology & Microbiology Faculty of Dental Sciences of this University via letter no. 849/OP/2020 dated 10th February, 2020. **EC Comment:** • Sample size justification needed. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P65*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
66.	Research proposal entitled ***"Efficacy of injectable platelet rich fibrin (I-PRF) with or without arthrocentesis in TMJ osteoarthritis patients"*** submitted by Dr. V.E. Shanthosh Kanna, JRII, Department of Oral & Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. OMS/126/2020 dated 8th February, 2020. **EC Comment:** The study will include 32 patients in each of two arms. Patients in one arm will be subjected to injection of PRF in TMJ and patients in other arm will be subjected to arthrocentesis followed by PRF injection. Various parameters related to control of pain and osteoarthiritis using cone beam computed tomography (CBCT) will be compared between two arms. There are some issues: • Will it be a randomized study? Which randomization methods will be used? • What is the standard of care in TMJ osteoarthritis? • Who will bear the cost of the treatment? • Who will bear the cost of the compensation/insurance? • The possible side-effects of the procedure/treatment have to be discussed in the patient information document. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P66***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Vimal Kumar Paliwal)
67.	Research proposal entitled ***"Gauging the Psychosocial salubrity of Oral cancer patients and their kinsfolk: A cross-sectional study"*** submitted by Dr. Shruti Singh, SRIII, Department of Oral Pathology Faculty of Dental Sciences of this University via letter no. 841/OP/2020 dated 6th February, 2020. **EC Comment:** • Methodology has not been explained • Sample size not calculated • Pt information sheet not attached **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P67*** ***(Primary Reviewer: Dr. Rajendra Nath)***
68.	Research proposal entitled ***"Curtailing the postoperative menaces in Oral cancer patients-A microbiological analysis"*** submitted by Dr. Jaya Singh, SRII, Department of Oral Pathology Faculty of Dental Sciences of this University via letter no. 840/OP/2020 dated 6th February, 2020. **EC Comment:** • Study protocol is not shown • Only a paragraph on Microbiology method's is written. • Protocol is not clear • How sample size was calculated? • How herbal extract will be prepared & in what doses will it be tested? • What will be the purpose & in what doses will it be tested? • What will be the purpose of looking at pre & post operative colony count **EC Decision:** Revise ***Ref. code: 101st ECM II B-Thesis/P68*** ***(Primary Reviewer: Dr. Amita Jain)***
69.	Research proposal entitled ***"Prevalence of pathological neonatal hyperbilirubinemia due to blood group incompatibility (both major & minor) and its clinical profile in neonatal unit: A prospective observational study"*** submitted by Dr. Govind Pandey, JRI, Department of Pediatrics of this University via letter no. 247/Ped/2020 dated 6th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P69*** ***(Primary Reviewer: Dr. Rajeev Garg)***
70.	Research proposal entitled ***"Clinical and echocardiographic parameters of neonates***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	of diabetic and non diabetic mothers and its correlation with cord blood insulin like growth factor 1 levels- A case control study" submitted by Dr. C. Tharuna, JRI, Department of Pediatrics of this University via letter no. 248/Ped/2020 dated 6th February, 2020. **EC Comment:** • The objective is to study the clinical and ECG differences of neonates of diabetic and non-diabetic mothers and its relation to cord blood Insulin like Growth Factor 1 levels and maternal HbA1c levels • Maternal blood sample and cord blood sample will be collected bur when and how much we do not know • A very elaborate data collection sheet is attached • Sample size is not given. Please consult with a statistician and settle for a doable sample size • The methodology needs to be described clearly **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P70*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
71.	Research proposal entitled ***"Evaluation of neutrophil lymphocyte ratio, platrlet lymphocyte ratio and ABO blood group as prognostic markers in patients with ovarian cancer"*** submitted by Dr. Deepshikha Rajput, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/456/2020 dated 10th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P71*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
72.	Research proposal entitled ***"Clinical audit of severe anaemia in obstetric patients in a tertiary care centre in northern India"*** submitted by Dr. Juhi Srivastava, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/453/2020 dated 10th February, 2020. **EC Comment:** • Sample size calculated not done? **EC Decision:** Provisionally approved ***Ref. code: 101st ECM II B-Thesis/P72*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
73.	Research proposal entitled ***"A study of third trimester fetal growth velocity in term pregnancies and its association with perinatal outcome"*** submitted by Dr. Prapti Modi, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/452/2020 dated 10th February, 2020. **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 101st ECM II B-Thesis/P73
	(Primary Reviewer: Dr. Smriti Bhadoria)
74.	Research proposal entitled ***"Evaluation of etiopathology and management of primary and secondary amenorrhoea in adolescent and young women at tertiary care centre"*** submitted by Dr. Shubham Singh, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/445/2020 dated 10th February, 2020. **EC Comment:** • Survey questionnaire is not provided. **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P74*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
75.	Research proposal entitled ***"Study of serum levels of copper, zinc and magnesium in gestational diabetes mellitus (GDM) and normal glucose tolerant pregnant women"*** submitted by Dr. Preeti Singh, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/426/2020 dated 10th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P75*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
76.	Research proposal entitled ***"Role of Serum Glycosylated Fibronectin in Preeclampsia and its association with Fetomaternal Outcome"*** submitted by Dr. Nazrana Ghayyur, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/424/2020 dated 10th February, 2020. **EC Comment:** • Kindly provide the calculated sample size and patient information sheet **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P76*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

77.	Research proposal entitled ***"Clinical audit of cesarean section done in second stage of labour in a tertiary care Hospital"*** submitted by Dr. Asna Rahman, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/437/2020 dated 10th February, 2020. **EC Comment:** • Kindly provide CRF • Kindly provide consent form as new format **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P77*** ***(Primary Reviewer: Dr. Amita Jain)***
78.	Research proposal entitled ***"Cardiovascular disease risk estimation among residents of urban slums, Lucknow"*** submitted by Dr. Deepshikha Pandey, JRI, Department of Community Medicine & Public Health of this University via letter no. 1317/CM/2020 dated 8th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P78*** ***(Primary Reviewer: Dr. Rajeev Garg)***
79.	Research proposal entitled ***"To study expression of tight junction protein claudin in odontogenic lesions"*** submitted by Dr. Tanveer Fatima, JRI, Department of Oral Pathology & Microbiology of this University via letter no. 848/OP/2020 dated 10th February, 2020. **EC Comment:** • The study aims to determine the immunohistochemical expression of Tight junction protein Claudin 1, 4, 7 in Odontogenic Keratocyst and Ameloblastoma • Sample size 60. Was it derived after consultation with a statistician? • Formalin fixed, paraffin embedded tissue specimen of 30 ameloblastoma and 30 odontogenic cyst form the material of this study. • How exactly will the consent be obtained. The patients are surely from the past. • The term 'minor change can be made in the best interest of the study' is not clearly understood as all changes have to get a prior sanction of the IEC **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P79*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

80.	Research proposal entitled ***"Infant and young child feeding practices and nutritional status of children aged 6-23 months in Lucknow"*** submitted by Dr. Anila Varghese, JRI, Department of Community Medicine of this University via letter no. 1318/OP/2020 dated 10th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P80*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
81.	Research proposal entitled ***"Study of economic burden on cancer patient and benefits to them from various cancer relief schemes in tertiary care Hospital of Lucknow"*** submitted by Dr. Rahul Verma, JRI, Department of Community Medicine & Public Health of this University via letter no. 1316/OP/2020 dated 10th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P81*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
82.	Research proposal entitled ***"Adoption of family planning methods among postpartum women in Lucknow"*** submitted by Dr. Neetu Shukla, JRI, Department of Community Medicine & Public Health of this University via letter no. 1301/OP/2020 dated 8th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P82*** ***(Primary Reviewer: Dr. Smriti Bhadoria)***
83.	Research proposal entitled ***"Study of growth, development and feeding practices of a birth cohort delivered in a tertiary care Hospital"*** submitted by Dr. Avinash Dubey, JRI, Department of Community Medicine & Public Health of this University via letter no. 1315/OP/2020 dated 10th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P83*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
84.	Research proposal entitled ***"A comparative study of cognitive functions between patients of recurrent depressive disorder, bipolar depression and healthy controls"*** submitted by Dr. Aathira J Prakash, JRI, Department of Psychiatry of this University via letter no. 2074/Psydated 8th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P84*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

85.	Research proposal entitled ***"A study of sexual functioning in male patients of opioid use disorder on maintenance treatment"*** submitted by Dr. Pranav Gautam, JRI, Department of Psychiatry of this University via letter no. 2072/Psy dated 8th February, 2020. **EC Comment:** • Questionnaire and opiate withdrawal scale not attached • Sample size not calculated **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P85*** ***(Primary Reviewer: Dr. Rajendra Nath)***
86.	Research proposal entitled ***"Identification and characterization of weak d variants in blood donors"*** submitted by Dr. Anurag Singh, JRI, Department of Transfusion Medicine of this University via letter no. 556/2020 dated 7th February, 2020. **EC Comment:** • Simple observational study Genetic work will be done at N11H. • Kindly provide consent form as new format **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P86*** ***(Primary Reviewer: Dr. Amita Jain)***
87.	Research proposal entitled ***"Delayed adverse reactions in blood donors"*** submitted by Dr. Sunil Kumar, JRI, Department of Transfusion Medicine of this University via letter no. 558/2020 dated 8th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P87*** ***(Primary Reviewer: Dr. Rajeev Garg)***
88.	Research proposal entitled ***"Evaluation of hematological and hormonal parameters in plateletpheresis donors"*** submitted by Dr. Pradeep Kumar Maurya, JRI, Department of Transfusion Medicine of this University via letter no. 557/2020 dated 7th February, 2020. **EC Comment:** • Alteration in haematological parameters, Thrombopoetin levels and Prothrombin levels will be studied in plateletpheresis donors of 18-65 years of age and over 50 Kg weight • Inclusion and exclusion criteria are clearly defined • Sample size 40. Statistically derived • Methodology is described in details • Data collection sheet is missing **EC Decision:** Approval after justification

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 101st ECM II B-Thesis/P88 ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
89.	Research proposal entitled ***"Hearing Assessment after total annular excision tympanoplasty"*** submitted by Dr. Devisha Agarwal, JR-I, Department of Otorhinolaryngology & Head & Neck Surgery of this University via letter no. 656/ENT/2020 dated 11th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM IIB-Thesis/P89*** ***(Primary Reviewer: Dr.Anoop Kumar Verma)***
90.	Research proposal entitled ***"A study on radiotherapy department in a tertiary care government Hospital"*** submitted by Dr. Supriya Singh, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2019/768 dated 18th December, 2019. **EC Comment:** • Write this after changing the title above ***"A study of the Resource and their utilization of Radiotherapy Department in a tertiary care Government hospital"*** **EC Decision:** Approval after justification ***Ref. code: 101st ECM IIB Thesis/P/90*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
91.	Research proposal entitled ***"A study on dialysis centre in a tertiary care government Hospital"*** submitted by Dr. John Paul G Momin, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2019/769 dated 18th December, 2019. **EC Decision:** Approved ***Ref. code: 101st ECM IIBThesis/P91*** ***(Primary Reviewer: Dr. Smriti Bhadoria)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 23rd May, 2020

Minutes Item no. III
Modification

K.G's Medical University U.P., Lucknow

III	Modification
7-	Modification of research proposal entitled ***"Study of Vitamin B12 supplementation in late life depression"*** submitted by Dr. Pooja Misal, JR-I, through Head, Department of G.M.H. of this University via letter no. nil dated nil. ***The above proposal forwarded to Dr. Vimal Kumar Paliwal & Dr. Preeti Agarwal, reply has given by Dr. Preeti with following comment:-*** • The authors must use Google forms format/ or online base questionnaire format instead of paper form for the study. ***Reply has given by P.I. which was reviewed by the Member-Secretary, IEC & Approved.*** **Action taken:** Provisionally approved ***Ref. code: 100th ECM IIB-Thesis/P18***

Thanks

Next Meeting date 15th June, 2020

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

K.G's Medical University U.P., Lucknow

Note: Due to COVID-19 pandemic, the meeting of 6th March, 2020 various different dates took place.

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. IA

Action taken

K.G's Medical University U.P., Lucknow

Note: Due to COVID-19 pandemic, the meeting of 6th March, 2020 various different dates took place.

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 101st ECM held on 15th June, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Minutes of the Institutional Ethics Committee Meeting was scheduled on **15th June, 2020 from 02:00 p.m.to 4:30 p.m.** in the **'Board Room',** Office of the Vice Chancellor, Administrative Block of this University.

The following members were present in the EC Meeting:

1- Dr. S.P.S. Gaur	- Chairman
2-Hon'ble Justice Vishnu Sahai	-Member
3-Dr. Surajit Bhattacharya	- Member
4-Mr. Yogesh Mishra	- Member
5-Dr. Manju Agrawal	- Member
6-Dr. Smriti Bhadouria	- Member
7-Dr. Anoop Kumar	- Member
8- Dr. Rajendra Nath	- Member
9- Dr. Preeti Agarwal	- Member
10-Dr. R.K. Garg	- Member-Secretary, IEC

The following members were not present in the Meeting:-

1-Dr. Vimal Kumar Paliwal	-Member (Send his written Comments)
2-Dr. Amita Jain	- Member (Send her written comment)
3-Dr. A.A. Sonkar	- Member (Send his written comment)
4-Dr. Rajeev Garg	- Member (Send his written comment)

IA	Action taken
	Par-a-97th ECM was held on 12th July, 2019
a1	Clarification research proposal entitled ***"Comparison between LMA proseal and I-gel airway in anaesthetized patients on spontaneous ventilation during daycare procedures"*** submitted by Dr. Neha Singh, JR-I, Department of Anaesthesiology of this University via letter no. nil dated 13th April, 2019. **EC Comment on 12th July, 2019:** • Kindly submit Conflict of interest form. It should be done in form of RCT. **EC Decision on 12th July, 2019:** Approval after justification ***The above proposal approved by the Member-Secretary, IEC.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Further Action taken: Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P32*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
a2	Clarification of research proposal entitled ***"Aldh1 cancer stem cell marker expression in oral squamous cell carcinoma"*** submitted by Dr. Vaibhav Gupta, JR-I, Department of Pathology of this University via letter no. nil dated 10th April, 2019. **EC Comment on 12th July, 2019:** • Dr. Vaibhav has not submitted the revised project. He has submitted only the answer to the reviewer document. Ethical clearance may be granted if the said corrections are made into the revised performa. • Kindly provide **"Stem Cell committe"** Approval letter **EC Decision on 12th July, 2019:** Approval after justification ***The above comment forwarded to P.I. response has given by the P.I. which was forwarded to Primary reviewer, reply has given by the reviewer & approved.*** **Further Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P34*** ***(Primary Reviewer: Dr. Amita Jain)***
a3	Clarification of research proposal entitled ***"A prospective study to compare quality of life and early outcomes between endovenous laser therapy, mechanochemical ablation therapy in patients having chronic venous insufficiency"*** submitted by Dr. Abhishek Mishra, JR-II, Department of General Surgery of this University via letter no. nil dated 24th May, 2019. **EC Comment on 12th July, 2019:** • It is comparative study. • Study involves two groups of PF, Which authors have decided arbitrarily (Saying non-randomized) in one group they will use EVLT machine and author gp-Mechochemical ablaltion. • Which is unethical may involve bias, Design it as RCT & get CTRI registrationon CONSORT guidelines. **EC Decision 12th July, 2019:** Approval after justification ***Dr. A.A. Sonkar did not take part in the discussion.*** The reviewer response provided by the reviewer Provisionally approved with condition to kindly submit the CTRI registration. **ActionTaken:** The above comment forwarded to the P.I. **EC Decision :** Kindly provide CTRI registration ***The above proposal approved by the Member-Secretary, IEC.*** **Further Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P93*** ***(Primary Reviewer: Dr. Rajeev Garg)***

Chairperson, IEG
King George's Medical University,
U.P., Lucknow

	Part-b-101st ECM was held on 15th June, 2020
b1	Clarification of research proposal entitled ***"Predictors of stent malapposition and restenosis in post primary PCI patients- an OCT based study"*** submitted by Dr. Swati Sharma, SR-II, Department of Cardiology of this University via letter no. nil dated 16th August, 2019. **EC Comment on 15th June, 2020:** • Please provide the details of the procedure of OCT, Will the patient be required to get admitted for this procedure? How long will be the hospital stay? • What are the known complications of doing OCT? Please discuss the complications in the patient's documentation Performa. **EC Decision on 15th June, 2020:** Approval after justification ***The above proposal approved by the Member-Secretary, IEC.*** **Further Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 99thECM IIB-Thesis/P1*** ***(Primary Reviewer: Dr. Rajeev Garg)***
	101st ECM was held on 16th May, 2020
b2	Clarification of research proposal entitled ***"Prostate cancer: probing of comprehensive (cellular and systemic) metabolomics- based biomarker as a surrogate of the histopathology- based gleason score grading"*** sponsored by ICMR New Delhi submitted by Dr. Manoj Kumar, Associate Professor, Department of Urology of this University via letter no. nil dated 22nd May, 2020. **EC Comment on 16th May, 2020:** • This study is to explore for surrogate biomarkers for the histo-pathological Gleason's Score of CA Prostate. • Three cohorts will be studied – healthy cohort, B.H.P and CA. Prostate • Study material comprises of clinical information, serum samples and histological specimens from BHP, CA Prostate and adjacent normal tissue • They will study the qualitative and quantitative differences of metabolomics of serum samples and cellular samples in these 3 cohorts. • An attempt will be made to generate comprehensive biomarkers from serum and cellular metabolomics and compare the same with Gleason's score • Sample size is missing • Methodology – what exactly will be done is missing. We know the material but what is the method? • Data collection sheet is missing • No background data or previous published literature provided • Is it ICMR funded? No evidence provided. **EC Decision on 16th May, 2020:** Approval after justification ***The above comment forwarded to P.I. response has given by the P.I. which was forwarded to Primary reviewer, reply has given by the revieer & approved.*** **Further Action taken:** Provisionally approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 101st ECM IIA/P6*** ***(Primary Reviewer: Dr. Surajit Bhattachrya)***
b3	Clarification of research proposal entitled "***Effectiveness of intravenous ferric CARBOXY maltose (FCM) in improving hemoglobin levels among pregnant women with moderate to severe anemia- A multi-site study***" sponsored by UPNHM submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynaecology of this University via letter no. 2803/19 dated 27th December, 2019. **EC Comment on 16th May, 2020:** • Study is funded by UPNHM. • Ethical clearance given by AIIMS which is a coordinating center. • FCM is approved by the DCGI. • There seems to be no provision of insurance of patients. • The patient's case sheet is not attached. **EC Decision on 16th May, 2020:** Approval after justification **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P10*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
b4	Clarification of research proposal entitled "***A follow up study of cognitive performance among adult survivors of hanging***" submitted by Dr. S.K. Kar, Associate Professor, Department of Psychiatry of this University via letter no. 2073/Psy dated 8th February, 2020. **EC Comment on 16th May, 2020:** • Duration of study is not mentioned. • No Indian studies on such subjects were reviewed. **EC Decision on 16th May, 2020:** Approval after justification ***The above proposal approved by the Member-Secretary, IEC.*** **Further Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P36*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
b5	Clarification of research proposal entitled "***Role of taurine, vitamin C, and vitamin E in neurological recovery of acute spinal cord injury: A prospective case-control study***" submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 11/P/OS/2020 dated 10h January, 2020. **EC Comment on 16th May, 2020:** • Taurine has a role in axonal regeneration and high dose Vitamin C and E improve neurotrophic state and reduce contents of NSE and S100B which signal neurologic recovery. • 3 ml blood and urine samples will be collected and followed up at 6 weeks, 3 months and 6 months.

Chairperson, IEC
King George's Medical University

	• Sample size is 54. Statistically calculated • One group will receive Vit. C 4000 mg x BD for 6 months, the second will get an additional Taurine 1 gm x TDS for six months and a third group will get Vitamin E 1000 IU x BD for 6 months • Why is a 4th group comprising all three Taurine, Vitamin c and E not there? • Clinical assessment by ASCI score, ASIA Impairment scale and QOL score • Study sequence clearly stated. • Data collection sheet missing. **EC Decision on 16th May, 2020:** Approval after justification ***The above comment send to P.I. reply provided by P.I. which was forwarded to Dr. Bhattacharya & approved.*** **Further Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P31*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
b6	Clarification of research proposal entitled "***The clinical presentation, management & outcomes among patients with chronic obstructive pulmonary disease patients-the COPD registry (INCOR) study***" sponsored by SRM MCH & RC, Kattankulathur submitted by Dr. Ajay Kumar Verma, Prof. Jr. Grade, Department of Respiratory Medicine of this University via letter no. 534/20 dated 1st June, 2020. **EC Comment on 16th May, 2020:** • The Multicentric study is a case registry. • The sponsorer & the budget are not disclosed (ticked on private Consent form is on old format). **EC Decision on 16th May, 2020:** Revise **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P38*** ***(Primary Reviewer: Dr. Amita Jain)***
b7	Clarification of research proposal entitled "***Assess the barriers for implementing nursing theory-based practices in the clinical among nursing students***" submitted by Dr. Suchana Roy Bhomik, Assistant Professor, KGMU College of Nursing of this University via letter no. 117/PF dated 7th February, 2020. **EC Comment on 16th May, 2020:** • Poorly written • What theory? • Which circumstance or clinical setting? **EC Decision on 16th May, 2020:** Re-write **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P42*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
	101st ECM was held on 23rd May, 2020

Chairperson, IEC
King George's Medical University
U.P., Lucknow

b8	Clarification of research proposal entitled ***"Evaluation of degradation pattern of different RNA types and gene expression (messenger RNA: HIFlaGAPDH, B-ACTIN, micro RNA: MIR 143, MIR125, ribosomal RNA) in human dental pulp tissue under varied temperature & storage time interval: development of an efficient post mortem interval (PMI) estimation method"*** sponsored by ICMR New Delhi submitted by Prof. Shalini Singh, Head, Department of Oral Microbiology & Patholohy of this University via letter no. nil 11th June, 2020. **EC Comment on 23rd May, 2020:** • Statistical analysis for selecting sample size is needed. Same may be implemented during project tenure. **EC Decision 23rd May, 2020:** **EC Decision:** Approved ***Ref. code: 101st ECM II A/P9*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
b9	Clarification of research proposal entitled ***"Etiology of acute meningoencephalities in children less than 5 years of age in North India"*** sponsored by Health Research, New Delhi submitted by Prof. Amita Jain,Department of Microbiology of this University via letter no. 365/2020 dated 26th May, 2020. **EC Comment:** • Budget requirement has not been discussed. **EC Decision:** Approval after justification ***The abov comment forwarded to the P.I. reply provide by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **EC Decision:** Approved ***Dr. Amita Jain did not take part in the discussion.*** ***Ref. code: 101st ECM II A/P11*** ***(Primary Reviewer: Dr. Rajendra Nath)***
b10	Clarification of research proposal entitled ***"Consumer's perspective on referral services for medical co-morbidities in tertiary care setting of North India"*** submitted by Dr. S.K. Kar, Associate Professor, Department of Psychiatry of this University via letter no. 2022/2020 dated 4th February, 2020. **EC Comment on 23rd May, 2020:** • Project is well crafted, however statistical analysis justifying sample size is not provided. Please include this during the execution of project. **EC Decision 23rd May, 2020:** Approval after justification ***The abov comment forwarded to the P.I. reply provide by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P25*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
b11	Clarification of research proposal entitled ***"Effect of beta-3 agonist (Mirabegron) and alpha blocker (Tamsulosin) on treatment of ureteral stent related symptoms: A***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	randomized controlled trial" submitted by Dr. Pavan Kumar S.K, SRII, Department of Urology of this University via letter no. nil dated 20th December, 2019. **EC Comment on 23rd May, 2020:** 50 subjects in three arms – placebo, mirabegron and tamsulosin. Randomization by chart. Body pain score and urinary symptom score will be compared. There are several issues: • Who will bear the cost of the medications and investigations? • DCGI approval of the drugs have to be submitted. • Who will bear the cost of insurance/compensation? The required information has to be submitted to ethics committee. • The study is written in past tense with inclusion of patients from Nov 2019. The part need to be re-written. Inclusion of patients can commence only after obtaining ethical clearance. **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to P.I., reply has given by P.I. which was forwarded to Primary reviewer, reply has provided by P.R. & approved with following condition:-*** **EC Decision:** Approved with condition after ensuring that the trial medications has to be bought by the department and patient should not pay for the drugs. ***Ref. code: 101stECM II B-Thesis/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
b12	Clarification of research entitled ***"Nocturia in men aged above 50 years with LUTS/BPH: prevalence, its predictive factors and association with nocturnal polyuria and comparative analysis of outcome after tamsulosin or silodosin therapy by doing an open label randomized controlled study"*** submitted by Dr. Gyanendra Singh, SRII, Department of Urology of this University via letter no. nil dated 23rd December, 2019. **EC Comment 23rd May, 2020:** • Sample size calculation not done **EC Decision 23rd May, 2020:** Approval after justification ***The abov comment forwarded to the P.I. reply provide by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **EC Decision:** Approved ***Ref. code: 101stECM II B-Thesis/P7*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
b13	Clarification of research proposal entitled ***Modi*** submitted by Dr. Sabahat Hasan, JRI, Department of Pharmacology of this University via letter no. OG/445/2020 dated 10th February, 2020. **EC Comment 23rd May, 2020:** • This study involves the other institute then KGMU, so brief CV of collaborator as mentioned in proforma should be submitted with justification of participation of other institute explaining how much and what part of work will be carried out

Chairman IEC
King George's Medical University
U.P., Lucknow

	there. **EC Decision 23rd May, 2020:** Revise & Re-submit ***The abov comment forwarded to the P.I. reply provide by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **EC Decision:** Approved ***Ref. code: 101stECM II B-Thesis/P41*** ***(Primary Reviewer: Dr.Rajeev Garg)***
b14	Clarification of research proposal entitled ***"Utilization of reproductive and Child Health services from urban primary Health centers of Lucknow"*** submitted by Dr. Santosh Kumar, JRI, Department of Community Medicine & Public Health of this University via letter no. 1299/CM/2020 dated 10th February, 2020. **EC Comment on 23rd May, 2020:** • Survey questionnaire is not provided **EC Decision on 23rd May, 2020:** Approval after justification ***The abov comment forwarded to the P.I. reply provide by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **EC Decision:** Approved ***Ref. code: 101stECM II B-Thesis/P55*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
b15	Clarification of research proposal entitled ***"Evaluation of CCL28 and CCR10 expression in oral squamous cell carcinoma"*** submitted by Dr. Manjit Kour Mehta, JRI, Department of Oral Pathology & Microbiology Faculty of Dental Sciences of this University via letter no. 849/OP/2020 dated 10th February, 2020. **EC Comment on 23rd May, 2020:** • Sample size justification needed. **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment reviewed by Member-Secretary, IEC & approved.*** **EC Decision:** Approved ***Ref. code: 101stECM II B-Thesis/P65*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
b16	Clarification of research proposal entitled ***"Evaluation of etiopathology and management of primary and secondary amenorrhoea in adolescent and young women at tertiary care centre"*** submitted by Dr. Shubham Singh, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/445/2020 dated 10th February, 2020. **EC Comment on 23rd May, 2020:** • Survey questionnaire is not provided. **EC Decision on 23rd May, 2020:** Approval after justification ***The abov comment forwarded to the P.I. reply provide by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 101st ECM II B-Thesis/P74
	(Primary Reviewer: Dr. Preeti Agarwal)
b17	Clarification of research proposal entitled ***"Clinical audit of cesarean section done in second stage of labour in a tertiary care Hospital"*** submitted by Dr. Asna Rahman, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/437/2020 dated 10th February, 2020. **EC Comment on 23rd May, 2020:** • Kindly provide CRF • Kindly provide consent form as new format **EC Decision on 23rd May, 2020:** Approval after justification ***The abov comment forwarded to the P.I. reply provide by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P77*** ***(Primary Reviewer: Dr. Amita Jain)***
b18	Clarification of research proposal entitled ***"To study expression of tight junction protein claudin in odontogenic lesions"*** submitted by Dr. Tanveer Fatima, JRI, Department of Oral Pathology & Microbiology of this University via letter no. 1016/OP/2020 dated 8th June, 2020. **EC Comment on 23rd May, 2020:** • The study aims to determine the immunohistochemical expression of Tight junction protein Claudin 1, 4, 7 in Odontogenic Keratocyst and Ameloblastoma • Sample size 60. Was it derived after consultation with a statistician? • Formalin fixed, paraffin embedded tissue specimen of 30 ameloblastoma and 30 odontogenic cyst form the material of this study. • How exactly will the consent be obtained. The patients are surely from the past. • The term 'minor change can be made in the best interest of the study' is not clearly understood as all changes have to get a prior sanction of the IEC **EC Decision on 23rd May, 2020:** Approval after justification ***Ref. code: 101st ECM II B-Thesis/P79*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
b19	Clarification of research proposal entitled ***"A study of sexual functioning in male patients of opioid use disorder on maintenance treatment"*** submitted by Dr. Pranav Gautam, JRI, Department of Psychiatry of this University via letter no. 2072/Psy dated 8th February, 2020. **EC Comment on 23rd May, 2020:** • Questionnaire and opiate withdrawal scale not attached • Sample size not calculated **EC Decision on 23rd May, 2020:** Approval after justification

Chairperson, IEC
King George's Medical University
U.P., Lucknow

		The abov comment forwarded to the P.I. reply provide by P.I. which was reviewed by the Member-Secretary, IEC & approved. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P85*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

IB-a	Expedited Review (General Proposals)
1-	Expedited review of research proposal entitled proposal entitled ***"Impact of breast cancer and its therapies on female sexuality"*** submitted by Dr. Surabhi Garg, SR, Department of Endocrine Surgery of this University via letter no. Endosurg/2020/1/20 dated nil. ***The above proposal forwarded to Dr. Anoop Kumar Verma & Dr. Rajiv Garg, reply has given by Dr. Verma with approval.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECMIB-a/P1***
2-	Expedited review of research proposal entitled proposal entitled ***"Appraisal of cardiac energetic metabolism using blood sample of cardiac hypertrophy (mild, moderate, and severe) subjects and 1H- as well as 31 P-Nuclear Magnetic Resonance spectroscopy (1H and 31P NMRS)"*** submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 736/cardio.Res/2020 dated 8th June, 2020. ***The above proposal forwarded to Dr. Surajit Bhattacharya & Dr. Preeti, reply has given by Dr. Bhattacharya with following opinion:-*** 1. Required sample size 180. 240 cases will be recruited. Are the remaining 60 your control group? This is not clear. Was a statistician consulted to derive this sample size? 2.. Cardiac hypertrophy will be proven by Echo-cardiography and they will comprise the study group of 180 cases. 3. Venous blood will be sampled - how much and how many times? 4. Data collection sheet is incomplete. It does not tell us what will be done with the collected venous blood sample. 5. Bilingual consent form is provided. ***The above opinion was forwarded to the Principal-Investigator, reply has given his P.I. which was forwarded to Dr. Bhattacharya & he has approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECMIB-a/P2***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. IB

Expedited Review (COVID-19)

K.G's Medical University U.P., Lucknow

IB	Expedited Review-COVID-19
1-	Expedited review of research proposal entitled proposal entitled ***"Impact on open chronic wound management in COVID-19 patients in a dedicated COVID-19 superspeciallity tertiary care hospital. Is wound SARS Cov2 (COVID-19) positive"*** submitted by Dr. Pooja Ramakant, Additional Officer, Department of Endocrine Surgery of this University via letter no. Surgery/2020/D.No. 179 dated 29th May, 2020. ***The above proposal forwarded to Dr. Preeti Agarwal & Dr. Vimla Kumar Paliwal, reply has given by Dr. Agarwal with approval.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IVECM IB-COVID-19/P1***
2-	Expedited review of research proposal entitled proposal entitled ***"Impact of ongoing COVID-19 pandemic on cytopathological services: An Instituional experience"*** submitted by Dr. Chanchal Rana, Associate Professor, Department of Pathology of this University via letter no.nil dated 26th May, 2020. ***The above proposal forwarded to Dr. Anoop Kumar Verma & Dr. Rajiv Garg, reply has given by Dr. Verma with approvel.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IVECM IB-COVID-19/P2***
3-	Expedited review of research proposal entitled proposal entitled ***"Transition from physical to virtual classroom amidst the crists of COVID-19: Students' and teachers' perspective and its utilization in improvement of current teaching methodology"*** submitted by Prof. Jyoti Chopra, Department of Anatomy of this University via letter no.85/ANAT/2020-21dated 23rd May, 2020. ***The above proposal forwarded to Dr. Anoop Kumar Verma & Dr. Rajiv Garg, reply has given by Dr. Verma with his approval.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IVECM IB-COVID-19/P3***
4-	Expedited review of research proposal entitled proposal entitled ***"Impact of 'Holistic and comprehensive assessment and personal caries plan' (ICCMSTM) in Pediatric population"*** submitted by Dr. Richa Khanna, Professor (Jr. Grade), Department of Pediatric & Preventive Dentistry, Faculty of Dental Sciences of this University via letter no.Pedo 679/2020 dated 6th May, 2020. ***The above proposal forwarded to Dr. Preeti Agarwal & Dr. Rajiv Garg, reply has given by Dr. Preeti with her approval.*** **Action taken:** Provisionally approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: IVECM IB-COVID-19/P4***
5-	Expedited review of research proposal entitled proposal entitled ***"Effect of nationwide lockdown in view of corona pandemic on profile of CNS tuberculosis patients presenting to a tertiary care hospital"*** submitted by Dr. Neeraj Kumar Assistant Professor, Department of Neurology of this University via letter no. 447/Neuro/20 dated 11th June, 2020. ***The above proposal forwarded to Dr. Anoop Kumar Verma & Dr. Rajiv Garg, reply have given both reviewers with their approval.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: IVECM IB-COVID-19/P5***
6-	Expedited review of research proposal entitled proposal entitled ***"Impact of lockdown on patients with subacute sclerosing panencephalitis amid corona pandemic"*** submitted by Dr. Shweta Pandey, Associate Professor, Department of Neurology of this University via letter no. nil dated 11th June, 2020. ***The above proposal forwarded to Dr. Anoop Kumar Verma & Dr. Preeti Agarwal.*** **Action taken:** Pending **EC Decision:** Approved ***Ref. code: IVECM IB-COVID-19/P6***
7-	Expedited review of research proposal entitled ***"A phase II safety and efficacy study on Prognosis of Moderate Pneumonia in COVID-19 patients with regular intravenous Immunoglobin therapy"*** submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine of this University via letter no. nil dated 4th June, 2020. ***The above proposal forwarded to Dr. Surajit Bhattacharya & Dr. Preeti Agarwal.*** **Action taken:** Provissionally Approved **EC Decision:** Approved ***The following documents were reviewed:-***

S. No	Documents Name	Version	Date
1.	Protocol Synopsis	2.0	25-May-2020
2.	Protocol	2.0	25-May-2020
3.	DCGI approval Letter	NA	NA
4.	Insurance Policy Declaration	NA	NA
5.	Case Report Form	2.0	25-May-2020
6.	Patient Information Sheet & Informed Consent Form –English	2.0	20-May-2020

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	7.	Patient Information Sheet & Informed Consent Form –English to Hindi	2.0	20-May-2020
	8.	Translation Certificate of Informed Consent Form- English to Hindi	NA	30-May-2020
	9.	Back translated Patient Information Sheet & Informed Consent Form – Hindi to English	2.0	20-May-2020
	10.	Back Translated Certificate of Informed Consent Form- Hindi to English	NA	30-May-2020
	11.	Draft CTA	NA	NA
	12	Site Documents		
		Investigator Undertaking	NA	01-Jun-2020
		Investigator Signature Page	NA	01-Jun-2020
		CV of PI (Dr. D Himanshu)	NA	01-Jun-2020
		MRC of PI (Dr. D Himanshu)	NA	01-Jun-2020
		CDA	NA	01-Jun-2020
		Site Declaration	NA	01-Jun-2020

Ref. code: IVECM IB-COVID-19/P7

8- Expedited review of research protocol no. CVD-19-CD-002 entitled ***"A Randomized, open label-2-treatment groups clinical trial evaluating the safety and efficacy of 2-Deoxy-D-Glucose as an adjunctive therapy to standard of care, in comparison to standard of care alone, in the Acute treatment of moderate to severe COVID-19 patients"*** submitted by Dr. Sudhir Kumar Verma, Associate Professor, Department of Medicine of this University via letter no. nil dated 8th June, 2020.

The above proposal forwarded to Dr. Anoop Kumar Verma & Dr. Preeti Agarwal. Reply received from both reviewers with their approval.

The following documents were reviewed:-

S. No.	Documents	Version Number and Version Date
1	Study Protocol	Version 2.0 dated 29 May 2020
2	Clinical trial protocol signature page for Version 2.0 dated 29 May 2020	Signed by the PI on 06 Jun 2020
3	Doctors Brochure & Scientific Rationale	

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	3.1	Doctors Brochure & Scientific Rationale	Version 1.0 dated 02 Jun 2020
	3.2	Supporting Literature -I	Released on 2005
	3.3	Supporting Literature -II	Released on 2013
	4	DCGI Approval Letter	Letter dated 21 May 2020
	5.	CTRI Registration	CTRI Acknowledgement Number REF/2020/06/034088 dated 03 Jun 2020
	6	Investigator Undertaking	Signed on 06 Jun 2020
	7	Investigator Curriculum Vitae, Medical registration certificate and GCP Certificate	Signed on 04 Jun 2020, MRC number: 52334
	8.	Patient Information sheet & Informed Consent Form (Main ICF)	
	4	DCGI Approval Letter	Letter dated 21 May 2020
	5.	CTRI Registration	CTRI Acknowledgement Number REF/2020/06/034088 dated 03 Jun 2020
	6	Investigator Undertaking	Signed on 06 Jun 2020
	7	Investigator Curriculum Vitae, Medical registration certificate and GCP Certificate	Signed on 04 Jun 2020, MRC number: 52334
	8.	Patient Information sheet & Informed Consent Form (Main ICF)	
	a	English	Patient Information Sheet & Informed Consent Form _ English_Version 2.0 dated 29 May 2020
	b	Hindi	Patient Information Sheet & Informed Consent Form _ Hindi_Version 2.0 dated 03 Jun 2020
	c	Hindi back Translation	Patient Information Sheet & Informed Consent Form _ Hindi to English_Version 2.0 dated 06 Jun 2020
	d	Translation Certificate for Hindi	Informed consent form English to Hindi on 03 Jun 2020
	e	Back Translation Certificate for Hindi	Informed consent form Hindi to English on 06 Jun 2020

Chairperson, IEC
King George's Medical University
U.P., Lucknow

9	Insurance Certificate	Insurance certificate No. 4067-CVD-19-CD-002 Valid from 01 Mar 2020 to 28 Feb 2021
10	Draft CTA	Version 4.0 and Date is not applicable
11	Draft eCRF outline	Version and Date is not applicable
12.	Financial Disclosure Questionnaire of PI	Signed on 06 Jun 2020

EC Decision: Approval subject to fulfillment & Administrative Formalities

Ref. code: IVECM IB-COVID-19/P8

Expedited review of research protocol version no. 3.4 dated 18th May, 2020 entitled ***"A Randomized, open label, parallel efficacy, active control, multicentre esploratory drug trial to evaluate efficacy and safety of an Ayurvedic Formulation (AYUSH-64) a adjunct treatment to standard of care for the management of mild to moderate COVID-19 patients"*** submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine of this University via letter no. nil dated 8th June, 2020.

The above proposal forwarded to Dr. Surajit Bhattacharya & Dr. Preeti Agarwal.

Reply received from both reviewers with their approval.

Dr. Bhattacharya has given his reply with following comments:-

AYUSH 64, a poly herbal preparation has been tested as safe and non-toxic in the dose of 500 mg/kg of body weight for 12 weeks.

It is found to be effective in fevers of unknown etiology, filarial lymphangitis and derangement of liver function besides its anti-malarial activity.

This herbal combination is being tried in COVID19 cases because of prior encouraging results in influenza patients.

Patients of COVID19 will be randomly alloted in 2 groups: Group 1 will receive AAYUSH64 with Standard of Care and Group 2 will get Standard of Care only. Sample size 40 - 20 in each group. Was this calculated after consulting a statistician?

Inclusion and exclusion criteria are clear but from the exclusion criteria the researchers are giving the impression that they are not very convinced about the effect of this drug in presence of any respiratory distress. But respiratory distress is one of the complications of this viral disease! So are the researchers not accepting defeat befor testing the drug? Why are respiratory distress patients being excluded?

Similarly Chronic, Severe, Unstable, Uncontrolled co-existent medical illness such as Diabetes, Hypertension, Cardiac disorders, liver, kidney disorders and lung disorders are being excluded because the researchers feel that

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	the drug may put these patients at increased risk during the study. But how do they know this? They have not yet tested the drug. They can always withdraw the drug if it worsens the situation, but not testing it and excluding these patients is baffling. For which sub-set of COVID19 patients is this drug being proposed then? Outcome measures are clearly defined Withdrawl criteria No. 1 'The patient can withdraw from the study at any point of time without assigning any reason.' What does this mean? Withdrawl has to be due to some reason! Dosage of test drug 1000mg BD for 12 weeks Duration of study 6 months A detailed statement of expenses provided In the section 'Expected outcome' point 2 and 3 require clarifications: 2. AYUSH 64 in conjunction with standard treatment care will help in better clearance of viral load. How do the researchers propose to infer this? 3. The drug will enhance the immune system and promote early recovery of patient from COVID – 19 infection, How do they propose to infer this? We need a data collection sheet to know what parameters are being observed and when. The Timeline and Events schedule needs to be expanded into a proper data collection sheet.I cannot find any mention of insurance covering this trial. ***The above comment was forwarded to the P.I., reply has given by P.I. which was reviewed by the Primary Reviewer & he has approved.*** **EC Decision:** Approval after with fulfillment & administrative all formalities ***Ref. Code: IV ECM IB-COVID-19/P9***

Chairperson, IEC
King George's Medical University
Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. IIA

New proposals

K.G's Medical University U.P., Lucknow

IIA	New Proposals
8.	Research proposal entitled "***Correlates of mental health/illness in patients with psychiatric disorder availing service from the Department of Psychiatry, King George's Medical University, Lucknow, U.P: A retrospective chart review***" submitted by Prof. P.K. Dalal, Head, Department of Psychiatry of this University via letter no. 1829/Psy dated 31st December, 2019. **EC Decision:** Approved ***Ref. code: 101stECM IIA/P8*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
15.	Research proposal entitled "***Clinical study to investigate and compare glycemic control, pharmacoeconomics, quality of life among patients with type-2 diabetes treated with different add on therapy***" sponsored by Indian Council of Medical Research New Delhi submitted by Prof. Amod Kumar Sachan, Head, Department of Pharmacology of this University via letter no. 12/Pharma/20 dated 4th January, 2020. **EC Decision:** Approved ***Ref. code: 101stECM IIA/P15*** ***(Primary Reviewer Dr. A.A. Sonkar:)***
17.	Research proposal entitled "***Combination therapy with pegylated interferon and ribavirin in childhood cancer survivors less than 12 years with chronic HEPATITIS C-a retrospective study***" submitted by Dr. Nishant Verma, Associate Professor, Department of Pediatrics of this University via letter no. nil dated 20th January, 2020. **EC Decision:** Approved ***Ref. code: 101stECM IIA/P17*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
24.	Research proposal entitled "***A case control study on estimation of DNA damage response (rH2AX) in salivary and soft tissue of oral squamous fibrosis and oral squamous cell carcinoma patients***" sponsored by ICMR, New Delhi submitted by Dr. Vikram Khanna, Associate Professor, Department of Oral Medicine & Radiology of this University via letter no. 93/OM&R-/20 dated 1st February, 2020. **EC Decision:** Approved ***Ref. code: 101stECM IIA/P24*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
35.	Research proposal entitled "***Evaluation of epigenetic mechanisms in pathogenesis of type2 diabetes with and without metabolic syndrome: a case control study***" sponsored by ICMR, New Delhi submitted by Dr. Gyanendra Kumar Sonkar, Associate Professor, Department of Biochemistry of this University via letter no. Bio/2020/953 dated 6th February, 2020.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

		EC Comment: • Kindly provide detailed of proposal. • Kindly provide the Patient Information Sheet Hindi & English **EC Decision:** Re-submit ***Ref. code: 101st ECM IIA/P35*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
43.		Research proposal entitled ***"Pattern of practice on mental health issues and attitude towards referral among general medical practitioners of North India"*** submitted by Dr. Suchana Roy Bhomik, Assistant Professor, KGMU College of Nursing of this University via letter no. 116/PF dated 6th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P43*** ***(Primary Reviewer: Dr.Smriti Bhadauria)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. IIB

Case study

K.G's Medical University U.P., Lucknow

IIB	Case Study
1.	Research proposal entitled ***"A study of corporate social responsibility resources in tertiary care government Hospital"*** submitted by Dr. Amit Kumar, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2019/767 dated 18th December, 2019. **EC Decision:** The study does not involve human subjects. Ethical clearance not needed. ***Ref. code: 101st ECM IIB CS/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"A study of narcotics policy in a tertiary care Teaching Hospital Lucknow, India"*** submitted by Dr. Ashutosh Kumar Sharma, JRIII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/097 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECMIIBCS/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Research proposal entitled ***"A study on the knowledge, attitudes and practices regarding hand hygiene amongst nursing staff in selected area of a tertiary care Teaching Hospital"*** submitted by Dr. Shashvat Kshitij Sinha, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/089 dated 7th February, 2020. **EC Comment:** • Kindly provide the Consent form as new format **EC Decision:** Re-submit ***Ref. code: 101st ECMIIBCS/P3*** ***(Primary Reviewer: Amita Jain)***
4.	Research proposal entitled ***"A study on unit cost of diet in tertiary care government Hospital"*** submitted by Dr. John Paul G Momin, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/019 dated 1st January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECMIIBCS/P4*** ***(Primary Reviewer: Dr. Rajeev Garg)***
5.	Research proposal entitled ***"To study on the Medical record in In patient Department in selected area of a tertiary care government Hospital "*** submitted by Dr. Prawaal Mehrotra, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Head, Department of Hospital Administration of this University via letter no. HA/2020/022 dated 17th January, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P5*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
6.	Research proposal entitled ***"To study of Physical Medicine and rehabilitation Department in a tertiary care government teaching Hospital"*** submitted by Dr. Preeti Bharti, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/025 dated 20th January, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
7.	Research proposal entitled ***"To study on the completeness of the surgical safety checklist with respect to the patients of surgical gastroenterology Department in a tertiary care government teaching Hospital at Lucknow"*** submitted by Dr. Shweta Singh, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/042 dated 24th January, 2020. **EC Comment:** • Research Hypothesis not written: • Objective not defined • What Selected areas will be studeid? **EC Decision:** Re-write & Re-submit ***Ref. code: 101stECMIIBCS/P7*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
8.	Research proposal entitled ***"A study of clientele satisfaction in the outpatient Department of a tertiary care government Hospital"*** submitted by Dr. Shreya Pandey, JRII through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/073 dated 7th February, 2020. **EC Decision:** Defer in next meetin because title is wrong by P.I. ***Ref. code: 101stECMIIBCS/P8*** ***(Primary Reviewer: Dr. Smriti Bhadoria)***
9.	Research proposal entitled ***"A study on MRI service in a tertiary care Government Teaching Hospital"*** submitted by Dr. Shreya Pandey, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/072 dated 7th February, 2020. **EC Decision:** Waiver granted ***Ref. code: 101stECMIIBCS/P9*** ***(Primary Reviewer: Dr. Preeti Agarwal)***

Chairperson, IEC
King George's Medical University
Lucknow

10.	Research proposal entitled ***"A work study of nurses in accident and emergency Department of a tertiary care Government Hospital"*** submitted by Dr. Naveen Chaturvedi, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/075 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P10*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
11.	Research proposal entitled ***"A study of clientele satisfaction in the outpatient Department of a tertiary care Government Hospital"*** submitted by Dr. Naveen Chaturvedi, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/074 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P11*** ***(Primary Reviewer: Dr. Rajendra Nath)***
12.	Research proposal entitled ***"A study of infectious disease ward in a tertiary care Government Hospital"*** submitted by Dr. Sandhya Yadav, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/079 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P12*** ***(Primary Reviewer: Dr. Amita Jain)***
13.	Research proposal entitled ***"A study of rescheduling of surgeries in a tertiary care Government Hospital"*** submitted by Dr. Sandhya Yadav, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/078 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P13*** ***(Primary Reviewer: Dr. Rajeev Garg)***
14.	Research proposal entitled ***"A study of on completeness of treatment card in a tertiary care Government Hospital"*** submitted by Dr. Preeti Bharti, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/071 dated 7th February, 2020. **EC Comment:** • The study aims to assess the completeness of treatment cards on different parameters of NABH standards and to suggest recommendations if any • Sample size not provided. From monthly admission records of previous years please come up with a sample size doable in 4 weeks and consult with statistician to see if your results will be statistically significant • Observational checklist – what all will be observed, is provided • Technique of case record sampling ensures maintaining confidentiality of

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	individual patients. But why do they need UHID of the patient? Just like the Name they can see whether the UHID is correctly mentioned in the treatment card or not. Why are they noting it? • Consent waiver is sought as the research involves analysis of data about units **EC Decision:** Approval after justification ***Ref. code: 101st ECMIIBCS/P14*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
15.	Research proposal entitled ***"A study of the utilization of laboratory equipments in trauma centre of a tertiary care Government Teaching Hospital at Lucknow"*** submitted by Dr. Shweta Budhiraja, JRII through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/076 dated 7th February, 2020. **EC Decision:** Waiver granted ***Ref. code: 101st ECMIIBCS/P15*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
16.	Research proposal entitled ***"A study on utilization of vertical transportation system in superspeciality Government Hospital"*** submitted by Dr. Sukriti Shah, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/087 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECMIIBCS/P16*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
17.	Research proposal entitled ***"A study on ayushman bharat pradhan mantri jan arogya yojna in selected area of a tertiary care Government Hospital"*** submitted by Dr. Anubha Agrawal, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/066 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECMIIBCS/P17*** ***(Primary Reviewer: Dr. Smriti Bhadoria)***
18.	Research proposal entitled ***"A study on costing of CSSD in a super specialty Hospital"*** submitted by Dr. Anubhuti, JRII through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/070 dated 7th February, 2020. **EC Decision:** No human subject enrolled in study. Ethical clearance not needed. ***Ref. code: 101st ECMIIBCS/P18*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
19.	Research proposal entitled ***"A study of geriatric mental Health Department in a tertiary care Government Teaching Hospital"*** submitted by Dr. Sukriti Shah, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Hospital Administration of this University via letter no. HA/2020/086 dated 7th February, 2020. **EC Decision:** The study does not involve human subjects.Ethical clearance not needed. ***Ref. code: 101stECMIIBCS/P19*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
20.	Research proposal entitled ***"A work study of residents in accident and emergency Department of a tertiary care Government Hospital"*** submitted by Dr. Shweta Budhiraja, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/077 dated 7th February, 2020. **EC Comment:** • Kindly provide Questionnaire **EC Decision:** Approval after justification ***Ref. code: 101stECMIIBCS/P20*** ***(Primary Reviewer: Dr. Rajendra Nath)***
21.	Research proposal entitled ***"A study of patient satisfaction on dietary service in a tertiary care Government Hospital"*** submitted by Dr. Anubhuti, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/069 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCSP21*** ***(Primary Reviewer: Dr. Rajeev Garg)***
22.	Research proposal entitled ***"A study of clientele satisfaction of dietary services in selected areas of a tertiary care Government Hospital"*** submitted by Dr. Anubha Agrawal, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/065 dated 7th February, 2020. **EC Comment:** • The researchers wish to study the patient satisfaction with various aspects of dietary services and suggest recommendations if any • Sample size 384. Statistically calculated • Patients in RALC IPD who have received at least 2 meals will be included • The questionnaire / data collection sheet is missing. It is important to know what is being asked and what are the patient's response options? It should be bilingual **EC Decision:** Approval after justification ***Ref. code: 101stECMIIBCS/P22*** ***(Primary Reviewer: Dr.Surajit Bhattacharya)***
23.	Research proposal entitled ***"A study of intensive care unit (Medicine) in selected area of a tertiary care Government Hospital"*** submitted by Dr. Anubha Agrawal, JRII,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/067 dated 7th February, 2020. **EC Decision:** The study does not involve human subjects.Ethical clearance not needed. ***Ref. code: 101st ECMIIBCS/P23*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
24.	Research proposal entitled ***"A study of mortuary unit of a tertiary care Government Teaching Hospital at Lucknow"*** submitted by Dr. Shweta Singh, JRII through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/063 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECMIIBCS/P24*** ***(Primary Reviewer:Dr. A.A. Sonkar)***
25.	Research proposal entitled ***"A study clientele satisfaction in the outpatient Department of a tertiary care Government Hospital"*** submitted by Dr. Shashvat Kshitij Sinha, JRII through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/090 dated 7th February, 2020. **EC Comment:** **Same is Ref. code 101 ECM IIBSC/P8** **EC Decision:** Defer in next meetin because title is wrong by P.I. ***Ref. code: 101st ECMIIBCS/P25*** ***(Primary Reviewer: Dr. Smriti Bhadoria)***
26.	Research proposal entitled ***"A study of orthopaedic surgery Department of a tertiary care Government Teaching Hospital"*** submitted by Dr. Shashvat Kshitij Sinha, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/088 dated 7th February, 2020. **EC Decision:** The study does not involve human subjects.Ethical clearance not needed. ***Ref. code: 101st ECMIIBCS/P26*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
27.	Research proposal entitled ***"A study of patient satisfaction on dietary service in a tertiary care Government Hospital"*** submitted by Dr. Shweta Singh, JRII through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/099 dated 8th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECMIIBCS/P27*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University
Lucknow

28.	Research proposal entitled ***"A study of the antibiotic prescription pattern in a tertiary care Government Teaching Hospital"*** submitted by Dr. Shweta Singh, JRII through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/068 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P28*** ***(Primary Reviewer: Dr. Rajendra Nath)***
29.	Research proposal entitled ***"A study on neonatal intensive care unit in a Tertiary care Government Teaching Hospital in Lucknow India"*** submitted by Dr. Anitta Jose Ellenkil, JRII through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/100 dated 8th February, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P29*** ***(Primary Reviewer: Dr. Amita Jain)***
30.	Research proposal entitled ***"A study of neurosurgery Department in tertiary care Government Hospital"*** submitted by Dr. John Paul G Momin, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/095 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P30*** ***(Primary Reviewer: Dr. Rajeev Garg)***
31.	Research proposal entitled ***"A study of Rheumatology Department in tertiary care Government Hospital"*** submitted by Dr. Supriya Singh, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/094 dated 7th February, 2020. **EC Comment:** • The aim of this study is to assess the National Quality Assurance Standards compliance in Immunology Department of KGMU – OPD, IPD and laboratories and to 8identify gaps as per NQAS and suggest recommendations • It is an observational descriptive cross-sectional study • A detailed study plan including service provisions, Patient Rights, Inputs, Support Services, Clinical Services, Infection Control and Outcome monitoring is provided • Markings will be 0 for no compliance 1 for partial compliance and 2 for full compliance and subsequently the data will be analyzed • Consent waiver is sought as the research involves analysis of data about units **EC Decision:** Approval after justification ***Ref. code: 101stECMIIBCS/P31*** ***(Primary Reviewer: Dr. Surjati Bhattacharya)***
32.	Research proposal entitled ***"A study on safety levels of disinfectants being used in***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	tertiary care Government Hospital" submitted by Dr. Supriya Singh, JRII through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/093 dated 7th February, 2020. **EC Decision:** The study does not involve human subjects.Ethical clearance not needed. ***Ref. code: 101stECMIIBCS/P32*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
33.	Research proposal entitled ***"Work study of nurses in a selected area of a tertiary care Government Teaching Hospital, Lucknow"*** submitted by Dr. Ashutosh Kumar Sharma, JRIII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/098 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P33*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
34.	Research proposal entitled ***"A study of out patient Department of a tertiary care Government Teaching Hospital Lucknow"*** submitted by Dr. Prawaal Mehrotra, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/101 dated 8th February, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P34*** ***(Primary Reviewer: Dr. Smriti Bhadoria)***
35.	Research proposal entitled ***"A study linen services in selected areas a tertiary care Government Teaching Hospital Lucknow"*** submitted by Dr. Prawaal Mehrotra, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/103 dated 8th February, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P35*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
36.	Research proposal entitled ***"A study the handwashing facilities in out patient Department a tertiary care Government Teaching Hospital Lucknow"*** submitted by Dr. Prawaal Mehrotra, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/102 dated 8th February, 2020. **EC Decision:** The study does not involve human subjects. Ethics clearance not needed ***Ref. code: 101stECMIIBCS/P36*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
37.	Research proposal entitled ***"A study of ayushman bharat yojana in a tertiary care***

Chairperson, IEC
King George's Medical University
Lucknow

	Government Teaching Hospital in Lucknow India" submitted by Dr. Ashutosh Kumar Sharma, JRIII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/096 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P37*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. IIB

Fellowships

K.G's Medical University U.P., Lucknow

IIB	Fellowship
1.	Research proposal entitled ***"To analyse thioredoxin as adjuvant to serum inflammatory markers in delayed fracture related infection"*** sponsored by ICMR. New Delhi submitted by Ms. Archana Raikwar, SRF Through his Mentor Prof. Ajai Singh, Head, Department of Paediatric Orthopaedics of this University via letter no.335/Paeel/Ortho/20 dated 17th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-FS/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"Neisseria gonorrhoeae and Chlamydia trachomatis infection in infertile women reaching to tertiary care centre"*** sponsored by ICMR. New Delhi submitted by Ms. Asmat Jahan, JRF Through his Mentor Prof. Raj Kumar Kalyan, Department of Microbiology of this University via letter no.736/20 dated 27th January, 2020. **EC Comment:** • Kindly calculate sample size , • Kindly provide Engilesh Informed Consent Form and Budget & see page -1 **EC Decision:** Approval after justification ***Ref. code: 101st ECM II B-FS/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Research proposal entitled ***"Levels of pesticides in hypothyroidic and infertile women: A biochemical and genotoxic study"*** sponsored by ICMR. New Delhi submitted by Dr. Saima Amjad, Through his Mentor Prof. A.A. Mahdi, Head, Department of Biochemistry of this University via letter no. Bio/2020/919 dated 27th January, 2020. **EC Comment:** • The present study will answer only objective one. To Prove and association cases & controles both will be required (Case Control design) • Why 200 cases will be enrolled? Sample size calculation is not done. • Kindly provide Inform Consent form as per new format. **EC Decision:** Revise ***Ref. code: 101st ECM II B-FS/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Research proposal entitled ***"To analyse nCD64 and thioredoxin as biomarkers for late fracture related infection"*** sponsored by AO Trauma Asia Pacific submitted by Dr. Sabir Ali, Through his Mentor Prof. Ajai Singh, Head, Department of Paediatric Orthopaedics of this University via letter no. 334/Paed/2020 dated 13th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-FS/P4*** ***(Primary Reviewer: Dr. Rajeev Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	5.	Research proposal entitled ***"Assessment of novel angiogenesis markers and their implications in correlation with vascular ultrastructures as prognostic indicators in urinary bladder carcinoma"*** sponsored by ICMR submitted by Ms. Niharika Maurya, Through his Mentor Dr. Atin Singhai, Additional Professor, Department of Pathology of this University via letter no. 132/2020 dated 24th January, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-FS/P5*** ***(Primary Reviewer: Dr. Surjait Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. IIB

Ph.D. Scholars

K.G's Medical University U.P., Lucknow

IIB.	New Thesis-Ph. D. Scholar(Student)
1.	Research proposal entitled "***Investigating the role of zearalenone, a mycoestrogen, in the promotion of endometrial cancer***" sponsored by ICMR, New Delhi submitted by Ms. Varsha Singh, JR, under the guidance of Dr. Smriti Agraeal, Additional Professor, Department of Obstetrics & Gynecology of this University via letter no. OG/361/2020 dated 4th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Ph.D/P1*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
2.	Research proposal entitled "***Single nucleotide polymorphism and expression of androgen receptor, IGF-1 receptor and PSA gene in prostate cancer patients with and without diabetes mellitus type-2***" submitted by Ms. Afreen Khan, Ph.D scholar under the guidance of Prof. Anu Chandra, Era's Lucknow Medical College & Hospital & CO PI Prof A.A. Madhi, Head, Department of Biochemistry of this University via letter no. 069/2020 dated 7th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECM II B-Ph.D/P2*** ***(Primary Reviewer: Dr. Rajeev Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. IIB

MBBS students

K.G's Medical University U.P., Lucknow

IIB	MBBS- Student
1.	Research proposal entitled ***"Cross-sectional study to assess knowledge and practices of medical students regarding the evidence-based learning strategies"*** submitted by Ms. Zareen Akhtar, MBBS Student Batch of 2018 & Kaushal Kishor Singh MBBS Student, 2018 through their guide Prof. Shally Awasthi, Head, Department of Pediatrics of this University this University via letter no. 262/Ped/2020 dated 6th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECMIIBMBBS/P1*** ***(Primary Reviewer: Dr.Amita Jain)***
2.	Research proposal entitled ***"Knowledge, attitude and practices of health-care professionals regarding standard operating procedures of phlebotomy"*** submitted by Mr. Kaushal Kishor Singh, MBBS Student Batch of 2018, & Sagar Rai MBBS Student 2017 Through their guide Dr. Sheetal Verma, Assistant Professor, Department of Microbiology of this University this University via letter no. 778/2020 dated 8th February, 2020. **EC Decision:** Approved ***Ref. code: 101st ECMIIBMBBS/P2*** ***(Primary Reviewer: Dr. Rajeev Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. IIC

New Drug Trials

K.G's Medical University U.P., Lucknow

II-C	Review of New Drug Trial
1-	Research Protocol entitled "***A phase II randomized, double blind, placebo controlled, parallel group, multi-centre study to evaluate the efficacy, safety and tolerability of TRC160334 as an Add-on to mesalamine in subjects with mild to moderately active ulcerative colitis***" sponsored by Torrent Pharmaceuticals Limited Research Centre submitted by Dr. Vivek Gupta, Department of Gastrointestinal Surgery of this University via letter no. nil dated 23rd December, 2019.

The following documents were reviewed:

Sr. No.	Documents	Version Number and Version Date
1	Study protocol	Version 1 dated 09 Jan 2019
2	Protocol signature pages	Version 1.0 dated 22 Jan 2019
3	Study protocol	Version 1.1 dated 09 Apr 2019
4	Protocol signature pages	Version 1.1 dated 24 May 2019
5	Investigators Brochure	Edition number 3.0 dated 09 Jan 2019
6	Subject Informed Consent Form in English	Version: India- Dr Vivek Gupta - English- Version 1.2 dated 30 Apr 19 Reference:India-English-Version 1.2 dated 24 Apr 2019
7	Translation of the Subject Informed Consent Form in Hindi	Version: India- Dr. Vivek Gupta - Hindi- Version 1.2 dated 10 May 2019 Reference: India- Dr. Vivek Gupta - English- Version 1.2 dated 30 Apr 2019
8	Back Translation of Subject Informed Consent Form Hindi to English	Version: India- Dr. Vivek Gupta - English Back Translated- Version 1.2 dated 10 May 2019 Reference: India- Dr. Vivek Gupta - Hindi- Version 1.2 dated 10 May 2019
9	Certificate for Translation of Subject Informed Consent in Hindi	Dated 16 May 2019

Chairperson, IEC
King George's Medical University
U.P., Lucknow

10	Certificate for Back Translation of Subject Informed Consent from Hindi to English	Dated 16 May 2019
11	Subject Paper Diary in English	Version 01 dated 10 Jan 2019
12	Translation of Subject Paper Diary from English to Hindi	Hindi Version 1 dated 16 Jan 2019
13	Back Translation of Subject Paper Diary Hindi to English	English Back Translation – Version 1 dated 22 Jan 2019
14	Certificate for Translation of Subject Paper Diary in Hindi	Dated 04 Feb 2019
15	Certificate for Back Translation of Subject Paper Diary from Hindi to English	Dated 04 Feb 2019
16	Subject E-Diary in English	English – Version 1 dated 10 Jan 2019
17	Translation of Subject E- Diary from English to Hindi	Hindi Version 1 dated 16 Jan 2019
18	Back Translation of Subject E- Diary from Hindi to English	English Back Translation – Version 1 dated 22 Jan 2019
19	Certificate for Translation of Subject E-Diary in Hindi	Dated 04 Feb 2019
20	Certificate for Back Translation of Subject E-Diary from Hindi to English	Dated 04 Feb 2019
21	Audio-visual Recording Informed Consent Form in English for vulnerable subjects	English - Version 01 dated 05-Feb-2019
22	Translation of Audio-visual Recording Informed Consent Form from English to Hindi for vulnerable subjects	Hindi – Version 1.0 dated 25-Feb-2019
23	Back Translation of Audio-visual Recording Informed Consent Form from Hindi to English for vulnerable subjects	English Back Translation– Version 01 dated 01-Mar-2019
24	Certificate for Translation of Audio-visual Recording Informed Consent Form in Hindi for vulnerable subjects	Dated 15 Mar 2019
25	Certificate for Back Translation of Audio-visual Recording Informed Consent Form from Hindi to	Dated 15 Mar 2019

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	English for vulnerable subjects	
26	Advertising material in English	Version 1, dated 12-Feb-2019
27	Translation of Advertising material from English to Hindi	Hindi – Version 1.0 dated 27 Feb 2019
28	Back Translation of Advertising material from Hindi to English	English Back Translation - Version 1.0 dated 01 March 2019
29	Certificate for Translation of Advertising material in Hindi	Dated 15 Mar 2019
30	Certificate for Back Translation of Advertising material from Hindi to English	Dated 15 March 2019
31	IBDQ Instructions – English (Review copy)	NA
32	IBDQ Translation from English to Hindi	NA
33	IBDQ Instructions sheet Translation from English to Hindi	NA
34	IBDQ Instructions Sheet Translation Certificate From English to Hindi	Dated 23 Mar 2017
35	IBDQ Translation Certificate from English to Hindi	Dated 22 Feb 2008
36	Study insurance policy No. 2999202336285600000	Valid from 21 Jul 2018 to 20 Jul 2019
37	Study insurance policy certificate No. 2999202336285600000	Valid from 31 December 2018 to 20 Jul 2019
38	Study insurance policy No. 2999202739069500000	Valid from 01 April 2019 to 31 March 2020
39	Draft Case Report Form	Draft copy Ver 1.0 dated 15 Jan 2019
40	Draft Clinical Trial Agreement	Version 02 dated 14-May-2019
41	DCGI Submission Letter	Dated 11 Feb 2019
42	Online Acknowledgement of DCGI submission	Dated 11 Feb 2019
43	Phase-II CT NOC Permission	Dated 8 Apr 2019

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	44	Investigator's Undertaking(previous version)	Signed 22 Jan 2019
	45	Updated Investigator's Undertaking	Signed 22 May 2019
	46	Principal Investigator - Curriculum Vitae	Signed 22 Jan 2019
	47	MRC	Signed 22 Jan 2019
	48	GCP Certificate	Signed 22 Jan 2019
	49	Patient Accrual Methods Declaration	Dated 22 Jan 2019
	50	CTRI	Dated 4 Jul 2019
	51	COA of Placebo	Dated 19 Jun 2019
	52	COA of TRC160334 tablet 2 mg	Dated 7 Jun 2019
	53	COA of TRC160334 tablet 4 mg	Dated 10 Jun 2019
	54	DCGI Notification for inclusion of new sites	Dated 17 Jul 2019
	55	Protocol Errata	Dated 29 Aug 2019
	56	Expanded eCRF_V1.0	Dated 09 Sep 2019
	57	Source Template	Version 01 dated 23 Sep 2019
	58	CGI Approval (NOC for Protocol amendment 1.1):	Dated 18 Sep 2019
		EC Decision: Approval after with fulfillment & administrative all formalities ***Ref. code: 101stECMIIC/P1*** ***(Primary Reviewer: Dr.Vimal Kumar Paliwal)***	
2.		Research Protocol no. RI-01-006 entitled "***A randomized, double-blind, parallel-group, phase III study to compare the efficacy, safety, and immunogenicity of proposed rituximab biosimilar (DRL- RI) with MAB THERA® in subjects with previously untreated, stage II- IV, cluster of differentiation (CD)20- positive, low tumour burden follicular lymphoma***" sponsored by Reddy's Laboratories S.A submitted by Dr. Sudhir Singh, Associate Professor, Department of Radiotherapy of this University via letter no. nil dated 4th January, 2020. ***The following documents were reviewed:*** ❖ Protocol RI-01-006 dated 4th Jan 2019 ❖ IB INVESTIGATOR BROCHURE; Version 5, 10 October 2018 ❖ Subject Case Report Forms, RI-01-006 V1.0 dated 14 Jan 19 ❖ Subject ID Card version 1.0 dated 30 Nov 2018 (English and Hindi) along with translation and validation certificate.	

Chairperson, IEC
King George's Medical University
U.P., Lucknow

AV ICF:

- 242435_RI-01-006_India_Dr. Sudhir Singh_AV ICF_English_Version 1.1_ 17 Dec 2019 based on the India Model ICF Version 1.0 _01 Feb 2019
- 242435_RI-01-006_India_Dr. Sudhir Singh_AV ICF_Hindi_Version 1.1_ 17 Dec 2019 based on the India Model ICF Version 1.0 _01 Feb 2019

  Translated from English to Hindi on 18 Dec 2019
- 242435_RI-01-006_India_Dr. Sudhir Singh_AV ICF_ Hindi to English_Version 1.1_ 17 Dec 2019 based on the India Model ICF Version 1.0 _01 Feb 2019

  Back Translated from Hindi to English on 18 Dec 2019

Main ICF:

- 242435_ RI_01_006_India_ Dr. Sudhir Singh_ Main ICF_English_Version 1.1 _17 Dec 2019 Based on Protocol RI-01-006_India Model ICF _Version 1.0_01 Feb 2019
- 242435_ RI_01_006_India_ Dr. Sudhir Singh_ Main ICF_ Hindi_Version 1.1 _17 Dec 2019 Based on Protocol RI-01-006_India Model ICF _Version 1.0_01 Feb 2019

  Translated from English to Hindi on 18 Dec 2019
- 242435_ RI_01_006_India_ Dr. Sudhir Singh_ Main ICF_ Hindi to English_Version 1.1 _17 Dec 2019 Based on Protocol RI-01-006_India Model ICF _Version 1.0_01 Feb 2019

  Back Translated from Hindi to English on 18 Dec 2019

Pregnant Participant ICF:

- 242435_ RI-01-006_India_Dr. Sudhir Singh _Pregnant Participant ICF_English _Version 1.1_17 Dec 2019; Based on Protocol RI-01-006_Pregnant Participant India Model ICF_Version 1.0_01 Feb 2019
- 242435_ RI-01-006_India_Dr. Sudhir Singh _Pregnant Participant ICF_ Hindi _Version 1.1_17 Dec 2019; Based on Protocol RI-01-006_Pregnant Participant India Model ICF_Version 1.0_01 Feb 2019

  Translated from English to Hindi on 18 Dec 2019
- 242435_ RI-01-006_India_Dr. Sudhir Singh _Pregnant Participant ICF_ Hindi to English_Version 1.1_17 Dec 2019; Based on Protocol RI-01-006_Pregnant Participant India Model ICF_Version 1.0_01 Feb 2019

  Back Translated from Hindi to English on 18 Dec 2019

Chairperson, IEC
King George's Medical University
U.P., Lucknow

Pregnant Partner ICF:

- 242435_ RI-01-006_India_Dr. Sudhir Singh_Pregnant Partner ICF_English_Vresion 1.1_17 Dec 2019
  Based on Protocol RI-01-006_Pregnant Partner India Model ICF_Version 1.0_01 Feb 2018

- 242435_ RI-01-006_India_Dr. Sudhir Singh_Pregnant Partner ICF_ Hindi _Vresion 1.1_17 Dec 2019
  Based on Protocol RI-01-006_Pregnant Partner India Model ICF_Version 1.0_01 Feb 2018

  Translated from English to Hindi on 18 Dec 2019

- 242435_ RI-01-006_India_Dr. Sudhir Singh_Pregnant Partner ICF_ Hindi to English _Vresion 1.1_17 Dec 2019
  Based on Protocol RI-01-006_Pregnant Partner India Model ICF_Version 1.0_01 Feb 2018

  Back Translated from Hindi to English on 18 Dec 2019

PK_PD ICF:

- 242435_ RI_01_006_India _Dr. Sudhir Singh PK_PD ICF_English_Version 1.1_17 Dec 2019
  Based on Protocol RI-01-006_PK_PD India Model ICF_Version 1.0_01 Feb 2018

- 242435_ RI_01_006_India _Dr. Sudhir Singh PK_PD ICF_ Hindi _Version 1.1_17 Dec 2019
  Based on Protocol RI-01-006_PK_PD India Model ICF_Version 1.0_01 Feb 2018

  Translated from English to Hindi on 18 Dec 2019

- 242435_ RI_01_006_India _Dr. Sudhir Singh PK_PD ICF_ Hindi to English _Version 1.1_17 Dec 2019
  Based on Protocol RI-01-006_PK_PD India Model ICF_Version 1.0_01 Feb 2018

  Back Translated from Hindi to English on 18 Dec 2019

- All translation and validation certificates are attached with respective ICF

❖ **Patient Material along with the translation certificate:**

English:

- 242435 GLOBAL Physician Letter 20190117 1.0 English
- 242435 GLOBAL Ring of Resources 20190117 1.0 English
- 242435 USA Participant Information Brochure 20190117 1.0 English
- 242435 USA Patient Infogetter 20190117 1.0 English
- 242435 USA Poster 20190117 1.0 English
- 242435 USA Study Guide 20190117 1.0 English

Hindi:

- 242435 India Participant Information Brochure 20190117 1.0 Hindi
- 242435 India Patient Infogetter 20190117 1.0 Hindi
- 242435 India Poster 20190117 1.0 Hindi
- 242435 India Study Guide 20190117 1.0 Hindi

Other documents:

Chairperson, IEC
King George's Medical University
U.P., Lucknow

- 242435 RI-01-006 IND 1813 CSA Sudhir Singh English 20190827 0.2
- CV dated 2 May 2019
- Investigator Undertaking dated 3 June 2019
- Insurance Certificate dated 28 Jan 2019
- IL for lab kits and IP dated 29 April 2019
- DCGI Approval Letter Dated 29 Apr 2019
- Drug CTRI
- CTRI Registration dated 7 June 2019

EC Decision: Approval after with fulfillment & administrative all formalities

Ref. code: 101stECMIIC/P2

(Primary Reviewer: Dr. Rajendra Nath)

3. Research Protocol no.PMZ-1620/CT-3.1/2019;CTNOC no. CT/ND/66/2019. entitled ***"A prospective, multi-centric, randomized, double-blind, parallel, phase-III clinical study to assess efficacy of PMZ-1620 along with standard treatment in patients of acute ischemic stroke"*** sponsored by Pharmazz India Pvt. Ltd. submitted by Dr. Sulekha Saxena, Assistant Professor, Department of Critical Care Medicine of this University via letter no. nil dated 7th January, 2020.

The following documents were reviewed:

Sl.No.	Documents
1.	DCGI CT NOC of phase-III study
2.	Phase III Clinical Trial study protocol (Protocol No.: PMZ-1620/CT-3.1/2019 (Version: 1.0, Dated 29th April, 2019) & Protocol signature page by PI
3.	Investigator's Brochure Version 04 dated 29th April 2019 & IB acknowledgement by Principal-Investigator
4.	Non-site specific inform consent document from English Version 1.0 dated 16th May, 2019
5.	Non-site specific inform consent document translated English to Hindi on dated 21st May 2019
6.	Non-site specific inform consent document Back translated from Hindi to English on dated 21st May, 2019
7.	Non-Site-specific audio-visual recording consent form English version 1.0 dated 3rd January, 2018
8.	Non-Site-specific audio-visual recording consent form translated from English to Hindi dated 8th January, 2018
9.	Non-Site-specific audio-visual recording consent form back translated from Hindi to English on 8th January, 2018

Chairperson, IEC
King George's Medical University
U.P., Lucknow

10.	Translation & Back translation certificated of non-site specific inform consent documents
11.	Translation & Back translation certificated of non-site specific Audio-visual recording consent form
12.	Draft case report form
13.	Principal-Investigator's CV and MCI registration certificate
14.	Site review form
15.	Principal-Investigator's Undertaking
16.	Principal-Investigator's Statement (Form 1572)
17.	Financial disclosure form (form 3455)
18.	Insurance Policy for study
19.	Draft of CTA
20.	CTRI registration

EC Decision: Approval after with fulfillment & administrative all formalities

Ref. code: 101stECMIIC/P3

(Primary Reviewer: Dr. Amita Jain)

4. Research Protocol no.ET1903001,Version:02,Date:15/07/19.entitled ***"Open label, randomized, controlled study to evaluate partial meal replacement program with prohance D targeting glycaemic levels and weight control in type II diabetic population"*** sponsored by SunPharma Industries Limite Sun House, submitted by Prof. Arvind Kumar Mishra, Department of Medicine of this University via letter no. nil dated nil.

The following documents were reviewed:

S.No	Documents
1	Study Synopsis _Version 01/27.09.2019
2	Clinical Study Protocol_ Version 01/27.09.2019
3	Patient Information Sheet and Inform Consent Documents English_ Version 01/27.09.2019
4	Patient Information Sheet and Inform Consent Documents Hindi_ Version 01/13.11.2019
5	Translation certificate Patient Information Sheet and Inform Consent Documents English to Hindi_ Version 01/13.11.2019

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	6	Patient Information Sheet and Inform Consent Documents Back Translation Hindi to English Version 01/14.11.2019
	7	Patient Information Sheet and Inform Consent Documents Back Translation Certificate Hindi to English Version 01/14.11.2019
	8	Drug Dosing card English _ Version 01/27.09.2019
	9	Drug Dosing card Hindi _ Version 01/13.11.2019
	10	Drug Dosing card Hindi Translation Certificate _ Version 01/13.11.2019
	11	Drug Dosing Card Back Translation Hindi to English _Version 01/14.11.2019
	12	Drug Dosing Card Back Translation Certificate Hindi to English _Version 01/14.11.2019
	13	Case Report Form_ Version 01/27.09.2019
	14	Investigator Brochure_ Version 01/27.09.2019
	15	SAE Report Form
	16	Insurance Policy
	17	DCGI Approval letter
	18	Investigator Undertaking
	19	CV & MRC of Principal Investigator
	20	Protocol Signature Page
	21	Draft Clinical Trial Agreement

EC Decision: Approval after with fulfillment & administrative all formalities

Trial closed

Ref. code: 101stECMIIC/P4

(Primary Reviewer: Dr. Rajeev Garg)

5. Research Protocol no. CRPL/CT/19/003 entitled "***A multicentric, randomized, open label, parallel group, comparative, phase III clinical study to evaluate the efficacy, safety and tolerability of ticagrelor SR tablets versus ticagrelor tablets on a background of aspirin therapy in patients with the history of myocardial infarction***" sponsored by Synokem Pharmaceuticals Ltd. New Delhi, submitted by Prof. Arvind Kumar Mishra, Department of Medicine of this University via letter no. nil dated 3rd January, 2020.

EC Comment:

- Sponsored by Synokem Pharmaceauticals Ltd.
- The test product is Ticagrelor SR 180 and 120 mg which will be given in Arm A and B - 1 OD x 24 weeks
- The test product is Ticagrelor SR 90 and 60 mg which will be given in Arm C and D - 1 OD x 24 weeks
- The efficacy, safety and tolerability of the drug in different dosage will be tested
- A 24 weeks study design has been provided along with a study flow cart
- Inclusion, Exclusion and Discontinuation criteria have been clearly specified
- A list of drugs that are prohibited with the drug Ticagrelor has been provided

Chairperson, IEC
King George's Medical University
U.P., Lucknow

- Sample size 320, 80 in each arm. Statistically derived
- Patient Information and Consent form in 2 languages attached
- Patient case reports form attached
- DGCI approval attached
- Insured by Bajaj Capital Insurance on December 2, 2019

EC Decision: Approval after jsutification

Ref. code: 101stECMIIC/P5

(Primary Reviewer: Dr. Surajit Bhattacharya)

6. Research Protocol no BGl-IA-CTP301 entitled "***A randomized, open label, parallel-group, multi- center phase 3 study to compare efficacy and safety of recombinant insulin aspart (Manufactured by BioGenomics Limited) with NovoRapid® (manufactured by novo nordisk), in adult patients with diabetes mellitus***" sponsored by Bio Genomics Pvt. Ltd, submitted by Prof. Himanshu, Department of Medicine of this University via letter no. nil dated 3rd January, 2020.

The following documents were reviewed:-

Sr. No.	DOCUMENTS	Version No	Date
1.	Protocol	3.0	October/2018
2.	Protocol Signature Page	3.0	October/2018
3.	Investigators Brochure	Edition 1	October/2017
4.	Case Report Form - Draft	0.5	18 Dec 2018
5.	Informed Consent Document - English	3.0	17 Oct 2018
5.1	Informed Consent Document Final Hindi	3.0	15 Nov 2018
5.2	Informed Consent Document English to Hindi	3.0	14 Nov 2018
5.3	Informed Consent Document Hindi to English	3.0	15 Nov 2018
5.4	Translation Certificate – Informed Consent Document Hindi – Forward, Backward and Final Translation	NA	21 Dec 2018
6.	Subject Diary English	1.0	NA
6.1	Subject Diary Hindi Final	1.0	21 Dec 2018
6.2	Subject Diary English to Hindi	1.0	18 Dec 2018
6.3	Subject Diary Hindi to English	1.0	20 Dec 2018
7.	Translation Certificate – Subject Diary Hindi – Forward, Backward and Final Translation	NA	24 Dec 2018
8.	CV, MRC and GCP of PI	NA	NA

Chairperson, IEC
King George's Medical University
U.P., Lucknow

9.	Investigators Undertaking	NA	25 Oct 2018
10.	Clinical Trial Agreements(CTA) Draft	NA	24 Dec 2018
11.	Insurance Certificate (HC/MUM/1171/CLT/2018/R2)	NA	16 Nov 2018
12.	DCGI Submission Letter Acknowledgement	NA	22 Jun 2018 22 Oct 2018
13.	CT NOC	1.0	30 Nov 2018

EC Decision: Approval after with fulfillment & administrative all formalities

Ref. code: 101stECMIIC/P6

(Primary Reviewer: Dr. Anoop Kumar Verma)

7. Research Protocol no. QL1205-002 entitled "***A randomized, phase3, double-masked, parallel-group, multicenter study to compare efficacy and safety of QL1205 versus lucentis® in subjects with neovascular age-related macular degeneration***" sponsored by Qilu Pharmaceuticals, Pvt. Ltd. submitted by Prof. Sanjiv Kumar Gupta, Department of Ophthalmology of this University via letter no. nil dated 3rd January, 2020.

The following doucuments were reviewed:-

1. Study Protocol - QL1205-002 - Version 2.0 dated 21Dec2018
2. Investigator's Brochure (Ranibizumab) Version 2.0 dated 10 Dec2018
3. Draft Case Record From (eCRF) Version 3.0 dated 26Mar2019
4. **Patient Information Sheet & Informed Consent form:**
   - i. **Site Specific Main Informed Consent Form (English & Hindi)**
     - a. QL1205-002_India_Main SIS-ICF_Dr. Sanjiv Kumar Gupta V1.1.1 Dated 23May2019_ENG
     - b. QL1205-002_India_Main SIS-ICF_Dr. Sanjiv Kumar Gupta V1.1.1 Dated 23May2019_HIN
     - c. CoT_QL1205-002_ India_Main SIS-ICF_Dr. Sanjiv Kumar Gupta V1.1.1 Dated 23May2019_HIN
   - ii. **Site Specific Optional Pharmacokinetic Testing Sub-study Informed Consent Form (English & Hindi)**
     - a. QL1205-002_India_Optional PK Testing SIS-ICF_Dr. Sanjiv Kumar Gupta V1.1.1 Dated 23May2019_ENG
     - b. QL1205-002_India_Optional PK Testing SIS-ICF_Dr. Sanjiv Kumar Gupta V1.1.1 Dated 23May2019_HIN
     - c. CoT_QL1205-002_India_Optional PK Testing SIS-ICF_Dr. Sanjiv Kumar Gupta V1.1.1 Dated 23May2019_HIN

EC Decision: Approval after with fulfillment & administrative all formalities

Ref. code: 101stECMIIC/P7

(Primary Reviewer: Dr. A.A. Sonkar)

8. Research Protocol no.LPS15396, Short Title: ARTEMIS-DM entitled "***A multicenter, multinational, prospective, interventional, single-arm, phase IV study evaluating the clinical efficacy and safety of 26 weeks of treatment with insulin glargine 300U/mL (GLA-300) in patients with type 2 diabetes mellitus uncontrolled on basal insulin***" sponsored by IQVIA RDS Pvt. Ltd submitted by Dr. Sudhir Kumar Verma, Assosciate Professor, Department of Medicine of this University via letter no. nil dated 16thJanuary,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

2020.

Trial Closed

Ref. code: 101stECMIIC/P8

(Primary Reviewer: Dr. Smriti Bhadoria)

9. Research Protocol no.0586-18: entitled "***A randomized, double-blind, multicentre, multinational comparative clinical study to compare the efficacy and safety of INTP24 against AVASTIN® in patients with unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer***" sponsored by Intas Pharmaceuticals Pvt. Ltd submitted by Prof. Rajendra Kumar, Department of Radiotherapy of this University via letter no. RT/RIC/20-1 dated 27thJanuary, 2020.

EC Decision: Approval after with fulfillment & administrative all formalities

Sr. No.	Study Document	Version No. & Date
01	Study Protocol	Version 1.1 Date 25th July 2019
02	Investigator's Brochure	Version 1.0 Date 14th Mar 2019
03	Informed Consent Document in English (Country specific-India)	Version 2.0 Date 25th July 2019
04	Informed Consent Document (Country specific-India) is translated from English to Hindi on 27 July 2019	Version 2.0 Date 25th July 2019
05	Informed Consent Document(Country specific-India) is Back translated from Hindi to English on 29 July 2019	Version 2.0 Date 25th July 2019
06	Translation and Back Translation certificate of ICD (Country specific-India) for English to Hindi, Hindi to English	----
07	Notarized Insurance Certificate (**OG-20-2202-3306-00000003**) and Policy	Effective Date 01st Jul 2019 & Termination Date 30th Jun 2020
08	Draft e-CRF	----
09	Draft Clinical Trial Agreement	----
10	Final CTRI	CTRI/2019/08/020665 [Registered on: 09/08/2019]
11	Investigator's undertaking	Dated 29th July 2019
12	Protocol Signature Page	Dated 29th July 2019
13	CV of Principal Investigator	Dated 01st Mar 2019

Chairperson, IEC
King George's Medical University
U.P., Lucknow

14	MRC of Principal Investigator	Dated 01st Mar 2019
15	DCGI Approval letter for version 1.0 dated 22 Feb 2019	Dated 15th July 2019
16	Import License	Dated 15th July 2019
17	Online DCGI Submission for the Version 1.1 dated 25 July 2019	Dated 16th Oct 2019
18	FDA-1572	Dated 19th Aug 2019
19	FDA 3455 of PI	Dated 05th Jul 2019
20	FDA 3455 of Sub-I-Dr. Vijay Kumar & Dr. Sameer Gupta	Dated 31st Jul 2019
21	FDA 3455 of Sub-I-Dr. Anant Mishra	Dated 08th Jul 2019

Ref. code: 101stECMIIC/P9

(Primary Reviewer: Dr. Smriti Bhadoria)

10. Research Protocol no. entitled "***A randomized, double-blind, parallel arm, dose optimization study to assess efficacy and safety of Hydroxychloroquine in type2 diabetes patients uncontrolled on metformin and sulfonylurea combination***" sponsored by IPCA Laboratories Pvt. Ltd submitted by Dr. D. Himanshu, Department of Medicine of this University via letter no. nil dated 1stFebruary, 2020.

EC Decision: Approval after with fulfillment & administrative all formalities

The following documents were reviewed:-

Sr. No	Documents	Versions/Date
1.	Clinical Trial Protocol	(Version number: 03, Version date 24/12/2019)
2.	Investigator's Brochure	(Version number: 02, Version date 01/11/2019)
3.	Case Record Form: Section-1	Version number: 03, Version date: 30/12/2019)
4.	Case Record Form: Section-2	Version number: 03, Version date: 30/12/2019)
5.	Patient Information Sheet in English, and	(Version number: 03, Version date:

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Hindi with translation certificates	24/12/2019)
6.	Back-translation of Patient Information Sheet in Hindi with back translation certificates.	(Version number: 03, Version date: 24/12/2019)
7.	Informed Consent Form in English, and Hindi with translation certificates	(Version number: 03, Version date: 24/12/2019)
8.	Back-translation of Informed Hindi Consent Form with back translation certificates.	(Version number: 03, Version date: 24/12/2019)
9.	Patient Diary in English and Hindi with translation certificates	(Version number: 02, Version date: 30/12/2019)
10.	Sample Size Letter	nil
11.	Insurance Policy	nil
12.	Indemnification Letter	nil
13.	Investigator's Consent	nil
14.	Undertaking by Investigator	nil
15.	Investigator's CV and MRC	nil
16.	Source of Funding	nil
17.	Financial Details	nil
18.	CTRI Registration	nil
19.	DCGI approval letter	nil

Ref. code: 101st ECMIIC/P10

(Primary Reviewer: Dr. Anoop Kumar Verma)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

11. Research Protocol no. Tuxedo-2 entitled "***Ultra-thin strut versus xience in a diabetic population with multi- vessel disease-2 India study***" sponsored by Academics and Research, Batra Hospital & Medical Research Centre; New Delhi submitted by Prof. Sharad Chandra, Department of Cardiology of this University via letter no. 796/Cardio/Res/2020 dated 29th January, 2020.

Sl. No.	Study Document	Version	Date
1.	Study Protocol	1.1	29 Oct 2019
2.	Investigator's Signature Page	1.0	16 Nov 2019
3.	Confidentiality Disclosure Document	NA	07 Oct 2019
4.	Package Insert	NA	12 Jun 2019
5.	Site Specific ICF-English	1.0	18 Nov 2019
6.	Site Specific ICF-Hindi Forward	1.0	18 Nov 2019
6.(b)	Site Specific ICF-Hindi Final	1.0	18 Nov 2019
6.(c)	Translation Certificate	NA	18 Nov 2019
7.	CV & MRC of Principal Investigator	NA	16 Nov 2019
8.	Undertaking by the Investigator and/or Institution	NA	16 Nov 2019
9.	Draft Case Report Form	0.1	03 Sep 2019
10.	DCGI Notification Letter	NA	28 Aug 2019
11.	Insurance Policy	NA	24 Jul 2019
12.	Draft Clinical Trial Agreement	NA	NA

EC Decision: Approval after with fulfillment & administrative all formalities

Ref. code: 101stECMIIC/P11

(Primary Reviewer: Dr. Rajendra Nath)

12. Research Protocol no. CR201-18 entitled "***A multicentre, double-blind, randomized, parallel-group, active-controlled, two part, phase III, global study to evaluate the pharmacokinetics, efficacy and safety of BP02 (Trastuzumab) in comparison with herceptin®-EU in patients with HER2-positive early breast cancer (EBC) and HER2-positive metastatic breast cancer(MBC)***" sponsored by Cura TeQ Biologics GmbH submitted by Dr. Shiv Rajan, Assistant Professr, Department of Surgical Oncology of this University via letter no. nil dated 4th February, 2020.

S. No	Document Title	Version	Date
1.	Study Protocol	Version 1.0	25/06/19
2.	Protocol Errata	NA	12/12/19

Chairperson, IEC
King George's Medical University

		3.	Investigator Brochure	Version 2.0 / 11/12/19
		4.	Informed Consent Form English	Version 1.0 Amendment-01 / 12/12/19
		5.	Informed Consent Form Hindi translated from English Informed Consent Form version 1.0 Amendment-01 dated12.12.2019	NA / 06/01/20
		6.	Translation certificate- English to Hindi	NA / 06/01/20
		7.	Back translated from Hindi to English Informed Consent Form	NA / 08/01/20
		8.	Back Translation certificate Hindi to English	NA / 08/01/20
		9.	Draft Case Report Form	Draft / 17/09/19
		10.	Investigator Undertaking	NA / 15/07/19
		11.	Investigator Protocol Agreement Page	NA / 15/07/19
		12.	Principal Investigator CV and MRC	NA / 15/07/19
		13.	Declaration for Providing Standard Care and Facility Declaration	NA / 15/07/19
		14.	CT NOC Approval letter	NA / 22/11/19
		15.	Insurance	NA / 24/01/20
		16.	Draft Clinical Trial Agreement	NA / NA
		17.	Copy of CTRI Registration Reference	NA / 07/01/20

EC Decision: Approval after with fulfillment & administrative all formalities

Ref. code: 101stECMIIC/P12

(Primary Reviewer: Dr. Amita Jain)

13. Research Protocol no.17775A entitled "***Open-label, flexible-dose study of vortioxetine in patient with major depressive disorder in India***" sponsored by H. Lundbeck A/S Confidential submitted by Prof. P.K. Dalal, Head, Department of Psychiatry of this University via letter no. 2037/Psy/2020 dated 5th February, 2020.

The following documents were examined and discussed in the meeting:-

1.a Clinical trial protocol, version 1.0 dated 24 Sep 2019

1.b Protocol Agreement page dated 24 Sep 2019

2.Investigator's Brochure edition 15, dated 28 31 Jul 2019

3.Investigator Undertaking dated 30Sep2019

Chairperson IEC
King George's Medical University
U.P. Lucknow

4.DCGI submission and Approval letter
5. Lund beck_ 17775A_Patient ID Card
   a. Patient ID card 16 Nov 2018 [Version 1.0(en)]
   b. Patient ID card 16 Nov 2018[Version 1.0{hi)].Translated from English to Hindi on 21 November 2018
   c. Back translation of Patient ID card 16 Nov 2018[Version 1.0(hi)].Back Translated from Hindi to English on 21 November 2018.
   d. Translation and back translation certificate for Patient ID card 16 Nov 2018[Version 1.0 (en)] in Hindi languages.

. Patient Health Questionnaire
   a. PHQ-9_English
   b. PHQ-9_ Hindi
   c. Back translation of PHQ-9 – Hindi
   d. Translation certificate for PHQ-9 English in Hindi Language
   e. Back translation Certificate for PHQ-9 for Hindi Languages

7. MINI –This is a site facing document (only for rater reference) and this document will be used by PI and site staff only hence translated version in all language will not be provided.
   a. M.I.N.I. 7.0.2_V 1English_US_2019_Jan_25
   b. M.I.N.I. 7.0.2_V 1_Hindi _IN_2019_Jan_28
   c. Translation certificate for Hindi M.I.N.I

8.Clinical Global Impression – Severity of illness (CGI-S)Scale
9. Clinical Global Impression –Improvement (CGI-I)Scale
10. Wash-out period memo dated 02 Nov 2018
11. Draft CTA
12. Draft Indemnification Agreement
13. Draft Data Processing Agreement
14. Blank CRF dated 16 Oct 2019
15.Main Informed Consent Forms
   a. Main _V3.IND(en)1.0_IN1010v1.0(10Dec2019)
   b. Main _V3.0IND(hi)1.0_IN1010v1.0(10Dec2019)Translated on 10 Dec2019
   c. Back Translation of main_V3.0IND(hi)1.0_IN1010v1.0(10 Dec2019)Back Translated from Hindi to English on 10 Dec 2019
   d. Translation certificate of main _V3.0IND(hi)1.0_IN1010v1.0(10 Dec2019)Back Translated on 10 Dec 2019 in Hindi language
   e. Back translated certificate of main_V3.0IND(hi)1.0_IN1010v1.0(10Dec2019)Back Translated from Hindi to English on 10Dec2019 in English language
16. Protocol memo dated 03Dec 2019
17. Pregnant Partner: Consent for Pregnancy Testing and Appropriate Follow-up ICF
   a. PP_V2.0IND(en)1.0_IN1010v1.0(22Oct2019)
   b. PP_V2 .0IND(HI)1.0_IN1010v1.0(22Oct2019) Translated on 01 November 2019
   c. Back Translation of PP_V2.0IND(hi)1.0_IN1010v1.0(22Oct2019)Translated from Hindi to English on 01 November2019
   d. Translation certificate of PP_V2.0IND(hi)1.0_IN1010v1.0(22Oct2019)Translated on 01 November 2019 in Hindi language
   e. Back translation certificate of PP_V2.0IND(hi)1.0_IN1010v1.0 (22Oct2019)Back Translated from Hindi to English on 01 November2019 in English language
18. Consent for A-V Recording of The Inform Consent Process
   a. Add_V7.0IND(en)1.0_IN1010v1.0(22Oct2019)
   b.Add_V7.0IND(hi)1.0_IN1010v1.0(22Oct2019)Translated on 24 October 2019
   c. Back Translation of Add_V7.0IND(hi)1.0_IN1010v1.0(22Oct2019) Back Translated from Hindi to English on 24 October 2019
   d. Translation certificate of Add_V7.0IND(hi)1.0_IN1010v1.0(22Oct2019) Back Translated from Hindi to English on 24 October 2019 in Hindi language

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	e.Back translation certificate of Back Translation of Add_V7.0IND(hi)1.0_IN1010v1.0(22Oct2019) Back Translated from Hindi to English on 24 October 2019 in English language 19. Audio Visual (A-V)Recording Declaration_V4.0IND(en)1.0_IN1010v1.0(22Oct2019) 20. a. Insurance Certificate dated 15Oct 2019(Validity:04 Oct 2019 till 31 May 2020) b. Insurance policy 21. CV of PI dated 18 Jan2019 22. MRC pf PI 23. GCP of PI 24. CTRI **EC Decision:** Approval after with fulfillment & administrative all formalities ***Ref. code: 101st ECMIIC/P13*** ***(Primary Reviewer: Dr. Rajeev Garg)***
14.	Research Protocol no. entitled "***A randomized, double-blind, parallel group, equivalence, multicentre phase III Trial to compare the efficacy, safety, pharmacokinetics and immunogenicity of HD204 to AVASTIN® in patients with metastatic or recurrent non-squamous non-small cell lung cancer***" sponsored by Prestige BioPharma Pte Ltd submitted by Dr. Naseem Akhtar, Associate Professor, Department of Surgical Oncology of this University via letter no. nil dated 8th January, 2020. **EC Decision:** Approved ***Withdraw by P.I.*** ***Ref. code: 101st ECMIIC/P14*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
15.	Research Protocol entitled "***Efficacy and safety of bolus injection of a novel thrombolytic agent (SMRZ-11) in patient with acute ST-segment elevation Myocardial infarction agent (STEMI): A phase 1/11 open-label, dose-escalation, multicenter, angiographic trial***" sponsored by Symmetrix Biotech Pvt. Ltd. submitted by Dr. Pravesh Vishwakarma, Associate Professor, Department of Cardiology of this University via letter no. 806/Cardio/2020 dated 4th February, 2020. The following documents were examined and discussed in the meeting 1. Undertaking, Consent Letter, CV and MRC of Principal Investigator (PI) and Co-PI 2. DCGI Approval for Phase II Clinical Trial 3. Clinical Trial Insurance Policy by HDFC Ergo Ltd 4. Patient Information Sheet and Informed Consent Form 5. EC Approval for same Study from Other Site 6. Amended Phase I/II Clinical Trial Protocol Approved By DCGI 7. Interim Report on Preliminary Phase II Study on 20mg Dose in STEMI patient as per DCGI recommendation 8. Investigator's Brochure 9. Draft Clinical Trial Agreement **EC Decision:** Approval after with fulfillment & administrative all formalities ***Ref. code: 101st ECMIIC/P15*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

16. Research Protocol no. BRADPL/PHF/PMS/05/19 entitled "***A post marketing, open label, multicentre study to evaluate the safety and efficacy of fixed dose combination of propranolol Hydrochloride 40 mg plus flunarizine 5mg and fixed dose combination of propranolol Hydrochloride 40 mg plus flunarizine 10mg in the prophylaxis of migraine without aura***" sponsored by Akums Drugs and Pharmaceuticals Pvt. Ltd. submitted by Dr. Harish Gupta, Assistant Professor, Department of Medicine of this University via letter no. nil dated 3th January, 2020.

S. No	Documents' Name	Version	Date
01	Protocol Synopsis	2.0	10-Dec- 2019
02	Protocol	2.0	10-Dec-2019
03	Investigator Brochure (IB)	1.0	21-May-2019
04	Case Report Form	2.0	10-Dec-2019
05	Patient Information Sheet & Informed Consent Form –English	2.0	10-Dec-2019
06	Patient Information Sheet & Informed Consent Form –Hindi	2.0	10-Dec-2019
07	Patient Information Sheet & Informed Consent Form –Hindi to English	2.0	10-Dec-2019
08	The Migraine Disability Assessment (MIDAS) Test Questionnaire – English	1.0	NA
09	The Migraine Disability Assessment (MIDAS) Test Questionnaire – Hindi	1.0	NA
10	The Migraine Disability Assessment (MIDAS) Test Questionnaire – Hindi to English	1.0	NA
11	Translation & Back Translation Certificates (PIS & ICF, MIDAS Questionnaire, Dosing Card)	NA	24-Dec-2019
12	CDSCO Notification	NA	18-Dec-2019
13	CTA	NA	NA
14	Site Documents	NA	NA
	I. Investigator Undertaking	NA	NA

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	II. PSP	NA	NA
	III. CV	NA	NA
	IV. MRC	NA	NA
15	Sponsor Indemnity Letter	NA	NA
16	Sponsor Udnrtaking	NA	NA
17	Insurance Policy	NA	NA

EC Decision: Approval after with fulfillment & administrative all formalities

Ref. code: 101stECMIIC/P16

(Primary Reviewer: Dr. A.A. Sonkar)

17. Research Protocol no. MLS/Promesa DES-1entitled "***A prospective, multicenter, single arm, open label study to evaluate safety and performance of promesa™ DES sirolimus eluting self-expandable nitinol peripheral stent system for treating superficial femoral artery (SFA) and lilac artery lesions***" sponsored by Meril Life Sciences Pvt.Ltd. submitted by Prof. Anit Parihar, Department of Radiodiagnosis of this University via letter no. nil dated 10th February, 2020.

The following documents were examined and discussed in the meeting:-

1. Promesa-DES _Protocol Version 2.0.0 dated 24 May 2019
2. Promesa-DES protocol signature page dated 03 Jan 2020
3. Investigators Brochure, Version 1.0.0 dated 28 Jul 2018
4. PIS & ICF_ English_ Version 2.0.0 dated 24 May 2019
5. PIS & ICF_ English to Hindi_ Version 2.0.0 dated 24 May 2019 translated from English to Hindi on 25 May 2019
6. PIS & ICF_ back translation Hindi to English _Version 2.0.0 dated 24 May 2019 back-translated from Hindi to English on 25 May 2019
7. Translation & Back Translation Certificates_Hindi
8- Insurance policy valid up-to 25 Oct 2020
9- Draft Clinical Trial Agreement
10- CV of Dr. Anit Parihar
11- MRC of Dr. Anit Parihar
12- Information for use
13- Investigator Undertaking by Dr.Anit Parihar version 2.0.0 dated 03 Jan 2020
14- Case Report Form dated 12 Aug 2019
15 -DCGI approval of clinical investigation plan of Promesa™DES-1 dated 12 Jul 2019
16 -DCGI acknowledgement of Protocol version 2.0.0 dated 29 May 2019

EC Decision: Approval after with fulfillment & administrative all formalities

Ref. code: 101stECMIIC/P17

(Primary Reviewer: Dr. Surajit Bhattacharya)

18. Research Protocol no. CTQJ230A12301entitled "***A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

disease" sponsored by Novartis Health Care Pvt. Ltd. submitted by Prof. S.K. Dwivedi, Department of Cardiology of this University via letter no. 804/Cardio/Res/2020 dated 4th February, 2020.

EC Comment:

- Non marketed drug-DCGI approval not provided secondary objectives are not clear.
- The management of complications is not defined precisely Clinical trial registry is also pending

EC Decision: Approval after justification

Ref. code: 101stECMIIC/P18

(Primary Reviewer: Dr. Preeti Agarwal)

19. Research Protocol no.ICR/18/003 entitled "***A multi-centric, open label study to evaluate safety and efficacy of Dalfampridine extended release tablets for walking improvement in patients with multiple sclerosis in India***" sponsored by Sun Pharma Laboratories Pvt. Ltd. submitted by Prof. Hardeep Singh Malhotra, Department of Neurology of this University via letter no. nil dated 5th February, 2020.

Sr No.	Details of document	Version No., Amendment No. , dated
1	Clinical Study Protocol and Appendices with LOC	Version – 2.0, dated 22/APR/2019
2	Investigator's Brochure with LOC	Version- 2.0, dated 23/APR/2019
3	Case Report Form and Unscheduled Booklet with list of changes	Version 2.0, Dated 07/MAY/2019
4	Patient Information Sheet and Informed Consent form in English, Hindi Languages with its LOC	Version- 2.0, dated 22/APR/2019
5	Translation certificates for Hindi language Patient Information Sheet and Informed Consent form	14/MAY/2019
6	Back translation certificates for Hindi language Patient Information Sheet and Informed Consent form	15/MAY/2019
7	DCGI CT NOC	30/JUL/2018
8	DCGI Notification Ack letter	20/SEP/2018
9	DCGI Notification Ack letter	09/JUL/2019
10	CTRI Letter	CTRI/2019/01/016948
11	Insurance Certificate	Valid from 01/Jul/2019 – 30/Jun/2020

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	12	Investigator Undertaking	30/MAY/2019
	13	Investigator CV & MRC	30/MAY/2019
	14	Draft CTA	Enclosed

EC Decision: Approval after with fulfillment & administrative all formalities

Ref. code: 101stECMIIC/P19

(Primary Reviewer: Dr. Rajendra Nath)

II-C **Registry Trial Review of New Drug Trial**

1- Research Protocol no.COR10649 entitled "***Effectiveness and safety of optical coherence tomography- guided PCI in Indian patients with complex lesions- A multicenter, prospective registry***" sponsored by JSS Clinical Research submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no.548/cardio/Res/19 dated 8th August, 2019.

The following documents were examined and discussed in the meeting

1. Study Protocol
2. Protocol signature page
3. Site specific ICF English
4. Site specific ICF Hindi Final
5. Site specific ICF Hindi Forward
6. Site specific ICF Hindi Backward
7. Translation Certificate
8. Case Report Form
9. Patient Assessment Form
10. CV of Principle Investigator
11. MRC of Principle Investigator
12. GCP Certificate of Principle Investigator
13. Draft Clinical Trial Agreement
14. Investigator's Undertaking
15. CTRI Registration
16. Insurance & Indemnity Certificate

EC Decision: Approval after with fulfillment & administrative all formalities

Ref. code: 101stECMIIC/P1

(Primary Reviewer: Dr. Preeti Agarwal)

Chairperson IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. IVA

Modifications

K.G's Medical University U.P., Lucknow

IV-A	Modification
1-	Modification of Research protocol no.**GS-US-419-3895** entitled ***"Combined Phase 3, double-blind, randomized, placebo-controlled studies evaluating the efficacy and safety of filgotinib in the Induction and maintenance of remission in subjects with moderately to severely active crohn's disease"*** M/s Klinera corporation submitted by Dr. Ajay Kumar, Assistant Professor, Department of Medicine of this University via letter no.nil dated 25th March, 2019. The following documents were examined and discussed in the meeting. 1. Study GS-US-419-3895, Protocol Amendment No. 7 dated 22nd August, 2019 2. Study GS-US-419-3895, Summary of changes dated 22nd August, 2019 for protocol Amendment No. 7 3. Subject information and informed consent main ICF English version 8.1.1 dated 23rd September, 2019 4. Subject information and informed consent translated from English to Hindi version 8.1.1 dated 28th September, 2019 5. Subject information and informed consent back translated from Hindi to English version 8.1.1 dated 30th September, 2019 6. Subject information and informed consent form (Translation and Back Translation with certificates) • English to Hindi: version 8.1.1 dated 28th September, 2019 • Hindi to English: version 8.1.1 dated 30th September, 2019 7. Sperm banking Information documents Dr. Ajay Kumar_English, Version: 1.1.1, dated 20th August, 2019. 8. Sperm banking information documents- Dr. Ajay Kumar (Translation & Back translation with certificates) • English to Hindi: Version 1.1.1 dated 20th August, 2019 • Hindi to English:Version 1.1.1 dated 21st August, 2019 **EC Decision:** Approved ***Ref.code:89th ECMIIC/P14-a*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Modification of Research protocol no.**GS-US-419-3896** entitled ***"A long-term extension study to evaluate the safety of Filgotinib in subjects with Crhon's disease"*** M/s Klinera corporation submitted by Dr. Ajay Kumar, Assistant Professor, Department of Medicine of this University via letter no.nil dated 25th March, 2019. The following documents were examined and discussed in the meeting. 1. ERT Screenshots English (India) • LogPadN5_Evening Dairy_IN_version 2.00 dated 19th Feb 2018 2. ERT Screenshots Hindi (India) • LogPadN5_Evening Dairy_IN_version 2.00 dated 15th Feb 2018 3. ERT Screenshots English Certificate (India) • LogPadN5_Evening Dairy_IN_version 2.00 dated 19th Feb 2018

Chairperson, IEC
King George's Medical University
U.P., Lucknow

4. ERT Screenshots Hindi Certificate (India)
   - LogPadN5_Evening Dairy_IN_version 2.00 dated 15th Feb 2018
5. SitePad6X_EQ5DL_English (India)_version 2.00_26th Nov, 2018
   - SitePad6X_EQ5-DL_Certificate_English (India)_version 2.00_30th Nov, 2018

EC Decision: Approved

Ref.code:89th ECMIIC/P14-b

(Primary Reviewer: Dr. Rajendra Nath)

3. Modification of Research protocol no.D169AC00001 entitled ***"A study to evaluate the effect of dapagliflozin on renal on outcomes and cardiovascular mortality in patients with chronic kidney disease"*** sponsored by M/s AstraZeneca submitted by Prof. S K. Sonkar, Department of Medicine of this University via letter no.nil dated 24th July, 2019.

EC Comment:

- The Consent form is revised.
- On first page add centre number & name of Investigator.

EC Decision: Approval after justification

Ref.code:84th ECMIIC/P7

(Primary Reviewer: Dr. Amita Jain)

4. Modification document of research protocol no.***GS-US-417-0304 "A multicenter, double- blind, long term extension study to assess the safety and efficacy of filgotinib in subjects with rheumatoid arthritis"*** Dr. Puneet Kumar, Department of Rheumatology of this University via letter no. Rh/CT/23/19 dated 28th June, 2019.

Sr. No.	Study Documents	Version No.	Date
1	Study Protocol	Amendment- 3	28-March-2019
2	Main-ICF subject information and informed consent form India (Dr. Puneet Kumar)	Version 7.1.1	20-May-2019
3	Subject Emergency Card Translation and Back Translation	Version - 2.0	English - 08-Oct-2019 English to Hindi : 05-Nov-2019 Hindi to Eng : 06-Nov-2019
4	Translation and back translation certificate subject information and informed consent form India	Version 7.1.1	English to Hindi : 05-June-2019 Hindi to English : 05-

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Dr. Puneet Kumar)		June -2019	

EC Decision: Approved

Ref. code: 86th ECM II-E/ P1

5. Modification of Research proposal no. SB3-G31-BC-E entitled ***"A long- term follow-up study for cardiac safety in the patients with HER2 positive early pr locally advanced breast cancer who have completed the SB3-G31-BC"*** submitted by Prof. Vijay Kumar, Department of Surgical Oncology of this University via letter no. nil dated 1st February, 2020.

The Following documents were reviewed in the EC Meeting:

1. Amended Clinical trial protocol along with List of changes - SB3-G31-BC- E_Version 2.1 dated 26Jul2019
2. Protocol Title Justification dated 31Jul2019
3. India specific Insurance Policy certificate dated 27Feb2019
4. Amended CRF – V2.1 dated 17Apr2019
5. Amended Clinical trial protocol along with List of changes - SB3-G31-BC- E_Version 2.2 dated 08Nov2019
6. DCGI Approval Letter _Protocol V2.2 dated 29Nov2019
7. Informed Consent Forms

A. Main ICF in Person Consent:

I. In Person-Main_V1.0IND(en)2.0_SB30614v1.0(05Dec2019)

II. List of Summary_In Person-Main_V1.0IND(en)2.0_SB30614v1.0(05Dec2019)

III. In Person-Main_V1.0IND(hi)2.0_SB30614v1.0(05Dec2019) - Translated on 06Dec2019

IV. In Person-Main_V1.0IND(hi)2.0_SB30614v1.0(05Dec2019)_Front Translation Certificates_06Dec2019

V. Back Translation of _ In Person-Main_V1.0IND(hi)2.0_SB30614v1.0 (05Dec2019) - Back Translated on 06Dec2019

VI. In Person-Main_V1.0IND(hi)2.0_SB30614v1.0(05Dec2019)_Back Translation Certificates_06Dec2019

B. Remote Main ICF:

I. Remote-Main_V1.0IND(en)2.0_SB30614v1.0(05Dec2019)

II. List of summary_Remote-Main_V1.0IND(en)2.0_SB30614v1.0(05Dec2019)

III. Remote-Main_V1.0IND(hi)2.0_SB30614v1.0(05Dec2019)- Translated on

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	06Dec2019 IV. Remote-Main_V1.0IND(hi)2.0_SB30614v1.0(05Dec2019)_Front Translation Certificates_06Dec2019 V. Back Translation of Remote-Main_V1.0IND(hi)2.0_SB30614v1.0(05Dec2019) - Back Translated on 06Dec2019 VI. Remote-Main_V1.0IND(hi)2.0_SB30614v1.0(05Dec2019)_Back Translation Certificates_06Dec2019 8. Amended CTA_Final_18Nov2019 **EC Decision:** Approved ***Ref. code: 96th ECM IID/P1*** ***(Primary Reviewer: Dr.Amita Jain)***
6.	Modification of Research protocol no.ALN-AT3SC-004 entitled "***ATLAS-A/B: "A phase 3 study to evaluate the efficacy and safety of fitusiran in patients with hemophilia A or B, without inhibitory antibodies to factor VIII or IX"*** sponsored by M/s Bajaj Allianz Generali Insurance Co Ltd. Ltd. submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology of this University via letter no.nil dated 3rd January, 2020. **EC Decision:** Approved ***Ref.code:90thECMIIC/P2*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
7.	Modification of Research protocol no.D169AC00001 entitled ***"A study to evaluate the effect of dapagliflozin on renal on outcomes and cardiovascular mortality in patients with chronic kidney disease"*** sponsored by M/s Astra Zeneca submitted by Prof. Satyendra Kumar Sonkar, Department of Medicine of this University via letter no.nil dated 3rd January, 2020. ***The following documents were reviewed in the EC Meeting:-***

Sl No	Document
1.	Adult Study Subject Information and Consent Form Master Version Number: 1.0, Master Version Date 31 October 2016 India Version Number 3.0 India Version Date 13 Jun 2019 - English **Translation:** • English to Hindi (India Version 3.0 dated 13 Jun 19) Translated on 15 Jun 2019. **Back Translation:** • Hindi to English (India Version 3.0 dated 13 Jun 19) Back translated on 15 Jun 2019

Chairperson, IEC
King George's Medical University
U.P., Lucknow

		Translation & Back Translation Certificates: • English to Hindi and Hindi to English

EC Decision: Approved

Ref.code:84th ECMIIC/P7

(Primary Reviewer: Dr. A.A. Sonkar)

8. Modification of Research protocol no. entitled ***"A prospective cohort, multicenter, non interventional, observational, real- world study to evaluate current clinical practices and quality of life in Indian essential hypertensive patients"*** sponsored by Bio Quest Solutions Pvt. Ltd. submitted by Dr. D. Himanshu, Department of Medicine of this University via letter no.nil dated 3rd January, 2020.

The following documents were reviewed in the EC Meeting:-

Sr.No	Title of Document	Version	Date
1.	Protocol	2.0	15-Feb-2019
2.	Protocol signature page	2.0	15-Feb-2019
3.	Case report form	2.0	15-Feb-2019
5.	Brief Medicine Questionnaire (BMQ) 1 English 2 Hindi 3 Hindi Back translation 4 Translation certificates (from English to Hindi) 5 Back Translation certificates (from Hindi to English)		
6.	Quality of Life Questionnaire 1 English 2 Hindi 3 Hindi Back translation 4 Translation certificates (from English to Hindi) 5 Back Translation certificates (from Hindi to English)		

EC Decision: Approved

Ref.code:96th ECMIIC/Pb3

(Primary Reviewer: Dr. Smriti Bhadoria)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

9. Modification of Research protocol no. ***GS-US-417-0304*** entitled ***"A multicenter, double- blind, long term extension study to assess the safety and efficacy of filgotinib in subjects with rheumatoid arthritis"*** submitted by Dr. Puneet Kumar, Department of Rheumatology of this University via letter no. CT/03/20 dated 4th January, 2020.

The following documents were reviewed in the EC Meeting:-

Sr. No.	Study Documents	Version No.	Date
1	Study Protocol	Amendment- 4	24-Sep-2019
2	Summary of Changes for study protocol amendment 4	NA	24-Sep-2019
3	Subject Emergency Card Translation and Back Translation	Version - 2.0	English - 08-Oct-2019 English to Hindi : 05-Nov-2019 Hindi to Eng : 06-Nov-2019
4	Subject Emergency Card Translation and Back Translation certificates	Version - 2.0	English to Hindi : 05-Nov-2019 Hindi to English: 06-Nov-2019
5	Patients Dosing Instructions Translation and Back Translation	Version - 2.0	English 08-Oct-2019 English to Hindi: 06-

Chairperson, IEC
King George's Medical University
U.P., Lucknow

			Nov-2019 Hindi to English: 07-Nov-2019
6	Patients Dosing Instructions Translation and Back Translation certificates	Version - 2.0	English to Hindi : 06-Nov-2019 Hindi to English: 07-Nov-2019
7	Summary of Changes of Informed Consent Form From Version 7.1.1 To Version 8.1.1	NA	03-Oct-2019
8	Main ICF- Subject Information and Informed Consent Form India(Dr. Puneet Kumar) Translation and Back Translation	Version- 8.1.1	English 13-Nov-2019 English to Hindi: 14-Nov-2019 Hindi to English: 15-Nov-2019
9	Main ICF- Subject Information and Informed Consent Form India(Dr. Puneet Kumar) Translation and Back Translation Certificates	Version-8.1.1	English to Hindi: 14-Nov-2019 Hindi to English: 15-Nov-2019
10	Audio-Visual Recording of Informed Consent	Version - 2.1.1	English - 19-Nov-2019 English to Hindi: 04-Dec-2019 Hindi to English: 05-Dec-2019
11	Audio-visual Recording of informed consent certificates	Version - 2.1.1	English to Hindi: 04-Dec-2019 Hindi to English: 05-Dec-2019
12	Partner pregnancy	Version - 2.1.1	English - 19-Nov-

Chairperson, IEC
King George's Medical University
U.P. Lucknow

		follow up consent form		2019 English to Hindi: 04-Dec-2019 Hindi to English: 05-Dec-2019
	13	Partner pregnancy follow up consent form certificates	Version - 2.1.1	English to Hindi : 04-Dec-2019 Hindi to English : 05-Dec-2019

EC Decision: Approved

Ref.code:86th ECMIIE/P1

(Primary Reviewer: Dr. Preeti Agarwal)

10. Modification of Research protocol no.16T-MC-AMAN entitled ***"A phase 3, Multicentre, Randomized, Double-Blind, Parallel, Placebo-controlled Induction study of Mirikizumab in Conventional-Failed and Biologic-Failed patients with Moderately to severely active ulcerative colitis-"*** sponsored by M/S Eli Lilly, USA submitted by Prof. Abhijit Chandra, Department of Surgical Gastroenterology of this University via letter no. nil dated 26th August, 2019.

The following documents were reviewed in the EC Meeting:-

1. Investigator's Brochure Mirikizumab (LY3074828), dated 13 Mar 2019-Clean Copy
2. Final eCRF (ASB-Annotated study bool for study design:16T-MC-AMAN) version 4 dated 14th September, 2018
3. LUCENT 2 (16T-MC-AMBG)-patients & site facing OPTIONAL recruitment and Retention resource materials-MOCK-Ups and explanations version 8.0 dated 2nd May, 2019
4. Patient retention items-currency conversion version 4
5. Informed consent form
   a. English Main_v2.01IND(en)1.0_2261v1.0 (27 Jun, 2019
   b. Hindi Main ICF translation-Main_v2.0IND (hi)1.0_2261v1.0_2261v1.0(27 Jun 2019) translated on 18 Jul 2019
   c. Hindi Main ICF BT-Main_v2.0IND (hi) 1.0_2261v1.0 (27 June 2019).Translated on 18 Jul 2019
   d. Hindi Main ICF translation and back translation Certificates.

EC Decision: Approval after fulfillment & Administrative formalities

Ref.code:95th ECMIIC/P10

(Primary Reviewer: Dr. Vimal Kumar Paliwal)

11. Modification of Research protocol no.GS-US-419-3895 entitled ***"Combined Phase 3, double-blind, randomized, placebo-controlled studies evaluating the efficacy and safety of filgotinib in the Induction and maintenance of remission in subjects with moderately to severely active crohn's disease"*** M/s Klinera corporation submitted by Dr. Ajay Kumar, Associate Professor, Department of Medicine of this University via letter no. nil dated 7th January, 2020.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

		The following documents were reviewed in the EC Meeting:- 1. Study GS-US-419-3895, Protocol Amendment No. 7 dated 22nd August, 2019 2. Study GS-US-419-3895, Summary of changes dated 22nd August, 2019 for protocol Amendment No. 7 3. Subject information and informed consent main ICF English version 8.1.1 dated 23rd September, 2019 4. Subject information and informed consent translated from English to Hindi version 8.1.1 dated 28th September, 2019 5. Subject information and informed consent back translated from Hindi to English version 8.1.1 dated 30th September, 2019 6. Subject information and informed consent form (Translation and Back Translation with certificates) • English to Hindi: version 8.1.1 dated 28th September, 2019 • Hindi to English: version 8.1.1 dated 30th September, 2019 7. Sperm banking information documents Dr. Ajay Kumar_English, Version: 1.1.1, dated 20th August, 2019. 8. Sperm banking information documents- Dr. Ajay Kumar (Translation & Back translation with certificates) • English to Hindi: Version 1.1.1 dated 20th August, 2019 • Hindi to English:Version 1.1.1 dated 21st August, 2019 **EC Decision:** Approved ***Ref.code:89th ECMIIC/P14-a*** ***(Primary Reviewer: Dr. Rajendra Nath)***
12.	Modification of Research protocol no.**GS-US-419-3896** entitled ***"A long-term extension study to evaluate the safety of Filgotinib in subjects with Crhon's disease"*** M/s Klinera corporation, submitted by Dr. Ajay Kumar, Associate Professor, Department of Medicine of this University via letter no. nil dated 7th January, 2020.	***The following documents were reviewed in the EC Meeting:-*** 1. Study GS-US-419-3896, Protocol Amendment No. 6 dated 5th Sept,2019 2. Study GS-US-419-3896, Summary of Changes dated 5th September,2019 for protocol amendment no.6 3. Subject information and informed consent Main ICF English versio 7.1.1 dated 3rd October, 2019 4. Subject information and informed consent form (Translation and Back Translation with Certificates) • English & Hindi version 7.1.1, dated 7th October, 2019 • Hindi to English:Version 7.1.1 dated 8th October, 2019 **EC Decision:** Approved ***Ref.code:89th ECMIIC/P14-b***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Amita Jain)
13.	Modification of Research protocol no.16T-MC-AMBG entitled ***"A phase 3, Multicentre, Double-Blind, Parallel Arm,-placebo-controlled maintenance study of Mirikzumab in patients with Moderately to severely active Ulcerative colitis"*** sponsored by M/S Eli Lilly, USA submitted by Prof. Abhijit Chandra, Department of Surgical Gastroenterology of this University via letter no. nil dated 26th December, 2019. ***The following documents were reviewed in the EC Meeting:-*** 1. Protocol 16T-MC-AMBG (a)_dated 12th September 2019 1.1. Summary of changes in Protocol 1.2. Synopsis of Protocol 2. Main_V3.0IND(en)1.0_2261v1.0(21 Nov 2019) 2.1 Main_V3.01IND (hi) 1.0_2261v1.0 (21 Nov 2019)Translated on 10 Dec 2019 2.2 Back Translation Main_v3.0 IND (hi) 1.0_2261v1.0(21 Nov 2019) Back Translated on 10 Dec, 2019 2.3 Translation and Back Translation certificate of Hindi Main_V3.0 IND(en)1.0_2261v1.0 (21 Nov 2019) 3. Summary of changes in informed consent from_V3.0 **EC Decision:** Approved ***Ref.code:95thECMIIC/P11***
	(Primary Reviewer: Dr. Rajeev Garg)
14.	Modification of Research protocol no.16T-MC-AMAN" entitled ***"A phase 3, Multicentre, Tandomozed, Double-Blind, Parallel, Placebo-controlled Induction study of Mirikizumab in Conventional-Failed and Biologic-Failed patients with Moderately to severely active ulcerative colitis"*** sponsored by M/S Eli Lilly, USA submitted by Prof. Abhijit Chandra, Department of Surgical Gastroenterology of this University via letter no. nil dated 1st January, 2020. ***The following documents were reviewed in the EC Meeting:-*** 1. Protocol 16T-MC-AMAN a)_dated 12th September 2019 1.1. Summary of changes in Protocol 1.2. Synopsis of Protocol 2. Main_V3.0IND(en)1.0_2261v1.0(21 Nov 2019) 2.1 Main_V3.01IND (hi) 1.0_2261v1.0 (21 Nov 2019)Translated on 10 Dec 2019 2.2 Back Translation Main_v3.0 IND (hi) 1.0_2261v1.0(21 Nov 2019) BackTranslated on 10 Dec, 2019 2.3 Translation and Back Translation certificate of Hindi Main_V3.0 IND(en)1.0_2261v1.0 (21 Nov 2019) 3. Summary of changes in informed consent form_V3.0

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref.code:95th ECMIIC/P10*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
15.	Modification of Research protocol no ***"Is QEEG a marker of cognition in depression? A case control study"*** submitted by Ms. Anamika Srivastava, under the guidance of Dr. Shrikant Srivastava, Department of Geriatric Mental Health of this University via letter no. 33/DGMH dated 16th January, 2020. **EC Decision:** Approved ***Ref.code:94th ECMIIBPh.D/P2*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
16.	Modification of Research protocol no EX9536-4388 SELECT entitled ***"Semaglutide effects on cardiovascular outcomes in people with overweight or obesity"*** sponsored by M/s Novo Nordisk Ltd. submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 410/Cardio/Res/19 dated 22nd May, 2019. ***The following documents were examined and discussed in the meeting:-*** 1. MyVal-1 PIS & ICF Hindi Version 2.0.0 Date 22 Sep 2018(Translated form English to Hindi on 7 Oct 2018) 2. MyVal-1 PIS & ICF English Version 2.0.0 Date 22 Sep 2018(Back Translated form Hindi to English on 7 Oct 2018) 3. MyVal-1 PIS & ICF English Version 2.0.0 Date 22 Sep 2018 4. Translation Certificate Version 2.0.0, 22 Sep 2018 5. Summary of changes **EC Decision:** Approved ***Ref.code:92th ECMIIC/P1*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
17.	Modification of Research protocol no. entitled ***"Pregnancy outcome in Indian women with endometriosis and biomarker correlation: A cohort study"*** submitted by Prof. Vinita Das, H.O.D, Department of Obstetrics & Gynecology of this University via letter no. 72/HRRC/Lko/19 dated 16th January, 2020. **EC Decision:** Approved ***Ref.code:85th ECMIIA/P17*** ***(Primary Reviewer: Dr. Smriti Bhadoria)***
18.	Modification of Research protocol no. ***"MyVal-1:*** entitled ***A prospective multicenter, single arm ,open label study of MyVal TM Transcatheter aortic valve replacement system in the treatment of severe symptomatic native aortic valve stenosis"*** submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 742/Cardio/Res/2020 dated 2nd January, 2020. ***The following documents were examined and discussed in the meeting:-*** 1. MyVal-1 PIS & ICF Hindi Version 2.0.0 Date 22Sep2018(Translated form English to Hindi on 7Oct2018)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

		2. MyVal-1 PIS & ICF English Version 2.0.0 Date 22Sep2018(Back Translated form Hindi to English on 7Oct2018) 3. MyVal-1 PIS & ICF English Version 2.0.0 Date 22Sep2018 4. Translation Certificate Version 2.0.0, 22Sep2018 5. Summary of changes **EC Decision:** Approved ***Ref.code:80th ECMIIC/P8*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
19	Modification of Research protocol no.KCP-330-023entitled:***"BOSTON- A phase 3 randomized, controlled, open-label study of selinexor, bortezomib and dexamethasone (SVD) versus borterzomib and dexamethasone (Vd) in patients with relaplsed or refractory multiple myeloma (RRMM)"*** sponsored by M/s Excel Life Sciences Pvt. Ltd. submitted by Dr. Shailendra Prasad Verma, Assistant Professor, Department of Clinical Hematology of this University via letter no. 83/CH/2020 dated 6thFebruary, 2020. ***The following documents were examined and discussed in the meeting:-***	

Sl.No.	List of Documents	Version/Date
1.	Informed Consent Form (ICF)- English	India Master ICF Version # 4.0; Dated 29/Nov/2019 Final Based on KCP-330-023 Version # 6.0; Dated 26/Sep/2019 Rest of World Mster Template-Protocol Version 4.0 dated 17th August, 2018 & IB Version 9.0 dated 13 Aug, 2019
	ICF Summary of changes	Attached
2.	Translated ICF –Hindi	India Hindi Master ICF Final Version 4.0, Date 03/Jan/2020 Based on KCP-330-023_ India Master ICF Version # 4.0 Dated 29/Nov/2019_Final Translated From English to Hindi on 03/Jan/2020
3.	Translation Certificate of ICF–English to Hindi	Date of translation: 03/Jan/2020 Issued on: 03/Jan/2020

Chairperson, IEC
King George's Medical University
Lucknow

		4.	Back Translated ICF – Hindi to English	Back Translation of India Hindi Master ICF Final Version 4.0 dated 03 /Jan /2020, Based on KCP-330-023_India Master ICF Version # 4.0 Dated 29/Nov/2019_Final Translated from English to Hindi on 03/Jan/2020 Back Translated From Hindi to English on 30/Jan/2020
		5.	Back Translation Certificate of ICF– Hindi to English	Date of Back translation: 30/Jan/2020 Issued on: 31/Jan/2020
		6.	Translated ICF –Hindi	India Hindi Master ICF Final Version 4.0, Date 03/Jan/2020 Based on KCP-330-023_ India Master ICF Version # 4.0 Dated 29/Nov/2019_Final Translated From English to Hindi on 03/Jan/2020
	EC Decision: Approval after fulfillment & Administrative formalities ***Ref.code:87th ECMIIC/P4*** ***(Primary Reviewer: Dr. Vimal Ku)mar Paliwal)***			
20.	Modification of Research protocol no.ZUV/TOSI/HQ/11/2015 entitled ***"A randomized controlled trial of influenza vaccine to prevent adverse vascular events"*** sponsored by M/s Population Health Research Institute (PHRI) submitted by Prof. Sharad Chandra, Department of Cardiology of this University via letter no.460/Cardio/Res/19 dated 13th June, 2019 & 800/cardio/2020 dated 4th February, 2020. ***The Following documents were reviewed in the EC Meeting:*** Amendment 1 dated 20-02-2019 • Amendment summary • Protocol, dated 20181204 –tracked versions • Appendix A, dated 20181204 –tracked versions • CRFs, version 3.5 with changes highlighted • McMaster ethics approval Amendment 2 Dated 03-05-2019 • Amendment summary, dated 20190503 • Protocol, dated 20180221 – tracked versions			

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Consent Addendum, dated 20190221 • McMaster ethics approval **EC Decision:** Approved ***Ref.code:82nd ECMIIC/P8*** ***(Primary Reviewer: Dr. Rajeev Garg)***
21.	Modification of Research protocol no. entitled ***"Cluster of differentiation (CD) panel and thioredoxin as biomarkers for delayed fracture related infections"*** submitted by Ms. Archana Raikwar Ph.D. Scholar through his Mentor Prof. Ajai Singh, Head, Department of Paediatric Orthopaedics of this University via letter no.370/Paed. Ortho/2020 dated 8th February, 2020. **EC Decision:** Approved ***Ref.code:100th ECMIIB PhD./P*** ***(Primary Reviewer: Dr. Amita Jain)***
22.	Modification of research proposal entitled ***"A study of expression of MMP isoforms and their correlation with severity of Paediatric flatfoot"*** submitted by Ms. Aashima Datta PhD. Scholar through his Mentor Prof. Ajai Singh, Head, Department of Paediatric Orthopaedics of this University via letter no.374/Paed.Ortho/2020 dated 10th February, 2020. **EC Decision:** Approved ***Ref.code:100th ECMIIB PhD./P*** ***(Primary Reviewer: Dr. Rajeev Garg)***
23.	Modification of Research proposal entitled ***"The mechanisms involved in the action of Furostanolic saponins (Furocyst) in regulating ovarian function in the dehydroepiandrosterone (DHEA) induced polycystic ovary of mouse and its clinical outcomes"*** submitted by Ms. Aparna Shukla, Ph.D. Scholar under the guidance of Dr. S.K. Singh, Department of CFAR this University via letter no. nil dated 10th February, 2020. **EC Decision:** Approved ***Ref. code: 95th ECM II B-Ph.D./ P1*** ***(Primary Reviewer: Dr.Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. IVB

Additional documents

K.G's Medical University U.P., Lucknow

IVB	Additional Documents
1-	Additional document of research protocol no. LPS15017/Global Premix entitled ***"A multicenter, open-label parallel group randomized controlled trial to compare IGlarLixi versus premixed insulin in patients with type 2 diabetes who have failed to achieve glycemic control with basal insulin and oral antidiabetic agents"*** sponsored by Sanofi Ltd submitted by Dr. D Himanshu, Associate Professor, Department of Medicine of this University via letter no.nil dated 11th April, 2019. **EC Decision:** Approved (Closed) ***Ref. code: 93rd ECMIIC/P2*** ***(Primary Reviewer: Dr. Surjati Bhattacharya)***
2.	Additional document of research protocol no.ALN-AT3SC-003 (EFC14769) entitled ***"Atlas-INH: A phase 3 study to evaluate the efficacy and safety of fitusiran in patients with hemophilia A or B, with inhibitory antibodies to factor VIII or IX"*** sponsored by M/s Bajaj Allianz Generali Insurance Co. Ltd. submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology of this University via letter no.nil dated 3rd January, 2020. ***The Following documents were reviewed in the EC Meeting:***

Sr. No.	Document/Language	Document Details/Versions
1.	Reminder Message_English	IND_LogPadN5_ReminderMessage_v1_English_20180810
2.	Reminder Message Hindi	IND_LogPadN5_ReminderMessage_v1_Hindi_20180910
3.	Reminder Message_Hindi_TC	IND_LogPadN5_ReminderMessage_v1_Hindi_Translation_Certificate_20180910
4.	English LogPadE5 Bleed Treatment Diary	Version 1.00, Fri Jun 16 2017
5.	English LogPadE5 Practice Diary	Version 1.00, Fri Jun 16 2017

Chairperson, IEC
King George's Medical University
U.P., Lucknow

6.	English LogPadE5 Prophylaxis Diary	Version 1.00, Fri Jun 16 2017
7.	English LogPadE5 Weekly Diary	Version 1.00, Fri Jun 16 2017

EC Decision: Approved

Ref. code: 90thECMIIC/P1

(Primary Reviewer: Dr. Anoop Kumar Verma)

3. Additional document of research protocol no.ALN-AT3SC-004 (EFC14768) entitled "***ATLAS-A/B: "A phase 3 study to evaluate the efficacy and safety of fitusiran in patients with hemophilia A or B, without inhibitory antibodies to factor VIII or IX"*** sponsored by M/s Bajaj Allianz Generali Insurance Co Ltd. Ltd. submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology of this University via letter no.nil dated 3rd January, 2020.

The Following documents were reviewed in the EC Meeting:

Sr. No.	Document/Language	Document Details/Versions
1.	Reminder Message English	IND_LogPadN5_ReminderMessage_v1_English_ 20180810
2.	Reminder Message Hindi	IND_LogPadN5_ReminderMessage_v1_Hindi_20 180910
3.	Reminder Message Hindi TC	IND_LogPadN5_ReminderMessage_v1_Hindi_Tr anslation_ Certificate_20180910
4.	English LogPadE5 Bleed Treatment Diary	Version 1.00, Fri Jun 16 2017
5.	English LogPadE5 Practice Diary	Version 1.00, Fri Jun 16 2017
6.	English LogPadE5 Prophylaxis Diary	Version 1.00, Fri Jun 16 2017
7.	English LogPadE5 Weekly Diary	Version 1.00, Fri Jun 16 2017

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	8.	Investigator Brochure SARA39774 Fitusiran	Investigator's brochure Edition 06 dated 15th March 2019 (PPD/ALN-AT3SC-003/Investigator's Brochure/Edition 06 dated 15th March 2019/013 to 021)
	9.	Investigator's Brochure-Summary of changes (Tabular format)	Version 2-IB edition 6.0, change tracking form for IB
	10.	Track change copy of Investigator's Brochure-SARA39774 Fitusiran	Investigator's brochure edition 06 dated 15th March, 2019.

EC Decision: Approved

Ref. code: 90thECMIIC/P2

(Primary Reviewer: Dr. A.A. Sonkar)
(Secondary Reviewer: Dr. Surajit Bhattacharya)

4. Additional document of research protocol no. ATLAS-OLE entitled "***An open label long term safety and efficacy study of fitusiran in patients with hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX***" sponsored by M/s Bajaj Allianz Generali Insurance Co Ltd. Ltd. submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology of this University via letter no.nil dated 14thJanuary, 2020.

Sr. No.	Document/Language	Document Details/Versions
1-	Investigators Brochure	Investigator's brochure Edition 06 dated 15March2019 (Controlled Copy No: PPD/LTE15174/Investigator's Brochure/Edition 06/Dated 15March2019 / 027-035)
2-	English LogPadE5 Bleed Treatment Diary	Fri Jun 16 2017 Version: 1.00
3-	English LogPadE5 Practice Diary	Fri Jun 16 2017 Version: 1.00
4-	English LogPadE5 Prophylaxis Diary	Fri Jun 16 2017 Version: 1.00
5-	English LogPadE5 Weekly Diary	Fri Jun 16 2017 Version: 1.00

Chairperson, IEC
King George's Medical University
U.P., Lucknow

6-	English Patient Instruction	Patient Instructions For Use For Fitusiran (SAR439774/ALN-AT3CSC) Vials Version 1.0, Dated 28 January 2019 Patient Instructions for Use for Fitusiran (SAR439774/ALN-AT3CSC) PFS-S Version 1.0, Dated: 24 January 2019
7-	Hindi Patient Instruction	a. Patient Instruction for use for Fitusiran (SAR439774/ALN-AT3CSC) Vials version 1.0 dated 28th Janaury, 2019 (Hindi) b. . Patient Instruction for use for Fitusiran (SAR439774/ALN-AT3CSC) PFS-S version 1.0, dated 24th Janaury, 2019 (Hindi)
8-	Patient Instruction Translation Certificate	Patient Instuructions for use for Fitusiran 9SAR439774/ALN-AT3CSC) Vials and PFS-S Hindi translation Certificate dated 19th February, 2019
9-	English Haemo-QOL kids SF	Haemo-QoL-Kids (8-16) – United Kingdom/English-Mapi. Haemo-QoL-Kids-SF_ AU2.0 _eng-GBori.doc

EC Decision: Approved

Ref. code: 90th ECMIIC/P1

(Primary Reviewer: Dr. Smriti Bhadoria)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. V

Annual Progress Reports

K.G's Medical University U.P., Lucknow

V-	Annual Progress Reports
1.	Annual Progress Report of research protocol no. entitled " ***The perceived stress and coping in community representative population of Uttar Pradesh"*** sponsored by UPHSSP submitted by Prof. P.K. Dalal, Head, Department of Psychiatry of this University via letter no. 1789/Psy Dated 20th December, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 90th ECMIIA/P16*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwwal)***
2.	Annual Progress Report of research protocol no. entitled ***"Training and clinical impact of cognitive behavior therapy workshops in a teaching Hospital in North India: A retrospective chart review"*** sponsored by UPHSSP submitted by Prof. P.K. Dalal, Head, Department of Psychiatry of this University via letter no. 1788/Psy Dated 20th December, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 93rd ECMIIA/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Annual Progress Report of research protocol no. entitled ***"Ergonomics in dentistry: really a practice or just a tactics"*** submitted by Dr. Sumit Kumar, Associate Professor, Department of Public Health Dentistry of this University via letter no. 573/PHD/19 Dated 23rd December, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 93rd ECMIIA/P20*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Annual Progress Report of research protocol no. 20170199 entitled ***"A multicenter, open-label, single-arm, study to evaluate safety and tolerability of Repatha in patients with homozygous familial hypercholesterolemia (HoFH) in India"*** sponsored by Amgen Technology Pvt. Ltd submitted by Dr. Virendra Atam, Head, Department of Endocrinology of this University via letter no. 200/ENDO/19 Dated 30th December, 2019. **EC Decision:** Reviewed & Noted ***Ref. code: 93rd ECMIIC/P1*** ***(Primary Reviewer: Dr. Rajeev Garg)***
5.	Annual Progress Report of research protocol no.EFC14875-Sotagliflozin entitled ***"A randomized double-blind, placebo- controlled, parallel –group, multicenter study to demonstrate the effects of sotagliflozin on cardiovascular and renal events in patients with type 2 diabetes, cardiovascular risk factors and moderately impaired renal function the scored trial"*** sponsored by M/s Sanofi Ltd submitted by Dr. Virendra Atam, Head, Department of Endocrinology of this University via letter no. 199/ENDO/19 Dated 30th December, 2019.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Reviewed & Noted ***Ref. code: 90th ECMIIC/P4*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
6.	Annual Progress Report of research protocol no. entitled ***"Repurposing of anticancer drugs for the treatment of Malaria"*** submitted by Dr. D. Himanshu, Department of Medicine of this University via letter no. MILU/20/Jan/06 Dated 6th January, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 93rd ECM IIA/P11*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
7.	Annual Progress Report of research protocol no. ICR/16/002 entitled ***"A randomized, multi- centric, open label, comparative study to evaluate efficacy and safety of fixed dose combination of pregabalin prolonged release and etoricoxib in comparison to etoricoxib alone in patients having chronic low back pain in India"*** sponsored by M/s Sun Pharma Laboratories Ltd. submitted by Dr. Ashish Kumar, Department of Orthopaedic Surgery of this University via letter no. 501/Ortho/RP/19 Dated 26th December, 2019. **EC Decision:** Reviewed & noted ***Ref. code: 92nd ECMIIC/P2*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
8.	Annual Progress Report of research protocol no. entitled ***"Oral features of newborns"*** submitted by Prof. Rakesh Kumar Chak, Head, Department of Paediatric & Preventive Dentistry of this University via letter no. 66/2020 Dated 13rd January, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 80th ECMIIA/P2*** ***(Primary Reviewer: Dr. Smrit Bhadoria)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. VI

Extension of previously approved trial

K.G's Medical University U.P., Lucknow

VI-	Extension of previously approved trial
1.	Extension of research protocol no entitled ***"A global registry to study the demographics, socioeconomic and clinical factors, etiologies, pathophysiology, management, barriers to care, outcomes of heart failure patients"(G-CHF Study)*** sponsored by M/s PHRI submitted by Prof. Sharad Chandra, Department of Cardiology this University via letter no. 801/Cardio/Res/2020 dated 4th February, 2020. **EC Decision:** Approval after fulfillment & Administrative formalities ***Ref. code: 86th ECM IIC/P3*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 101st "Institutional Ethics Committee" Meeting held on 15th June, 2020

Item no. VII

Other Matter

K.G's Medical University U.P., Lucknow

VII	Other Matter with the permission of Chair
1-	Due to some reason this trial was not continued Research protocol No. WOC/SPA/CT-41/14 entitled: ***"Prospective, open-label, non-comparative, multicenter, phase IV trial to evaluate the safety and efficacy of Spasmoproxyvon plus capsules (FDC of tramadol 50mg + Dicyclomine 10mg + Acetaminophen 325mg) of Wockhardt limited in management of severe acute spasmodic pain"*** sponsored by M/s Wockhardt Ltd. submitted by Prof. Rekha Sachan, Department of Obst. & Gynaecology via letter no. OG/526/20 dated 13th February, 2020. **EC Decision:** Permission granted ***The above protocol was approved on 3rd November, 2017.*** ***Ref. code: 87th ECM IIC/P7***
2-	Due to change the topic as per direction by the Dean, KGMU ***"Expression of SCAMP3 gene in Oral cancer patients with special reference to clinicopathological features"*** instead of ***"Expression of SCAMP3 and methylated DNA in circulating cell free nucleic acid in oral cancer patients with special reference to disease prognosis- A pilot study"*** submitted by Dr. Saurabh Kumar Singh, JR-I, Department of General Surgery. **EC Decision:** Approved ***Dr. A.A. Sonkar did not take part in the discussion.***
3-	Due to change the topic as per direction by the Dean, KGMU ***""Expression of scamp 3 gene in carcinoma gall bladder patients with special reference to clinicopathological features"*** instead of ***"Expression of SCAMP3 and methylated DNA in circulating cell free nucleic acid in carcinoma gall bladder patients with special reference to disease prognosis – A pilot study"*** submitted by Dr. Niyatank Tyagi, JR-II, Department of General Surgery. **EC Decision:** Approved ***Dr. A.A. Sonkar did not take part in the discussion.***
4-	As per own requested by the P.I. to add the two Co-guides in her research proposal entitled ***"Volumetric analysis of prefrontal cortex and magnetic resonance spectroscopy in late life psychosis"*** submitted by Dr. Nimitha K.J. SR-II, Department of G.M.H. of this University via letter no. 184/DGMH dated 7th March, 2020. **EC Decision:** Permission granted to add the two Co-guieds, Dr. Bhupendra Singh and Dr. Rakesh Kumar Tripathi both are Associate Professor, G.M.H. of this University. ***Ref. code: 100th ECM IIB Thesis/P8***
5-	As per own request to the P.I. of research proposal entitled ***"Study on association of genetic mutations with resistance level of fluoroquinolones in multi- drug resistant mycobacterial tuberculosis"*** to change the Co-Guide Prof. Urmila Dhakkad in place of

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Dr. Praveen Kumar, submitted by Dr. Deepti Jaiswar, JR-I, Department of Microbiology of this University **EC Decision:** Permission granted ***Dr. Amita Jain did not take part in the discussion.*** ***Ref. code: 97th ECM II B-Thesis/P2*** ***(Previous Primary Reviewer: Dr. Balendra Pratap Singh)***
6-	Due to qouram was not complete because the Lay man, Mr. Ram Niwas Jain was demise on the same day ie. 6th March, 2020 that was EC Meeting day so this Modification could not review on 6th March, 2020 the research protocol no. KCP-330-023 entitled: ***"BOSTON- A phase 3 randomized, controlled, open-label study of selinexor, bortezomib and dexamethasone (SVD) versus borterzomib and dexamethasone (Vd) in patients with relaplsed or refractory multiple myeloma (RRMM)"*** sponsored by M/s Excel Life Sciences Pvt. Ltd. submitted by Dr. Shailendra Prasad Verma, Assistant Professor, Department of Clinical Heamatology of this University via letter no.189/CH/19 dated 14th March, 2019. **EC Decision:** Approved ***Ref.code:87th ECM IIC/P4*** ***(Primary Reviewer: Dr. Balendra Pratap Singh)***

Next Meeting Date will be scheduled on 18th August, 2020 (Friday)

Thanks

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

K.G's Medical University U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IA
Action taken

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 102nd ECM held on 18th August, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Minutes of the 102nd ***"Institutional Ethics Committee"*** Meeting was held on **18th August, 2020 (Tuesday) from 02.00 till 5.00 p.m.** in the **'Board Room',** Office of the Vice Chancellor, Administrative Block of this University.

The following members were present in the Meeting: -

1- Prof.S.P. S Gaur	**-Chairman**
2- Justice Hon'ble Vishnu Sahai	**- Member**
3- Dr. Surajit Bhattacharya	**-Member**
4- Dr. Smriti Bhadauria	**-Member**
5- Dr. Preeti Agarwal	**-Member**
6- Dr. Manju Agrawal	**-Member**
7- Prof. Rajendra Nath	**-Member**
8- Prof. Anoop Kumar Verma	**-Member**
9- Mr. Yogesh Mishra	**-Member**
10- Prof. R. K. Garg	**-Member-Secretary, Ex-officio**

The following Members were not present:

1- Dr. Vimal Kumar Paliwal	**-Member (Send his written comment)**
2- Prof. A.A. Sonkar	**-Member (Send his written comment)**
3- Prof. Amita Jain	**-Member (Send her written comment)**
4- **Prof. Rajiv Garg**	**-Member (Send his written comment)**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 102nd ECM held on 18th August, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Meeting started with welcoming of our new Vice Chancellor Lieutenant General Dr. Vipin Puri. All members who were present were introduced to our new Vice Chancellor.

I-A	Action Taken
	Part-a 96th EC Meeting was held on 10th May, 2019
a1.	Clarification of research proposal entitled ***"Comparative evaluation to see the effect of normal saline-O2 and ozone therapy on hard and soft tissue in dental implant surgery"*** submitted by Dr. Abhay Kumar Dixit, JR-I, Department of Prosthodontics, Crown & Bridge, Faculty of Dental Sciences of this University via letter no. 24/19 dated 6th April, 2019. **EC Comment on 10th May, 2019:** • How will the authors intend to choose patients for normal saline, O2 and ozone treatment? • Is ozone treatment standard of care? If yes, will not offering ozone treatment to a subgroup of patients will amount to depriving patients from the standard care? • The PI has not provided the details of ozone treatment in the methods section. • Who will provide the cost of ozone treatment? • The methods section needs to detail the complications of the ozone treatment. The possible complications of the either of the study treatment should also be detailed in the patient information document. • Patient's performa has to be submitted along with the revised proposal. **EC Decision 10th May, 2019:** Approval after justification ***The above comment forwarded to P.I., response received from P.I. which was forwarded to the Primary reviewer, he approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96th ECM II B-Thesis/P51*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
	Part-b- 97th EC Meeting was held on 12th July, 2019
b1	Research proposal entitled ***"Clinical and radiographic evaluation of efficacy of MTA, biodentine, & silver diamine fluoride as indirect pulp capping materials in primary***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	molars" submitted by Dr. Durga R, JR-I, Department of Paediatric and Preventive Dentistry, Faculty of Dental Sciences of this University via letter no. nil dated 15th June, 2019. **EC Comment on 12th July, 2019:** • It an RCT design, methodology is incomplete and the PI has to register the trial with the trial registry. **EC Decision on 12th July, 2019:** Revise & Re-submit ***The above comment forwarded to P.I., response received from P.I. which was reviewed by the Member-Secretary, IEC & he approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 97thECM II B-Thesis/P125*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
b2	Clarification of research proposal entitled ***"Metagenomic analysis of salivary and plaque microbiota in diabetic and non-diabetic individuals"*** submitted by Dr. Jyotsana Agarwal, JR-II, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences of this University via letter no. nil dated 17th June, 2019. **EC Comment on 12th July, 2019:** • Diabetes is associated with higher incidence of root caries and their plaque has a different and aggressive bacterial flora. Bacteria from caries and plaque spill into the saliva. • This is a cross-sectional study in adults between 30 to 60 years of age • Sample size is 30 – 15 diabetic and 15 non-diabetic. Was this figure statistically derived? • Samples will be obtained in fasting condition in the morning but no data collection sheet is provided and so we do not know what will be observed. • We need a data collection sheet which should have the demographic details, the diabetic status, their oral hygiene, their tobacco / paan / betel nut habit as these people have not been excluded in your study. • Signature of f Dr. A.B. Pant was missing. **EC Decision on 12th July, 2019:** Approval after justification

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	The above comment forwarded to P.I., response has given by P.I. which was reviewed by the Primary reviewer &he has given the following comment: **Comment:** • ***The data collection sheet still does not include what will be done with the saliva sample?*** • ***What all will be observed in each case abd documented for subsequent analysis?*** ***The above comment again forwarded to the P.I. & she has not given her reply till 25th January, 2020.*** **EC Decision on 25th January, 2020:** Pending ***The above decision forwarded to the P.I. via letter no.44/Ethics/2020 dated 11th February, 2020 then the P.I. has given her reply which was reviewed by the Member-Secretary, IEC & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P150*** ***(Primary Reviewer: Dr. Surajit Bhattachrya)***
c	**Part-c- 99th EC Meeting was held on 18th October, 2019**
c1	Clarification of research proposal entitled ***"A radiological study on patients of osteoarthritis to establish relationship of kellgren-Lawrence grading score with knee range of motion and average pain score"*** sponsored by Research Cell K.G.M.U Lucknow submitted by Mr. Prince Rai, MBBS 2018 through his Mentor Dr. Archana Rani, Department of Anatomy of this University via letter no. nil dated 26th August, 2019. **EC Comment on 18th October, 2019:** • As the study is based on radiographs of patients. Principal-Investigator should involve the treating doctor/any rheumatologist in the study. **EC Decision on 18th October, 2019:** Approval after justification ***The above comment forwarded to the P.I. response has given by P.I. which was reviewed by the Member-Secretary, IEC & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 99th ECM IIB IMR-S/P8*** ***(Primary Reviewer: Dr. Anoop Kumar Varma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

d	**Part-d- 100th EC Meeting was held on 25th January, 2020**
d-1	Clarification of research proposal entitled ***"Evaluation of clinical and anti-inflammatory effect of tea tree oil used as an adjunctive treatment of chronic periodontitis"*** submitted by Dr. Shubham Sharma, JR-I, Department of Periodontology, Faculty of Dental Sciences of this University via letter no. nil dated 14th September, 2019. **EC Comment on 25th January, 2020:** • Source ad brand/make of tea tree oil may be specified. Furthermore, adverse effect/allergies following oral exposure need to be elaborated in the review section & accordingly measures are to be suggested in case of an episode. **EC Decision on 25th January, 2020:** Approval after justification **EC Decision:** Approved ***Ref. code: 100thECM II B-Thesis/P6*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
e	**Part-e EC Meeting was held on 16th May, 2020**
e1	Clarification of research proposal entitled ***"Volumetric analysis of mastoid air cells in different malocclusions in 3D CBCT"*** submitted by Dr. Akhilanand Chaurasia, Assistant Professor, Department of Oral Medicine and Radiology, Faculty of Dental Sciences of this University via letter no. nil dated 16th January, 2020. **EC Comment on 16th May, 2020:** • Consent form is not as per new format • Study plan is not clear • Sample size calculation is also not clear (not at all) inclusion & exclusion criteria are copied & pasted, as such favour some where (in past tense) • Budget & financial support is not mentioned • Cannot be approved in current form **EC Decision on 16th May, 2020:** Re-submit ***The above comment forwarded to the P.I. response has been given by P.I. which was reviewed by the Primary reviewer & she approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101stECM IIA/P12***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Amita Jain)
e2	Clarification of research proposal entitled **"*The morphometric analysis of mandibular condyle and coronoid process in different malocclusion in 3D CBCT*"** submitted by Dr. Akhilanand Chaurasia, Assistant Professor, Department of Oral Medicine and Radiology of this University via letter no. nil dated 16th January, 2020. **EC Comment on 16th May, 2020:** • The study aims to evaluate the volume of mandibular condyle and coronoid process and correlate it with age, sec and skeletal deformities using 3D CBCT • Guidelines for patient information sheet is attached without making any attempt to construct a study specific patient information sheet • Sample size 152, statistically calculated. • Data collection sheet is missing. What exactly will be observed – what dimensions, what volumes? • Will the patient also be physically examined? A big and tall man will have a bigger condyle as compared to a small and short woman! In Coronoid process significant appositional bone growth secondary to abnormal stresses mediated by the tendon of the temporalis muscle does occur so the patients have to be examined and a data collection **EC Decision on 16th May, 2020:** Re-submit ***The above comment forwarded to the P.I. response has been given by P.I. which was reviewed by the Primary reviewer & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P13*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
e3.	Clarification of research proposal entitled **"*To elucidate the role of WWOX (WW domain-containing oxidoreductase) gene in osteosarcoma: A prospective case control study*"** sponsored by ICMR, New Delhi submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 14/P/OS/2020 dated 14th January, 2020. **EC Comment on 16th May, 2020:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Pt. information sheet missing **EC Decision on 16th May, 2020:** Approval after justification ***The above comment forwarded to the P.I. response has been given by P.I. which was reviewed by the member-Secretary, IEC & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101stECM IIA/P28*** ***(Primary Reviewer: Dr. Rajendra Nath)***
f	**Part-f- 101st EC Meeting was held on 16th May, 2020**
f1	Clarification of research proposal entitled ***"A study on association of diabetes mellitus, Hypertension and Hyperthyroidism with their blood parameters"*** submitted by Dr. Priyanka Singh, Associate Professor, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences of this University via letter no. 823/OP/2020 dated 29th January, 2020. **EC Comment on 16th May, 2020:** • Study designed did not mentioned • Objectives did not match with the material method. **EC Decision on 16th May, 2020:** Approval after justification ***The above comment forwarded to the P.I. response has given by P.I. which was reviewed by the Primary reviewer & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101stECM IIA/P23*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
f2	Clarification of research proposal entitled ***"The clinical presentation, management & outcomes among patients with chronic obstructive pulmonary disease patients-the COPD registry (INCOR) study"*** sponsored by SRM MCH & RC, Kattankulathur submitted by Dr. Ajay Kumar Verma, Department of Respiratory Medicine of this University via letter no. 146/2019 dated 10th February, 2020. **EC Comment on 16th May, 2020:** • The Multicentric study is a case registry.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• The sponsorer & the budget are not disclosed (ticked on private Consent form is on old format). **EC Decision on 16th May, 2020:** Revise ***The above comments were forwarded to the PI. The reply has given by the P.I. The reply was reviewed by the Member-Secretary, IEC and he approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101stECM IIA/P38*** ***(Primary Reviewer: Dr. Amita Jain)***
	101st EC Meeting was held on 23rd May, 2020
f3	Clarification of research proposal entitled ***"Comparison of tetrachromic VOF stain with routine H&E staining techniques for characterizing stromal soft and hard tissue components"*** submitted by Prof. Shaleen Chandra, Head, Department of Oral Pathology Faculty of Dental Sciences of this University via letter no. 1024/OP/2020 dated 12th June, 2020. **EC Comment on 23rd May, 2020:** • Project aims to compare the efficiency of two specific techniques in terms of their ability to adequately characterize tissue components. It has significant application. **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I. response has given by P.I. which was reviewed by the Primary reviewer & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101stECM IIA/P34*** ***(Primary Reviewer: Dr. Smriti Bhadauri)***
f4	Clarification of research proposal entitled ***"Endoscopic colpopexy for grade 3 and 4 uterine and vaginal vault prolapsed"*** submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology of this University via letter no. 264/2020 dated 9th June, 2020. ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer he approved it.*** **Action taken:** Provisionally approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 101st ECM IIA/P40*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
f5	Clarification of research proposal entitled ***"Effect of beta-3 agonist (Mirabegron) and alpha blocker (Tamsulosin) on treatment of ureteral stent related symptoms: A randomized controlled trial"*** submitted by Dr. Pavan Kumar S.K, SRII, Department of Urology of this University via letter no. nil dated 20th December, 2019. **EC Comment on 23rd May, 2020:** • 50 subjects in three arms – placebo, mirabegron and tamsulosin. Randomization by chart. Body pain score and urinary symptom score will be compared. There are several issues: • Who will bear the cost of the medications and investigations? • DCGI approval of the drugs has to be submitted. • Who will bear the cost of insurance/compensation? The required information has to be submitted to ethics committee. • The study is written in past tense with inclusion of patients from Nov 2019. The part needs to be re-written. Inclusion of patients can commence only after obtaining ethical clearance. **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer he again given his comment:*** **Comment:** • **The trial medications have to be bought by the department and patient should not pay for the drugs.** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
f6	Clarification of research proposal entitled ***"Voiding dysfunction after vesicovaginal fistula repair: prevalence, predictive factors and comparative analysis of functional outcomes between laparoscopic, open transabdominal and transvaginal repair"*** submitted by Dr. Mayank Jain, SRII, Department of Urology of this University via letter

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	no. nil dated 20th December, 2019. **EC Comment on 23rd May, 2020:** • Sample size not calculated • How many cases will be subject to each arm of surgical intervention? • Consent form is as per old version **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101stECM II B-Thesis/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
f7	Clarification of research proposal entitled ***"A combined retrospective- prospective cohort study for efficacy of internal urethrotomy followed by CIC with and without clobetasol ointment in the management of stricture urethra"*** submitted by Dr. Mukesh Kumar, JRII, Department of Urology of this University via letter no. nil dated 21st December, 2019. **EC Comment on 23rd May, 2020:** • Patients who have undergone internal urethrotomy will be followed up to compare the effect of CIC with or without Clobetasol ointment by uroflometry, RGU or MCU • Data collection sheet has been provided • Sample size is missing. We need this for statistical significance of the results • Follow up schedule and outcome criteria defined • Catheterization schedule standardized **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101stECM II B-Thesis/P5*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

f8	Research proposal entitled ***"Intracranial meningiomas: retrospective review of 10 Years"*** submitted by Dr. Aditya Varshney, SRI, Department of Neurosurgery of this University via letter no. nil dated 4th January, 2020. **EC Comment on 23rd May, 2020:** • This is a follow-up study of cases who were died as Meningiomas in last 10 years (Not a retrospective study) 1. There is not clause for cases who are not traceable or who died 2. How many cases are actually registered in the department? 3. How consent will be taken because patient may not be physically present. 4. Consent form is on old format. **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer she approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101stECM II B-Thesis/P12*** ***(Primary Reviewer: Dr. Amita Jain)***
f9.	Clarification of research proposal entitled ***"Effects of BOTULINUM toxin injection with casting in children of spastic cerebral palsy: A randomized controlled trial"*** submitted by Dr. Shivansh Vishwakarma, JRI, Department of Physical Medicine & Rehabilitation of this University via letter no. 2679/20 dated 15th January, 2020. **EC Comment on 23rd May, 2020:** • Prekect is well written and problems are defined nicely however, owing to BOTULINUM TOXIN being bio-hazard, its use must have prior approval from Institutional BioSafety Committee. • There is no such certificate in the proposal. • Second opinion from Bio-safety Incharge will be appreciable • Recommended under the conditions that Use, Disposal and Handling of Botulinum toxin are in accordance with Institutional Biosafety Guidelines.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision on 23rd May, 2020: Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer she approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P17*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
f10.	Clarification of research proposal entitled ***"Major salivary gland ultrasound and elastography as a predictor of disease activity in patients of primary sjogren's syndrome"*** submitted by Dr. Chandwar Kunal Ashutosh, SR, Department of Rheumatology of this University via letter no. Rh/80/20 dated 16th January, 2020. **EC Comment on 23rd May, 2020:** 30 patients of Sjogren syndrome will be subjected to ultrasound and elastography of submandibular and parotid glands. • Inclusion of patients in the study should start after obtaining the ethical clearance. The study duration cannot start from December 2019. • Please provide a brief CV of the collaborators from outside the institute. **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. &which was reviewed by the Member-Secretary, IEC & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P19*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
f11.	Clarification of research proposal entitled ***"Clinical, laboratory profile and outcomes of patients presenting with digital gangrene to a rheumatology clinic in a tertiary care Hospital"*** submitted by Dr. Kriti Kishor, SR, Department of Rheumatology of this University via letter no. Rh/79/20 dated 16th January, 2020. **EC Comment on 23rd May, 2020:** • English-ICF not complete • Sample size calculation not done

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision on 23rd May, 2020: Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer she approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P20*** ***(Primary Reviewer: Dr. Rajendra Nath)***
f12	Clarification of research proposal entitled ***"To report culture positivity by various methods for processing of gastric aspirate collected from pediatric cases of suspected pulmonary tuberculosis"*** submitted by Dr. Rajeev Sharma, JRI, Department of Microbiology of this University via letter no. 752/2020 dated 3rd February, 2020. **EC Comment on 23rd May, 2020:** • Kindly provide sample size **EC Decision on 23rd May, 2020:** Approval after justification ***The above comments were forwarded to the PI. The reply was reviewed by the Member-Secretary, IEC and he approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P30*** ***(Primary Reviewer: Dr. Rajendra Nath)***
f13	Clarification of research proposal entitled ***"Association of APLASTIC anemia with viruses-A case control study"*** submitted by Dr. Gerlin Varghese, JRI, Department of Microbiology of this University via letter no. 753/2020 dated 3rd February, 2020. **EC Comment on 23rd May, 2020:** • The objective is to study the association of Apalstic Anaemia with Human Parvo virus B19, Cytomegalovirus, Epstin Barr Virus, Adeno virus, Measles virus, Human Herpes virus 6, Hepatitis virus A, B, C and E and Varicella Zoster Virus. It also intends to study the progression of these viruses in patients receiving immune-suppressive therapy • A patient data form has been attached which includes demographic details, clinical examination and laboratory findings

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Blood samples will be collected – How much? How many times? When? • Sample size 76. 38 study group and 38 control. Which individuals are in control group? How this sample size was derived, particularly when there are so many variables. **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer she approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P32*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
f14	Clarification of research proposal entitled ***"Blood culture positive neonatal sepsis in a tertiary care intensive care unit: A descriptive observational study"*** submitted by Dr. Ankit Pachauri, JRI, Department of Pediatrics of this University via letter no. 227/Ped/2020 dated 4th February, 2020. **EC Comment on 23rd May, 2020:** • Project aims to compare the efficiency of two specific techniques in terms of their ability to adequately characterize tissue components. It has significant application. **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer she approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P34*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
f15	Clarification of research proposal entitled ***"Site specific distribution of CD68 positive microglia in optic pathway of human cadaver"*** submitted by Dr. Chetana Sharma, JRI, Department of Anatomy of this University via letter no. 659/ANAT/2020 dated 4th February, 2020. **EC Comment on 23rd May, 2020:** • Exclusion criteria is not provided

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision on 23rd May, 2020: Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer she approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P36*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
f16.	Clarification of research proposal entitled ***"Evaluation and correlation of different palatal RUGAE pattern, INTERINCISOR width, INTERCANINE width and INTERCANINE width in North Indian population- A comparative study"*** submitted by Dr. Supriya Sharma, SR, Department of Oral Pathology & Microbiology of this University via letter no. 835/OP/2020 dated 4th February, 2020. **EC Comment on 23rd May, 2020:** • Poorly written • Waiver may be provided. • Comparing only male and felaled. Hence data is anonymous **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer she approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P37*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
f17	Clarification of research proposal entitled ***"To study prognostic implications of plasma fibrinogen, D-dimer and various epithelial-to mesenchymal transition markers in patients with non-muscle invasive bladder cancer"*** submitted by Dr. Sahil Singhla, SRI, Department of Urology of this University via letter no. nil dated 6th February, 2020. **EC Comment on 23rd May, 2020:** • Pt information sheet & calculated sample Size **EC Decision on 23rd May, 2020:** Approval after justification

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer he approved it. **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P48*** ***(Primary Reviewer: Dr. Rajendra Nath)***
f18.	Clarification of research proposal entitled ***"Sonographic anatomy and topographical variability of sural nerve in the leg"*** submitted by Dr. Untika Singh, JRI, Department of Anatomy of this University via letter no.675/ANAT/2020 dated 8th February, 2020. **EC Comment on 23rd May, 2020:** • There are 100 proposed volunteers who will for in study subjects. • Consent form should be for Volunteers. • Variables of analysis should be listed. **EC Decision on 23rd May, 2020:** Revise & Re-submit ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P49*** ***(Primary Reviewer: Dr. Amita Jain)***
f19	Research proposal entitled ***"Efficacy and NSAID sparing effect of conventional synthetic disease modifying anti-rheumatic drugs (DMARD) in patients of spondyloarthritis"*** submitted by Dr. Juhi Dixit, SRI, Department of Rheumatology of this University via letter no. Rh/81/2020 dated 16th January, 2020. **EC Comment on 23rd May, 2020:** • The study aims to evaluate the efficacy and NSAID sparing effect of conventional DMARDs in patients of spondiloarthritis • Sample size is 100. How was it derived? • Data collection sheet with History, Clinical Examination, Ankylosing Spondilitis Disease Activity Score (ASDAS), Bath Ankylosing Spondilitis Disease activity Index (BASDAI), Bath Ankylosing Spondilitis Functional Index (BASFI), Maastricht Ankylosing Spondilitis Enthesitis Index (MASES)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	and laboratory investigations attached • Which DMARD will be used and in what dosage? (Sulphasalazine / MTX) • What will be the follow up schedule? • How will we look for adverse effects and how will we manage them? • Discontinuation and withdrawal criteria should be spelt out. • Methodology not clear. We need a study plan from start to finish. **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by the Member-Secretary, IEC & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P51*** ***(Primary Reviewer: Dr. Surajit Bhattacarya)***
f20	Clarification of research proposal entitled ***"Association of resistin 420 and 62 gene polymorphisms in patients with oral submucous fibrosis (OSMF) and oral cancer patients"*** submitted by Dr. Roop Ganguly, SRI, Department of Oral and Maxillofacial Surgery of this University via letter no. OMS/12/2020 dated 10th February, 2020. **EC Comment on 23rd May, 2020:** • Sample size not calculated only number is given • Methodology not given in detail • Related Questionnaire AND Pt information sheet not submitted **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P58*** ***(Primary Reviewer: Dr. Rajendra Nath)***
f21	Clarification of research proposal entitled ***"Comparative evaluation of effects of yoga and oral hygiene interventions in asthmatic patients with periodontal diseases: A randomised control trial"*** submitted by Dr. Pooja Garg, JRI, Department of

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Periodontology Faculty of Dental Sciences of this University via letter no. 1627/P/2020 dated 10th February, 2020. **EC Comment on 23rd May, 2020:** • The aim is to estimate the effect of Yoga and Oral Hygiene interventions on spasmodic and periodontal parameters of asthmatics with periodontal disease • Sample size 80, 20 in each group. Statistically calculated. But what are these groups? • Salivary levels of IL1b by ELISA will be used as a parameter for which 5 ml saliva will be collected and compared after 6 months. • Now where is the R.C.T in all this? Please follow the Consort guidelines and redesign the study • How will Yoga be standardized for all patients? Which research contributor is the expert in Yoga and with what qualifications? • Data collection sheet is not provided **EC Decision on 23rd May, 2020:** Re-submit ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P61*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
f22	Clarification of research proposal entitled ***"Gauging the Psychosocial salubrity of Oral cancer patients and their kinsfolk: A cross-sectional study"*** submitted by Dr. Shruti Singh, SRIII, Department of Oral Pathology, Faculty of Dental Sciences of this University via letter no. 841/OP/2020 dated 6th February, 2020. **EC Comment on 23rd May, 2020:** • Methodology has not been explained • Sample size not calculated • Pt information sheet not attached **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer he approved it.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Action taken: Provisionally approved **EC Decision:** Approved ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P67*** ***(Primary Reviewer: Dr. Rajendra Nath)***
f23.	Clarification of research proposal entitled ***"Curtailing the postoperative menaces in Oral cancer patients-A microbiological analysis"*** submitted by Dr. Jaya Singh, SRII, Department of Oral Pathology Faculty of Dental Sciences of this University via letter no. 840/OP/2020 dated 6th February, 2020. **EC Comment on 23rd May, 2020:** • Study protocol is not shown • Only a paragraph on Microbiology method's is written. • Protocol is not clear • How sample size was calculated? • How herbal extract will be prepared & in what doses will it be tested? • What will be the purpose & in what doses will it be tested? • What will be the purpose of looking at pre & post operative colony count **EC Decision on 23rd May, 2020:** Revise ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer she approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P68*** ***(Primary Reviewer: Dr. Amita Jain)***
f24	Clarification of research proposal entitled ***"Clinical and echocardiographic parameters of neonates of diabetic and non diabetic mothers and its correlation with cord blood insulin like growth factor 1 levels- A case control study"*** submitted by Dr. C. Tharuna, JRI, Department of Pediatrics of this University via letter no. 248/Ped/2020 dated 6th February, 2020.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment on 23rd May, 2020: • The objective is to study the clinical and ECG differences of neonates of diabetic and non-diabetic mothers and its relation to cord blood Insulin like Growth Factor 1 levels and maternal HbA1c levels • Maternal blood sample and cord blood sample will be collected bur when and how much we do not know • A very elaborate data collection sheet is attached • Sample size is not given. Please consult with a statistician and settle for a doable sample size • The methodology needs to be described clearly **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to the P.I., reply has given by PI. & reviewed by primary reviwer he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P70*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
f25	Clarification of research proposal entitled ***"Role of Serum Glycosylated Fibronectin in Preeclampsia and its association with Fetomaternal Outcome"*** submitted by Dr. Nazrana Ghayyur, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/424/2020 dated 10th February, 2020. **EC Comment on 23rd May, 2020:** • Kindly provide the calculated sample size and patient information sheet **EC Decision on 23rd May, 2020:** Approval after justification ***The above comments were forwarded to the PI. The reply was reviewed by reviewed by primary reviwer he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P76*** ***(Primary Reviewer: Dr. Rajendra Nath)***
f26.	Clarification of research proposal entitled ***"Identification and characterization of weak d***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	variants in blood donors" submitted by Dr. Anurag Singh, JRI, Department of Transfusion Medicine of this University via letter no. 556/2020 dated 7th February, 2020. **EC Comment:** • Simple observational study Genetic work will be done at N11H. • Kindly provide consent form as new format **EC Decision:** Approval after justification ***The above comments were forwarded to the PI. The reply was reviewed by reviewed by primary reviwer she approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P86*** ***(Primary Reviewer: Dr. Amita Jain)***
f27.	Clarification of research proposal entitled ***"Evaluation of hematological and hormonal parameters in plateletpheresis donors"*** submitted by Dr. Pradeep Kumar Maurya, JRI, Department of Transfusion Medicine of this University via letter no. 557/2020 dated 7th February, 2020. **EC Comment on 23rd May, 2020:** • Alteration in haematological parameters, Thrombopoetin levels and Prothrombin levels will be studied in plateletpheresis donors of 18-65 years of age and over 50 Kg weight • Inclusion and exclusion criteria are clearly defined • Sample size 40. Statistically derived • Methodology is described in details • Data collection sheet is missing **EC Decision on 23rd May, 2020:** Approval after justification ***The above comments were forwarded to the PI. The reply was reviewed by reviewed by primary reviwer he approved it and he approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P88*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

f28	Clarification of research proposal entitled ***"Efficacy of injectable platelet rich fibrin (I-PRF) with or without arthrocentesis in TMJ osteoarthritis patients"*** submitted by Dr. V.E. Shanthosh Kanna, JRII, Department of Oral & Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. OMS/126/2020 dated 8th February, 2020. **EC Comment on 23rd May, 2020:** The study will include 32 patients in each of two arms. Patients in one arm will be subjected to injection of PRF in TMJ and patients in other arm will be subjected to arthrocentesis followed by PRF injection. Various parameters related to control of pain and osteoarthiritis using cone beam computed tomography (CBCT) will be compared between two arms. There are some issues: • Will it be a randomized study? Which randomization methods will be used? • What is the standard of care in TMJ osteoarthritis? • Who will bear the cost of the treatment? • Who will bear the cost of the compensation/insurance? • The possible side-effects of the procedure/treatment have to be discussed in the patient information document. **EC Decision on 23rd May, 2020:** Approval after justification ***The above comments were forwarded to the PI. The reply was reviewed by reviewed by primary reviwer he approved it and he approved.*** **EC Decision:** Approved ***Ref. code: 101stECM II B-Thesis/P66*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
g	**EC Meeting was held on 15th June, 2020**
g1	Clarification of research proposal entitled ***"A study on the knowledge, attitudes and practices regarding hand hygiene amongst nursing staff in selected area of a tertiary care Teaching Hospital"*** submitted by Dr. Shashvat Kshitij Sinha, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Administration of this University via letter no. HA/2020/089 dated 7th February, 2020. **EC Comment on 15th June, 2020:** • Kindly provide the Consent form as new format **EC Decision on 15th June, 2020:** Re-submit ***The above comments were forwarded to the PI. The reply was reviewed by the Member-Secretary, IEC and he approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECMIIBCS/P3*** ***(Primary Reviewer: Amita Jain)***
g2	Clarification of research proposal entitled ***"To study on the completeness of the surgical safety checklist with respect to the patients of surgical gastroenterology Department in a tertiary care government teaching Hospital at Lucknow"*** submitted by Dr. Shweta Singh, JRII through her Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/042 dated 24th January, 2020. **EC Comment on 15th June, 2020:** • Research Hypothesis not written: • Objective not defined • What Selected areas will be studied? **EC Decision on 15th June, 2020:** Re-write & Re-submit ***The above comments were forwarded to the PI. The reply was reviewed by the Member-Secretary, IEC and he approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECMIIBCS/P7*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
g3.	Clarification of research proposal entitled ***"A study of on completeness of treatment card in a tertiary care Government Hospital"*** submitted by Dr. Preeti Bharti, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/071 dated 7th February, 2020.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment on 15th June, 2020: • The study aims to assess the completeness of treatment cards on different parameters of NABH standards and to suggest recommendations if any • Sample size not provided. From monthly admission records of previous years please come up with a sample size doable in 4 weeks and consult with statistician to see if your results will be statistically significant • Observational checklist – what all will be observed, is provided • Technique of case record sampling ensures maintaining confidentiality of individual patients. But why do they need UHID of the patient? Just like the Name they can see whether the UHID is correctly mentioned in the treatment card or not. Why are they noting it? • Consent waiver is sought as the research involves analysis of data about units **EC Decision on 15th June, 2020:** Approval after justification ***The above comments were forwarded to the PI. The reply was reviewed by reviewed by primary reviwer he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101stECMIIBCS/P14*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
g4.	Clarification of research proposal entitled ***"A study of clientele satisfaction of dietary services in selected areas of a tertiary care Government Hospital"*** submitted by Dr. Anubha Agrawal, JRII, Through her Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/065 dated 7th February, 2020. **EC Comment on 15th June, 2020:** • The researchers wish to study the patient satisfaction with various aspects of dietary services and suggest recommendations if any • Sample size 384. Statistically calculated • Patients in RALC IPD who have received at least 2 meals will be included • The questionnaire / data collection sheet is missing. It is important to know what is being asked and what are the patient's response options? It should be bilingual

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision on 15th June, 2020: Approval after justification ***The above comments were forwarded to the PI. The reply was reviewed by reviewed by primary reviwer he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECMIIBCS/P22*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
g5	Clarification of research proposal entitled ***"A study of Rheumatology Department in tertiary care Government Hospital"*** submitted by Dr. Supriya Singh, JRII through her guide Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/094 dated 7th February, 2020. **EC Comment on 15th June, 2020:** • The aim of this study is to assess the National Quality Assurance Standards compliance in Immunology Department of KGMU – OPD, IPD and laboratories and to 8 identify gaps as per NQAS and to suggest recommendations. • It is an observational descriptive cross-sectional study • A detailed study plan including service provisions, Patient Rights, Inputs, Support Services, Clinical Services, Infection Control and Outcome monitoring is provided • Markings will be 0 for no compliance 1 for partial compliance and 2 for full compliance and subsequently the data will be analyzed • Consent waiver is sought as the research involves analysis of data about units **EC Decision on 15th June, 2020:** Approval after justification ***The above comments forwarded to the PI. The reply from the PI was reviewed by the reviewer. The reviewer again had a comment-*** • EC Committee feels the title of the research means absolutely nothing. It does not convey any information about the research. They should replace it with what they state in the aim of the research. **EC Decision:** Approval after justification ***Ref. code: 101st ECMIIBCS/P31*** ***(Primary Reviewer: Dr. Surjati Bhattacharya)***
g6.	Clarification of the research proposal entitled ***"Levels of pesticides in hypothyroidic and***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	infertile women: A biochemical and genotoxic study" sponsored by ICMR New Delhi submitted by Dr. Saima Amjad, through his guide Prof. A.A. Mahdi, Head, Department of Biochemistry of this University via letter no. Bio/2020/919 dated 27th January, 2020. **EC Comment:** • The present study will answer only objective one. To Prove and association cases & controles both will be required (Case Control design) • Why 200 cases will be enrolled? Sample size calculation is not done. • Kindly provide Inform Consent form as per new format. **EC Decision:** Revise ***The above comments were forwarded to the PI. The reply was reviewed by reviewed by primary reviwer he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-FS/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
h	**Modification**
h1	Clarification of the Modification of the research protocol no. ZUV/TOSI/HQ/11/2015 entitled ***"A randomized controlled trial of influenza vaccine to prevent advisory V ascular events"*** submitted by Prof. Sharad Chandra, Department of Cardiology of this University via letter no.954/cardio/Res/2020 dated 18th June, 2020. ***The above comments were forwarded to the PI. The reply was reviewed by the Member-Secretary, IEC and he approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 82nd ECM IIC/P8*** ***(Primary Reviewer: Dr. Rajeev Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 102nd ECM held on 18th August, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

29th July, 2020

Minutes of the meeting of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** of King George's Medical University U.P was held on 29th July, 2020 at **1.30 p.m. onwards** in the **"Board Room",** Administrative Block of this University.

The following members were present in the Meeting:-

1. **Hon'ble Shri Vishnu Sahai - Chairman**
2. **Dr. Manju Agrawal - Social Worker**
3. **Mr. Yogesh Mishra - Lay man**
4. **Dr. Rajiv Garg - Senior Clinician**
5. **Dr. Rajendra Nath -Basic Medical Scientist**
6. **Dr. R.K. Garg -Member-Secretary, Ex-officio**

Sl.	DCGI
I-	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 743/Cardio/Res/2020 dated 2nd January, 2020, 765/Cardio/Res/2020 dated 17th January, 2020 & 768/Cardio/Res/2020 dated 20th January, 2020 respectively.
a	**<u>Death</u>** **Subject ID no. 010-0025** **Subject Initial:** M-K **SAE term:** Death **Causality:** Unknown

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Event: Cough with sputum, Breathlessness and low grade fever **Gender:** F **Age:** 50 yrs old **Weight:** 73 KG **Height:** 152 CM **Start Date:** 20th September, 2017 **Subject History:** ***Principal-Investigator has informed at our, Subject LAR informed us yesterday that subject got hospitalized in our department on 26th December, 2019 at 07:40 pm, she had a complaint of cough with sputum, breathlessness and low grade fever and at 01:27 pm on 27th December, 2019 she passed away.*** **ADR-sub-Committee decision:** • Since from a perusal of papers it appears that there was no nexus between the **death** of the deceased and the study drug administered to her namely Reveroxaban and no post-mortem of the corpse of the deceased was done, no case for compensation is made out.
b	**Death** **Subject ID no. 010-0030** **Subject Initial:** D-K **SAE term:** Death **Causality:** Cardio-respiratory arrest **Event:** RHD with left sided hemiparesis due thromboembolism **Gender:** M **DOB:** 05-07-1994

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Weight: 40 KG **Height:** 160 CM **Start Date:** 24th January, 2018 **Subject History:** ***Principal-Investigator has notify that the SAE occurred at our center, We made a call (today i.e. 16th January, 2020) to subject for 24 months follow-up, Subject's LAR answered a call and revealed that Subject developed, breathlessness for which he was taken to the local hospital and there he got hospitalized on 31st August, 2019 and managed medically on 4th September, 2019 at 14:30 he passed away due to cardio Respiratory arrest.*** **ADR-sub-Committee decision:** Since from a perusal of papers it appears that there was no nexus between be study drug administered to the deceased namely Rivpxoxaban (generic name of the drug W-arfarim) and his death, which took place on account of cardio-respiratory arrest and no post-mortem of the corpse of the deceased was done no case for compensation is made out.
c	**Death** **Subject ID no. 010-0068** **Subject Initial:** B-G **SAE term:** Death **Causality:** Unknown **Event:** Subject felt uneasiness, shivering, dizziness and syncope **Gender:** F **Age:** 55 kg **Weight:** 40 KG

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Height: 155 CM **Start Date:** 25th September, 2018 **Subject History:** ***Principal-Investigator has notify that the SAE occurred at our center, We made a unscheduled call (today i.e-16-01-2020) to subject to retrieve IP bottle, her LAR answered a call and told us that subject passed on 21st November, 2019 at home, she developed shivering, dizziness and syncope. They called local doctor to see her and he confirmed that she died. Subject was not taken to any hospital hence o documents are available.*** **ADR-sub-Committee decision:** **Since from was a perusal of papers it appears that there was no nexus between the study drug administered to the deceased namely reveroxaban and her death and the cause of her death was unknown and no post morterm of the carpse of the deceased was done, no case for compensation is made out.**
d	**Death** **Subject ID no. 010-0012** **Subject Initial:** A **SAE term:** Death **Causality:** Unknown **Event:** Hospitalized for chest pain **Gender:** F **Age:** 29 year **Weight:** 50 KG **Height:** 150 CM **Start Date:** 2nd August, 2017

Chairperson, IEC
King George's Medical University
U.P., Lucknow

Subject History:

Site made a call to subject 010-0012 for 30th Month follow-up on 4th March, 2020, her LAR answered chest pain on 18th September, 2019 and for two days she was hospitalized in local hospital and then passed away on 21st September, 2019. Subject developed chest pain on 18th September, 2019 and for two days she was hospitalized in local hospital and then passed away 21st September, 2019.(Subject's LAR did not provided any documents and he confirmed that no documents were obtained from the hospital, hence course of event is not clear). They provide us crimination certificate.

ADR-sub-Committee decision:

Since from a perusal of papers it appears that these was no nexus between the death of the deceased and the study drug administered to her and the deceased died on account of chest pain in a local hospital and the LAR did not provide any documents pertaining to the death of the deceased no case for compensation arises.

Ref. code: 83rd ECM IIC/P6

29th July, 2020 (Non-DCGI)

The Minutes of the meeting of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** of King George's Medical University U.P was held on 29th July, 2020 at **1.30 p.m. onwards** in the **"Board Room",** Administrative Block of this University.

The following members were present in the Meeting:-

1. **Hon'ble Shri Vishnu Sahai - Chairman**
2. **Dr. Manju Agrawal - Social Worker**
3. **Mr. Yogesh Mishra - Lay man**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

4. Dr. Rajiv Garg - **Senior Clinician**

5. Dr. Rajendra Nath -**Basic Medical Scientist**

6. Dr. R.K. Garg -**Member-Secretary, Ex-officio**

Sl.	Non- DCGI
I-a	ADR of research protocol no. Research protocol no. ZUV/TOSI/HQ/11/2015 entitled ***"A randomized controlled trial of influenza vaccine to reduce adverse vascular events"*** sponsored by M/s Population Health Research Institute (PHRI) submitted by Prof. Sharad Chandra Department of Cardiology of this University via letter no. 761/cardio/Res/20 dated 14th January, 2020 762/Cardio/Res/20 dated 14th January, 2020 respectively. Respectively. **<u>Death</u>** **Subject ID no. 046109** **Subject Initial:** Z-K **SAE term:** Death **Gender:** F **Age:** 61 yrs old **Weight:** 55 KG **Height:** 150 CM **Start Date:** 11th July, 2019 **Subject History:** ***Principal-Investigator has informed SAE occurred at our, Subject was called for M-18 follow up visit, her son answered us that patient passed away on 11th July, 2019 at around 11:30 P.M. He said that patient was having complaint of breathlessness and chest pain since afternoon. Patients was taken to the hospital and on the way to the***

Chairperson, IEC
King George's Medical University

	hospital patient expired. **ADR-sub-Committee decision:** **Since a perusal of papers shows that when a follow-up telephonic call was made to the patient on 14th January, 2020 her son informed to that the patients had passed away on 11th July 2019, around 11.30 pm and he also informed that be died on way to on account of complaint of breathlessness and chest pain and no autopsy was done no case for compensation is made out.**
b	**Death** **Subject ID no. 0653025** **Subject Initial:** Z-K **SAE term:** Death **Causality:** Cardio-respiratory arrest **Event:** RHD with left sided hemiparesis due thromboembolism **Gender:** F **Age: 61 yrs** **Weight:** 55 KG **Height:** 150 CM **Start Date:** 11th July 2019 **Subject History:** ***Principal-Investigator has notify that the SAE occurred at our center, Subject was called for M-18 follow up visit, her son answered us that patient passed away on 11th July 2019 at around 11:30 P.M. He said that patient was having complaint of breathlessness and chest pain since afternoon. Patient was having complaint of breathlessness and chest pain since afternoon. Patient was taken to the hospital and on the way to the hospital and on the way to the hospital patients expired. No autopsy was***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	done and his son doesn't provide any documents. **ADR-sub-Committee decision:** Since a perusal of papers shows that when on 14th January, 2020 a call to the patient was made for a follow-up visit her son informed that the patient had passed away on 11th July, 2019 and he also informed that as the patient was complaining of breathlessness and chest pain she was taken to hospital but died on the way to hospital and no autopsy was done no case for compensation is made out. ***Ref. code: 83rd ECM IIC/P6***

18th August, 2020

Minutes of the meeting of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** of King George's Medical University U.P was held on 18th August, 2020 at 1.30 p.m. onwards in the "Board Room", Administrative Block of this University.

The following members were present in the Meeting:-

1-	Hon'ble Justice Vishnu Sahai	- Chairman
2-	Dr. Manju Agrawal	- Member
3-	Dr.Rajiv Garg	-Member
4-	Dr. Rajendra Nath	-Member
5-	Mr. Yogesh Mishra	-Member
6-	Dr. R.K. Garg	- Member-Secretary, ex-officio

Sl.	Non-DCGI
I-	ADR of research Research proposal entitled ***"A Phase II, Open label, randomized controlled trial to assess the safety and efficacy of convalescent plasma to limit***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	COVID-19 associated complications in moderate disease" version 1.3 dated 18th April, 2020 submitted by Dr. D. Himanshu, Associate Professor, Department of Medicine of this University sponsored by ICMR, New Delhi via letter no. nil dated 18th June, 2020, 22nd June, 2020, 15th June, 2020 & 18th July, 2020.
a	**Death** **Subject ID no. 40-R-001** **Subject Initial:** J-P-G **SAE term:** Death **Causality:** Collapsed **Event:** Weight loss , 4 days fever with 2 days of a febrile period with altered mental status **Age:** 75 yrs old **Weight:** 40 KG **Height:** 178 CM **Start Date:** 2nd June, 2020 **Subject History:** ***Principal-Investigator has informed to the Committee, Subject was admitted in COVID-ICU with complaint of significant weight loss for 1 month, 4 days of fever with 2 days of a febrile period with altered mental status. The patient was already receiving treatment of Tuberculosis and bed sore and was being evaluated for intra abdominal malignancy.*** ***On the of randomization the patient had BP of 130/70 PR was 104 and RR was 22 and GCS was E4V4M5 and maintaining spo2 of 90 to 93% on room air and evident severe wasting. Over the ICU stay patient had persistent altered sensorium of GCS***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

12/15. The patient was given a standard care of treatment and care. He developed progressive Hypoxia with altered mental sencorium which was complicated with sepsis. On 14th June patient developed hypotension and began to hyper ventilates with sp02 less than 80% on high flow oxygen in this view patient was intubated. After few hours the patient developed a systole and given series of CPR sessions including repeated doses of adrenaline defibrillation and calcium Gluconate but eventually succumbed to death at 10:40 AM on 14th June, 2020.

ADR Committee Decision:

- Since from a perusal of papers it appears that these was no blemish/fault in the treatment of the deceased and the immediate cause of his death was Disseminated Tuberculosis no case for compensation arises.

b

Death

Subject ID no. 40-R-002

Subject Initial: M-L-A

SAE term: Death

Causality: Cardiac arrest

Event: Lung disease and type 2 diabetes mellitus

Age: 60 yrs old

Gender: Male

Weight: 68 KG

Height: 155 CM

Start Date: 2nd June, 2020

Subject History:

Principal-Investigator has informed to the Committee, lung disease and type 2

Chairperson, IEC
King George's Medical University
U.P., Lucknow

diabetes mellitus and was on prednisolone 05 mg and OHA's got admitted with complains of breathlessness and dry cough for 2 days and tested COVID-19 positive. He had persistent hypoxemia and was offered plasma therapy on 15th June, 2020 and 16th June, 2020. There was progressive hupoxia and he was incubated and mechanically ventilated but developed cardiac arrest and cannot be revived even after multiple CPR. He was declared dead on 17th June, 2020.

ADR Committee Decision:

- Since from a perusal of papers it appears that there was no blemish/fault in the treatment of the deceased are the immediate cause of his death was Respiratory Failure no case for compensation arises.

c **Death**

Subject ID no. 40-R-006

Subject Initial: P-S

SAE term: Death

Causality: Septic shock
Event: diabetes mellitus

Age: 60 yrs old
Gender: Male

Weight: 67 KG

Height: 176 CM

Start Date: 2nd June, 2020

Subject History:

Principal-Investigator has informed to the Committee, known case of diabetes mellitus admitted in COVID ICU with complaints of fever with dry cough and

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	shortness of breath. Examination revealed tachypnea with hypoxia and stable vitals on 20th June, 2020. He was started on inhalational oxygen and standard treatment COVID-19 treatment along with insulin, Antibiotics and aspirin, Over stay his hypocia progressed and in this view he was transfused plasma with standard precautions and 12:05 AM on 21st June, 2020. Around 01:20 AM he experienced increased shortness of breath and progressive hypotension. In this view we dept possibility of acute coronary syndrome transfusion related reaction, pulmonary embolism, septic shock and cardio genic shock and started standard resuscitation with fluid vasopressures and steroids. There was no response and so he was incubated and mechanically ventilated but and he finally succumb to death at 08:10 AM on 21st June, 2020. **ADR Committee Decision:** • Since from a perusal of papers of blemish/fault in the treatment of the deceased and the immediate cause of his death was Respiratory Failure no case for compensations arises. ***Ref.Code: 101st ECM IB/P12***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IB
Expedited Review proposals
(General & COVID-19)

K.G's Medical University U.P., Lucknow

IB	Expedited review (General proposals)
a1	Expedited review of research proposal entitled proposal entitled ***"A work study of nursing staff in the trauma ventilator unit tertiary care government hospital at Lucknow"*** submitted by Dr. Anshuman Shukla, MHA II, via his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/106 dated 8th February, 2020. ***The above proposal reviewed by Dr. Anoop & Dr. Rajiv. EC Committee has decided following comment:*** **EC Decision:** Kindly revise the title, in current for it conveys little meaning. ***Ref. code: 102nd ECM IB/Pa1***
a2	Expedited review of research proposal entitled proposal entitled ***"A study of clientele satisfaction in OPD of Cardiology department in a tertiary care government hospital at Lucknow"*** submitted by Dr. Anshuman Shukla, MHA II, via his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/104 dated 8th February, 2020. ***The above proposal reviewed by Dr. Anoop & Dr. Rajiv. Both the reviewers have approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM IB/Pa2***
a3	Expedited review of research proposal entitled proposal entitled ***"Development of intergrative psychological intervenntionl program for management of problematic technology use among adolescents"*** sponsored by ICMR, New Delhi submitted by Dr. Shweta Singh, Additional Officer Clinical Psychologist, Department of Psychiatry of this University via letter no. 2913/Psy dated 22nd July, 2020. ***The above proposal was reviewed by Dr. Preeti Agarwal & Dr. Vimal Paliwal. Both the reviewers have approved it.*** **Action taken:** Provisionally approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 102nd ECM IB/Pa3***
II-B	**Expedited review-COVID-19**
1-	Expedited review of research proposal entitled proposal entitled ***"An International multi-centre appraisal of the management of acute cholecystitis during COVID-19 pandemic: The CHOLECOVID AUDIT"*** submitted by Prof. A.A. Sonkar, Head Department of Surgery (Gen.) of this University via letter no. 1114 dated 24th June, 2020. ***The above proposal was reviewed by Dr. Preeti Agarwal & Dr. Vimal Paliwal. Both the reviewers have approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/P1***
2-	Expedited review of research proposal entitled proposal entitled ***"Impact of COVID-19 pandemic outbreak on access to health care and psychological health in cancer patients"*** submitted by Dr. Shiv Rajan, Department of Surgical Oncology of this University via letter no. nil dated 20th June, 2020. ***The above proposal was reviewed by Dr. Preeti Agarwal & Dr. Vimal Paliwal. Both the reviewers have approved it.*** ***The following doucuments were reviewed by Dr. Agarwal:*** • Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/P2***
3-	Expedited review of research proposal entitled proposal entitled ***"A study on pooling SARS CoV-2 test samples on Abbott m20000 platform"*** submitted by Prof. Vimala

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Venkatesh, Department of Microbiology of this University via letter no. 027/ICIC/SRL/2020 dated 20th June, 2020. ***The above proposal was reviewed by Dr. Abhinav & Dr. Vimal Paliwal. Both the reviewers have approved it.*** ***The following doucuments were reviewed by Dr. Agarwal:*** • Check list • Executive summary • Waiver form **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/P3***
4-	Expedited review of research proposal entitled proposal entitled ***"Assessment of knowledge, attitude and practices towards hydroxychloroquine pre-exposure prophylaxis for COVID-19 among health care professionals"*** submitted by Dr. Ajay Kumar Verma, Professor Jr. Grade Department of Repiratory Medicine of this University via letter no. 604/20 dated 19th June, 2020. ***The above proposal was reviewed by Dr. Preeti Agarwal & Dr. Anoop. Both the reviewers have approved it.*** ***The following doucuments were reviewed by above mentioned both reviewers:*** • Check list • Executive summary • English & Hindi Informed Consent Forms • CV of Dr. Arpita Singh, Associate Professor, Department of **Pharmacology**, Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow, India • Dr. Hemant Kumar, Assistant Professor, Department of **Respiratory Medicine**, Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow, India • Dr. Preeti Gupta, Assistant Professor, Department of Ophthalmology, Hind Institute of Medical Sciences, Sitapur, U.P., India • Prof. Atul Jain, Head, Department of Pharmacology, Dr. Ram Manohar Lohia

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Institute of Medical Sciences, Lucknow, India **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: V^th ECMIB-COVID-19/P4***
5-	Expedited review of research proposal entitled protocol no. AYUSH-CSIR-HCP-01 version 3.5 dated 1st June, 2020 entitled ***"Ashwagandha for the prophylaxis against SARS-CoV-2 infection: A randomized hydroxychloroquine controlled clinical trial in Health care providers"*** submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine of this University via letter no. 1404/Med/2020 dated 22nd June, 2020. ***The above proposal was reviewed by Dr. Rajiv & Dr. Vimal Paliwal. Both the reviewers have approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approval subject to fulfillment & Administrative Formalities ***Ref. code: V^th ECMIB-COVID-19/P5***
6-	Expedited review of research proposal entitled ***"Antiviral effect of inhalational lipids in respiratory and gastrointestinal epithelium-implications for COVID-19"*** submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology of this University via letter no. 263/2020 dated 9th June, 2020 & email dated 4th July, 2020. ***The above proposal was reviewed by Dr. Surajit & Dr. Vimal Paliwal. Both the reviewers have approved it.*** ***Dr. Surajit has given his reply with following comments:*** • It is a prospective cohort study to be completed in 3 months. • 2. What is the sample size and how was it derived? • 3. What will be observed? There is no data collection sheet attached. • 4. What is a comprehensive pre-procedure documentation and what will be observed during the 2 weekly follow up? • 5. Why are we presuming that the preventive layer of inhaled medication will

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	protect these patients? Where is the literature to support this presumption? • 6. We are going to use statistics on which data? We have given the same dose of the aerosol/lipid and measured nothing. So we require a detailed data collection sheet to understand the proposed research project. ***The above comment forwarded to the P.I., responce has given by P.I. which was forwarde to Dr. Bhattacharya, he approved it.*** ***The following doucuments were reviewed by Dr. Bhattacharya:*** • Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/6***
7-	Expedited review of research proposal entitled ***"Hematological parameters in COVID-19 patients-A single center experience from North India"*** submitted by Dr. S.P.Verma, Associate Professor & Head, Department of Clinical Hematology of this University via letter no. 257/ch/2020 dated 1st June, 2020. ***The above proposal was reviewed by Dr. Rajeev & Dr. Vimal Paliwal. Both the reviewers have approved it.*** ***The following doucuments were reviewed by Dr. Rajiv Garg:*** • Check list • Executive summary • English & Hindi Informed Consent Forms • Study proforma **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/P7***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

8-	Expedited review of research proposal entitled ***"Prognostic indicators of COVID-19 confirmed cases admitted in KGMU"*** submitted by Dr. Wahid Ali, Additional Professor, Department of Pathology of this University via endorsement no. 637/ch/2020 dated 1st June, 2020 & 10th June, 2020. ***The above proposal was reviewed by Dr. Rajeev & Dr. Vimal Paliwal. Both the reviewers have approved it.*** ***The following doucuments were reviewed by Dr. Rajiv Garg:*** • Check list • Executive summary • English & Hindi Informed Consent Forms ***Dr. Garg has given his response with following comment:*** • Proposal aims to explore the prognostic indicators by means of hematological, biochemical and immunological parameters (Imunoglobulins, Interleukin and TNF). • 2. The study proforma is incomplete as it should have the outcome parameters of the studied patients, that is what happened to them with these baseline characterstics, also it is not clear how many times these parameters will be checked that is just at the initiation or daily/ weekly or whatever it is, a timeline should also be mentioned. • 3. Just an advice that Annexure 7 guideline is meant for the guideline to make Informed consent form and not just to annexed. • The study appears good and can be asked to revise and resubmit or may be asked for presentation. ***The above comments were forwarded to the P.I. response received by P.I. which was forwarded to Dr. Garg, he has approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/P8***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

9-	Expedited review of research proposal entitled ***"A randomized controlled trial to assess the safety and efficacy of convalescent plasma to limit COVID-19 associated complications in critically ill patients"*** submitted by Prof. Tulika Chandra, Head, Department of Transfusion Medicine of this University via letter no. 107(A)/2020 dated 3rd June, 2020 & 158/2020 dated 8th July, 2020. **Comments by Dr Surajit** 1-It is a RCT. How will the randomization be done? Consort guidelines? If the randomization is not blind and if clinicians pick and choose cases depending on co-morbidities then are we adhering to the principles of RCT? 2. The hypothesis is that convalescent plasma will improve outcome of critically ill patients. So if a patient is in study group and he deteriorates and the family requests for convalescent plasma therapy then [a] will he be denied Convalescent Plasma treatment? [b] will he be offered the treatment and taken out of the study? [c] will he be considered as a failure of the standard of care? 2. Sample size 226 each in study and control groups. 3. While standard of care will be offered to all patients the study group will receive 2 doses of 200 ml of Convalescent Plasma. 4. Inclusion and exclusion criteria are clear 5. Primary and secondary outcomes have been clearly defined. 6. An outline of the data collection sheet has been provided 7. A bilingual consent form has been provided ***The responses were reviewed by Dr. Surajit & Dr. Vimal Paliwal. Both the reviewers have approved it.*** **Action taken:** Provisionally approved **EC Comment:** • Kindly provide CONSORT guidelines **EC Decision:** Approval after modification ***Ref. code: Vth ECMIB-COVID-19/P9***
10-	Expedited review of research proposal entitled ***"A study on psychosocial problems, mental health and sleep quality of frontline health care workers following the Corona***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	virus disease (COVID-19) duty protocol and quarantine" submitted by Dr. Darshan Bajaj, Associate Professor, Department of Respiratory Medicine of this University via letter no.nil dated 7th July, 2020. ***The above proposal was reviewed by Dr. Preeti & Dr. Vimal Paliwal. Both the reviewers have approved it.*** ***The following doucuments were reviewed by both reviewers:*** • Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/P10***
11-	Expedited review of research proposal entitled ***"Feasibility, efficacy and effectiveness of pooled sample testing strategy (Pooled NAAT) for molecular testing of COVID-19"*** submitted by Prof. Amita Jain, Head, Department of Microbiology of this University via letter no.569/20 dated 7th July, 2020. ***The above proposal was reviewed by Dr. Preeti & Dr. Vimal Paliwal. Both the reviewers have approved it.*** ***The following doucuments were reviewed by both reviewers:*** • Check list • Executive summary • Waiver form **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/P11***
12-	Expedited review of research proposal entitled ***"An open label multi-centre randomized control trial for reinitiating intravesical BCG therapy vs resumption in patients of non***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	muscle invasive bladder cancer with interruption of therapy due to the COVID-19 (ICON study)" submitted by Prof. S.N. Sankhwar, Head, Department of Urology of this University via letter no.nil dated 2nd June, 2020. ***The above proposal was reviewed by Dr. Surajit & Dr. Vimal Paliwal.*** **Comments from Dr. Bhattacharya were as follows** This is a multicentric study being conducted in 6 centres. Objectives are precise and well defined. Inclusion and exclusion criteria are clear. Study design flowchart is provided. **Data collection sheet is not provided - what will be observed and compared in the two groups?** ***The reply has provided from PI which was reviewed by Dr. Bhattacharya. Dr. Bhattacharya finally approved it.*** **Action taken:** Provisionally approved **EC Decision**: Approved ***Ref. code: Vth ECMIB-COVID-19/P12***
13-	Expedited review of research proposal entitled ***"Paediatric tumour surgery during the COVID-19 pandemic: an international, multicentre, observational cohort study"*** submitted by Dr. Ankur Bajaj, Associate Professor, Department of Neurosurgery of this University via letter no.nil dated 8th June, 2020. ***The above proposal was reviewed by Dr. Preeti & Dr. Rajiv. Both the reviewers have approved it.*** ***The following doucuments were reviewed by both reviewers:*** • Check list • Executive summary

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Waiver form **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: V^th ECMIB-COVID-19/P13***
14-	Expedited review of research proposal entitled ***"Clinical evaluation of Chyawanprash for the prevention of COVID-19 among health care personnel-An open label, prospective randomized controlled study"*** submitted by Dr. Satyendra Kumar Sonkar, Professor Jr. Grade, Department of Medicine of this University via letter no.nil dated 8th June, 2020. ***Comments by Dr Surajit*** The two Ayurvedic products being studied are Chawanprash and a poly herbal combination Their immunopotentiating abilitues will be the objective of this study. 2. The subjects on whom these will be tested are high risk quarantined subjects following COVID-19 exposure but not sero-positivity. 3. Three treatment groups of 60 patients each and 2 control group of 40 patients each form the material of this study. Both treatment and control will have one set of normal subjects and one set of subjects with known co-morbidities which make them immuno-compromised. The immono compromised treatment groups are 2, one treated with Chawanprash and one with poly-herbal extract. 4. Study duration 84 days. 5. Clinical and immunological parameters to be investigated on day 0, 21 and 84 are defined. 6. The constituents of the poly-herbal combination have been defined. 7. Chawanprash is produced by different companies and have different constituents. Which Chawanprash will be used and what are its constituents. 8. Who is the Ayurveda expert in this study? The CRAS Unit Ayurveda Consultant should have a name and he/she should sign the research proposal. 9. A budget of Rs. 10,00,000 is proposed but no expense is shown towards the premium of an insurance to cover this study. Will this study, being done on patients with co-morbidities, not be covered by insurance? Who will pay for the compensation if anything goes wrong and the patient/relatives blame the Ayurvedic produce for the worsening of the clinical condition. A diabetic can go into renal failure by a nephrotoxic drug or have arrhythmia or hepato-toxicity. I feel the presence of an Ayurveda expert and and insurance to cover any mishap is mandatory to safeguard the interest of the Institution conducting the study. ***The reply was reviewed by Dr. Surajit & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: V^th ECMIB-COVID-19/P14***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

15-	Expedited review of research proposal entitled ***"To evaluate the COVID-19 rapid antigen kit for rapid diagnosis of COVID-19 disease"*** submitted by Prof. Amita Jain, Head, Department of Microbiology of this University via letter no.615/2020dated 15th July, 2020. ***The above proposal was reviewed by Dr. Preeti & Dr. Anoop Kumar Verma. Both the reviewers have approved it.*** ***The following doucuments were reviewed by both reviewers:*** • Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: V^th ECMIB-COVID-19/P15***
16-	Expedited review of research proposal entitled ***"To assess impact of COVID-19 pandemic on urological services, practice and training"*** submitted by Dr. Manish Kumar Agarwal, SR, Department of Urology of this University via letter no.314 dated 7th July, 2020. ***The above proposal was reviewed by Dr. Preeti & Dr. Vimal Paliwal. Both the reviewers have approved it.*** ***The following doucuments were reviewed by both reviewers:*** • Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: V^th ECMIB-COVID-19/P16***
17-	Expedited review of research proposal entitled ***"National registry on COVID-19 infection among pregnant women and their neonates"*** submitted by Prof. Uma Singh, Head,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Department of Obst. & Gynaecology of this University via letter no.120/HRRC-Lko/2020 dated 21st July, 2020. ***The above proposal was reviewed by Dr. Preeti & Dr. Vimal Paliwal. Both the reviewers have approved it.*** ***The following doucuments were reviewed by both reviewers:*** • Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/P17***
18	Expedited review of research protocol no. CRSC20006 entitled ***"A randomized, double-blind, two arm, placebo controleed clinical trial to compare the efficacy and safety of Mycobacterium w administered along with standard of care versus placebo administered along with standard of care, in adult Covid-19 positive patients hospitalize but not critically ill"*** submitted by Prof. Suryakant, Head, Department of Respiratory Medicine of this University via letter no.nil dated 22nd July, 2020. ***The above proposal was further reviewed by Dr. Surajit & Dr. Amita. Both the reviewers have approved it.*** **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/P18***
19	Expedited review of research protocol no. CRSC20005 entitled ***"A randomized, double-blind, two arm, placebo controleed clinical trial to evaluate the efficiacy and safety of Mycobacterium w in preventing COVID-19 in subjects at risk of getting infected with COVID-19"*** submitted by Prof. Ajay Kumar Verma, Department of Respiratory Medicine of this University via letter no.nil dated 22nd July, 2020. 1. Study sponsored by Cadilla Pharmaceutical Ltd. and supported by C.S.I.R.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	2. This is a Phase III clinical trial and the primary objective is to evaluate whether administration of M.w reduces the incidence of COVID-19 infections among those who are in close contact with COVID-19 patients. 3. Sample size 4,000. Initial enrollment of 400 cases 4. Randomization in 2 groups – Investigational group who will receive suspension of heat killed (autoclaved) M.w and Control group who will receive a placebo 5. Two sets of individuals will be chosen for both these groups – (a) healthcare workers providing direct care to COVID-19 cases and (b) persons living in the same household as COVID-19 patients. 6. The study will require 6 visits to the hospital in 8 weeks 7. Initially 400 subjects will be evaluated in 8 weeks. Then revision of the study design may be done, if required and then further subjects will be recruited after DSMB/MC review 8. The investigator's brochure of M.w is provided and it has details of chemical and pharmaceautical properties, non-clinical in-Vivo and in-Vitro studies and effects on human as an immunomodulator. M.w is Mycobacterium. Indicus Pranii, a member of Mycobacterium Evium complex. 9. Permission of D.G.C.I. is attached 10. Bilingual consent form is attached 11. Case Report form is attached 12. The trial is registered with C.T.R.I 13. Insurance in the form of professional indemnity of INR 1Cr. And of Clinical Trial INR 2Cr. Is provided by The Oriental Insurance Company and is expiring on 30.08.2020. The trial will not be completed by then. ***The above proposal was reviewed by Dr. Surajit & Dr. Rajendra. Both the reviewers have approved it.*** ***Advice: Approved subject to Insurance cover of the entire trial period.*** **EC Decision:** Provisionally approved ***Ref. code: Vth ECMIB-COVID-19/P19***
20	Expedited review of research protocol no. CDRI-CLINICAL-2/2020 version 2 dated 4th June, 2020 entitled ***"A phase 3, randomized, double-blind, placebo control trial of efficacy, safety and tolerability of antiviral drug unifenovir vs standard care of therapy in non-severe COVID-19 patients"*** submitted by Prof. Virendra Atam, Department of Respiratory Medicine of this University via letter no.nil dated 22nd July, 2020.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Comments by Dr Surajit 1. This is a CSIT approved Phase III clinical trial for a new anti-viral agent Umifenovir 2. It is a randomized, double blind, placebo-controlled trial which aims to assess the efficacy, safety and tolerability of Umifenovir in COVID-19 patients 3. Sample size is 132, 66 in each arm – study and control; statistically derived. 4. Randomization is by SNOSE 5. Study group will receive Umifenovir 800mg BD for 14 days + SOC and Control group will receive Placebo + SOC 6. Duration of study is 28 days and timing of assessment of various parameters are explained 7. The investigator's brochure of the test drug is provided with non-clinical studies and clinical experiences 8. Permission of D.G.C.I. is attached 9. Bilingual consent form is attached 10. Case Report form is attached 11. The trial is registered with C.T.R.I 12. CSIR has given undertaking to insure against any serious side effects as per New Clinical Trial Rules, 2019. ***The above proposal was reviewed by Dr. Surajit & Dr. Rajendra. Both the reviewers have approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approval subject to fulfillment & Administrative Formalities ***Ref. code: Vth ECMIB-COVID-19/P20***
21	Expedited review of research proposal entitled ***"Impact of enhanced personal protective equipment (PPEs) uses on physical and psychological characteristics among corona warriors and tertiary health care centres"*** submitted by Mr. Sachin Dwivedi, Clinical Instructor through Dean, Faculty of Nursing of this University via letter no.1052/X-51 dated 18th July, 2020. ***The above proposal was reviewed by Dr. Preeti & Dr. Abhinav. Both the reviewers have approved it.*** ***The following doucuments were reviewed by both reviewers:***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/P21***
22	Expedited review of research proposal entitled ***"GlobalSurg-CovidSurg week: Determining the optimal timing for surgery following SARS-CoV-2 infection"*** submitted by Dr. Shiv Rajan, Assistant Professor, Department of Surgical Oncology of this University via letter no.SONC/858/2020 dated 30th July, 2020. ***The above proposal was reviewed by Dr. Preeti. She has approved it.*** ***The following doucuments were reviewed by Dr. Agarwal:*** • Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/P22***
23	Expedited review of research proposal entitled ***"Development of viral kit for simultaneous isolation of viral kit by major nemoforbes and rapid detection of novel corona virus by higly percent gold noninfectious"*** submitted by Prof. Amita Jain, Head, Department of Microbiology of this University via letter no.695/2020 dated 28th July, 2020. ***The above proposal was reviewed by Dr. Preeti & Dr. Vimal. Responses from them are received & they approved it.*** ***The following doucuments were reviewed by above mentioned both reviewers:*** • Check list • Executive summary • English & Hindi Informed Consent Forms

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Action taken: Provisionally approved **EC Decision:** Approved ***Ref. code: V^th ECMIB-COVID-19/P23***
24	Expedited review of research proposal entitled ***"Understanding host immune response to SARS-Cov-2 virus infection: A case-control study"*** submitted by Prof. Amita Jain, Head, Department of Microbiology of this University via letter no.571/2020 dated 7th July, 2020. ***The above proposal was reviewed by Dr. Preeti & Dr. Vimal. Responses from them are received & they approved it.*** ***The following doucuments were reviewed by above mentioned both reviewers:*** • Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: V^th ECMIB-COVID-19/P24***
25	Expedited review of research proposal entitled ***"Comparison of rate of hospital admissions of acute coronary syndrome patients in Cardiology Department during COVID-19 outbreak"*** submitted by Dr. Swati Sharma, SR, Department of Cardiology of this University via letter no.nil dated 17th July, 2020. ***The above proposal was reviewed by Dr. Preeti & Dr. Vimal. Both the reviewers have approved it.*** ***The following doucuments were reviewed by above mentioned both reviewers:*** • Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: V^th ECMIB-COVID-19/P25***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

26	Expedited review of research proposal entitled ***"To study the effect of lockdown on social and financial aspects in patients of renal failure with CKD stage 5D: a questionnaire based, multicenter, cross-sectional study"*** submitted by Dr. Medhavi Gautam, Assistant Professor, Department of Medicine of this University via letter no.1712/MED/2020 dated 17th July, 2020. ***The above proposal was reviewed by Dr. Preeti & Dr. Vimal. Both the reviewers have approved it.*** ***The following doucuments were reviewed by above mentioned both reviewers:*** • Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: V^th ECMIB-COVID-19/P26***
27	Expedited review of research proposal entitled ***"Cross sectional study assessing survival of SARS CoV-2 and clinic-pathologic findings from autopsy". (Prospective title)*** Dr. Shiuli, Assistant Professor, Department of Forensic Medicine of this University via letter no.402/FMT/2020 dated 21st July, 2020. ***Dr. Anoop Kumar Verma & Dr. Preeti Agarwal did not take part in the EC Meeting.*** ***The following doucuments were reviewed by Dr. Rajiv Garg:*** • Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: V^th ECMIB-COVID-19/P27***
28	Expedited review of research proposal entitled ***"CovidSurg-Week study"*** submitted by Dr.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ankur Bajaj, Associate Professor, Department of Neurosurgery of this University via letter no.NS-972 dated 23rd July, 2020. ***The above proposal was reviewed by Dr. Preeti & Dr. Rajiv. Both the reviewers have approved it.*** ***The following doucuments were reviewed by above memtioned both reviewers:*** • Check list • Executive summary • English & Hindi Informed Consent Forms **Action taken:** Provisionally approved **EC Decision:** Approved **Cancelled by P.I.** ***Ref. code: Vth ECMIB-COVID-19/P28***
29	Expedited review of research proposal entitled proposal entitled ***"The impact of COVID-19 pandemic on the provision, practice and outcomes of vascular surgery"*** submitted by Dr. Ambrish Kumar, Additional Officer, Department of Vascular Surgery of this University via letter no. 03/VS/2020 dated 20th July, 2020. ***The above proposal was reviewed by Dr. Preeti Agarwal & Dr. Vimal Paliwal. Both the reviewers have approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM IB/P29***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IIA
New proposals

K.G's Medical University U.P., Lucknow

II-A	New Proposal
1.	Research proposal entitled "***To study the role of dietary nutrients as a risk factor for the clinic-radiological severity of osteoarthritis***" submitted by Prof. Ajai Singh, Head, Department of Paediatric Orthopaedics of this University via letter no.371/Paed-Orth/2020 dated 8th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Executive Summary • Copy of PI Undertaking • Patient Data Sheet **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled "***An observational qualitative study of curcumin (Lozenges) in oral submucous fibrosis (OSMF)***" sponsored by Gelnova Laboratories India Pvt. Ltd submitted by Dr. Abhishek Bahadur Singh, Assistant Professor, Department of OTO-Rhino-Laryngology & Head & Neck Surgery of this University via letter no.866/ENT/ABS/2020 dated 11th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly provide sample size with calculation • What is validity? • What is being measured? **EC Decision:** Approval after justification ***Ref. code: 102nd ECM IIA/P2***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Rajendra Nath)
3.	Research proposal entitled "***Dental casting alloy and ceramic induced health hazards among Dental laboratory technicians- A case control study***" sponsored by ICMR submitted by Dr. Kalpana Singh, Additional Professor, Department of Biochemistry of this University via letter no. Bio/2020/959 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Research proposal entitled "***Association between BMP4, WNT, angiopoietin-2 and HLA-G gene polymorphisms and cleft lip with or without cleft palate***" submitted by Dr. Nitu Nigam, Assistant Professor, Department of Center for Advance Research of this University via letter no. CFAR/2020/61 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • The CL/P is syndromic and non-syndromic type. The genes have been identified for syndromic type but for non-syndromic the authors have tried to identified the candidate gene. • The identified candidate genes are BMP4, WNT, Angiopoietin-2 and HLA-G. Particularly in non-syndromic CL/P. • There is a mention of patient from department of pediatric surgery but no Co PI has been involved from that department. • This study involves genotyping and study of gene polymorphism, but financial support has not been disclosed as budget they have mentioned nil. **EC Decision:** Approval after justification

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 102nd ECM IIA/P4 ***(Primary Reviewer: Dr. Rajeev Garg)***
5.	Research proposal entitled **"*Randomized comparative study of effect of pecs block and transverses thoracis muscle plane block on ultra-fasttracking of patients undergoing cardiac surgery*"** submitted by Dr. Rati Prabha, Assistant Professor, Department of Anesthesiology of this University via letter no. Anes/155/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • This is a randomized, single blind, parallel group, interventional study • The aim of this study is to determine which pain reduction technique between Transversus Thoracis muscle plane block and PECS block is better for ultra-fast tracking of patients undergoing cardiac surgery. • Anaesthesia and surgery will be similar in both groups. After surgery one of the two blocks will be given and pain reduction will be assessed by comparing duration from end of surgery to removal of E.T tube, total analgesics given, duration of ICU stay and total hospitalization. • Complications can be haemothorax and pneumothoeax. • Block will be USG guided. • Methodology is clearly defined. • Randomization will be done by opaque sealed envelopes. • Inclusion and exclusion criteria are clearly defined. • Sample size is 20 in each group. Statistically derived. • Bilingual consent form is provided. **EC Decision: Approved** ***Ref. code: 102nd ECM IIA/P5*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
6.	Research proposal entitled **"*Pattern of immunobullous disorders in children and their outcome: an observational study*"** submitted by Dr. Parul Verma, Associate Professor, Department of Dermatology Venereology and Leprosy of this University via letter no.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	42/2020 dated 19th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
7.	Research proposal entitled "***The role of oral health-related risk factors in cognitive function in elders: A case control study with an interventional nested research***" sponsored by Technology Bhawan, New Delhi submitted by Prof. Balendra Pratap Singh, Department of Prosthodontics Faculty of Dental Sciences of this University via letter no. 135/2020 dated 11th May, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Case sheet **EC Decision:** Approved ***Dr. R.K. Garg did not take part in the discussion.*** ***Ref. code: 102nd ECM IIA/P7*** ***(Primary Reviewer: Dr. Rajeev Garg)***
8.	Research proposal entitled "***Study of various treatment options and psychological analysis of patients with mastalgia in a tertiary care centre***" submitted by Dr. Gitika Nanda Singh, Associate Professor, Department of General Surgery of this University via letter no. 352/2020 dated 11th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Kindly provide sample size with calculated. • Kindly provide Inclusion & Exclusion Criteria **EC Decision:** Revise & Resubmit ***Ref. code: 102nd ECM IIA/P8*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
9.	Research proposal entitled ***"Pharmaco-epigenetic alterations and treatment outcome in type2 diabetes mellitus (Y2DM)"*** sponsored by Centre of Excellence, Government Lucknow submitted by Prof. Kauser Usman, Department of Medicine of this University via letter no. 413/MED/2020 dated 15th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • CV of Dr. Monisha Banerjee **EC Comment:** • Sample size given but statistical analysis to arrive on this sample size has not been presented. **EC Decision:** Provissionally approved ***Ref. code: 102nd ECM IIA/P9*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
10.	Research proposal entitled ***"To study outcomes of different treatment strategies in patients with stent thrombosis"*** submitted by Prof. Abhishek Gupta, Department of Cardiology of this University via letter no. 807/Cardio/Res/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • CRF **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P10***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer:Dr. Vimal Kumar Paliwal)
11.	Research proposal entitled "***Predicting safe ear disease using AI protocol***" sponsored by Joint Collaboration by KGMU and IIT Kanpur and SRMIST Chennai submitted by Prof. Anupam Mishra, Department of Otorhinolaryngology and Head and Neck Surgery of this University via letter no. 856/ENT/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • CV of Prof. Jayant Kumar Singh, IIT, Kanpur • CV of Ms. Angira Katyayan, SRMIST, Chennai, India • CV of Mr. Mohd. Aamir Khan,GLA University, Mathura, India **EC Comment:** • Study design not mentioned clearly • Sample size disparity between Initial summary (100+100) and protocol (200 + 200) • Should be corrected and sample size calculation should be given **EC Decision:** Approval after justification ***Ref. code: 102nd ECM IIA/P11*** ***(Primary Reviewer:Dr. Rajendra Nath)***
12.	Research proposal entitled "***Effect of OPRM1 A118G polymorphism and its association with post-operative pain and opioid consumption after major abdominal surgery in North Indian population: A prospective observational study***" submitted by Dr. Tanmay Tiwari, Associate Professor, Department of Anaesthesiology of this University via letter no. Anaes/168/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 102nd ECM IIA/P12 ***(Primary Reviewer: Dr. A.A. Sonkar)***
13.	Research proposal entitled "***Topical coconut oil application and incidence of sepsis in neonates-An open-label randomized controlled trial***" sponsored by The Procter & Gamble Company P&G Plaza Cincinnati, Ohio submitted by Dr. Arpita, Assistant Professor, Department of Pediatrics of this University via letter no. 411/Ped/2020 dated 24th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • CV of Prof. Vivek Narendran, Division of Neonatology, Cincinnati Children's Hospital, Cincinnati, OH • CV of Dr. Marty O. Visscher, James L. Winkle College of Pharmacy, University of Cincinnati, Cincinnati, OH • MOU **EC Comment:** • Blood/tissue samples being sent abroad but facility is not available in India.How to send? **EC Decision:** Approval after justification ***Ref. code: 102nd ECM IIA/P13*** ***(Primary Reviewer Dr. Rajendra Nath)***
14.	Research proposal entitled "***Efficacy and tolerability of topical 1% menthol lotion in treatment of primary localized macular cutaneous amyloidosis: A randomized triple blinded placebo-controlled trial***" submitted by Dr. Swastika Suvirya, Additional Professor, Head, Department of Dermatology and Venereology of this University via letter no. 51SkinVD/2020 dated 5th March, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• CRF • CV of Dr. Suaib Luqman,Associate Professor, Central Institute of Medicinal of Aromatic Plants, Lucknow • Dr. Kiran Preet Malhotra, Associate Professor, Department of Pathology, RMLIMS, Lucknow **EC Comment:** • Kindly provide the sampl size. • What will be the number of subjects enrolled? • Why it is Infleplied? **EC Decision:** Approval after justification ***Ref. code: 102nd ECM IIA/P14*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
15.	Research proposal entitled "***Evaluation of autophagic and epithelial-to-mesenchymal transition (EMT) biomarkers for their clinical impact in patients with urothelial bladder cancer***" sponsored by ICMR Govt. of India submitted by Prof. Apul Goel, Department of Urology of this University via letter no. 5161/URO/2020 dated 3rd March, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • CV of Prof. Sudhir Mehrotra, Head, Department of Biochemistry, University of Luckow, Lucknow • CV of Dr. Minal Garg, Assistant Professor, Department of Biochemistry, University of Luckow, Lucknow • CV of Dr. Niraj Kumar, Assistant Professor, Multidisciplinary Clinical and Translational Research (MCTR), Translational Health Sciences and Technology Institute (THSTI), FBD-GGN Expressway, Faridabad, Haryana • Budget **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P15*** ***(Primary Reviewer: Dr. Rajeev Garg)***
16.	Research proposal entitled "***Periodontal pathogen Fusobacterium nucleatum in Head and Neck cancer patients***" sponsored by CDHR New Delhi submitted by Prof. Uma Shanker Pal, Department of Oral and Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. OMSD/260/2020 dated 16th March, 2020.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	The following documents were reviewed in the EC Meeting:- • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Sanctioned letter of Budget **EC Comment:** 1-The study aims to evaluate the presence of Fusobacterium nucleatum in Head & Neck cancer specimens and patients and to find a relationship between its DNA status and the clinic-pathological features of Head & Neck cancers. 2. Project sponsored by Department of Health Research DHR, M.O.I.H & F.W. 3. Budget is 34 lakhs approximately. 4. Review of Literature is adequate 5. Sample will be biopsy from Cancer site and adjoining normal site and blood sample. 6. Quantification of F.nucleatum DNA in cancer specimen will be done by q PCR assay. 7. Sample size is 100. How was this derived? Was a statistician involved? **EC Comment:** Approval after modification ***Ref. code: 102nd ECM IIA/P16*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
17.	Research proposal entitled ***"Association of interferon inducible genes; IFI16 and AIM2 with HPV status and p16 expression on squamous cell carcinoma of oropharynx and Oral cavity among North Indian population"*** sponsored by ICMR New Delhi submitted by Prof. U. S. Singh, Head, Department of Pathology of this University via letter no. nil dated 16th March, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 102nd ECM IIA/P17
	(Primary Reviewer: Dr. A.A. Sonkar)
18.	Research proposal entitled "***Missed pancreatic injury in patients undergoing conservative management of blunt abdominal trauma: causes, sequelae and management***" submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology of this University via letter no. SG/257/2020 dated 8th June, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • This is a retrospective analysis of data maintained in the Consent form patient? • How P.I. proposes to take the consent from patient? • Consent forms in Hindi & English are different. **EC Desicision:** Revise & Re-submit
	Ref. code: 102nd ECM IIA/P18
	(Primary Reviewer: Dr. Amita Jain)
19.	Research proposal entitled "***Effectiveness of video assisted teaching module on knowledge regarding triage system among staff nurses working at KGMU Lucknow U.P***" submitted by Mrs. Rashmi P. John, Assistant Professor, Department of KGMU College of Nursing of this University via letter no. 134/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • ***Kindly change the above title in place of written this "To study the effectiveness of video assisted teaching model for triaging of trauma patients or staff nurses working in KGMU".*** **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 102nd ECM IIA/P19
	(Primary Reviewer: Dr. A.A. Sonkar)
20.	Research proposal entitled "***Evaluation of maternal and fetal outcomes in women diagnosed with GDM or normoglycaemia using IADPSG criteria, among women diagnosed with normoglycaemia by DIPSI criteria: prospective multi-centre observational cohort study***" sponsored by ICMR New Delhi submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynaecology of this University via letter no. OG/267/2020 dated 11th May, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Desicision:** Approved ***Ref. code: 102nd ECM IIA/P20*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
21.	Research proposal entitled "***Impact and efficacy of in-house designed breast prosthesis models-high and low fidelity types and comparing their efficacy in teaching breast examination to women***" submitted by Dr. Pooja Ramakant, Additional Professor, Department of Endocrine Surgery of this University via letter no. 166/01/2020 dated 19th May, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly provide sample size Calculation **EC Decision:** Approval after justification ***Ref. code: 102nd ECM IIA/P21*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
22.	Research proposal entitled "***Randomized controlled phase3 trial on comparing efficacy and safety of neo-adjuvant concurrent chemo-radiation with neoadjuvant***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	chemotherapy alone in patients with locally advanced breast cancer" submitted by Dr. Pooja Ramakant, Additional Professor, Department of Endocrine Surgery of this University via letter no. 167/01/2020 dated 19th May, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Hindi version of the consent form needs to be revised. **EC Decision:** Approval after justification ***Ref. code: 102nd ECM IIA/P22*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
23.	Research proposal entitled ***"Effect of stress and workload on the empathy of Medical resident Doctors- A cross-sectional study"*** submitted by Prof. Manish Bajpai, Department of Physiology of this University via letter no. 1859/PHY/2020 dated 17th June, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P23*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
24.	Research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo-controlled trial"*** sponsored by ICMR New Delhi submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 902/Cardio/Res/2020 dated 19th May, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Case Report Form • List of Digoxin study participating centre **EC Comment:** • The aim of this research is to know in patients with Rheumatic Heart Disease How does the use of Digoxin affect mortality and does it reduce the incidence of worsening of heart failure. • Data Management and Statistical Unit at IIPL Delhi will develop a web base randomization and data entry interface. • 4 year study period. Request for INR 4.75 Crore funding. 12 centres will conduct this study. • Inclusion and exclusion criteria are clearly defined. • Randomized patients will receive Digoxin or placebo at the dose prescribed by testing physician. • Bilingual consent form is provided. • Outcome criteria are defined. • Data collection sheet is provided. **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P24*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
25.	Research proposal entitled "***Quality of life assessment of epithelial ovarian cancer patients after curative treatment***" submitted by Dr. Shiv Rajan, Assistant Professor, Department of Surgical Oncology of this University via letter no. nil dated 22nd May, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Study Questionnaires (EORTC QLQ-C30,EQ-5D-3L,EORTC QLQ-OV28) **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P25*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
26.	Research proposal entitled "***Development of nanotechnology-based drug delivery systems loaded herbal medicinal plant against oral bacteria***" sponsored by ICMR New Delhi submitted by Prof. Shadab Mohammad, Head, Department of Oral & Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. OMSD/326/2020 dated 27th May, 2020.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	The following documents were reviewed in the EC Meeting:- • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P26*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
27.	Research proposal entitled "***A comprehensive study of the effect of time restricted meal intake on sleep, hormones, anthropometric parameters including epigenetics and genetics (SHAPE) in patients of type2 diabetes mellitus***" sponsored by ICMR New Delhi submitted by Prof. Narsingh Verma, Department of Physiology of this University via letter no. nil dated 20th May, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P27*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
28.	Research proposal entitled "***One novel platform for multiple biomarker detection of knee osteoarthritis: A case-control study***" sponsored by ICMR New Delhi submitted by Prof. R. N. Srivastava, Department of Orthopedics of this University via letter no.78/POS/2020 dated 30th May, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • CV of Dr. Devendra Parmar, Chief Scientist, Developmental Toxicology Division, IITR, Lucknow. **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P28*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

29.	Research proposal entitled ***"Enalpril versus propranolol in treatment of infantile hemangioma: A randomized controlled trial for better alternative"*** submitted by Dr. Archika Gupta, Associate Professor, Department of Pediatric Surgery of this University via letter no. 438/Ped Sgy/2020 dated 6th June, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • CV of Prof. Ravi Kanojia, Department of Pediatric Surgery, Postgraduate Institute of Medical Education & Research, Chandigar. • CV of Dr. Sunita Singh, Associate Professor, Department of Pediatric Surgery, All India Institute of Medical Sciences, Raipur **EC Comment:** • The study is a RCT to prove superiority of one method over other. • CONSORT guidelines are not followed. • How the patients will be ensured? • Can not be approved in current format. **EC Desicision:** Revise & Re-submit as per CONSORT guidelines ***Ref. code: 102nd ECM IIA/P29*** ***(Primary Reviewer: Dr. Amita Jain)***
30.	Research proposal entitled ***"Validation of the fistula risk score for post-operative pancreatic fistula after pancreatoduodenectomy"*** submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology of this University via letter no. SG/258/2020 dated 8th June, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P30*** ***(Primary Reviewer: Dr. Rajiv Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

31.	Research proposal entitled "***Characterization of novel micro RNAs for their possible association with MMP2/9 mediated angiogenesis and tumor invasion in urothelial carcinoma of bladder patients***" sponsored by DST-SERB Core Research Grant submitted by Prof. Apul Goel, Department of Urology of this University via letter no. 271/URO/2020 dated 9th June, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • CV of Dr. Minal Garg, Assistant Professor, Department of Biochemistry, University of Lucknow • Budget **EC Comment:** • The aim of this study is to investigate the molecular and cellular mechanisms of cancer progression and their association with recurrence of tumour to predict outcome. • So validation of biomarkers for early diagnosis and progression of cancer of Urinary Bladder is being pursued. • Methodology is clearly defined. • Sample size – 60 non-muscle invasive CA-Urinary Bladded and 40 muscle invasive CA. Urinary Bladder. • Bilingual consent form is provided. • Tissue samples will be obtained from TUR-BT specimens for study group and TURP for BHP for the control group. • 3 year duration of study. Budget Rs. 49,10,708.00 **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P31*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
32.	Research proposal entitled "***Determining the global outcomes of traumatic brain injury in low-, middle-, and high-income countries: A prospective, international cohort study***" sponsored by GNS & OHSU Brain Institute submitted by Dr. Ankur Bajaj, Associate Professor, Department of Neurosurgery of this University via letter no. NS/749/2020

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	dated 12th June, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Desicision:** Approved ***Ref. code: 102nd ECM IIA/P32*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IIB
Thesis

K.G's Medical University U.P., Lucknow

II-B	New Thesis-Resident
1.	Research proposal entitled ***"Evaluation of MALDI-TOF for dermatophyte identification"*** submitted by Dr. Riddhi Singh, JRI, Department of Microbiology of this University via letter no. 777/2020 dated 8th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P1*** ***(Primary Reviewer: Dr. Vimla Kumar Paliwal)***
2.	Research proposal entitled ***"Evaluation of peri-implant soft and hard tissues between internal hexagonal and internal conical type of implant abutment connection: A randomized controlled trial"*** submitted by Dr. Aditi Mishra, JRI, Department of Prosthodontics Crown & Bridge Faculty of Dental Sciences of this University via letter no. 1034/2020 dated 11th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Research proposal entitled ***"Use of flash glucose monitoring device in detecting hypoglycemic episodes and its association with various modifiable and nonmodifiable risk factors of predicting hypoglycemia in children and adolescents of type 1 diabetes mellitus in north Indian population: A prospective observational study"*** submitted by Dr. Tooba Qamar, JRI, Department of Paediatrics of this University via letter no.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	274/Paed/2020 dated 11th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • CV of Prof. Vijayalakshmi Bhatia, Department of Endocrinology, SGPGIMS, Lucknow **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Research proposal entitled ***"HYPOSPADIAS with shallow and anteriorly migrated glans groove: prevention of meatal stenosis with tubularised incised plate urethroplasty"*** submitted by Dr. Saurabh Srivastav, SRI, Department of Pediatrics Surgery of this University via letter no. 90/2020/Pedsy/2020 dated 11th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved. ***Ref. code: 102nd ECM II B-Thesis/P4*** ***(Primary Reviewer: Dr. Rajiv Garg)***
5.	Research proposal entitled ***"Immunoexoression of tumor associated macrophages–CD 68 and CD163 in renal tumor"*** submitted by Dr. Nancy Gupta, JRI, Department of Pathology of this University via letter no. 176/2020 dated 8th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • The objective is to assess the immune-histochemical expression of CD68 and

Chairperson, IEC
King George's Medical University

	CD163 in renal tumours and their correlation with clinic-pathological parameters. • Inclusion and exclusion criteria are clearly defined • Sample size 80. Statistically derived • Bilingual consent form is provided. • **Data collection sheet is missing.** • **What clinical and other investigational data -will be gathered** **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P5*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
6.	Research proposal entitled ***"Effect of two different inspiratory pressure level during pressure controlled face-mask ventilation for anaesthesia induction in children: A randomized trial"*** submitted by Dr. Tripti Singh, JRI, Department of Anaesthesiology of this University via letter no. 188/2020 dated 13th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Objectives are not clear • Need to clarifiy the constitution of groups **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
7.	Research proposal entitled ***"Ultrasound guided quadratus lumborum block versus transverses abdominis plane block for laproscopic inguinal hernia repair and appendicectomy using ropivacaine with dexmedetomidine"*** submitted by Dr. Vaghela Shashiraj, JRI, Department of Anaesthesiology of this University via letter no. 191/2020 dated 13th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P7*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
8.	Research proposal entitled ***"Association between ankle brachial index and severity of coronary artery disease"*** submitted by Dr. Akanksha Tandon, JRI, Department of Physiology of this University via letter no. 1592/2020 dated 24th January, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P8*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
9.	Research proposal entitled***"Study of level of annexin A2 in pre-eclampsia and normal pregnant women"***submitted by Dr. Pratima Shukla, JRI, Department of Obstetrics & Gynaecology of this University via letter no. 454/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P9*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
10.	Research proposal entitled ***"Study of microbial causes and role of c-reactive protein in the management of nasal polyposis"***submitted by Dr. Santosh Kumar Prasad, JRI, Department of OTO-Rhino-Laryngology & Head & Neck Surgery of this University via letter no. 857ENT/AM/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision** Approved ***Ref. code: 102nd ECM II B-Thesis/P10*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
11.	Research proposal entitled***"High intensity interval training vs moderate intensity continuous training: An efficacy based study on VO2max"***submitted by Dr. Ahmad Falah Shabbir, JR, Department of Physiology of this University via letter no. 1591/PHY/2020 dated 24th January, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly provide the sample size with calculation. **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P11*** ***(Primary Reviewer: Dr. Rajendra Nath)***
12.	Research proposal entitled***"Study on correlating cfDNA (Cell free DNA) levels with histopathological progression of Oral cancer to validate its usefulness as a diagnostic marker"***submitted by Dr. Nikhil Gupta, JR, Department of Oral Pathology & Microbiology Faculty of Dental Sciences of this University via letter no. 847/OP/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 102nd ECM II B-Thesis/P12
	(Primary Reviewer: Dr. Amita Jain)
13.	Research proposal entitled ***"Effect of carbohydrate loading in diabetic patients undergoing laparoscopic cholecystectomy"*** submitted by Dr. Kavita Yadav, JRI, Department of Anaesthesiology of this University via letter no. Anas/159/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • This study is a RCT, where these are two groups of patients, one arm of patients will receive 50gm of maltodextrin in 400 ml water 2/hr prior to surgery,the other group will be NPO. • So, it requires clinical trial registration. **EC Decision:** Approval after justification
	Ref. code: 102nd ECM II B-Thesis/P13
	(Primary Reviewer: Dr. Rajiv Garg)
14.	Research proposal entitled ***"Comparison of bone loss around submerged and non-submerged implants during osseointegration phase"*** submitted by Dr. Manisha Verma, JR, Department of Periodontology Faculty of Dental Sciences of this University via letter no. 1629/P-2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** 1. The objective is to evaluate peri-implant crestal bone loss during osteo-integration period and comparing submerged and non-submerged implants with healing abutments

Chairperson, IEC
King George's Medical University

	of different designs 2. If this is a R.C.T we need Consort guidelines. How will randomization be done? 3. Sample size is a must for ethical clearance. The sample size is based on number of variables being chased and it cannot be based on any patient based analysis. Please consult a statistician with your study plan 4. Inclusion and exclusion criteria are clearly defined 5. 4 parameters will be observed – Modified Plaque Index, Modified Gingival Index, Pocket depth and radiographic evaluation. 6. 3 intra-operative X-Rays on day of implant, 1 month and 3 months after implant placement will be done. 7. Bilingual consent form is provided. 8. Data collection sheet is provided **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P14*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
15.	Research proposal entitled ***"To determine levels of zearalenone in women with heavy menstrual bleeding"*** submitted by Dr. Ayushi Nayyar, JRI, Department of Pbstetrics & Gynaecology of this University via letter no. 1629/P-2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly mention sample size with its calculation **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P15*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
16.	Research proposal entitled ***"Comparative evaluation of dexmedetomidine nebulisation and ketamine nebulisation as an adjuvant to lignocaine for awake fiberoptic intubation"*** submitted by Dr. Bhawana Sharma, JRI, Department of Anaesthesiology of

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	this University via letter no. Ana/162/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) Patient Information Sheet Hindi & English **EC Comment:** • This study should be registered with CTRI. **EC Decision:** Provisionally approved ***Ref. code: 102nd ECM II B-Thesis/P16*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
17.	Research proposal entitled ***"Comparison of monitored anaesthesia care with spinal anaesthesia in day care varicose vein surgery and its effect on stress gene expression"*** submitted by Dr. Nannam Spandana, JRI, Department of Anaesthesiology of this University via letter no. Ana/166/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P17*** ***(Primary Reviewer: Dr. Smriti Bhadiouria)***
18.	Research proposal entitled ***"Comparative study of melatonin versus gabapentin on post operative pain and anxiety in breast cancer surgery: A prospective comparative study"*** submitted by Dr. Kanika Bansal, JRI, Department of Anaesthesiology of this University via letter no. Ana/178/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	Ref. code: 102nd ECM II B-Thesis/P18
	(Primary Reviewer: Dr. Preeti Agarwal)
19.	Research proposal entitled ***"Evaluation of anxiety using faces anxiety scale in ICU patients using noise ablating headphones during nighi time versus ICU patients receiving usual care"*** submitted by Dr. Rouble Jalota, JRI, Department of Anaesthesiology of this University via letter no. Ana/158/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P19*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
20.	Research proposal entitled ***"Comparison of clinical performance of I-GEL and lma blockbuster™ in adult patients during general anaessthesia"*** submitted by Dr. Prerna Prabhat Das, JRI, Department of Anaesthesiology of this University via letter no. Ana/167/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P20*** ***(Primary Reviewer: Dr. Rajendra Nath)***
21.	Research proposal entitled ***"Assessment of contextual and individual barriers to Oral healthcare utilization in periodontitis patients on Anderson behavioural model frame work: A multivariate analysis"*** submitted by Dr. Vidyadhar Paswan, JRII, Department of Periodontology Faculty of Dental Sciences of this University via letter no. 1628/P-2020 dated 10th February, 2020.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	The following documents were reviewed in the EC Meeting:- • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly provide complete check list. • This is a questionnaire-based study & kindly provide questionnaire. • English ICF is incomplete **EC Decision:** Revise & Re-submit ***Ref. code: 102nd ECM II B-Thesis/P21*** ***(Primary Reviewer: Dr. Amita Jain)***
22.	Research proposal entitled ***"Clinical audit of pre-eclampsia and eclampsia cases in tertiary care centre in North India"*** submitted by Dr. Neha Chaudhary, JRII, Department of Obstetrics & Gynaecology of this University via letter no. OG/455/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P22*** ***(Primary Reviewer: Dr. Rajiv Garg)***
23.	Research proposal entitled ***"A comparative study between platelet rich plasma and prolotherapy for pain relief in patients of knee osteoarthritis"*** submitted by Dr. Satyendra Singh Yadav, JRI, Department of Anaesthesiology of this University via letter no. Anaes/193/2020 dated 13th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** 1-The aim of this study is to measure pain relief by Visual Analog Scale improvement in joint stiffness and complications in therapy at 1 week, 1 month, 3 month and 6 month after PRP and PLR. 2. Inclusion and exclusion criteria are clearly defined 3. Sample size 64, 32 in each group; statistically calculated. 4. Bilingual consent form is provided. 5. Prolotherapy will be done using 25% Dextrose 6. Intra-articular injection in knee joint will be done under C-Arm guidance 7. How will the randomization be done? 8. If this is an RCT, then Consort guidelines need to be followed. **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P23*** ***(Primary Reviewer:Dr. Surajit Bhattacharya)***
24.	Research proposal entitled ***"Evaluation of effect of preoperative duloxetine on reducing postoperative morphine requirement after open radical cholecystectomy: A randomised control study"*** submitted by Dr. Nida Haider, JRI, Department of Anaesthesiology of this University via letter no. Anaes/177/2020 dated 12th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P24*** ***(Primary Reviewer: Anoop Kumar Verma)***
25.	Research proposal entitled ***"A comparative study of blunt trauma chest patient***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	managed by surgical fixation versus conservative management with epidural analgesia in critical care unit" submitted by Dr. Abhishek Bhaskar, JRI, Department of Anaesthesiology of this University via letter no. Anaes/172/2020 dated 11th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P25*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
26.	Research proposal entitled ***"Comparison of clonidine vs midazolam-fentanyl in monitored anaesthesia care for varicose vein surgery and its correlation with pain modulating COMT gene"*** submitted by Dr. Manish Kumar, JRI, Department of Anaesthesiology of this University via letter no. Anaes/200/2020 dated 14th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P26*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
27.	Research proposal entitled ***"Randomized double-blind prospective study to evaluate the effect of oral pregabalin in upper limb surgeries under brachial plexus block"*** submitted by Dr. Shailendra Singh, JRI, Department of Anaesthesiology of this University via letter no. Anaes/163/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P27*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
28.	Research proposal entitled ***"Immunohistochemical expression of tumor associated macrophages CD-68 and CD-163 in urinary bladder carcinoma and its analysis with clinicopathological parameter"*** submitted by Dr. Shweta Verma, JRI, Department of Pathology of this University via letter no. 177/2020 dated 8th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P28*** ***(Primary Reviewer: Dr. Vimla Kumar Paliwal)***
29	Research proposal entitled ***"Clinicopathological spectrum of spindle cell soft tissue tumors and their immunohistochemistry correlation"*** submitted by Dr. Swati Agnihotri, JRI, Department of Pathology of this University via letter no. 175/2020 dated 8th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P29*** ***(Primary Reviewer: Dr. Rajendra Nath)***
30.	Research proposal entitled ***"Prognostic significance of podoplanin in oral squamous cell carcinoma"*** submitted by Dr. Deval Brajesh Dubey, JRI, Department of Pathology of this University via letter no. 174/2020 dated 8th February, 2020.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	The following documents were reviewed in the EC Meeting:- • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Study type is not clear • "Prospective" is the method of enrollment. • Questionnaire for collection of data is not provided **EC Decision:** Revise & Re-submit ***Ref. code: 102nd ECM II B-Thesis/P30*** ***(Primary Reviewer Dr. Amita Jain)***
31.	Research proposal entitled ***"Serum visfatin levels for mortality prediction in critically ill paediatric intensive care unit patients"*** submitted by Dr. Gaurav Singh, JRI, Department of Pediatrics of this University via letter no. 292/Ped/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** There are certain issues regarding the study:- 1- Where serum visfatin level testing be done, what would be the cost? 2- Who is going to bear the cost if it is just an academic tool /investigational tool not approved for routine use? **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P31*** ***(Primary Reviewer: Dr.Rajiv Garg)***
32.	Research proposal entitled ***"A follow up study of children and adolescents with depressive disorders"*** submitted by Dr. Shreya Shukla, JRI, Department of Psychiatry of

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	this University via letter no. 2079 /Psy/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** 1. The objective is to study the short term outcome of evaluation of symptom profile of Major Depressive Disorders, Persistent Depressive Disorders and other specific depressive disorders in children and adolescents 2. Inclusion and exclusion criteria are clearly defined 3. Sample size is 55. Statistically derived 4. Bilingual consent form is provided. 5. A semi structures proforma will be used in this study and it has been provided 6. 5 specific rating scales will be used for global assessment, rating depression and life events. These scales have been provided **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P32*** ***(Primary Reviewer: Surajit Bhattacharya)***
33.	Research proposal entitled ***"Maternal hypothyroidism and its correlation with preterm labour and neonatal status"*** submitted by Dr. Pratishtha Dubey, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/463/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P33*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

34.	Research proposal entitled ***"Combined use of LETROZOLE and CLOMIPHENE citrate for ovulation induction in women undergoing infertility treatment"*** submitted by Dr. Tamanna Gupta, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/435/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P34*** ***(Primary Reviewer: Dr. A.A.Sonkar)***
35.	Research proposal entitled ***"Clinical audit on maternal and fetal outcome in multiple pregnancy in tertiary care Hospital"*** submitted by Dr. Shweta Tyagi, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/457/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P35*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
36.	Research proposal entitled ***"Correlation of serum magnesium level in pregnancy with obstetric outcome"*** submitted by Dr. Shruti Agarwal, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/433/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment: • According to randamly 1000 sample size mention by Principal Investigator, but on what basis? • By which technique Mg level will be measured. • A clinical Biochemist/Clinical Pathologist must be a part of the study. **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P36*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
37.	Research proposal entitled ***"BMI (Who Versus Asian Criteria) in first trimester and its correlation with pregnancy outcome"*** submitted by Dr. Sujata Singh, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/451/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P37*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
38.	Research proposal entitled ***"Awareness about carcinoma breast and practices related to self breast examination among women in Lucknow "*** submitted by Dr. Shipra, JRI, Department of Community Medicine & Public Health of this University via letter no. 1319/CM dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly provide the Sample size

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P38*** ***(Primary Reviewer: Dr. Rajendra Nath)***
39.	Research proposal entitled ***"A study of bronchiectasis in moderate to severe category patients of chronic obstructive pulmonary disease by using high resolution computed tomography (HRCT) thorax"*** submitted by Dr. Ankit Dineshbai Patel, JR, Department of Respiratory Medicine of this University via letter no. 582/Res/2020 dated 12th June, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly provide study protocol. **EC Decision:** Revise & Re-submit ***Ref. code: 102nd ECM II B-Thesis/P39*** ***(Primary Reviewer: Dr.Amita Jain***
40.	Research proposal entitled ***"Diagnostic performance of fine needle aspiration cytology (FNAC) in classification of breast masses and its correlation with Histopathology"*** submitted by Dr. Loreno. E Enny, JRII, Department of Endocrine Surgery of this University via letter no. 57/2020 dated 8th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P40*** ***(Primary Reviewer: Dr. Rajiv Garg)***
41.	Research proposal entitled ***"Comparative evaluation of implant stability and hard tissue changes in single and multiple drill osteotomy with immediate loading-***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	randomized control trial" submitted by Dr. Jyotsna Vimal, JRI, Department of Prosthodontics & Crown & Bridge, Faculty of Dental Sciences of this University via letter no. 1025/2020 dated 10th February, 2020. **EC Comment:** 1. The objective is to study the comparative evaluation of ISQ values and implant healing in single and multiple drill osteotomy with immediate loading. 2. Healing will be assessed by Osteoprotegrin (OPG) levels in saliva at day 0, 3 weeks, 6 weeks & 12 weeks and crestal bone loss at 12 weeks and 24 weeks. 3. If this is a R.C.T we require Consort guidelines 4. Sample size is 14 in each group. This is statistically calculated on the basis of variation of crestal bone loss. So how are the other 2 variables - Salivary OPG and Implant Stability Quotient being accommodated? 5. Randomization will be done by a computer generated random allocation programme 6. Inclusion and exclusion criteria are clearly defined 7. Methodology is clear 8. Data collection sheet is provided 9. Bilingual consent form is provided. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P41*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
42.	Research proposal entitled ***"A study on gram negative non-fermentative bacilli causing bacteraemia in adult intensive care units"*** submitted by Dr. Sangeeta Singh, JRI, Department of Microbiology of this University via letter no. 756/2020 dated 3rdFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P42*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
43.	Research proposal entitled ***"Identification of urinary isolates from catheter associated infections in intensive care patients by MALDI-TOF MS Vs conventional methods"*** submitted by Dr. Anuj Kumar, JRI, Department of Microbiology of this University via letter no. 754/2020 dated 3rd February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P43*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
44.	Research proposal entitled ***"A study of cognitive functioning & depressive mood and their relationship with glycemic control in elderly type2 diabetes patients: A cross-sectional study"*** submitted by Dr. Fatima Khan, JRI, Department of Pharmacology and Therapeutics of this University via letter no. 141/Pharma/2020 dated 13th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P44*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
45.	Research proposal entitled ***"Histopathological spectrum analysis of CNS tumours in tertiary care centre-A5 year study"*** submitted by Dr. Manisha Raj, JRI, Department of

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Pathology of this University via letter no. 234/2020 dated 12th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Prospective & Retrospective study including patient specific information like age, gender with clinical presentation. • How will retrospective patients be taken as agreed? • Kindly provide waiver form **EC Decision:** Revise & Re-submit ***Ref. code: 102nd ECM II B-Thesis/P45*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
46.	Research proposal entitled ***"Early and effective diagnosis of sepsis using flow cytometry"*** submitted by Dr. Pratima Verma, JRI, Department of Pathology of this University via letter no. 204/2020 dated 12th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P46*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
47.	Research proposal entitled ***"Utility of IHC marker CD105 in prognostication of urinary bladder carcinoma"*** submitted by Dr. Seema, JRI, Department of Pathology of this University via letter no. 186/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P47*** ***(Primary Reviewer: Dr. Rajendra Nath)***
48.	Research proposal entitled ***"To study role of T regulatory cells in CML patient before and after tyrosine kinase inhibitor therapy"*** submitted by Dr. Sweta Kanaujia, JRI, Department of Pathology of this University via letter no. 187/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Questionnaire is not provided. • What is the study type? • If this is case control/observational/cohort study? • Sample size calculation is only possible after deciding the study type • How many cases & how many controls will be enrolled? **EC Decision:** Revise & Re-submit ***Ref. code: 102nd ECM II B-Thesis/P48*** ***(Primary Reviewer: Dr. Amita Jain)***
49.	Research proposal entitled ***"The changes in recurrent laryngeal narve conduction with intraoperative continuous neuromonitoring and changes in tracheal cuff pressure during thyroidectomy"*** submitted by Dr. Nancy Raja, SR, Department of Endocrine Surgery of this University via letter no. nil dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	Ref. code: 102nd ECM II B-Thesis/P49
	(Primary Reviewer: Dr. Rajiv Garg)
50.	Research proposal entitled ***"Effect of biomimetic self-assembling peptides(P11-4) on 'initial carious lesions' in pediatric patients: A randomized controlled trial"*** submitted by Dr. Mohd Zeeshan Anees, JRI, Department of Paediatric & Preventive Dentistry Faculty of Dental Sciences of this University via letter no. 205/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** 1. The study aims to evaluate the effect of self assembling P11-4 peptides on initial stage of caries in permanent tooth of paediatric patients and to compare it with CPP-ACP F varnish 2. This is a R.C.T in which in the same mouth there will be a control 3. L side in which CPP-APP F varnish will be applied on all teeth including the initial carious lesions and an experimental side in which self assembling P11-4 peptides will be applied followed by CPP-ACP F varnish 4. Inclusion and exclusion criteria are clearly defined 5. Sample size is 27. Statistically derived 6. Randomization will be done between 6 blocks of 4 teeth 7. Bilingual consent form is provided. 8. Outcomes to be observed have been defined. 9. If it is a R.C.T we need Consort guidelines. **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P50*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
51.	Research proposal entitled ***"A study of cases of gastric tube pull up for pure oesophageal atresia and long gap tracheoesophageal fistula"*** submitted by Dr. Nirpex Tyagi, SR, Department of Paediatric Surgery of this University via letter no.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	105/Ped/2020 dated 19th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P51*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
52.	Research proposal entitled ***"Comparative evaluation of antimicrobial efficacy of propolis as an intracanal irrigant: A randomised control trial"*** submitted by Dr. Divya Pal, JRI, Department of Conservative Dentistry and Endodontics Faculty of Dental Sciences of this University via letter no. 887/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Describe sample size & Method of Randomization • Change tension material & methods • Signature missing of Dr. Suib Luqman in check list & kindly provide his CV because he is out sider. • Signature of P.I. & date are missing in annexure 2 (Undertaking by P.I.) **EC Decision:** Revise & Re-submit ***Ref. code: 102nd ECM II B-Thesis/P52*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
53.	Research proposal entitled ***"Comparative analysis of [RHPDGF-BB] recombinant human platelet derived growth factor, [B-TCP] beta tricalcium phosphate and biodentine as direct pulp capping agent: randomized clinical trial"*** submitted by Dr. Vasanth M N, JRI, Department of Conservative Dentistry and Endodontics Faculty of Dental Sciences of this University via letter no. 889/2020 dated 10th February, 2020.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	The following documents were reviewed in the EC Meeting:- • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Source of recombinant PDGFBB needs to be clarified. • Owing to test agent being recombinant product, if it is being used for the first time by investigators in human for stated condition, an approval letter from institutional bioethics committee may be required in support of this application • Even though investigators have not included inclusion/exclusion criteria in proposal (declaration for same is there in the questionnaire), yet in methodological section they have indicated that 'suitable number of patient fulfilling all the inclusion criteria will be selected'. The suitable number and fulfilling criteria needs to be explained adequately. **EC Decision:** Revise & Re-submit ***Ref. code: 102nd ECM II B-Thesis/P53*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
54.	Research proposal entitled ***"Outcomes of rapid versus conventional pre-operative preparation in patients undergoing thyroidectomy for graves' diseases-A prospective study"*** submitted by Dr. Upander Kumar, SR, Department of Endocrine Surgery of this University via letter no. ENDOSURG/2020/01/75dated 22nd February, 2020. **EC Comment:** • Kindly provide sample size with calculate • How will it be decided which patient will came into which group I or II? • If Randomization will be performed how will it be done? **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P54*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
55.	Research proposal entitled ***"Evaluation of healing by ultrasound color Doppler***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	imaging after peri-apical endodontic surgery using platelet rich fibrin (PRF) and injectable platelet rich fibrin (IPRF)" submitted by Dr. Manisha Lal, JRI, Department of Conservative Dentistry and Endodontics Faculty of Dental Sciences of this University via letter no. 886/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P55*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
56.	Research proposal entitled ***"Clinical and radiographic comparison of indirect pulp capping using amniotic membrane and platelet rich fibrin in permanent molars"*** submitted by Dr. Lalruatfeli, JRI, Department of Conservative Dentistry and Endodontics Faculty of Dental Sciences of this University via letter no. 888/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P56*** ***(Primary Reviewer:Dr. Rajendra Nath)***
57.	Research proposal entitled ***"A comparative evaluation of mineral trioxide aggregate, 3mixtatin and tempophore™ medicaments for pulpotomy in primary teeth: A randomized controlled trial"*** submitted by Dr. Gunna Madhuri, JRI, Department of Paediatric & Preventive Dentistry Faculty of Dental Sciences of this University via letter no. Pado/209/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly provide complete checklist • This RCT is not as per CONSORT guidelines • How patients will be enrolled. **EC Decision:** Revise & Re-submit ***Ref. code: 102nd ECM II B-Thesis/P57*** ***(Primary Reviewer: Dr. Amita Jain)***
58.	Research proposal entitled ***"A comparative evaluation of intranasal combinations of midazolam-ketamine, dexmedetomidine-ketamine, midazolam-fentanyl and dexmedetomidine-fentanyl for procedural sedation and analgesia in paediatric dental patients: randomised controlled trial"*** submitted by Dr. Agarwal Abhilasha Kishanlal, JRI, Department of Paediatric & Preventive Dentistry Faculty of Dental Sciences of this University via letter no. Pado/207/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly provide Clinical trial registration. **EC Decision:** Approval after justification ***Dr. Rajendra Nath did not take part in the discussion.*** ***Ref. code: 102nd ECM II B-Thesis/P58*** ***(Primary Reviewer: Dr. Rajiv Garg)***
59.	Research proposal entitled ***"Evaluation of magnetic nanoparticles as pulpotomy medicament in primary teeth: randomized control trial"*** submitted by Dr. Kumari Charul, JRI, Department of Paediatric & Preventive Dentistry Faculty of Dental Sciences of this University via letter no. Pado/208/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** 1. The aim is to evaluate the effectiveness of magnetic nanoparticles (MNPs) as a pulpotomy medicament in primary molars and to compare its effectiveness to MTA 2. Inclusion and exclusion criteria are clearly defined 3. Two groups – study group will receive MNPs and control group will get MTA. Rest of the treatment will be the same 4. Sample size 24 in each group. Statistically derived 5. Randomization will be computer generated 6. Bilingual consent form is provided. 7. What will be observed and when? 8. A data collection sheet is missing 9. If it is a RCT then we need Consort guidelines **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P59*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
60.	Research proposal entitled ***"A comparative evaluation of standard and anodized abutments on immediately loaded implants in fresh extraction sockets-A single blinded randomized control trial"*** submitted by Dr. Rohini R, JRI, Department of Prosthodontics and Crown & Bridge, Faculty of Dental Sciences of this University via letter no. 1028/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P60*** ***(Primary Reviewer: Dr.Anoop Kumar Verma)***
61.	Research proposal entitled ***"Evaluation of role of exogenous melatonin in prevention of delirium in postoperative patients admitted in intensive care unit"*** submitted by Dr.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Kriti Gupta, JRI, Department of Anaesthesiology of this University via letter no. Anaes/160/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Describe how the patient would be randomized? • Has it been registered with DCGI/CTRI as per the need? **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P61*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
62.	Research proposal entitled ***"Comparative study of perioperative effect of premedication with melatonin versus pregabalin in total hip arthrolasty under spinal anaesthesia"*** submitted by Dr. Akash Mishra, JRI, Department of Anaesthesiology of this University via letter no. Anaes/169/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P62*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
63.	Research proposal entitled ***"Cuffed versus uncuffed endotracheal tubes in infants undergoing elective surgery in prone position: peritubal leak at standardized ventilator settings"*** submitted by Dr. Priyanka Singh, JRI, Department of Anaesthesiology of this University via letter no. Anaes/207/2020 dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved. ***Ref. code: 102nd ECM II B-Thesis/P63*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
64.	Research proposal entitled ***"Effect of erector spinae block and pecs block on quality of recovery and analgesia after modified radical mastectomy: A randomized control double blind study"*** submitted by Dr. Md. Hammad Mohsin, JRI, Department of Anaesthesiology of this University via letter no. Anaes/192/2020 dated 13th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Please define the known/unknown/possible list of complications of said blocks. Please also suggest the measures the PI shall take in case a study subject suffers any complications of the said procedure. **EC Comment:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P64*** ***(Primary Reviewer: Dr.Vimal Kumar Paliwal)***
65.	Research proposal entitled ***"Prospective observational study of incidence and factors associated with failed spinal anaesthesia in obstetric patients"*** submitted by Dr. Jharna Mili, JRI, Department of Anaesthesiology of this University via letter no. Anaes/161/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 102nd ECM II B-Thesis/P65
	(Primary Reviewer: Dr. Rajendra Nath)
66.	Research proposal entitled ***"Randomised control trial of ultrasound guided parasternal intercostals nerve block and transvers thoracis muscle plane block for post operative analgesia im cardiac surgical patients"*** submitted by Dr. Sachindra Yadav, JRI, Department of Anaesthesiology of this University via letter no. Anaes/165/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • This RCT is not as per CONSORT guidelines • No provision for patient's ensurance? **EC Decision:** Revise & Re-submit ***Ref. code: 102nd ECM II B-Thesis/P66*** ***(Primary Reviewer: Dr.Amita Jain)***
67.	Research proposal entitled ***"Vaginal microflora in patients with preterm premature rupture of membranes (PPROM) and its association with fetomaternal outcome"*** submitted by Dr. Pankhuri Jaiswal, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/460/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P67*** ***(Primary Reviewer: Dr. Rajeev Garg)***
68.	Research proposal entitled ***"Vitamin B12 and folic acid levels in pregnant women at delivery and their correlation with obstetric outcome"*** submitted by Dr. Mitali Gupta,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/448/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • The objective is to study the prevalence of Vitamin B12 and Folic Acid deficiency in pregnant women and to assess the maternal and foetal outcome due to the same. • Inclusion and exclusion criteria are clearly defined • Sample size 150. Statistically derived • Bilingual consent form is provided. • 5ml maternal blood will be drawn for B12 and Folic Acid radio-immunoassay. • Data collection sheet is attached. **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P68*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
69.	Research proposal entitled ***"Evaluation of etiological factors of thrombocytopenia in pregnancy and its effects on feto-maternal outcomes"*** submitted by Dr. Akanksha Pandey, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/458/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P69*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
70.	Research proposal entitled ***"Study of red cell distribution width and platelet indices in pre-eclampsia and it's correlation with its severity"*** submitted by Dr. Preeti

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Vishwakarma, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/459/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P70*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
71.	Research proposal entitled ***"Correlation of second trimester rlevated maternal serum alpha fetoprotein with fetomaternal outcome"*** submitted by Dr. Priti, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/434/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P71*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
72.	Research proposal entitled ***"Randomised controlled trial to compare efficacyof cryotherapy and thermocoagulation for management of cervical ectropion"*** submitted by Dr. Babita Kumari, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/461/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 102nd ECM II B-Thesis/P72 ***(Primary Reviewer: Dr. Preeti Agarwal)***
73.	Research proposal entitled ***"AMH levels in different phenotypes of infertile women with PCOS"*** submitted by Dr. Nupur Rawat, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/436/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P73*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
74.	Research proposal entitled ***"Prediction of malignancy in adenexal masses by international ovarian tumor analysis (IOTA) scoring system"*** submitted by Dr. Yamini Sharma, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/447/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P74*** ***(Primary Reviewer: Dr. Rajendra Nath)***
75.	Research proposal entitled ***"Clinicopathological evaluation of abnormal uterine bleeding in perimenopausal women"*** submitted by Dr. Himani Pandey, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/425/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P75*** ***(Primary Reviewer: Dr. Amita Jain)***
76.	Research proposal entitled ***"Effect of spiritual music in old age patients undergoing lower limb surgery under spinal anesthesia"*** submitted by Dr. Ashiquee Arya, JRI, Department of Anaesthesiology of this University via letter no. Anaes/227/2020 dated 20th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly provide Clinical trial registration. **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P76*** ***(Primary Reviewer: Dr. Rajiv Garg)***
77.	Research proposal entitled ***"Comparison of maintenance, emergence and recovery characteristics of isoflurane, sevoflurane and desflurane in patients undergoing general anaesthesia"*** submitted by Dr. Muqtadir Jamal, JRI, Department of Anaesthesiology of this University via letter no. Anaes/173/2020 dated 11st February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** 1. The aim is to compare the emergence characterestics of sevoflurane, isoflurane and desflurane and their effect on mental, psychomotor and cognitive functions, peri-

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	operative haemodynamic stability and post-operative side effects 2. Inclusion and exclusion criteria are clearly defined 3. Sample size 120 – 40 in each group of Isoflurane, Seboflurane and Desflurane. Bilingual consent form is provided. 4. Nausea, Vomiting and Sedation will be measured bt Ramsay Sedation Score 5. Recovery pattern will be assessed by Modified Alfred Scoring System and Mini Mental Status Examination on 0, 6, 24 Hrs and every day for 6 days **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P77*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
78.	Research proposal entitled ***"Effect of two different doses of gabapentin premedication on emergence agitation and postoperative pain control in pediatric patients: A comparative randomized control trial"*** submitted by Dr. Ankur Choukan, JRI, Department of Anaesthesiology of this University via letter no. Anaes/181/2020 dated 12th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P78*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
79.	Research proposal entitled ***"Septicemia in critically ill patients: prospective study on epidemiology, risk factor and role of maldi tof-ms for species identification of the organisms causing septicemia"*** submitted by Dr. Kuldeep Singh Sindhlian, JRI, Department of Anaesthesiology of this University via letter no. Anaes/179/2020 dated 12th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 102nd ECM II B-Thesis/P79*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
80.	Research proposal entitled ***"The pattern of radiculogram as predictor of outcome for selective nerve root blocks"*** submitted by Dr. Prakhar Mishra, JRI, Department of Orthopaedics of this University via letter no. 1350/05/2020 dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P80*** ***(Primary Reviewer:Dr. Smriti Bhadouria)***
81.	Research proposal entitled ***"Serum magnesium levels in community acquired pneumonia and its association with clinical severity (on day 3) and adverse outcomes in children < 5 years of age: nested case control study"*** submitted by Dr. Sanjukta Mukhopadhyay, JRI, Department of Paediatrics of this University via letter no. 289/Ped/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P81*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
82.	Research proposal entitled ***"Candida sepsis in neonates in a neonatal intensive care unit: A cross-sectional study"*** submitted by Dr. Ajitesh Singh, JRI, Department of Paediatrics of this University via letter no. 290/Ped/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P82*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
83.	Research proposal entitled ***"A comparative study of prognostic and diagnostic biochemical indicators of stable vs vulnerable plaque in coronary artery disease subjects"*** submitted by Dr. Menka Mishra, JRI, Department of Pathology of this University via letter no. 248/2020 dated 14th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P83*** ***(Primary Reviewer: Dr. Rajendra Nath)***
84.	Research proposal entitled ***"Study of immunohistochemical P53 expression in bone marrow biopsy of acute myeloid leukemia and myelodysplastic syndrome"*** submitted by Dr. Tanvi Qamar, JRI, Department of Pathology of this University via letter no. 189/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P84*** ***(Primary Reviewer: Dr. Amita Jain)***
85.	Research proposal entitled ***"Microvessel density assessment in gynaecological maligancies"*** submitted by Dr. Mohammad Aslahuddin, JRI, Department of Pathology

Chairperson, IEC
King George's Medical University,
U.P., Lucknow

	of this University via letter no. 247/2020 dated 14th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P85*** ***(Primary Reviewer: Dr. Rajiv Garg)***
86.	Research proposal entitled ***"Heavy metal levels & oxidative stress in children with extra hepatic portal vein obstruction: A case control study"*** submitted by Dr. Neha Sonker, JRI, Department of Paediatrics of this University via letter no. 285/Ped/2020 dated 8th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Data Collection form **EC Comment:** • The purpose of this study is to establish the clinical profile of children with EHPOV, to study Blood CU, Mn, Zn and Pb levels in them and to compare the same with control group. • Control will be healthy volunteers from OPD and children about to be discharged from IPD. • Inclusion and exclusion criteria are clearly defined. • Sample size 100 – 50 in study and 50 in Control group. Statistically derived. • Bilingual consent form is provided. • 3-4 ml of blood from venepuncture only once is required. • Data collection sheet is required • Kindly provide the CV of Dr. Kauser Ansari, Senior Scientist, CSIR-IITR, Lucknow (Outsider)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P86*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
87.	Research proposal entitled ***"Hospital based study for prevalence of humoral primary immunodeficiency diseases (PID) in children with recurrent infections"*** submitted by Dr. Swati Yadav, JRI, Department of Paediatrics of this University via letter no. 283/Ped/2020 dated 7th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionnaire **EC Comment:** • There are many discrepancies in filling of IEC form **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P87*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
88.	Research proposal entitled ***"Pediatric pulmonary tuberculosis prevalence, risk factors and functional impairment: A prospective hospital based observational study"*** submitted by Dr. Chumben Tungoe, JRI, Department of Paediatrics of this University via letter no. 291/Ped/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P88*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
89.	Research proposal entitled ***"To assess the efficacy of immunosuppressive therapy with equine ATG and cyclosporine in children with severe and very severe acquired***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	aplastic anemia: A prospective observational study" submitted by Dr. Harshita Baiswar, JRI, Department of Paediatrics of this University via letter no. 288/Ped/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P89*** ***(Primary Reviewer:Dr. Smriti Bhadouria)***
90.	Research proposal entitled ***"To assess the effect of two days injectable dexaethasone therapy in resolution of uncomplicated parapneumonic effusion in Hospitalized children aged 1 month-14 years- A single blinded randomized trial"*** submitted by Dr. Anshika Mishra, JRI, Department of Paediatrics of this University via letter no. 300/Ped/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly provide the CV of Prof. G.G. Agarwal, Department of Statistics, Lucknow University, Lucknow **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P90*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
91.	Research proposal entitled ***"Prevalence of congenital rubella infection in infants with congenital heart disease: A cross sectional study"*** submitted by Dr. Anamika Sachan, JRI, Department of Paediatrics of this University via letter no. 309/Ped/2020 dated 11st February, 2020. ***The following documents were reviewed in the EC Meeting:-***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P91*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
92.	Research proposal entitled ***"Comparison of blood lactate levels with lactate clearance for predicting mortality in children presenting with shock"*** submitted by Dr. Devina Singh, JRI, Department of Paediatrics of this University via letter no. 293/Ped/2020 dated 10thFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • CRF **EC Comment:** • Kindly provide the CV of Dr. Prabhakar Mishra, Associate Professor, Department of Biostatistics & Information, SGPGIMS, Lucknow **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P92*** ***(Primary Reviewer: Dr. Rajendra Nath)***
93.	Research proposal entitled ***"Prevalance and predictors of bacterial meningitis in newborn infants at risk of sepsis"*** submitted by Dr. Prerna Priyadarshini, JRI, Department of Paediatrics of this University via letter no. 286/Ped/2020 dated 8thFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• CRF **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P93*** ***(Primary Reviewer: Dr. Amita Jain)***
94.	Research proposal entitled ***"Effect of antenatal steroids on thyroid hormone function in preterm neonates- A prospective observational study"*** submitted by Dr. Ranjana Singh, JRI, Department of Paediatrics of this University via letter no. 276/Ped/2020 dated 7thFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P94*** ***(Primary Reviewer: Dr. Rajiv Garg)***
95.	Research proposal entitled ***"Neonatal disease severity score for prediction of mortality in hospitalised neonates"*** submitted by Dr. Hera Fatima, JRI, Department of Paediatrics of this University via letter no. 261/Ped/2020 dated 6thFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** 1-The aim of this study is to validate a reliable yet simple scoring system, Modified Sick Neonate Score, to assess the severity of illness in newborns at arrival to a health facility to predict risk of mortality and see if the score can be improved. 2. It is a cross-sectional observational study 3. Inclusion and exclusion criteria are clearly defined 4. Sample size 480. Statistically derived

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	5. Bilingual consent form is provided. 6. Respiratory rate, Heart Rate, Axillary temperature, Capillary refill time, Random Blood Sugar, Gestational Age and Birth weight will be noted. 7. A case record form is provided. **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P95*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
96.	Research proposal entitled ***"Etiology and outcome of acute meningoencephalitis in children below 5 years of age: A prospective observational study"*** submitted by Dr. Richa Singh, JRI, Department of Paediatrics of this University via letter no. 294/Ped/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Data collection form **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P96*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
97.	Research proposal entitled ***"Proportion of infantile cholestasis with low or normal GGT in children with cholestatic liver disorder at tertiary care centre in northern India"*** submitted by Dr. Sonali Singh, JRI, Department of Paediatrics of this University via letter no. 263/Ped/2020 dated 6th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P97***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. A.A. Sonkar)
98.	Research proposal entitled ***"The efficacy of periarticular infiltration and adductor canal block on early functional recovery and pain control in total knee replacement"*** submitted by Dr. Fatima Khan, JRI, Department of Anaesthesiology of this University via letter no. Anae/249/2020 dated 26thFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P98***
	(Primary Reviewer: Dr. Smriti Bhadouria)
99.	Research proposal entitled***"Conventional open reduction approach vs endoscopic approach for orbital floor repair a comparison"*** submitted by Dr. Ravi Katrolia, JRI, Department of Oral and Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. OMSD/260/2020 dated 24thFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • The patients will be divided into two groups as per treatment offered to them; however no baseline details provided for which patient will be candidate for endoscopic approach or open one. If randomization will be performed, provide level of blinding to be done.No sample size justification provided. **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P99***

Chairperson IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Preeti Agarwal)
100.	Research proposal entitled ***"Assessment of preoperative predictors of difficult laparoscopic cholecystectomy and post cholecystectomy syndrome"*** submitted by Dr. Shubham Nayak, JRI, Department of General Surgery of this University via letter no. 451/2020 dated 26thFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P100*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
101.	Research proposal entitled ***"A comparative study between preoperative carbohydrate loading versus fasting for Paediatric anaesthesia in urogenital surgeries"*** submitted by Dr. Sumedha Harish, JRI, Department of Anaesthesiology of this University via letter no. Anaes/174/2020 dated 11th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P101*** ***(Primary Reviewer: Dr. Rajendra Nath)***
102.	Research proposal entitled ***"A comparative study of sensory processing in children and adolescents with attention deficit hyperactivity disorder and healthy controls"*** submitted by Dr. Indu Rani, JRI, Department of Psychiatry of this University via letter no. 2080/Psy/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Patient Information Sheet Hindi & English **EC Comment:** • This study involves children. • Hence consent form has to be parental, not for patient • Consent form should be in layman language **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P102*** ***(Primary Reviewer: Dr. Amita Jain)***
103.	Research proposal entitled ***"A comparative study on alexithymia, emotional regulation and impulsivity in borderline personality disorder and healthy control"*** submitted by Dr. Huma Fatima, JRII, Department of Psychiatry of this University via letter no. 2082/Psy/2020 dated 10thFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P103*** ***(Primary Reviewer: Dr. Rajiv Garg)***
104.	Research proposal entitled ***"A study of sexual dysfunctions in patients with obsessive compulsive disorder"*** submitted by Dr. Amit Kumar Singh, JRI, Department of Psychiatry of this University via letter no. 2106/Psy/2020 dated 13rdFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** 1. The objective is to study sexual dysfunctions in patients of OCD 2. Inclusion and exclusion criteria of Study and Control group are clearly defined

Chairperson IEC
King George's Medical University
U.P., Lucknow

	3. Sample size 45 for each group – Study and Control. Statistically derived 4. Bilingual informed consent form is provided. 5. A semi-structured socio-demographic and clinical proforma is attached 6. Tools of evaluation of OCD, Changes in Sexual functioning in males and females, Sexual QOL questionnaire for males and females and a General health questionnaire are attached. **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P104*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
105.	Research proposal entitled ***"A study of perceived coercion in non-affective psychotic disorders"*** submitted by Dr. Garima Singh, JRI, Department of Psychiatry of this University via letter no. 2090/Psy/2020 dated 11stFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P105*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
106.	Research proposal entitled ***"A study of illness perception beliefs regarding medication and treatment adherence in adolescents with attention deficit hyperactivity disorder"*** submitted by Dr. Nitika Singh, JRI, Department of Psychiatry of this University via letter no. 2081/Psy/2020 dated 10thFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 102nd ECM II B-Thesis/P106 ***(Primary Reviewer: Dr. A.A. Sonkar)***
107.	Research proposal entitled ***"A study of psychiatric morbidity, impulsivity, executive function and cortical excitability in patients with migraine"*** submitted by Dr. Nikhilesh B Shirahatti, JRI, Department of Psychiatry of this University via letter no. 2089/Psy/2020 dated 11th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly calculate the sample size **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P107*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
108.	Research proposal entitled ***"A study of psychiatric morbidity, sexual functioning and quality of life in perimenopausal femalesattending gynaecology OPD at a tertiary care Hospital"*** submitted by Dr. Teena Bansal, JRI, Department of Psychiatry of this University via letter no. 2104/Psy/2020 dated 12nd February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P108*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
109.	Research proposal entitled ***"A study of mental capacity in mania"*** submitted by Dr. Ritu Gunjyal, JRI, Department of Psychiatry of this University via letter no. 2086/Psy/2020 dated 10thFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P109*** ***(Primary Reviewer:Dr. Vimal Kumar Paliwal)***
110.	Research proposal entitled ***"A comparative study of stigma in recurrent depressive disorder and schizophrenia"*** submitted by Dr. Abhimanyu Singh, JRI, Department of Psychiatry of this University via letter no. 2107/Psy/2020 dated 13th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P110*** ***(Primary Reviewer:Dr. Rajendra Nath)***
111.	Research proposal entitled ***"A study of structural and resting state MRI of adolescent with early onset schizophrenia"*** submitted by Dr. Sumit Modi, JRI, Department of Psychiatry of this University via letter no. 2103/Psy/2020 dated 12nd February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Study design is wrong • Can not be observational cross-sectional involving cases & controls • The Consent form in English is missing • Kindly provide the CV of Dr. Uttam Kumar, Additional Officer, CBMR, SGPGIMS, Lucknow

Chairperson, IEC
King George's Medical University

	EC Comment: Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P111*** ***(Primary Reviewer: Dr. Amita Jain)***
112.	Research proposal entitled ***"Role of the inclusion of partial body weight supported treadmill training in routine rehabilitation protocol of paraplegics with respect to its effects on pulmonary function: A randomized controlled trial"*** submitted by Dr. Srutarshi Ghosh, JRIII, Department of Physical Medicine and Rehabilitation of this University via letter no. 2832/2020 dated 27th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** 1. The aim of this study is to serially measure the pulmonary functions in paraplegics receiving routine rehabilitation protocol with Partial Body Weight Support Treadmill Training (PBWSTT) and to compare it with PFT in paraplegics who are not receiving PBWSTT 2. Inclusion and exclusion criteria are clearly defined 3. Sample size 20 – how was this calculated? Was a statistician involved? 4. Bilingual consent form is provided. 5. Methodology is described in detail 6. A working proforma is attached 7. How will the randomization be done? If it is a RCT then we need Consort guidelines. **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P112*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
113.	Research proposal entitled ***"Comparison of continuous infusion of ropivacaine and fentanyl with intermittent bolus doses of ropivacaine and fentanyl for epidural labour analgesia-A randomized open label study"*** submitted by Dr. Pallavee Priyadarshini,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	JRI, Department of Anaesthesiology of this University via letter no. Anase/269/2020 dated 28th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly provide CTRI registration. **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P113*** ***(Primary Reviewer: Dr. Rajiv Garg)***
114.	Research proposal entitled ***"Anterior cruciate ligament reconstruction using peroneus longus as a graft vs hamstring tendon"*** submitted by Dr. Shitanshu Kumar Singh, JRI, Department of Orthopaedics of this University via letter no. 1389/OS/2020 dated 20thFebruary, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P114*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
115.	Research proposal entitled ***"Ischemic and bleeding profile of patients on dual antiplatelet therapy beyond 1 year of index acute coronary syndrome/percutaneous intervention"*** submitted by Dr. Mohammad Ahmad Husain, JRI, Department of Medicine of this University via letter no. 517/MED/2020 dated 3rd March, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 102nd ECM II B-Thesis/P115*** ***(Primary Reviewer:Dr. A.A. Sonkar)***
116.	Research proposal entitled ***"Outcome analysis of Arnold chiari malformation: A retrospective review of 10 years"*** submitted by Dr. Amit Kumar Deol, SRI, Department of Neurosurgery of this University via letter no. NS/124/2020 dated 25th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P116*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
117.	Research proposal entitled ***"Pain assessment in mechanically ventilated patients in intensive care units: A prospective observational comparative study"*** submitted by Dr. Safdhar Hasmi R, JRI, Department of Anaesthesiology of this University via letter no. Anaes/268/2020 dated 28th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P117*** ***(Primary Reviewer: Preeti Agarwal)***
118.	Research proposal entitled ***"Gait analysis in patients with wide resection and endoprosthesis replacement around knee"*** submitted by Dr. Sharad Verma, JRI, Department of Orthopaedics of this University via letter no. 1348/OS/2020 dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P118*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
119.	Research proposal entitled ***"Edaravone-based intervention in spinal cord injury through modulation of superoxidedismutase (SOD) and catalase (CAT) gene expression"*** submitted by Dr. Nayank Gautam, JRI, Department of Orthopaedics of this University via letter no. 1349/OS/2020 dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P119*** ***(Primary Reviewer: Dr. Rajendra Nath)***
120.	Research proposal entitled ***"Therapeutic outcome and monitoring of patients coming to psychiatry OPD with schizophrenia in tertiary care Hospital of northern India: A prospective observational study"*** submitted by Dr. Mithilesh Kumar, JRI, Department of Pharmacology & Therapeutics of this University via letter no. 197/Phar/2020 dated 5th March, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • The proposal is questionnaire based. • Kindly provide Questionnaire **EC Comment:** Approval after justification

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 102nd ECM II B-Thesis/P120 ***(Primary Reviewer: Dr. Amita Jain)***
121.	Research proposal entitled ***"Comparsion of nebulised ketamine-dexmedetomidine versus intravenous ketamine-dexmedetomidine for awake fibreoptic intubation"*** submitted by Dr. Chaitra S, JRI, Department of Anaesthesiology of this University via letter no. Anaes/278/2020 dated 7th March, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Kindly provide CTRI **EC Comment:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P121*** ***(Primary Reviewer: Dr. Rajiv Garg)***
122.	Research proposal entitled ***"Analysis of functional and radiological short term outcomes of uncemented total hip replacement"*** submitted by Dr. Md. Ash Ar Reza, JRI, Department of Orthopaedics of this University via letter no. 1355/OS/2020 dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • The aim of this study is to assess the functional and radiological short-term outcome of uncemented THR • Inclusion and exclusion criteria are clearly defined • Sample size 42. Statistically derived. • Bilingual consent form is provided. • Functional outcome will be assessed by Modified Harris Hip Score – pain ,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	deformity, ROM and limb length discrepancy. • X.Ray Pelvis AP and Lateral will show acetabular cup inclination, femoral stem positioning, horizontal and vertical centre of rotation, infection, distortion, Subsidence, loosening of implant, Osteolysis, Hetrotopic ossification, peri-prosthetic fracture and Stress shielding. • **Data collection sheet is missing. What will be observed and when?** **EC Decision:** Approval after justification ***Ref. code: 102nd ECM II B-Thesis/P122*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
123.	Research proposal entitled ***"Role of blood sugar monitoring in flap and limb revascularization surgeries"*** submitted by Dr. Manigandan K, SRI, Department of Plastic Surgery of this University via letter no. 250/2020 dated 4th March, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P123*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
124.	Research proposal entitled ***"Prospective study to define success and optimum follow up after urethral reconstruction by open surgical techniques in urethral stricture disease"*** submitted by Dr. Ravi Lohani, SRI, Department of Urology of this University via letter no. nil dated 13th March, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Different topic/title and in consent form.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• PI did not read it before sending **EC Decision:** Re-submit full proposal ***Ref. code: 102nd ECM II B-Thesis/P124*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
125.	Research proposal entitled ***"Effect of waist-hip ratio, uterine size and body mass index on sensory block level of spinal anaesthesia and hemodynamics during caesarean section"*** submitted by Dr. Vindu Yadav, JRI, Department of Anaesthesiology of this University via letter no. Anaes/240/2020 dated 25th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P125*** ***(Primary Reviewer:Dr. Smriti Bhadouria)***
126.	Research proposal entitled ***"A prospective study to evaluate role of spinal cord decompression in thoracolumbar traumatic spinal injury- A pilot study"*** submitted by Dr. Dharmendra Kumar, JRI, Department of Othopaedics of this University via letter no. 1347/05/2020 dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P126*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
127.	Research proposal entitled ***"Histopathological study of lungs in unclaimed dead bodies in king george's medical University mortuary Lucknow"*** submitted by Dr. Vishal Sharma, JRI, Department of Forensic Medicine & Toxicology of this University via letter no. 325/FMT/2020 dated 2nd June, 2020.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	The following documents were reviewed in the EC Meeting:- • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P127*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
128.	Research proposal entitled ***"Epidemiology and risk factors of neurocysticercosis-food borne parasite "Greatest Global Concern"*** submitted by Dr. Madhumathi G. S., JRIII, Department of Community Medicine and Public Health of this University via letter no. 313/CM/2020 dated 9th June, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P128*** ***(Primary Reviewer: Dr. Rajendra Nath)***
129.	Research proposal entitled ***"ALDH1 cancer stem cell marker expression in oral squamous cell carcinoma"*** submitted by Dr. Vaibhav Gupta, JRII, Department of Pathology of this University via letter no. nil dated 1stJune, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P129*** ***(Primary Reviewer: Dr. Amita Jain)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IIB
Fellowship

K.G's Medical University U.P., Lucknow

IIB	Fellowship
1.	Research proposal entitled ***"The effect of progressive resistance exercises and sports activities on bone mineral density, muscle strength, functional ability and quality of life in the children and adolescence with hemophilia"*** sponsored by Woman Scientist Scheme submitted by Ms. Geeta Suri, via his Mentor Dr. S.P. Verma, Associate Professor, Head, Department of Clinical Hematology of this University via letter no.256/CH/20 dated 1st June, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM II B-FS/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IIB
Young Scientist

K.G's Medical University U.P., Lucknow

IIB	Young Scientist- Master of Dental Sciences
1	Research proposal entitled ***"Evaluation of the PLATYSMA flap in the management of Oral submucous fibrosis (OSMD)"*** sponsored by DHR. New Delhi submitted by Dr. Aastha Singh, Young Scientist through her Mentor Prof. Uma Shamker Pal, Department of Oral and Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. OMSD/375/2020 dated 19th June, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Santioned letter of Govt. of India, Ministry of Health and Family Welfare, Department of Health Research with budget **EC Comment:** • Project aims to employ a seemingly safe but relatively lesser used procedure. The results of earlier trial are not presented therefore it is difficult to understand the possible complications/ reasons for this procedure not being in practice. • Procedure is technique oriented, and requires specific expertise. Even though minimal, chances of risk are there. Neither procedure associated risks are defined, nor is clear decision provided on provision of compensation. • Sample size has been defined but statistical analysis justifying the number of subjects being recruited is not given. **EC Decision:** Approval after justification ***Ref. code: 102nd ECM IIB-R/P1*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IIB

Ph.D. Scholars

K.G's Medical University U.P., Lucknow

II-B.	Ph. D. Scholar
1-	Research proposal entitled "***A prospective case control study to assess erectile dysfunction in men with symptomatic BPH and to see the impact of medical therapy on erectile dysfunction in men with symptomatic BPH***" submitted by Dr. Rishi Kant Gyani, PhD Scholar-2017 through his guide Prof. S.N. Sankhwar, Head, Department of Urology of this University via letter no. URO/260/2020 dated 2nd June, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Ethical approval may be granted but the registration for the PhD program applied in 2017. **EC Decision:** Reviewer has approved it. ***Ref. code: 102nd ECM II B-Ph.D/P1*** ***(Primary Reviewer: Dr. Rajiv Garg)***
2.	Research proposal entitled "***Effect of food grade pure flaxseed oil intake on tobacco craving in tobacco Dependent patients: A randomized double-blind placebo-controlled study***" submitted by Ms. Anjali Singh, PhD Scholar, via his Mentor Prof. Narsingh Verma, Department of Physiology of this University via letter no. 1711/PHY/2020 dated 19th March, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment:** • Detailed study design and methodology, aims and objectives not mentioned • Inclusion and Exclusion criteria not mentioned • Sample size- only number given-345, but sample size calculation not done. **EC Comment:** Approval after justification ***Ref. code: 102nd ECM II B-Ph.D/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IIB

Master's in Hospital Administration (MHA)

K.G's Medical University U.P., Lucknow

II-B	Master's in Hospital Administration(MHA)
1.	Research proposal entitled ***"A study of milk bank in a tertiary care Government Hospital at Lucknow"*** submitted by Dr. Anshuman Shukla, through his Mentor Dr. Nitin Dutt Bhardwaj, Department of Hospital Administration of this University via letter no. HA/2020/107 dated 8th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Waiver form **EC Comment:** • The research proposal has nicely laid the foundation of the study and if planning, designing, making policies, finalizing procedures and arranging equipments is all that has to be done then no ethical clearance is required. • It is the human resource that needs ethical clearance. Who is the actual milk doner? How are they being screened? We need consent from the donor mother as well as the mother of the neonate receiving the donation. How do we ensure that the donor mother's child is not harmed? **EC Decision:** Approval after justification ***Ref. code: 102nd ECM IIB MHA/P1*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
2.	Research proposal entitled ***"A study of medical records format in a tertiary care Government teaching Hospital"*** submitted by Dr. Saumya Sajiv Kumar Sharma, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/124 dated 19th February, 2020. ***The following documents were reviewed in the EC Meeting:-***

Chairperson, IEC
King George's Medical University

	• Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Waiver form **EC Decision:** Approved ***Ref. code: 102nd ECM IIB MHA/P2*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
3.	Research proposal entitled ***"A study of facility of vertical transportation through lifts in a tertiary care Government Hospital in Lucknow"*** submitted by Dr. Anshuman Shukla, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/105 dated 8th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Waiver form **EC Decision:** Approved ***Ref. code: 102nd ECM IIB MHA/P3*** ***(Primary Reviewer: Dr. A.A. Sonkar)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IIB

Case study

K.G's Medical University U.P., Lucknow

IIB	Case Study
1.	Research proposal entitled ***"A study of clientele satisfaction in the main OPD complex of a tertiary care government Hospital"*** submitted by Dr. Shashvat Kshitij Sinha, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/257 dated 8thJune, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Interview schedule **EC Decision:** Approved ***Ref. code: 102nd ECMIIBCS/P1*** ***(Primary Reviewer:Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"A study of clientele satisfaction in the outpatient services of physical medicine and rehabilitation Department of a tertiary care government Hospital"*** submitted by Dr. Shreya Pandey, JRII, Through his Mentor Dr. Nitin Dutt Bhardwaj, Assistant Professor, Head, Department of Hospital Administration of this University via letter no. HA/2020/256 dated 8thJune, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Interview schedule **EC Decision:** Approved ***Ref. code: 102nd ECMIIBCS/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IIB

Proposal of MBBS-Student

K.G's Medical University U.P., Lucknow

II-B	MBBS- Student
1.	Research proposal entitled ***"Serum uric acid measurement by using traditional wet chemistry versus dry chemistry fully autoanalyzer"*** sponsored by ICMR-STS New Delhi submitted by Ms. Girjanand Mishra, MBBS Student Through his Mentor Dr. Kalpana Singh, Additional Professor, Department of Biochemistry of this University this University via letter no. Bio/134/2020 dated 19th June, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECMIIBMBBS-S/P1*** ***(Primary Reviewer:Dr. Amita Jain)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IIB

M.Phil

K.G's Medical University U.P., Lucknow

II-B	M. Phil
1.	Research proposal entitled ***"A comparative study of interference control, rejection sensitivity, expressed emotions and interpersonal support in adolescents with attention deficit hyperactivity disorder with healthy control"*** submitted by Ms. Aastha Pant, Through his Mentor Dr. Pooja Mahour, Associate Professor, Department of Psychiatry of this University this University via letter no. 2085/Psy/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionaire **EC Decision:** Approved ***Ref. code: 102nd ECMIIB M.Phil/P1*** ***(Primary Reviewer:Dr. Surajit Bhattacharya)***
2.	Research proposal entitled ***"A comparative study of metacognition and social cognition in patient with major depressive disorder and bipolar disorder (currently in depression)"*** submitted by Ms. Krittika Sinha, Through his Mentor Dr. Pooja Mahour, Associate Professor, Department of Psychiatry of this University this University via letter no. 2084/Psy/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionaire **EC Decision:** Approved ***Ref. code: 102nd ECMIIB M.Phil/P2*** ***(Primary Reviewer:Dr. Rajiv Garg)***
3.	Research proposal entitled ***"A comparative study of metacognitive beliefs and response inhibition in obsessive compulsive disorder and generalized anxiety disorder"*** submitted by Mr. Sachin Kumar Prajapati, via his Mentor Prof. Shweta Singh, Department of Psychiatry of this University this University via letter no. 2083/Psy/2020 dated 10th

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved. ***Ref. code: 102nd ECMIIB M.Phil/P3*** ***(Primary Reviewer:Dr. Preeti Agarwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IIC

New Drug Trials

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 102nd ECM held on 18th August, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

<table>
<tr><th>II-C</th><th>Review of New Drug Trial</th></tr>
<tr><td>1.</td><td>Research Protocol no. entitled "A prospective observational multi-centric clinical trial to evaluate microscopic examination of various clinical samples by artificial intelligence-based system" sponsored by SEVAMOB Ventures Ltd. submitted by Prof. Prashant Gupta, Department of Microbiology of this University via letter no. nil dated 10th February, 2020.
The following documents were reviewed in the EC Meeting:-

<table>
<tr><th>Sr. No.</th><th>Document</th></tr>
<tr><td>1</td><td>Study Synopsis_Version_1.0</td></tr>
<tr><td>2</td><td>Clinical study protocol version_SVL-01/CT/01-2020</td></tr>
<tr><td>3</td><td>Patient information sheet and information consent document Hindi_Version</td></tr>
<tr><td>4</td><td>Patient information sheet and information consent document English_Version</td></tr>
<tr><td>5</td><td>Check list</td></tr>
<tr><td>6</td><td>DCGI NOC</td></tr>
<tr><td>7</td><td>Investigator Broucher</td></tr>
</table>

EC Decision: Approval subject to fulfillment & Administrative Formalities
Ref. code: 102nd ECMIIC/P1
(Primary Reviewer:Dr. Anoop Kumar Verma)</td></tr>
<tr><td>2.</td><td>Research Protocol no.ICR/191003 entitled "A randomized, multi-centric, double blind, double dummy, active controlled, parallel, comparative study to evaluate efficacy and safety of fixed dose combination of silodosin and solifenacin capsules in comparison to silodosin capsules in male patients having benign prostatic hyperplasis (BPH)/ lower urinary tract symptoms (LUTS) with over active bladder (OAB)" sponsored by Sun Pharma Laboratories Ltd. submitted by Prof. S.N. Sankhwar, Department of Urology of this University via letter no. nil dated 25th February, 2020.</td></tr>
</table>

Chairperson, IEC
King George's Medical University
U.P., Lucknow

The following documents were reviewed in the EC Meeting:-

Sr. No.	Document	Version & date
1	Information Brochure	Version 1.1, Dated 23/DEC/2019
2	Clinical Study Protocol and Appendices	Version 2.0, Dated 09/DEC/2019
3	Case Record Form and Unscheduled booklet with its Amendment History	Version 2.0, Dated 24/DEC/2019
4	Bladder Diary English and Hindi (Screening, Post Randomization visit 02, post Randomization visit 03, post Randomization visit 04)	Version 1.0, Dated 25/JUL/2019
5	Bladder Diary Hindi Translation certificate	07/Dec/2019
6	Bladder Diary Hindi Back-Translation certificate	09/Dec/2019
7	Site Specific Patient Information Sheet and Informed Consent form in English and Hindi language	Version 2.0.1, Dated 14/FEB/2020
8	Translation and Back-Translation certificate for Site Specific Patient Information Sheet and Informed Consent form in Hindi language	17/FEB/2020
9	DCGI CTNOC (CT-06-06/2020 & CT-11/FDC/20/0009	Dated 14/FEB/2020
10	Insurance Policy	4067/119274809/03/000 (From 01 July 2019 to 30 June 2020)
11	Draft Clinical Trial Agreement	Enclosed
12	CTRI	REF/2020/02/031733
13	Investigator Undertaking	Enclosed
14	CV and MRC certificate of PI	Enclosed

EC Decision: Approval after with fulfillment & administrative all formalities

Ref. code: 102nd ECMIIC/P2

Chairperson, IEC
King George's Medical University
U.P., Lucknow

(Primary Reviewer: Dr. Rajiv Garg)

3. Research Protocol no.TALO3001entitled"***A prospective, randomized, open-label, comparative, multi-centric, phase III clinical study to evaluate the efficacy and safety to triamcinolone acetonide 0.1% w/w and lignocaine Hydrochloride 2.0% w/w oromucosal gel with Dologel-CT (choline salicylate 8.7%w/w, lignocaine Hydrochloride 2.0% w/w, and benzalkonium chloride 0.01%w/w) in treatment of recurrent aphthous stomatitis (TAILOR)***" sponsored by Abbot Healthcare Pvt. Ltd. submitted by Dr. U.S. Pal, Department of Oral & Maxillofacial Surgery of this University via letter no. nil dated 3rd June, 2020.

Sr. No	Documents	Version number and date
1-	Protocol	Version 1.0 dated 27-Mar-2018
2-	Protocol	version 1.1 dated 6th March, 2020
3-	Summary of changes	Not Applicable
4-	Investigator Protocol signature Page	Version 1.1 dated 06-Mar-2020 signed on 11-May-2020
5-	Investigator Brochure	Edition IB-TALO-02 dated 06-Mar-2020
6-	Patient Information Sheet and Informed Consent Form in English	Version 1.1 dated 15 May 2020
7-	Patient Information Sheet and Informed Consent Form translated in Hindi	Version 1.1 dated 18 May 2020
8-	Patient Information Sheet and Informed Consent Form back translated from Hindi to	Version 1.1 dated 18 May

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	English	2020
9.	Patient Information Sheet and Informed Consent Form Translation certificate Hindi	Dated 18-May-2020
10.	Patient Information Sheet and Informed Consent Form Back translation certificate from Hindi to English	Dated 18-May-2020
11	Source Document 1 in English	Version 1.0 Dated 11-Mar-2020
12	Source Document 1 translated in Hindi	Version 1.0 Dated 08-May-2020
13	Source Document 1 back translated from Hindi to English	Version 1.0 Dated 08-May-2020
14	Source Document 1 Translation certificate Hindi	Dated 08-May-2020
15	Source Document 1 Back translation certificate from Hindi to English	Dated 08-May-2020
16	Source Document 2 in English	Version 1.0 Dated 11-Mar-2020
17	Source Document 2 translated in Hindi	Version 1.0 Dated 08-May-2020
18	Source Document 2 back translated from Hindi to English	Version 1.0 Dated 08-May-2020
19	Source Document 2 Translation certificate Hindi	Dated 08-May-2020

Chairperson, IEC
King George's Medical University
U.P., Lucknow

20	Source Document 2 Back translation certificate from Hindi to English	Dated 08-May-2020
21	Patient Diary in English	Version 1.1 Dated 02-Apr-2020
22	Patient Diary translated in Hindi	Version 1.1 Dated 13-May-2020
23	Patient Diary back translated from Hindi to English	Version 1.1 Dated 13-May-2020
24	Patient Diary Translation certificate Hindi	Dated 13-May-2020
25	Patient Diary Back translation certificate from Hindi to English	Dated 13-May-2020
26	Case Record Form(CRF)	Version 1.1 dated 15-Apr-2020
27	Draft CTA	Version: Draft
28	Investigator's Undertaking	Dated: 16-Mar-2020
29	Financial Disclosure(FDF)	Dated 11-May-2020
30	Updated CV Of PI	CV dated 16-Mar-2020;
31	MRC of Principal Investigator	MRC attested on 17-Mar-

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	GCP Certificate	2020 GCP attested on 16-Mar-2020
32	DCGI NOC for clinical trial	Dated: 19-Dec-2019
33	Insurance Certificate	Policy number: 4067/126600216/01/000 Policy expiration date: 31-Dec-2020 Certificate dated: 03-Apr-2020
34	Patient Accrual Method	Dated 29-May-2020

EC Decision: Approval after with fulfillment & administrative all formalities

Ref. code: 102nd ECMIIC/P3

(Primary Reviewer: Dr. Amita Jain)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IID

Nurses

K.G's Medical University U.P., Lucknow

II-D	Nurses
1.	Research proposal no. entitled ***"A descriptive study to assess the level of knowledge and attitude of hypertensive patients regarding lifestyle modification in hypertensive clinic in OPD KGMU Lucknow, U.P"*** submitted by Ms. Saurabh Singh, Ms. Seema Kumaree, Ms. Sejal Mishra, Ms. Shalini Yadav, Ms. Sheetal Gond, Mr. Sheikh Ubaid Ahmed, Mr. Sheshan Patel, Ms. Shivani Singh, Through his Mentor Mr. Omprakash Veragi, Department of KGMU College of Nursing of this University via letter no. 135/X.51 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionnaire **EC Decision:** Approved. ***Ref. code: 102nd ECM IID/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal no. entitled ***"A descriptive study to assess the quality of life among patient undergoing chemotherapy admitted in oncology and radiotherapy Department, KGMU, Lucknow"*** submitted by Mr. Abhishek Kumar, Mr. Abhishek Maurya, Mr. Abhishek Singh, Mr. Ajay Kumar Yadav, Mr. Alok Kumar Yadav, Mr. Aman Chaudhary, Amit Kumar, Mr. Amrendra Kumar Through his Mentor Mr. Ankit Raj Srivastava, & Mr. Ravi Jhajhria, Department of KGMU College of Nursing of this University via letter no. 140/X.51 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionnaire

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment: • Kindly provide Samle size calculation **EC Decision:** Approval after justification ***Ref. code: 102nd ECM IID/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Research proposal no. entitled ***"A study to assess the knowledge regarding diabetes self care management on diabetic patients in selected wards of KGMU, Lucknow, U.P"*** submitted by Miss. Akriti Verma, Miss. Anamika Bharti, Miss. Anjali Gautam, Miss Anjali Kumari, Miss. Ankit Sachan, Miss. Anshu Singh, Miss. Archana Gautam, Miss. Arti Singh Through his Mentor Miss. Manisha Anand & Mrs. Versha Rani, Department of KGMU College of Nursing of this University via letter no. 131/X.51 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionnaire **EC Decision:** Approved. ***Ref. code: 102nd ECM IID/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Research proposal no. entitled ***"A descriptive study to assess health problems and quality of life among traffic police personnel at selected areas, Lucknow. U.P., India"*** submitted by Mr. Roshani, Mr. Ranveer Gautam, Ms. Ruby, Mr. Sachin Kumar, Ms. Saher Fatima, Mr. Sanjay Kumar, Mr. Santosh Kumar, Mr. Satyam Dixit Through his Mentor Mr. Bhagwant Singh & Ms. Loveena Arpita Samuel, Department of KGMU College of Nursing of this University via letter no. 144/X.51 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Patient Information Sheet Hindi & English • Questionnaire **EC Decision:** Approved ***Ref. code: 102nd ECM IID/P4*** ***(Primary Reviewer:Dr. Rajeev Garg)***
5.	Research proposal no. entitled ***"A study to assess the effectiveness of structured teaching programme on knowledge regarding polycystic ovarian syndrome among adolescent girls at selected Government School, Lucknow, U.P"*** submitted by Ms. Poornima Verma, Mr. Pradeep Kumar Yadav, Ms. Pragya Mishra, Ms. Priti Sahani,Ms. Priya Verma, Ms. Priyanka Maurya, Ms. Priyanka Yadav, Ms. Rachna Gangwar Through his Mentor Ms. Hina Singh & Ms. Supriya Singh Department of KGMU College of Nursing of this University via letter no. 143/X.51 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionnaire **Comments by Dr Surajit** 1. The aim is to assess the pre test level of knowledge regarding PCOS in adolescent girl students, to assess the effectiveness of a structured teaching programme as well as association between their pre test knowledge scores and selected demographic variables. 2. Samole size is 56 3. Duration of study is 6 months 4. Consent to be signed by both the adolescent and an acceptable representative – teacher/parent 5. A questionnaire related to demographic variables, a self structured questionnaire related to PCOS with 30 easily understandable multiple choice questions and answer key and score key are provided in 2 languages. 6. A structured teaching programme on PCOS is attached. This is in English and Kasturba Kanya Inter College, Sahadatgunj is a Hindi medium school. **EC Decision:** Approved ***Ref. code: 102nd ECM IID/P5***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Surajit Bhattacharya)
6.	Research proposal no. entitled ***"A study to assess the relationship between life satisfaction and quality of sleep among geriatric population admitted at selected old age homes in Lucknow"*** submitted by Ms. Shreya Arya, Mr. Sudheer Kumar, Ms. Suman Soni, Ms. Suman Yadan, Ms. Swati Sharma, Ms. Tanu Pandey, Ms. Tanya Maheshwar Through his Mentor Mr. G. Srinivasan, Department of KGMU College of Nursing of this University via letter no. 136/X.51 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionnaire **EC Decision:** Approved ***Ref. code: 102nd ECM IID/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
7.	Research proposal no. entitled ***"A study to assess the effectiveness of planned teaching programme on knowledge regarding use of incentive spirometry in post-operative patient undergone abdominal surgery admitted in surgery ward at KGMU, Lucknow, U.P"*** submitted by Mr. Madhusudhan Vishwkarma, Mr. Madhusudha, Ms. Mallika Basumate, Mr. Meeeaj Ahmad, Mr. Mohd.Tehami Aftab, Ms. Neelam Yadav, Ms. Neetu Kumari, Ms. Neha Through his Mentor Mrs. Juhi Nair, & Mrs. Kumkum Yadav, Department of KGMU College of Nursing of this University via letter no. 141/X.51 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionnaire **EC Decision:** Approved ***Ref. code: 102nd ECM IID/P7*** ***(Primary Reviewer:Dr. A.A. Sonkar)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

8.	Research proposal no. entitled ***"A pre-experimental study to assess the effectiveness of planned teaching programme on knowledge regarding home based management of obesity among adolescents students in selected Schools of Lucknow, U.P"*** submitted by Ms. Deepti, Mr. Dinesh Kumar Maurya, Ms. Divyanshi Mishra, Mr. Durgesh Kumar Shukla, Mr. Gajraj Prasad, Ms. Goldi Singh, Mr. Hemant Rai, Ms. Himanshi Verma Through his Mentor Mr. Migron Rubin & Ms. Amanjeet Kaur, Department of KGMU College of Nursing of this University via letter no. 145/X.51 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionnaire **EC Decision:** Approved ***Ref. code: 102nd ECM IID/P8*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
9.	Research proposal no. entitled ***"A study to asses the effect of structured teaching program on knowledge regarding prevention of gestational diabetes mellitus among antenatal mothers in queen mary Hospital, KGMU Lucknow"*** submitted by Mr. Uday Singh, Ms. Varsha Gautam, Ms. Vikas Gupta, Mr. Vikas Yadav, Mr. Vineet Kumar, Mr. Vrij Bhushan Mishra, Ms. Jyoti Rathore Through his Mentor Mrs. Priyanka Singh & Ms. Jaya Sharma, Department of KGMU College of Nursing of this University via letter no. 146/X.51 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionnaire **EC Decision:** Approved ***Ref. code: 102nd ECM IID/P9*** ***(Primary Reviewer:Dr. Preeti Agarwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

10.	Research proposal no. entitled ***"A descriptive study to assess the risk of obstructive sleep apnoea syndrome in patients visiting Cardiology OPD, King George's Medical University, Lucknow, Uttar Pradesh"*** submitted by Ms. Jyoti Bala, Ms. Jyoti Devi, Ms. Jyoti Kumari, Mr. Jaidev, Mr. Jitendra Kumar Singh, Mr. Kamlesh Verma, Mr. Kailash Ms. Krati Tiwari, Through his Mentor Mr. Sachin Dwivedi & Mrs. Sarla Singh, Department of KGMU College of Nursing of this University via letter no. 147/X.51 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionnaire **EC Decision:** Approved ***Ref. code: 102nd ECM IID/P10*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
11.	Research proposal entitled ***"A study to assess the effectiveness of pamphlet on knowledge regarding intra uterine contraceptive device among post natal mothers in queen mary Hospital, Lucknow"*** submitted by Mr. Arvind Singh, Mr. Ashutosh Kumar, Mr. Ayush Masih, Mr. Bhoopendra Kumar Verma, Mr. Bipindra Singh, Mr. Chandra Prakash, Ms. Deeksha, Ms. Deeksha Verma, Through his Mentor Ms. Monica Lal & Ms. Aditi Mecarty, Department of KGMU College of Nursing of this University via letter no. 138/X.51 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English • Questionnaire **EC Decision:** Approved ***Ref. code: 102nd ECM IID/P11*** ***(Primary Reviewer: Dr. Rajendra Nath)***
12.	Research proposal no. entitled ***"Pre-procedural and post-procedural anxiety among patients undergoing coronary angiography in Department of Cardiology, KGMU,***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Lucknow" submitted by Ms. Neha Qadir, Ms. Nidhi Maurya, Ms. Nidhi Patel Ms. Nidhi Rathore, Ms. Nidhi Yadav, Mr. Mimish Kumar Gupta, Ms. Nivedita Patel, Ms. Poonam Yadav, Through his Mentor Mrs. Roohi Elizabeth Peter & Mr. Nayan Paul, Department of KGMU College of Nursing of this University via letter no. 142/X.51 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM IID/P12*** ***(Primary Reviewer: Dr. Amita Jain)***
13.	Research proposal no. entitled ***"Impact of web-based nurse-led programme among poor glycemic control type-2 diabetic patients"*** submitted by Mr. Sachin Dwivedi, Through his Mentor Prof. Narsingh Verma, Head, Department of KGMU College of Nursing of this University via letter no. 3932/X.51 dated 8th April, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Decision:** Approved ***Ref. code: 102nd ECM IID/P13*** ***(Primary Reviewer:Dr. Rajiv Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 102nd ECM held on 18th August, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

IIE-	Extension of previously approved trial
1.	Extension of research protocol no.PMZ-1620/CLINICAL-2.3/2018;DCGI CT NOC no. CT/ND/18/2018 entitled ***"A prospective, multicentric, randomized, double blind, saline controlled phase II clinical study to compare the safety and efficacy of PMZ1620 therapy along with standard supportive care in patients of acute spinal cord injury"*** sponsored by M/s Pharmazz India Pvt. Ltd. submitted by Dr. Shah Waliullah, Assistant Professor, Department of Orthopedic Surgery this University via letter no. nil. Dated 13rd February, 2020. **EC Decision:** Approved ***Ref. code: 93rdECM IIC/P12*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. III

Modifications

K.G's Medical University U.P., Lucknow

III-	Modification
1.	Modification of Research protocol no. D169AC00001 entitled ***"A study to evaluate the effect of dapagliflozin on renal on outcomes and cardiovascular mortality in patients with chronic kidney disease"*** sponsored by M/s AstraZeneca submitted by Dr. Satyendra Sonkar, Department of Medicine of this University via letter no.nil dated 11th February, 2020. ***The following documents were reviewed in the Meeting:-*** **Sr. No. / Documents** 1. Clinical study protocol-Version 3.0 dated 22 January, 2020 2. Memo-CSP Protocol Addendum- Version 2.0 dated 07 December, 2017 **EC Decision:** Approved ***Ref.code:84th ECMIIC/P7*** ***(Primary Reviewer: Dr. Rajendra Nath)***
2.	Modification of Research protocol no. INVICTUS ver 3.0 dated 8th November, 2019 entitled ***"Investigation of rheumatic AFTreatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** sponsored by M/s Gilead Sciences Inc submitted by Dr. Rishi Sethi, Department of Cardiology of this University via letter no.822/Cardio/Res/2020 dated 27th February, 2020. ***The following documents were reviewed in the Meeting:-*** 1.English Echocardiography Consent during and after pregnancy Final version 3.0 dated 08/11/2019 2. Hindi Echocardiography Consent during and after pregnancy Final version 3.0 dated 08/11/2019 **EC Decision:** Approved ***Ref.code:83rd ECMIIC/P6*** ***(Primary Reviewer: Dr. Amita Jain)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

3. Modification of Research protocol no. ATLS-OLE: entitled ***"An open label long term safety and efficacy study of fitusiran in patients with Hemophilia A or B, with or without inhibitory antibodies to factoe VII or IX"*** submitted by Dr. S. P. Verma, Department of Clinical Hematology of this University via letter no.nil dated 1st May, 2020.

The following documents were reviewed in the Meeting:-

Sr. No.	Documents/Language	Document/Language
1.	ALN-AT3SC-004 (Sanofi Genzyme EFC14769) Patient Agreement to DTP_English	Version and Date: 2.0 07-May-2020
2.	ALN-AT3SC-004 (Sanofi Genzyme EFC14769) Patient Agreement to DTP_Hindi and Translation Certificate	Version and Date: 2.0 07-May-2020
3.	ALN-AT3SC-004 (Sanofi Genzyme EFC14769) Patient Agreement to DTP_Hindi to English and Translation Certificate	Version and Date: 2.0 07-May-2020
4.	ALN-ALN_AT3SC-004 (Sanofi Genzyme EFC14769) Investigators' Brochure Edition 7 Memo on Typographical Error (For EC Notification	Dated 03 July, 2020

EC Decision: Approved

Ref.code:90th ECMIIC/P2

(Primary Reviewer: Dr. Rajendra Nath)

4. Modification of Research protocol no.TERIFL08918 entitled ***"A single arm phase IV clinical trial to describe the safety and efficacy of TeriflunomidE in patients with relapsing forms of multiple scierosis (SAFE trial)"*** sponsored by M/s SANOFI submitted by Prof. Hardeep Singh Malhotra, Department of Neurology of this University via letter no.nil dated 8th April,

Chairperson, IEC
King George's Medical University
U.P., Lucknow

2020.

The following documents were reviewed in the Meeting:-

Sr. No.	Documents/Language	Document/Language
2.	Amended Clinical Trial Protocol 02	Version 2.0 electronic (2.0) dated 07-Jun-2019
3.	Core Study information and informed consent form (English)	India Version 2.1 dated 25-Jun-2019
3.	Core Study information and informed consent form (English to Hindi)	India Version 2.1 dated 25-Jun-2019 Hindi translation dated 19-Jun-2019
4.	Core Study information and informed consent form (English to Hindi) Translational certificate	Dated 19-Jul-2019
5.	Core Study information and informed consent form (Hindi to English)	India Version 2.1 dated 25-Jun-2019 Hindi back translation dated 19-Jun-2019
6.	Core Study information and informed consent form (Hindi to English) Translational certificate	Dated 19-Jul-2019
7.	Case report form	Version 3.0 dated 7-Jun-2019

EC Decision: Approved

Ref.code:93rdECMIIC/P11

(Primary Reviewer: Dr. Anoop Kumar Verma)

5. Modification of Research protocol no .C3601002 (REVISIT) entitled ***A Phase 3 Prospective,***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

Randomized, Multicenter, Open Label, Central Assessor Blinded, Parallel Group, Comparative Study To Determine The Efficacy, Safety And Tolerability of Aztreonam Avibactam (ATM AVI) ± Metronidazole (MTZ) Versus Meropenem ± Colistin (MER ± COL) For the Treatment of Serious Infections Due to Gram – Negative Bacteria, Including Metallo B Lactamase (MBL) – Producing Multidrug Resistant Pathogens, For Which There Are Limited Or No Treatment Options" M/s Parexel submitted by Prof. Sandeep Tiwari, Head, Department of Trauma Surgery of this University via letter no.nil dated 24th June, 2020.

The following documents were reviewed in the Meeting:-

ICFs

- 234454_C3601002_India Dr. Sandeep Tiwari ICF_English_V 4.0_30 March 2020
- based on Study level ICD Version 6.0; dated 24 Jan 2020

- 234454_C3601002_India Dr. Sandeep Tiwari ICF_Hindi_V 4.0_30 March 2020
- based on Study level ICD Version 6.0; dated 24 Jan 2020
- Translated from English to Hindi on 05 May 2020 by RWS Life Sciences, Inc.

- 234454_C3601002_India Dr. Sandeep Tiwari ICF_Hindi_Back_Translation_V4.0_30 March 2020
- based on Study level ICD Version 6.0; dated 24 Jan 2020
  - Back Translated from Hindi to English on 05 May 2020 by RWS Life Sciences, Inc.

  - Translation and validation certificates are attached along with respective ICF

Other documents

- Protocol adminsistrative latter dated 03 Sep 2019
- IB Memo dated 13 Aug 2019
- Clinical Trial Safety Update Report 28-FEB-2018 through 27-AUG-2018 and Report dated 01-SEP-2018
- Clinical Trial Safety Update Report 28-FEB-2019 through 27-AUG-2019 and Report dated 01-SEP-2019

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• EDMC letter dated 30 Jan 2019 • Clinical Supply Letter dated 12 March 2020 • Clinical Supply Letter dated 16 October 2019 • SAE Line Listing Reporting Period: 01-JAN-1900 Through 17-APR-2020 • DCGI Notification dated 15 April 2020 of amendment ICF V4.0 dated 30 March 2020 • CTRI Registration certificate number CTRI/2018/09/015762 updated on 26 Feb 2020 • Renewal Insurance certificate dated 31 Jan 2020 **EC Decision:** Approved ***Ref.code:89th ECMIIC/P9*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
6-	Modification of research Protocol no. RI-01-006 entitled "***A randomized, double-blind, parallel- group, phase III study to compare the efficacy, safety, and immunogenicity of proposed rituximab biosimilar (DRL- RI) with MAB THERA® in subjects with previously untreated, stage II- IV, cluster of differentiation (CD)20- positive, low tumour burden follicular lymphoma***" sponsored by Reddy's Laboratories S.A submitted by Dr. Sudhir Singh, Professor Jr. Grade, Department of Radiotherapy of this University via letter no. nil dated 13th May, 2020. ***The following documents were reviewed in the Meeting:-*** ❖ Protocol RI-01-006 version 3 dated 4 Dec 2019 ❖ IB INVESTIGATOR BROCHURE; Version 7.0, 13 Sep 2019 **Main ICF:** • 242435_RI_01_006_India Dr. Sudhir Singh Main ICF_English_Version 2.0_16 Jan 2020 Based on Protocol RI-01-006_Model ICF _Version 4.0_30 Dec 2019 • 242435_RI_01_006_India Dr. Sudhir Singh Main ICF_Hindi_Version 2.0_16 Jan 2020

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Based on Protocol RI-01-006_Model ICF _Version 4.0_30 Dec 2019 Translated from English to Hindi on 06 Feb 2020 • 242435_ RI_01_006_India Dr. Sudhir Singh Main ICF_ Hindi to English_Version 2.0_16 Jan 2020 Based on Protocol RI-01-006_Model ICF _Version 4.0_30 Dec 2019 Back Translated from Hindi to English on 06 Feb 2020 **Other documents:** • 242435 GLOBAL Physician Letter 20190620 2.0 English Patient Infogetters **EC Decision:** Approved ***Ref.code:101st ECM IIC/P2*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. IV

Annual Progress Reports

K.G's Medical University U.P., Lucknow

IV-	Annual Progress Reports
1.	Annual Progress Report of research proposal entitled ***"Multicentric prospective hospital based sentinel surveillance to determine the etiology of acute bacterial meningitis in children with conventional and molecular methods"*** submitted by Prof. Shally Awasthi, Head, Department of Pediatrics of this University via letter no. nil Dated 6th March, 2020. **EC Decision:** Review & Noted ***Ref. code: 90th ECMIIA/P4*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Annual Progress Report of research protocol no. entitled ***"Prospective multicounty pneumococcal colonization research in children and adults"*** sponsored by Foundation Merieux submitted by Prof. Shally Awasthi, Head, Department of Pediatrics of this University via letter no. nil Dated 6th March, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 91th ECMIIA/P7*** ***(Primary Reviewer: Dr. Rajendra Nath)***
3.	Annual Progress Report of research protocol no. entitled ***"A comparative analysis between haplotyping, lip prints, tongue prints and thumb prints to aid in characterization and individual identification for forensic use"*** sponsored by ICMR, New Delhi submitted by Prof. Shaleen Chandra, Head, Department of Oral Pathology and Microbiology, Faculty of Dental Sciences of this University via letter no. 922/OP/2020 Dated 12th March, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 94th ECMIIA/P2*** ***(Primary Reviewer:Dr. Amita Jain)***
4.	Annual Progress Report of research protocol no. entitled ***"A study on retinoic acid responsive or non responsive Oral premalignant disorders by PRAME expression analysis"*** sponsored by Women Science and Technology, Govt. of India submitted by Prof. Shaleen Chandra, Head, Department of Oral Pathology and Microbiology, Faculty

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	of Dental Sciences of this University via letter no. 921/OP/2020 Dated 12th March, 2020. **EC Decision:** Proposal did not start because funds were not received. ***Ref. code: 95thECMIIA/P8*** ***(Primary Reviewer:Dr. Rajeev Garg)***
5.	Annual Progress Report of research protocol no. entitled ***"Congenital rubella syndrome surveillance in India"*** submitted by Prof. Shally Awasthi, Head, Department of Pediatrics of this University via letter no. 547/Ped/2020 Dated 18th March, 2020. • IEC sanction on February 22, 2019. Project started on June 1, 2019 • Total patients enrolled till Feb. 2020 + 253; Positive cases = 46 (18.1%) • Total mothers screened for seropositivity of Rubella = 301; Positive cases 266 (88.3%) • No serious adverse side effects • No protocol deviation **EC Decision:** Reviewed & noted ***Ref. code: 95thECMIIA/P24*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
6.	Annual Progress Report of research protocol no. 0063-17 entitled ***"A global, multicenter, three arms, open- label randomized study to evaluate the efficacy and safety of nanosomal docetaxel lipid suspension compared to taxotere® (Docetaxel Injection Concentrate) in triple- negative breast cancer patients with locally advanced or metastatic breast cancer after failure to prior chemotherapy"*** sponsored by Lamda Therapeutic Research Pvt. Ltd submitted by Dr. Sameer Gupta, Department of Surgical Oncology of this University via letter no. nil Dated 16th March, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 95thECMIIC/P4*** ***(Primary Reviewer:Dr. Anoop Kumar Verma)***
7.	Annual Progress Report of research protocol no.PMZ-1620/CLINICAL-2.2/2017;DCGI CT NOC No. CT/ND/66/2017entitled ***"A prospective, mulitcentre, randomized, double blind placebo controlled Phase II clinical study to compare the safety and efficacy of PMZ-1620 therapy along with standard supportive care in subjects of mild to moderate Alzheimer's disease"*** sponsored by Pharmaz India, Pvt. Ltd. submitted by Dr.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Shrikant Srivastava, Department of Geriatric Mental Health of this University via letter no. nil Dated 18th March, 2020. **EC Decision:** Reviewed & Noted ***Ref. code: 93rdECMIIC/P8*** ***(Primary Reviewer:Dr. A.A.Sonkar)***
8.	Annual Progress Report of research protocol no. entitled ***"A study to evaluate the efficacy of herbal preparations as cognitive enhancers in older adults"*** submitted by Dr. Shrikant Srivastava, Department of Geriatric Mental Health of this University via letter no. 193/OGMH/2020 Dated 19th March, 2020. **EC Decision:** Reviewed & Noted ***Ref. code: 94thECMIIA/P10*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
9.	Annual Progress Report of research protocol no. ***SYNAPSE-ICU:*** entitled ***"An international prospective observational studY on iNtrAcranial pressure in intensive care (ICU)"*** Funding by European Society of Intensive Care Medicine (ESICM) Submitted by Dr. Suhail Sarwar. Siddiqui, Assistant Professor, Department of Critical Care Medicine of this University via letter no. CCH/967/2020 Dated 18th March, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 95thECMIIA/P26*** ***(Primary Reviewer: Dr. Preeti Agarwal)***

Chairperson, IEC
King George's Medical University

K.G's Medical University U.P., Lucknow

Minutes of 102nd "Institutional Ethics Committee" Meeting held on 18th August, 2020

Item no. V

Other Matters

K.G's Medical University U.P., Lucknow

V	Other Matter-With the permission of Chair
1-	As per own request by P.I. Dr. Sameer Gupta, Professor (Jr.Grade), Department of Surgical Oncology of this University to add the Labortory Charakdhar Diagnotic Private Limited, Lucknow in the research protocol no. 0063-17 entitled ***"A global, multicenter, three arms, open- label randomized study to evaluate the efficacy and safety of nanosomal docetaxel lipid suspension compared to taxotere® (Docetaxel Injection Concentrate) in triple- negative breast cancer patients with locally advanced or metastatic breast cancer after failure to prior chemotherapy"*** sponsored by Lamda Therapeutic Research Pvt. Ltd. via letter no. nil dated 6th June, 2020. **EC Decision:** Permission granted ***Ref. code: 95th ECM IIC/P4***
2-	**Reg. Patient agreement to DTP (Direct to Patient) V2.0** research protocol no. ATLAS-OLE entitled ***"An open label long term safety and efficacy study of fitusiran in patients with hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX"*** sponsored by M/s Sanofi Genzyme submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology of this University via letter no.nil dated 10th July, 2020. **EC Decision:** Permission granted ***Ref. code: 90th ECMIIC/P1***
3-	As per direction of the Ministry of Ayush that the number patients revised 40 to 50 entitled ***"A Randomized, open label, parallel efficacy, active control, multicentre esploratory drug trial to evaluate efficacy and safety of an Ayurvedic Formulation (AYUSH-64) a adjunct treatment to standard of care for the management of mild to moderate COVID-19 patients"*** submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine of this University via letter no. MICU/2020/Jul/165 dated 11th July, 2020. **EC Decision:** Permission granted

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: IVECM IB-COVID-19/P9
4-	As per requested by the Principal-Investigator of the research proposal entitled ***"A study on dialysis centre in a tertiary care government Hospital"*** to change the Chief Supervisor Dr. Nitin Dutt Bhardwaj, Assistnat Professor, Department of Hospital Administration in place of Prof. U.B. Mishra of this University submitted by Dr. John Paul G Momin of this University via letter no. HA/2020/325 dated 16th July, 2020. **EC Decision:** Permission granted ***Ref. code: 101st ECM IIBThesis/P91***
5-	As per requested by the Principal-Investigator of the research proposal entitled ***"16s microbial profiling of gall bladder cancer"*** sponsored by Research Cell KGMU Lucknow ***to change the Co-Investigator Dr. S.K. Singh, Department of CFAR in place of Dr. Neetu Singh she was terminated, Also the Principal-Investigator want to increase the extension of the above proposal because due to technical problems he could not initiate the work*** submitted by Dr. Shiv Rajan, Department of Surgical Oncology of this University via letter no. SONC/706/20 dated 24th June, 2020. **EC Decision:** Permission granted ***Ref. code: 98th ECM II B IMR-F/P1***
6-	As per own request by the Principal-Investigator of the Research proposal entitled ***"Short term ICU training and its usefulness in increasing surge capacity during COVID-19 oNDEMIC:A SINGLE CENTRE EXPERIENCE"*** to extend the period till 31st August, 2020, submitted by Dr. Suhail Sarwar Siddiqui, Assistant Professor, Department of Critical Care Medicine of this University via letter no. CCM/2020/1228. **EC Decision:** Permission granted ***Ref.Code: 101st ECM IB/P4***
7-	As per own request by the Prinicipal-Investigator of the trial that **Patient agreement to DTP (Direct to Patient) V2.0** in this research protocol no. ***ATLAS-A/B:*** entitled ***"A***

Chairperson IEC
King George's Medical University
U.P., Lucknow

	phase 3 study to evaluate the efficacy and safety of fitusiran in patients with hemophilia A or B, without inhibitory antibodies to factor VIII or IX" sponsored by M/s Sanofi Genzyme submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology of this University via letter no.nil dated 3rd January, 2020. **EC Decision:** Permission granted ***Ref.code:90th ECMIIC/P2***

The next EC Meeting will be scheduled on 27th November, 2020 (Friday)

Thanks

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

K.G's Medical University U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. IA

Action Taken

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 103rd ECM held on 27th November, 2020

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Minutes of the 103rd ***Institutional Ethics Committee*** Meeting to be held on **27th November, 2020 (Friday) from 02.30 p.m. till 4.30 p.m.**in the **'Board Room',** Office of the Vice Chancellor, Administrative Block of this University.

The following EC Members were present in the Meeting:-

1- Prof.S.P. S Gaur	**-Chairman**
2- Justice Hon'ble Vishnu Sahai	**- Member**
3- Dr. Surajit Bhattacharya	**-Member**
4- Dr. Manju Agrawal	**-Member**
5- Mr. Yogesh Mishra	**-Member**
6- Dr. Rajiv Garg	**-Member**
7- Dr. Rajendra Nath	**-Member**
8- Dr. Preeti Agarwal	**-Member**
9- Prof. Shally Awasthi	**-Member-Secretary, Ex-officio**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

IA	Action Taken
	Part-a- 97th EC Meeting was held on 12th July, 2019
a1	Clarification of research proposal entitled ***"To evaluate the genetic association of MTR, MTRR, MTHFR in non syndromic cleft lip, cleft palate and cleft lip with palate in paediatric patients in northern India"*** submitted by Dr. Aravindhan A, JR-I, Department of Paediatric and Preventive Dentistry, Faculty of Dental Sciences of this University via letter no. nil dated 13th June, 2019. **EC Comment on 12th July, 2019:** • Though the desisn is non-randomised but the PI has callously written RCT in one place only. **EC Decision on 12th July, 2019:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by* member Secretary *& approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 97th ECM II B-Thesis/P129*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
a2.	Clarification of research proposal entitled ***"Assessment of efficacy of low level laser therapy (LLLT) with all trans retinoic acid in comparison to efficacy of steroids in osmf patients"*** submitted by Dr. Nahid Hasan, JR-I, Department of Oral Medicine and Radiology, Faculty of Dental Sciences of this University via letter no. nil dated 8th June, 2019. **EC Comment 12th July, 2019:** • Kindly provide Case record form • Sample size is not calculated • How & what mentioned is planned? **EC Decision 12th July, 2019:** Approval after justification ***The above comments forwarded to the P.I., reply was proved by the P.I. which was reviewed by the Primary reviewer & she raised following comment:***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Comment: • This is a clenical trial as appears from provided document • Properly planned study details with full proposal should be provided • Candiidate needs guidance ***The above comment again forwarded to the P.I. reply received from P.I. on 27th November, 2020.*** **EC Decision:** Forwarded to Primary reviewer ***Ref. code: 97th ECM II B-Thesis/P147*** ***(Primary Reviewer: Dr. Amita Jain)***
	Part-b- 98th EC Meeting was held on 6th September, 2019
b1.	Clarification of research proposal entitled ***"Prevalence of dyslipidemia in nonobese obstructive sleep apnea (OSA)"*** submitted by Dr. Jyoti Bajpai, SR-III, Department of Respiratory Medicine of this University via letter no. nil dated 6th August, 2019. **EC Comment on 6th September, 2019:** • Your proposal mentined study design at two places on page no. 10, which needs to be corrected. • More over according to the objective mentioned, it has to be simple observational study. So why authors do mentioned case control needs tobe clarified? • Sample size not mentioned please • This proposal needs re-submission with propoer study design and sample size. **EC Decision on 6th September, 2019:** Re-submit ***The above comment forwarded to the P.I., reply has given by P.I. which was forwarded to the Primary reviewer response was provided by the Primary reviewer with following comment:*** • Methodology is still not clear • Under Heading of Intervention-observational study is mentioned which is not appropriate

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Please elaborate the study methodology; preferably give flow chart of work **EC Decision:** Approved ***Ref. code: 98th ECM II B-Thesis/P8*** ***(Primary Reviewer: Dr. Rajeev Garg)***
b2	Clarification of research proposal entitled ***"Cathepsin S as an early biomarker for cardio vascular disease in patients of chronic kidney disease"*** submitted by Dr. Prashant Kumar Singh, JR-II, Department of Medicine of this University via letter no. 2157 dated 26th September, 2020. **EC Comment on 6th September, 2019:** • Kindly attach case sheet **EC Decision on 6th September, 2019:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by* member Secretary *& approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 98th ECM II B-Thesis/P10*** ***(Previous Primary Reviewer: Dr. Balendra Pratap Singh)***
	Part-c-100th EC Meeting was held on 25th January, 2020
c1	Clarification of research proposal entitled ***"To study the prevalence of MDR and XDR tuberculosis in patients with tubercular pericardial effusion in a tertiary care centre, North India"*** submitted by Dr. Akshyaya Pradhan, Associate Professor, Department of Cardiology of this University via letter no. 701/Cardio/Res/19 dated 2nd December, 2019. **EC Comment on 25th January, 2020:** • Where will tuberculosis microbiology be done? • Inform consent form empty, need composition as per revised format. **EC Decision on 25th January, 2020:** Approval after justification ***The above comment forwarded to the P.I. reply has given by P.I. which was reviewed***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	by the Member-Secreatary, IEC & approved. **Action takedn:** Provisionally approved **EC Decision:** Approved ***Ref. code: 100th ECM II A/P9*** ***(Primary Reviewer: Dr. Rajeev Garg)***
c2	Clarification of research proposal entitled "***Study of lipid profile in statin naïve Indian patients presenting with acute coronary syndrome: data from high volume tertiary care center in India***" submitted by Dr. Akshyaya Pradhan, Associate Professor, Department of Cardiology of this University via letter no. 700/Cardio/Res/19 dated 2nd December, 2019. **EC Comment on 25th January, 2020:** • What are criteria for high volume? • Methodology should be in greater detail. • Detail of protocol is missing (except the inclusion and exclusion criteria) • Calculated sample size is not mentioned. • Budget is not mentioned **EC Decision on 25th January, 2020:** Resubmit ***The above comment sent to the P.I. response received from P.I. which was forwarded to the Primary reviewer & he approved it.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 100th ECM II A/P10*** ***(Primary Reviewer: Dr. Rajendra Nath)***
c3.	Clarification of reacerch proposal entitled "***A prospective observation study to evaluate clinical outcomes of perindopril in stable heart failure patients switched from Ramipril***" submitted by Dr. Akshyaya Pradhan, Associate Professor, Department of Cardiology of this University via letter no. 699/Cardio/Res/19 dated 2nd December, 2019. **EC Comment on 25th January, 2020:** • There is no detailed protocol. The consent form is not as per requirement. • Details of methodology are not given. Please disclose any conflict of interest. Who will fund the project?

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision on 25th January, 2020: Resubmit ***The above comment forwarded to the P.I. reply has given by P.I. which was reviewed by the Primary Reviewer, after reviewed she has given with following Comment:*** • **No consent form attached.** • **Who will fund the study?** • **Does P.I. suggest taking the consent or not?** • **Objectives do not match with rest of the protocol & are unclear.** • **P.I. mentioned that protocol is approved by Ethics Committee. If so please provide the EC Ref. Code/Copy of Approval letter.** ***The above comment forwarded to the P.I., reply has given by the P.I. which was again reviewed by the Primary reviewer with following comment:-*** • **Approved with comment that source of funding is not declared.** ***The above comment forwarded to the P.I., reply waited from P.I.*** **EC Decision:** Kindly clarify the **"Source of funding"** ***Ref. code: 100thECM II A/P11*** ***(Primary Reviewer: Dr. Amita Jain)***
c4.	Clarification of reacerch proposal entitled ***"Role of fibroblast growth factor (FGF), epidermal growth factor (EGF) in repair of tympanic membrane perforation"*** submitted by Dr. Onkar Vedak, SR-I, Department of Otorhinolaryngology and Head-Neck Surgery of this University via letter no. nil dated 24th October, 2019. **EC Comment on 25th January, 2020:** • Kindly calculate the sample size. • Are these two agents approved for human use? • It should be submitted in a RCT format. **EC Decision on 25th January, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was forwarded to the Primary reviewer & he approved it.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 100thECM II B-Thesis/P7*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Part-d- 101st EC Meeting was held on 16th May, 2020
d1	Clarification of research proposal entitled "***Study of light pollution ALAN (Artificial light At Night) as a zeitgeber in ECOS (epigenetics, circadian gene expression, oxidative stress and sleep quality) in patients of metabolic syndrome***" sponsored by Indian Council of Medical Research New Delhi submitted by Prof. Narsingh Verma, Department of Physiology of this University via letter no. nil dated 24th January, 2020. **EC Comment on 16th May, 2020:** • Pt information sheet missing • Study design and methodology not clearly discussed • Sample size not calculated **EC Decision on 16th May, 2020:** Approval after justification ***The above comment forwarded to the P.I. response provided by the P.I. which was reviewed by the Primary reviewer & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101stECM IIA/P19*** ***(Primary Reviewer: Dr. Rajendra Nath)***
d2	Clarification of research proposal entitled "***Prevalence of germline EGFR T790M mutation in India: A nationwide cross sectional survey of newly diagnosed non-small cell lung carcinoma patients***" sponsored by Indian Council of Medical Research New Delhi submitted by Prof. Divya Mehrotra, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences of this University via letter no. OMSD/RP/800/19 dated 20th December, 2019. **EC Comment on 16th May, 2020:** • Consent forms are not as per new format, this study is a multicentre study under MRV at KGMU. Prof. Divya is a Dental Surgeon & is In-charge of this Unit. • This proposal is on lung cancer through she has included one person each from Respiratory Medicine & Pathology, is it ethical to have PI from Dentistry? **EC Decision on 16th May, 2020:** Revise

Chairperson, IEC
King George's Medical University

	The above comment forwarded to the P.I. response provided by the P.I. which was reviewed by Dr. Shally Awasthi, Member-Secretary, IEC & she approved it. **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P20*** ***(Primary Reviewer: Dr. Amita Jain)***
d3	Clarification of research proposal entitled ***"Role of taurine, supplementation in neurological recovery of acute spinal cord injury (ASCI) subjects: A prospective case-control study"*** submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 969/OS/2019 dated 16th December, 2019. **EC Comment on 16th May, 2020:** • Patient information sheet missing **EC Decision on 16th May, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by the the Member-Secretary, IEC & he approved it.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM IIA/P37*** ***(Primary Reviewer: Dr. Rajendra Nath)***
d4	Clarification of research proposal entitled ***"Demographic, psychiatric and molecular profileof extensively drug resistant tuberculosis patients (A Pilot Study)"*** submitted by Dr. Yash Jagdhari, JRI, Department of Respiratory Medicine of this University via letter no. 2004 dated 22nd August 2020. **EC Comment on 16th May, 2020:** • As Psychiatric evaluation is being also evaluated in the study someone from the Department of Psychiatry is needed. **EC Decision on 16th May, 2020:** Approval after justification ***The above comment forwarded to P.I., reply has given by P.I. which was reviewed by the Member-Secretary, IEC & he approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 101st ECM II B-Thesis/P9 ***(Primary Reviewer: Dr. Preeti Agarwal)***
d5.	Clarification of research proposal entitled ***"Evaluation of risk of fall in knee osteoarthritis: A cross- sectional study"*** submitted by Dr. Juhika Kaur Nagi, JRI, Department of Physical Medicine & Rehabilitation of this University via letter no. 2665/20 dated 7th January, 2020. **EC Comment on 23rd May, 2020:** • Why half of sample size calculated? • Topic should be rewritten? • Eg. BSS and TUG in evaluation of risk of fall. **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to P.I., reply has given by P.I. which was reviewed by the Primary Reviewer & he approved it.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P16*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
d6.	Clarification of research proposal entitled ***"A study of urine TCA cycle metabolites as a marker of nephropathy in type2 diabetes mellitus"*** submitted by Dr. Ammar Sabir Siddiqui, JRI, Department of Medicine of this University via letter no. 285/MED/2020 dated 31st January, 2020. **EC Comment on 23rd May, 2020:** • No Co-PI from Singapore is included in the study. • Funding of study is not provided, • International transfer of biomedical material should be done with certain safeguards and these were not discussed in the study. • Case report form is not attached. • Conflict of interest has to be declared by PI and co-PIs. **EC Decision on 23rd May, 2020:** Approval after justification ***The above comment forwarded to P.I., reply has given by P.I. which was reviewed by the the***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Member-Secretary, IEC & he approved it. **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P29*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
d7.	Clarification of research proposal entitled ***"A comparative analysis of the APRI and FIB-4 score for predicting severe fibrosis in chronic liver disease"*** submitted by Dr. David Zothansanga, JR, Department of Medicine of this University via letter no. 284/MED/2020 dated 31st January, 2020. **EC Comment on 23rd May, 2020:** • It appears candidate has not understood the proforma which is self explanatory, there are lots of mistakes in that, it is requested to go through it and fill it responsibly. **EC Decision on 23rd May, 2020:** Re-submit ***The above comment forwarded to P.I. reply has given by P.I. which was forwarded to the reviewer but he has not given his reply.*** **EC Decision:** Re-submit in the appropriate format, Get it forwarded by the Guide. ***Ref. code: 101st ECM II B-Thesis/P31*** ***(Primary Reviewer: Dr. Rajeev Garg)***
d8	Clarification of research proposal entitled ***"Clinical audit of severe anaemia in obstetric patients in a tertiary care centre in northern India"*** submitted by Dr. Juhi Srivastava, JRI, Department of Obstetrics & Gynaecology of this University via letter no. Nil dated 30th September, 2020. **EC Comment on 16th May, 2020:** • Sample size calculated not done? **EC Decision on 16th May, 2020:** Provisionally approved ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Member Secretary,***IEC & approved it. **Action taken:** Provisionally approved **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 101st ECM II B-Thesis/P72
	(Primary Reviewer: Dr. A.A. Sonkar)
	Part-e- 102nd EC Meeting was held on 18th August, 2020
e1.	Research proposal entitled ***"An observational qualitative study of curcumin (Lozenges) in oral submucous fibrosis (OSMF)"*** sponsored by Gelnova Laboratories India Pvt. Ltd submitted by Dr. Abhishek Bahadur Singh, Assistant Professor, Department of OTO-Rhino-Laryngology & Head & Neck Surgery of this University via letter no.866/ENT/ABS/2020 dated 11th February, 2020. **EC Comment on 18th August, 2020:** • Kindly provide sample size with calculation • What is validity? • What is being measured? **EC Decision on 18th August, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Member Secretary,***IEC & approved it. **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
e2	Clarification of research proposal entitled ***"Pharmaco-epigenetic alterations and treatment outcome in type2 diabetes mellitus (Y2DM)"*** sponsored by Centre of Excellence, Government Lucknow submitted by Prof. Kauser Usman, Department of Medicine of this University via letter no. 413/MED/2020 dated 15th February, 2020. **EC Comment on 18th August, 2020:** • Sample size given but statistical analysis to arrive on this sample size has not been presented. **EC Decision on 18th August, 2020:** Provissionally approved ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Member Secretary,IEC.***

Chairperson, IEC
King George's Medical University

	EC Decision: Approved ***Ref. code: 102nd ECM IIA/P9*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
e3	Clarification of research proposal entitled "***Efficacy and tolerability of topical 1% menthol lotion in treatment of primary localized macular cutaneous amyloidosis: A randomized triple blinded placebo-controlled trial***" submitted by Dr. Swastika Suvirya, Additional Professor, Head, Department of Dermatology and Venereology of this University via letter no. 51SkinVD/2020 dated 5th March, 2020. **EC Comment on 18th August, 2020:** • Kindly provide the sampl size. • What will be the number of subjects enrolled? • Why it is Infleplied? **EC Decision on 18th August, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Member Secretary,*** IEC & approved it. **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P14*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
e4.	Clarification of research proposal entitled "***Periodontal pathogen Fusobacterium nucleatum in Head and Neck cancer patients***" sponsored by CDHR New Delhi submitted by Prof. Uma Shanker Pal, Department of Oral and Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. OMSD/260/2020 dated 16th March, 2020. **EC Comment on 18th August, 2020:** • The study aims to evaluate the presence of Fusobacterium nucleatum in Head & Neck cancer specimens and patients and to find a relationship between its DNA status and the clinic-pathological features of Head & Neck cancers. • Project sponsored by Department of Health Research DHR, M.O.I.H & F.W.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Budget is 34 lakhs approximately. • Review of Literature is adequate • Sample will be biopsy from Cancer site and adjoining normal site and blood sample. • Quantification of F.nucleatum DNA in cancer specimen will be done by q PCR assay. • Sample size is 100. How was this derived? Was a statistician involved? **EC Comment on 18th August, 2020:** Approval after modification ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Primary reviewer,IEC &he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P16*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
e5.	Clarification of research proposal entitled "***Missed pancreatic injury in patients undergoing conservative management of blunt abdominal trauma: causes, sequelae and management***" submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology of this University via letter no. SG/257/2020 dated 8th June, 2020. **EC Comment on 18th August, 2020:** • This is a retrospective analysis of data maintained in the Consent form patient? • How P.I. proposes to take the consent from patient? • Consent forms in Hindi & English are different. **EC Desicision on 18th August, 2020:** Revise & Re-submit ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Primary Reviewer with following comment:-*** • No clarification provided request for restrospective data analysis is made. • Can be requested to revise proposal accordingly • "Re-submit" for Ethical Waiver **Action taken:** The above comment was forwarded to P.I., reply waited by P.I. **EC Decision:** Forwarded to the Primary reviewer ***Ref. code: 102nd ECM IIA/P18***

Chairperson, IEC
King George's Medical University

	(Primary Reviewer: Dr. Amita Jain)
e6	Clarification of research proposal entitled "***Impact and efficacy of in-house designed breast prosthesis models-high and low fidelity types and comparing their efficacy in teaching breast examination to women***" submitted by Dr. Pooja Ramakant, Additional Professor, Department of Endocrine Surgery of this University via letter no. 166/01/2020 dated 19th May, 2020. **EC Comment on 18th August, 2020:** • Kindly provide sample size Calculation **EC Decision on 18th August, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Member Secretary,***IEC ***& he approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P21*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
e7.	Clarification of research proposal entitled "***Randomized controlled phase3 trial on comparing efficacy and safety of neo-adjuvant concurrent chemo-radiation with neoadjuvant chemotherapy alone in patients with locally advanced breast cancer***" submitted by Dr. Pooja Ramakant, Additional Professor, Department of Endocrine Surgery of this University via letter no. 167/01/2020 dated 19th May, 2020. **EC Comment on 18th August, 2020:** • Hindi version of the consent form needs to be revised. **EC Decision on 18th August, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Primary reviewer,IEC & he approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM IIA/P22*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

e8	Clarification of research proposal entitled ***"Immunoexoression of tumor associate macrophages–CD 68 and CD163 in renal tumor"*** submitted by Dr. Nancy Gupta, JRI Department of Pathology of this University via letter no. 176/2020 dated 8th February 2020. **EC Comment on 18th August, 2020:** • The objective is to assess the immune-histochemical expression of CD68 and CD163 in renal tumours and their correlation with clinic-pathological parameters. • Inclusion and exclusion criteria are clearly defined • Sample size 80. Statistically derived • Bilingual consent form is provided. • Data collection sheet is missing. • What clinical and other investigational data -will be gathered **EC Decision on 18th August, 2020:** Approval after justification ***The above comment forwarded to the Principal-Investigator, response received fron P.I. which was reviewed by the Primary reviewer & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
e9	Clarification of research proposal entitled ***"Effect of two different inspiratory pressur level during pressure controlled face-mask ventilation for anaesthesia induction i children: A randomized trial"*** submitted by Dr. Tripti Singh, JRI, Department o Anaesthesiology of this University via letter no. nil dated nil. **EC Comment on 18th August, 2020:** • Objectives are not clear • Need to clarifiy the constitution of groups **EC Decision on 18th August, 2020:** Approval after justification ***The above comment forwarded to P.I., reply has given by P.I. which was forwarded to th reviewer, response has received from reviewer & he approved.***

Chairperson, IEC
King George's Medical University
U.P. Luc

	ActionTaken: Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P6*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
e10	Clarification of research proposal entitled***"High intensity interval training vs moderate intensity continuous training: An efficacy based study on VO2max"***submitted by Dr. Ahmad Falah Shabbir, JR, Department of Physiology of this University via letter no. nil dated nil. **EC Comment on 18th August, 2020:** • Kindly provide the sample size with calculation. **EC Decision on 18th August, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by* member Secretary *& approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P11*** ***(Primary Reviewer: Dr. Rajendra Nath)***
e11.	Clarification of research proposal entitled***"Effect of carbohydrate loading in diabetic patients undergoing laparoscopic cholecystectomy"*** submitted by Dr. Kavita Yadav, JRI, Department of Anaesthesiology of this University via letter no. Anas/159/2020 dated 10th February, 2020. **EC Comment on 18th August, 2020:** • This study is a RCT, where these are two groups of patients, one arm of patients will receive 50gm of maltodextrin in 400 ml water 2/hr prior to surgery, the other group will be NPO. • So, it requires clinical trial registration. **EC Decision on 18th August, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was forwarded the Primary reviewer, response pending by the Primary Reviewer.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Kindly provided the CTRI registration ***Ref. code: 102nd ECM II B-Thesis/P13*** ***(Primary Reviewer: Dr. Rajiv Garg)***
e12	Clarification of research proposal entitled ***"To determine levels of zearalenone in women with heavy menstrual bleeding"*** submitted by Dr. Ayushi Nayyar, JRI, Department of Pbstetrics & Gynaecology of this University via letter no. 1629/P-2020 dated 10th February, 2020. **EC Comment on 18th August, 2020:** • Kindly mention sample size with its calculation **EC Decision on 18th August, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by* member Secretary *& approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P15*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
e13	Clarification of research proposal entitled ***"Assessment of contextual and individua barriers to Oral healthcare utilization in periodontitis patients on Anderson behavioura model frame work: A multivariate analysis"*** submitted by Dr. Vidyadhar Paswan, JRII Department of Periodontology Faculty of Dental Sciences of this University via lette no.Nil dated Nil. **EC Comment on 18th August, 2020:** • Kindly provide complete check list. • This is a questionnaire-based study & kindly provide questionnaire. • English ICF is incomplete **EC Decision on 18th August, 2020:** Revise & Re-submit ***The above comment forwarded to P.I., reply has given by P.I. which was reviewed by th Primary reviewer & she approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 102nd ECM II B-Thesis/P21 ***(Primary Reviewer: Dr. Amita Jain)***
e14.	Clarification of research proposal entitled ***"A comparative study between platelet rich plasma and prolotherapy for pain relief in patients of knee osteoarthritis"*** submitted by Dr. Satyendra Singh Yadav, JRI, Department of Anaesthesiology of this University via letter no. Anaes/193/2020 dated 13th February, 2020. **EC Comment on 18th August, 2020:** • The aim of this study is to measure pain relief by Visual Analog Scale improvement in joint stiffness and complications in therapy at 1 week, 1 month, 3 month and 6 month after PRP and PLR. • Inclusion and exclusion criteria are clearly defined • Sample size 64, 32 in each group; statistically calculated. 4. Bilingual consent form is provided. • Prolotherapy will be done using 25% Dextrose • Intra-articular injection in knee joint will be done under C-Arm guidance • How will the randomization be done? • If this is an RCT, then Consort guidelines need to be followed. **EC Decision on 18th August, 2020:** Approval after justification ***The above comment forwarded to P.I., reply has given by P.I. which was reviewed by the Primary reviewer & he approved it with following condition:*** • ***I think you will have to talk to the researchers. They are not understood what we want. Alternatively you can approve it with a note.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	ActionTaken: Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P23*** ***(Primary Reviewer:Dr. Surajit Bhattacharya)***
e15.	Research proposal entitled ***"Prognostic significance of podoplanin in oral squamous cell carcinoma"*** submitted by Dr. Deval Brajesh Dubey, JRI, Department of Pathology of this University via letter no. 174/2020 dated 8th February, 2020. **EC Comment on 18th August, 2020:** • Study type is not clear • "Prospective" is the method of enrollment. • Questionnaire for collection of data is not provided **EC Decision on 18th August, 2020:** Revise & Re-submit ***The above comment forwarded to the P.I. response received from P.I. which was reviewed by the Primary reviewer with following comment:*** • **PI should submit the whole proposal with changes to make it possible to understand the changes needs otherwise it is not possible to understand the protocol.** ***The above comment forwarded to the P.I. response received from P.I. which was again reviewed by the Primary reviewer with following comment:*** • **The study design is too poor to answer the research question. The candidate needs same guidance in designing the study.** • **References & review is ok** • **No Consent form is attached** • **Need to Plan better** **Action taken:** The reply was send to the P.I. dated 11th November, 2020. Response given by the P.I. on 27th November, 2020. **EC Decision:** Forwarded to the Primary reviewer ***Ref. code: 102nd ECM II B-Thesis/P30*** ***(Primary Reviewer Dr. Amita Jain)***

Chairperson, IEC
King George's Medical University
Lucknow

e16	Clarification of research proposal entitled ***"Correlation of serum magnesium level in pregnancy with obstetric outcome"*** submitted by Dr. Shruti Agarwal, JRI, Department of Obstetrics & Gynaecology of this University via letter no. nil dated nil **EC Comment on 18th August, 2020:** • According to randamly 1000 sample size mention by Principal Investigator, but on what basis? • By which technique Mg level will be measured. • A clinical Biochemist/Clinical Pathologist must be a part of the study. **EC Decision on 18th August, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was forwarded to the Primary Reviewer & she approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P36*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
e17	Clarification of research proposal entitled ***"Awareness about practices related to self breast examination among women in Lucknow"*** submitted by Dr. Shipra, JRI, Department of Community Medicine & Public Health of this University via letter no. nil dated 5th September, 2020. **EC Comment on 18th August, 2020:** • Kindly provide the Sample size **EC Decision on 18th August, 2020:** Approval after justification ***The above comment forwarded to P.I., reply has given by P.I. which was reviewed by the Member-Secretary, IEC & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P38*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

e18	Clarification of research proposal entitled ***"A study of bronchiectasis in moderate to severe category patients of chronic obstructive pulmonary disease by using high resolution computed tomography (HRCT) thorax"*** submitted by Dr. Ankit Dineshbai Patel, JR, Department of Respiratory Medicine of this University via letter no. Nil dated Nil. **EC Comment on 18th August, 2020:** • Kindly provide study protocol. **EC Decision on 18th August, 2020:** Revise & Re-submit ***The above comment forwarded to P.I., reply has given by P.I. which was forwarded to the reviewer, response has received from reviewer & she approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P39*** ***(Primary Reviewer: Dr.Amita Jain)***
e19.	Clarification of research proposal entitled ***"Histopathological spectrum analysis of CNS tumours in tertiary care centre-A5 year study"*** submitted by Dr. Manisha Raj, JRI, Department of Pathology of this University via letter no. 234/2020 dated 12th February, 2020. **EC Comment on 18th August, 2020:** • Prospective & Retrospective study including patient specific information like age, gender with clinical presentation. • How will retrospective patients be taken as agreed? • Kindly provide waiver form **EC Decision on 18th August, 2020:** Revise & Re-submit ***The above comment forwarded to P.I., reply has given by P.I. which was forwarded to the reviewer, response has received from reviewer & she approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 102nd ECM II B-Thesis/P45
	(Primary Reviewer: Dr. Preeti Agarwal)
e20.	Clarification of research proposal entitled ***"To study role of T regulatory cells in CML patient before and after tyrosine kinase inhibitor therapy"*** submitted by Dr. Sweta Kanaujia, JRI, Department of Pathology of this University via letter no. 187/2020 dated 10th February, 2020. **EC Comment on 18th August, 2020:** • Questionnaire is not provided. • What is the study type? • If this is case control/observational/cohort study? • Sample size calculation is only possible after deciding the study type • How many cases & how many controls will be enrolled? **EC Decision on 18th August, 2020:** Revise & Re-submit ***The above comment forwarded to P.I., reply has given by P.I. which was forwarded to the reviewer, response has received from reviewer with following comment:*** • **P.I. has not resubmitted the full revised proposal, therefore, it is not possible to review this.** **Action taken:** The above comments send to the P.I. with condition to kindly re-submitt the revised full proposal. ***The above comment was forwarded to the P.I. reply has given by the P.I., then the above comment forwarded to the reviewer, reviewer has given again her reply with following comment:*** • **No case report/record form is attached.** **Action taken:** The above comment forwarded to the P.I. with condition to kindly submit the CRF on 11th Novenber, 2020. **EC Decision:** CRF Forwarded to the Primary reviewer ***Ref. code: 102nd ECM II B-Thesis/P48***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Amita Jain)
e21.	Clarification of research proposal entitled ***"Comparative evaluation of antimicrobial efficacy of propolis as an intracanal irrigant: A randomised control trial"*** submitted by Dr. Divya Pal, JRI, Department of Conservative Dentistry and Endodontics Faculty of Dental Sciences of this University via letter no. 887/2020 dated 10th February, 2020. **EC Comment on 18th August, 2020:** • Describe sample size & Method of Randomization • Change tension material & methods • Signature missing of Dr. Suib Luqman in check list & kindly provide his CV because he is out sider. • Signature of P.I. & date are missing in annexure 2 (Undertaking by P.I.) **EC Decision on 18th August, 2020:** Revise & Re-submit ***The above comment forwarded to P.I., reply has given by P.I. which was forwarded to the reviewer; response has not received from reviewer.*** **ActionTaken:** None **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P52*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
e22.	Clarification of research proposal entitled ***"Evaluation of role of exogenous melatonin in prevention of delirium in postoperative patients admitted in intensive care unit"*** submitted by Dr. Kriti Gupta, JRI, Department of Anaesthesiology of this University via letter no. Anaes/160/2020 dated 10th February, 2020. **EC Comment on 18th August, 2020:** • Describe how the patient would be randomized? • Has it been registered with DCGI/CTRI as per the need? **EC Decision on 18th August, 2020:** Approval after justification ***The above clarificationws forwarded to the Primary Reviewer but no response given by him.*** **ActionTaken:** None **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 102nd ECM II B-Thesis/P61
	(Primary Reviewer: Dr. A.A. Sonkar)
e23	Clarification of research proposal entitled ***"Effect of erector spinae block and pecs block on quality of recovery and analgesia after modified radical mastectomy: A randomized control double blind study"*** submitted by Dr. Md. Hammad Mohsin, JRI, Department of Anaesthesiology of this University via letter no. nil dated 18th February, 2020. **EC Comment on 18th August, 2020:** • Please define the known/unknown/possible list of complications of said blocks. Please also suggest the measures the PI shall take in case a study subject suffers any complications of the said procedure. **EC Comment on 18th August, 2020:** Approval after justification ***The above comment forwarded to P.I., reply has given by P.I. which was forwarded to the reviewer, response has received from reviewer & he approved.*** **EC Decision:** Approved **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P64*** ***(Primary Reviewer: Dr.Vimal Kumar Paliwal)***
e24	Clarification of research proposal entitled ***"Randomised control trial of ultrasound guided parasternal intercostals nerve block and transvers thoracis muscle plane block for post operative analgesia im cardiac surgical patients"*** submitted by Dr. Sachindra Yadav, JRI, Department of Anaesthesiology of this University via letter no. Anaes/165/2020 dated 10th February, 2020. **EC Comment on 18th August, 2020:** • This RCT is not as per CONSORT guidelines • No provision for patient's ensurance? **EC Decision on 18th August, 2020:** Revise & Re-submit ***The above comment forwarded to P.I., reply has given by P.I. which was reviewed by the***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Member-Secretary, IEC & he approved it. **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P66*** ***(Primary Reviewer: Dr.Amita Jain)***
e25	Clarification of research proposal entitled ***"Effect of spiritual music in old age patients undergoing lower limb surgery under spinal anesthesia"*** submitted by Dr. Ashiquee Arya, JRI, Department of Anaesthesiology of this University via letter no. Anaes/227/2020 dated 20th February, 2020. **EC Comment on 18th August, 2020:** • Kindly provide Clinical trial registration. **EC Decision on 18th August, 2020:** Approval after justification ***The above comment forwarded to P.I., reply has given by P.I. which was reviewed by the Member-Secretary, IEC & he approved it.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P76*** ***(Primary Reviewer: Dr. Rajiv Garg)***
e26	Clarification of research proposal entitled ***"To assess the effect of two days injectable dexaethasone therapy in resolution of uncomplicated parapneumonic effusion in Hospitalized children aged 1 month-14 years- A single blinded randomized trial"*** submitted by Dr. Anshika Mishra, JRI, Department of Paediatrics of this University via letter no. 2306/Ped/2020 dated 18th September, 2020. **EC Comment on 18th August, 2020:** • Kindly provide the CV of Prof. G.G. Agarwal, Department of Statistics, Lucknow University, Lucknow **EC Decision on 18th August, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	the Member Secretary, IEC & he approved. **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P90*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
e27	Clarification of research proposal entitled ***"Comparison of blood lactate levels with lactate clearance for predicting mortality in children presenting with shock"*** submitted by Dr. Devina Singh, JRI, Department of Paediatrics of this University via letter no. 293/Ped/2020 dated 10th February, 2020. **EC Comment on 18th August, 2020:** • Kindly provide the CV of Dr. Prabhakar Mishra, Associate Professor, Department of Biostatistics & Information, SGPGIMS, Lucknow **EC Decision on 18th August, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Member Secretary, IEC & he approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P92*** ***(Primary Reviewer: Dr. Rajendra Nath)***
e28	Clarification of research proposal entitled***"Conventional open reduction approach vs endoscopic approach for orbital floor repair a comparison"*** submitted by Dr. Ravi Katrolia, JRI, Department of Oral and Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. OMSD/260/2020 dated 24th February, 2020. **EC Comment on 18th August, 2020:** • The patients will be divided into two groups as per treatment offered to them; however no baseline details provided for which patient will be candidate for endoscopic approach or open one. If randomization will be performed, provide level of blinding to be done.No sample size justification provided.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision on 18th August, 2020: Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Primary Reviewer, IEC & she approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P99*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
e29.	Clarification of research proposal entitled ***"Role of the inclusion of partial body weight supported treadmill training in routine rehabilitation protocol of paraplegics with respect to its effects on pulmonary function: A randomized controlled trial"*** submitted by Dr. Srutarshi Ghosh, JRIII, Department of Physical Medicine and Rehabilitation of this University via letter no. 2832/2020 dated 27th February, 2020. **EC Comment on 18th August, 2020:** • The aim of this study is to serially measure the pulmonary functions in paraplegics receiving routine rehabilitation protocol with Partial Body Weight Support Treadmill Training (PBWSTT) and to compare it with PFT in paraplegics who are not receiving PBWSTT. • Inclusion and exclusion criteria are clearly defined • Sample size 20 – how was this calculated? Was a statistician involved? • Bilingual consent form is provided. • Methodology is described in detail. • A working proforma is attached • How will the randomization be done? If it is a RCT then we need Consort guidelines.

Chairperson, IEC
King George's Medical University

	EC Decision on 18th August, 2020: Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Primary Reviewer, IEC & he was given following comment:-*** • Sample size will depend on the number of variables the researchers are chasing and so a meeting with the statistician is required to finalize the study plan, particularly because it is a raer condition as the researcher is claiming. • Please give us a filled Consort guidelines form. **ActionTaken:** The above comment forwarded to the P.I., reply pending from P.I. **EC Decision:** Reply awaited by P.I. ***Ref. code: 102nd ECM II B-Thesis/P112*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
e30	Clarification of research proposal entitled ***"Comparsion of nebulised ketamine-dexmedetomidine versus intravenous ketamine-dexmedetomidine for awake fibreoptic intubation"*** submitted by Dr. Chaitra S, JRI, Department of Anaesthesiology of this University via letter no. Anaes/278/2020 dated 7th March, 2020. ***The following documents were reviewed in the EC Meeting:-*** • Check list • Undertaking by the P.I. • Brief Description of proposal/Summary (500 words) • Patient Information Sheet Hindi & English **EC Comment on 18th August, 2020:** • Kindly provide CTRI **EC Comment on 18th August, 2020:** Approval after justification ***The above comment forwarded to the P.I. reply has given by P.I. which was approved by the Member-Secretary, IEC & she approved it.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P121*** ***(Primary Reviewer: Dr. Rajiv Garg)***
e31	Clarification of research proposal entitled ***"Prospective study to define success and***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	optimum follow up after urethral reconstruction by open surgical techniques in urethral stricture disease" submitted by Dr. Ravi Lohani, SRI, Department of Urology of this University via letter no. nil dated Nil. **EC Comment on 18th August, 2020:** • Different topic/title and in consent form. • PI did not read it before sending **EC Decision on 18th August, 2020:** Re-submit full proposal ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Member Secretary & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P124*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
e32	Clarification of research proposal no. entitled ***"A descriptive study to assess the quality of life among patient undergoing chemotherapy admitted in oncology and radiotherapy Department, KGMU, Lucknow"*** submitted by Mr. Abhishek Kumar, Mr. Abhishek Maurya, Mr. Abhishek Singh, Mr. Ajay Kumar Yadav, Mr. Alok Kumar Yadav, Mr. Aman Chaudhary, Amit Kumar, Mr. Amrendra Kumar through their guides Mr. Ankit Raj Srivastava, & Mr. Ravi Jhajhria, College of Nursing of this University via letter no. 140/X.51 dated 10th February, 2020. **EC Comment on 18th August, 2020:** • Kindly provide Samle size calculation **EC Decision on 18th August, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was reviewed by the Member Secretary & approved.*** **ActionTaken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM IID/P2***

Chairperson, IEC

	(Primary Reviewer: Dr. Rajendra Nath)
e33	Research proposal entitled ***"Evaluation of the PLATYSMA flap in the management of Oral submucous fibrosis (OSMF)"*** sponsored by DHR. New Delhi submitted by Dr. Aastha Singh, Fellowship Programme to Young Scientist through her Mentor Prof. Uma Shamker Pal, Department of Oral and Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. OMSD/375/2020 dated 19th June, 2020. **EC Comment on 18th August, 2020:** • Project aims to employ a seemingly safe but relatively lesser used procedure. The results of earlier trial are not presented therefore it is difficult to understand the possible complications/ reasons for this procedure not being in practice. • Procedure is technique oriented, and requires specific expertise. Even though minimal, chances of risk are there. Neither procedure associated risks are defined, nor is clear decision provided on provision of compensation. • Sample size has been defined but statistical analysis justifying the number of subjects being recruited is not given. **EC Decision on 18th August, 2020:** Approval after justification ***The above comment sent to the P.I. response received from P.I. which was forwarded by the Primary Reviewer, reply pending.*** **ActionTaken:** None **EC Decision:** Approved ***Ref. code: 102nd ECM IIB-YS/P1*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
e34	Clarification of reserach proposal entitled ***"Hospital based study for prevalence of humoral primary immunodeficiency diseases (PID) in children with recurrent infections"*** submitted by Dr. Swati Yadav, JRI, Department of Paediatrics of this University via letter no. 283/Ped/2020 dated 7th February, 2020. **EC Comment on 18th August, 2020:** • There are many discrepancies in filling of IEC form **EC Decision on 18th August, 2020:** Approval after justification ***The above comment forwarded to the P.I. which was reviewed by Prof. Shally Awasthi, Member-Secretary, IEC & she approved it.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Action taken: Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P87*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
f	**Part-f- ADR-sub-Commettee Meeting held on today**
	Minutes of the meeting of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** held on today i.e. 27th November, 20201 from 1.30 till 2.15 pm of King George's Medical University U.P ,Lucknow. ***The following members were present in the Meeting:-*** **1. Hon'ble Justice Vishnu Sahai -Chairman** **2. Dr. Rajiv Garg - Member** **3. Dr. Rajendra Nath - Member** **4. Dr. Manju Agrawal -Member** **5. Mr. Yogesh Mishra -Member** **6. Dr. Shally Awasthi -Member Secretary, ex-officio** **Sl. DCGI** I- ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 1057/Cardio/Res/2020 dated 24th August, 2020, 1082/Cardio/Res/2020 dated 14th September, 2020 & 1136/Cardio/Res/2020 dated 26th September, 2020. a **Death**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Subject ID no. 010-0011 **Subject Initial:** N-- **SAE term:** Death on 16th March, 2020 **Causality:** Unknown **Event:** Subject felt syncope and fainted at home **Gender:** F **Age:** 23 yrs old **Weight:** 363 KG **Height:** 151 CM **Start Date:** 3rd August, 2017 **Subject History:** ***Site made a call subject# 010-0011 for 36th month follow-up visit, her LAR answered a call and told us that subject passed away-on 16th March, 2020. She did her morning activity and then she syncope and fainted. Subject expired at home. She was not taken to any hospital and no autopsy was done. They provide us death certificate.*** **ADR-sub-Committee decision:** Since a perusal of papers shows that there was no nexus between the study drug-**'Rivaroxaban'** administered to the subject, and her death and no autopsy of the corpse of deceased, who died at home, was done, no case for compensation arises.
b	**Death** **Subject ID no. 010-0035** **Subject Initial:** S--

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	SAE term: Death **Causality:** Sudden Cardiac Arrest **Event:** Heart failure (Breathlessness) with severe leg pain **Gender:** F **DOB:** 05-07-199456 yrs ole **Weight:** 50 KG **Height:** 172 CM **Start Date:** 20th February, 2018 **Subject History:** ***Site placed a call to subject# 010-0035 for 30th month follow-up visit and then the site become aware of this event that subject passed away on 16th February, 2020 at around 4 a.m. Patient developed breathlessness (DOE-NYHA IV) i.e. Heart Failure associated with leg pain (Severe) for these complains, patient was admitted in Trauma Centre (KGMU. Lucknow, UP) and succumbed to death due to sudden cardiac arrest in the hospital. Documents could not be available because all documents. No autopsy was done.*** **ADR-sub-Committee decision:** **Since a perusal of papers shows that there was no nexus between warfarin (the study drug administered to the subject) and her death, which was on account of heart failure, no autopsy on the corpse of the deceased was done and no documents were available, as they were destroyed by attendants of the subject after her cremation, no case for compensation arises.**
c	**<u>Death</u>** **Subject ID no. 010-0045**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

Subject Initial: U-Y

SAE term: Death

Causality: None

Event: Non cardio vascular Death (Suicide)

Gender: M

Age: 24 years old

Weight: 40 KG

Height: 155 CM

Start Date: 25th September, 2018

Subject History:

Site placed many calls to subject# 010-0045 for 30th month follow-up visit. Then we had sent letter at his place for Follow up. After receiving the letter subject's LAR called us and revealed that subject was committed suicide at home on date 24th February, 2020 at 8:45 PM. They informed the Police, FIR was launched. Autopsy was done. LAR provided a copy of the police application and death certificate only but they denied providing and autopsy report.

ADR-sub-Committee decision:

Since a perusal of papers shows that there was no nexus between Piraroxaban (the study drug administered to the subject) and his death and the LAR informed that the subject committed suicide at home, no case for compensation arises.

Ref. code: 83rd ECM IIC/P6

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. IB
Expedited review on COVID-19

K.G's Medical University U.P., Lucknow

IB	Expedited Review-COVID-19
1.	Expedited review of research proposal entitled ***"Pattern of acute ML admissions in India during COVID-19 era: a cardiological society of India study"*** sponsored by Cardiological Society of India submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 1032/Cardio/Res/2020 dated 10th August, 2020. ***The above proposal was forwarded to Dr. Preeti Agarwal & Dr. Rajendra Nath & both are approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: VIECM IB-COVID-19/P1***
2.	Expedited review of research proposal entitled ***"Spectrum of movement disorders in recovered patients of COVID-19 attending Neurology OPD: prospective study"*** submitted by Dr. Shweta Pandey, Associate Professor, Department of Neurology of this University via letter no. 185/Neuro/2020 dated 28th August, 2020. ***The above proposal was forwarded to Dr. Preeti Agarwal & Dr. Rajendra Nath response given by Dr. Nath & he approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: VIECM IB-COVID-19/P2***
3.	Expedited review of research proposal entitled ***"Fetomaternal outcome in COVID positive pregnant patients at tertiary care centre of northern India"*** submitted by Dr. Manju Lata Verma, Associate Professor, Department of Obstetrics and Gynecology of this University via letter no. nil dated 8th September, 2020. ***The above proposal was forwarded to Dr. A.A. Sonkar & Dr. Vimal Kumar Paliwal response was given by Dr. Sonkar & he approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: VIECMIB-COVID-19/P3
4.	Expedited review of research proposal entitled "***Vulnerable effect of lockdown on perinatal mortality during COVID-19 pandemic***" submitted by Dr. Manju Lata Verma, Associate Professor, Department of Obstetrics and Gynecology of this University via letter no. nil dated 4th September, 2020. ***The above proposal was forwarded to Dr. A.A. Sonkar & Dr. Rajiv Garg response was given by Dr. Sonkar & he approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: VIECMIB-COVID-19/P4***
5.	Expedited review of research proposal entitled "***Prevalence of SARS-CoV-2 antibodies in population of Uttar Pradesh, India: A cross-sectional study***" sponsored by Swasthya NH mission and IDSP,UP submitted by Prof. Amita Jain, Department of Microbiology of this University via letter no. 955/2020 dated 8th September, 2020. ***The above proposal was forwarded to Dr. Rajendra Nath & Dr. Preeti Agarwal, response was given both reviewers & they approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: VIECMIB-COVID-19/P5***
6.	Expedited review of **Modification** of research protocol no. entitled " ***A multicenter, phase III, double-blind, randomized, placebo controlled study to evaluate the efficacy of Recombinant BCG VPM1002 in reducing infection incidence and disease severity of SARS-COV-2/COVID-19 among high-risk subject***" submitted by Dr. D. Himanshu, Associate Professor, Department of Medicine of this University via letter no. nil dated 19th August, 2020. ***Due to urgency of COVID-19, the above proposal was forwarded to Dr. Rajendra Nath for review & ask the opinion of other Members with Complete quarm, response was given by Dr. Nath & he approved, also the other Members given these approval by email.*** **Action taken:** Provisionally approved

Chairperson, IEC
King George's Medical University

	EC Decision: Approved ***Ref. code: 101 ECM IB/P8***
7	Expedited review of research protocol no. entitled ***"A double blind, multi centre, two arm, randomized, placebo controlled Phase III clicical study to evaluate the efficacy and safety of Thymosin a -1 (Ta-1) asan add on treatment to existing standard of care treatment in moderate to severe COVID-19 patients"*** submitted by Prof. S.K. Sonkar, Department of Medicine of this University via letter no. nil dated 19th August, 2020. ***The above proposal was forwarded to Dr. Vimal Kumar Paliwal & Dr. Surajit Bhattacharya, response was given by Dr. Bhattacharya & he approved it.*** **Opinion of Dr. Bhattacharya:-** • This is a double blind, multi centre, two arms, randomized, placebo controlled Phase III clicical study to evaluate the efficacy and safety of Thymosin a -1 (Ta-1) asan add on treatment to existing standard of care treatment in moderate to severe COVID-19 patients. • This is being conducted in 7 centres in India and is sponsored by Gufic Biosciences Ltd. • Sample size is 120, 80 in active arm and 40 in placebo arm • Stratified block randomization will be done • Participants, investigators and outcome assessors will be blinded • Inclusion and exclusion criteria are clear • Primary and secondary outcomes are specified. • The active arm patients will receive SOC plus two sub cutaneous injections of 1.6mg Ta-1 from Day 1 to Day 7 • The placebo arm patients will receive SOC plus two sub cutaneous injections of placebo from Day 1 to Day 7 • A detailed study protocol has been provided • A case report form is attached • DGCI approval is attached dated August 19, 2020 • The trial is insured by Raheja QBE General Insurance Co. Ltd and the indemnity is INR 10,000,000 for every claim. **Opinion of Dr. Vimal:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Thymosin alpha-1 is a kind of polypeptide harmone produced by thymic epithelial cells that can effectively increase T cell number, support T cell differentiation, maturation and reduce cell apoptosis. • It is to be administered as subcutaneous injection thrice daily for 7 days in study group. • The background of the study appears sound and appropriate for the setting of COVID-19 related moderate to severe SARS. It is indicated in the treatment of Hepatitis B. • The required DGCI approval for the study is obtained. • The insurance policy is valid up to August 2021. • Sample size is calculated to be 120 **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: VIECM IB-COVID-19/P7***
8	Expedited review of research proposal entitled ***"National Clinical Registry of COVID-19"*** sponsored by ICMR, New Delhi submitted by Dr. D. Himanshu, Department of Medicine of this University via letter no. nil dated 19th August, 2020. ***The above proposal was forwarded to Dr. Preeti Agarwal & Dr. A.A. Sonkar, response was given by Dr. Sonkar & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: VIECM IB-COVID-19/P8***
9	Expedited review of research proposal entitled ***"A Randomized, Open Label ,Parallel Efficancy,Active Control,Multi-Centre Exploratory Drug Trial to Evaluate Effincacy and Safety of an Ayurvedic Formulation-II(Sanshamani Vati Plus) as Adjunct Treatment to Standard of care for the management of Mild to Moderate COVID-19 Patient"*** submitted by Dr. S.K. Sonkar, Prof. Jr. Grade, Department of Medicine via letter dated 14th September, 2020 & 19th October, 2020. ***The above protocol forwarded to Dr. Preeti Agarwal & Dr. Rajendra Nath for***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	review, reply has given by Dr. Rajendra Nath with following comment: • IEC Summary form not submitted • Kindly submit CTRI registration copy • Please submit Insurance Certificate • Please submit budget sheet ***The above comment forwarded to Dr. Rajendra Nath for review, reply received by the Primary Reviewer & he apporoved it:*** **Action taken:** Provisionally approved **EC Decision:** Approval after with fulfillment & administrative all formalities ***Ref. code: VIECM IB-COVID-19/P9***
10	Expedited review of research proposal entitled ***"Assessing knowledge, attitude and practices towards invermectink pre-exposure [rophylaxix for COVID-19 among Health Care Professionals"*** submitted by Dr. Ajay Kumar Verma, Prof. Jr. Grade Department of Respiratory Medicine via letter 968/20 dated 8th October, 2020. **EC Decision:** Approved ***Ref. code: VIECM IB-COVID-19/P10***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. IC
Expedited review on General proposals

K.G's Medical University U.P., Lucknow

IC	Expedited-General proposal
1.	Expedited review of research proposal entitled "***Clinicopathological, treatment and outcome study of head and neck sarcomas: a retrospective study***" submitted by Prof. Hari Ram, Department of Oral & Maxillofacial Surgery of this University via letter no. 505/OMSD/2020 dated 11th August, 2020. ***The above proposal was forwarded to Dr. Vimal Kumar Paliwal ,Dr.Preeti Agarwal & Dr. Rajiv Garg.*** ***Response received from Dr. Paliwal with his following comment:*** **Opinion of Dr. Paliwal:** **This is a retrospective chart review of head and neck sarcomas to evaluate the spectrum of clinicopathological and treatment outcome. The PI has applied for waiver of consent & Provisionally approved.** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 103rd ECM IC/P1***
2.	Expedited review of research proposal entitled "***Tools for the integrated management of childhood illness evaluation of pulse oximetry and clinical decision support algorithms in primary care pragmatic cluster randomized controlled trial, with embedded mixed methods, cost and cost-effectiveness studies in India and tanzania***" submitted by Prof. Shally Awasthi, Head, Department of Pediatrics of this University via letter no. nil dated 6th July, 2020. ***The above proposal was forwarded to Dr. Rajendra Nath for review, response has given by Dr. Nath & he approved.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 103rd ECM IC/P2***
3.	Expedited review of research proposal entitled "***To evaluate the efficacy of an alternative heparin based rota-flush solution in patients with severe coronary artery calcificagion undergoing rotational atherectomy***" submitted by Dr. Rajeev Krishna Choudhary, SR, Department of Cardiology of this University. ***The above proposal was forwarded to Dr. Preeti agarwal, response received from Dr.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Agarwal & she approved. **Action Taken:** Provisionally approved **EC Decision:** Approved ***Current Ref. code: 103rd ECM IC/P3*** ***Previous Ref. Code:99th ECM IIB-Thesis/P5***
4.	Expedited review of research proposal entitled "***Design and development of computer vision based screening tool for automatic diagnosis of osteroporosis in women***" submitted by Prof. Anit Parihar, Department of Radiodiagnosis of this University via letter no. nil dated 5th October, 2020.. ***The above proposal was forwarded to Dr. Rajendra Nath & Dr. A.A. Sonkar, response has given by both reviewers & they approved with following condition:-*** **Opinion of Dr. Nath:-** • Study design not mentioned, but it seems to be Analytical computer based comparative AI study, but P.I. should give the detail of exact study design to the Ethics Committee at the earliest. **Opinion of Dr. Sonkar:-** • Provisionally approved **Action Taken:** Get the reply to the comment. ***Current Ref. code: 103rd ECM IC/P4***
5	Expedited review of research proposal entitled "***Radiological patterns of lung injury on HRCT in COVID-19 patients: An experience from tertiary care center in India***" submitted by Dr. Amit Kumar Verma, Department of Radiodiagnosis of this University via letter no. 512/RD/2020 dated 22nd September, 2020. ***The above proposal was forwarded to Dr. Rajendra Nath & Dr. Preeti Agarwal, response has given by both reviewers & they approved.*** **EC Decision:** • Provisionally approved with condition to kindly get the calculate sample size. **Action Taken:** Get the reply to the comment. ***Current Ref. code: 103rd ECM IC/P5***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. ID
Modification of Expedited review

K.G's Medical University U.P., Lucknow

ID	Modification-Expedited Review
1	Expedited review of **Modification for CSP Ver 4.0** under the research protocol no. D169AC00001 ***"A study to evaluate the effect of Dapagliflozin on Renal Outcomes and Cardiovascular Mortality in Patients with Chronic Kidney Disease"*** submitted by Dr. S.K. Sonkar, Professor (Jr. Grade), Department of Medicine of this University via letter no.nil dated 12th November, 2020. ***The above modification was forwarded to Dr. Rajendra Nath, for review, reply has given by Dr. Nath & he approved it.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. Code 84th ECM IIC/P7*** ***(Primary Reviewer:Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. IIA
New Proposals

K.G's Medical University U.P., Lucknow

II-A	New Proposal
1.	Research proposal entitled ***"Corneal hysteresis in adult Indian population"*** submitted by Dr. Rajat Mohan Srivastava, Assistant Professor, Department of Ophthalmology of this University via letter no.305/OPH/2020 dated 26th June, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Copy of protocol • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rdECM IIA/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"Study of prognostic factor in IHPS"*** submitted by Dr. Archika Gupta, Associate Professor, Department of Paediatric Surgery of this University via letter no.455/Ped Sey/2020 dated 30th June, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Copy of protocol • Undertaking by the P.I. • Hindi & English ICF **EC Comment:** • Kindly calculate the sample size **EC Decision:** Approval after justification ***Ref. code: 103rdECM IIA/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

3.	Research proposal entitled **"*Overview of patients referred to orthoptic clinic of a tertiary care facility in India*"** submitted by Dr. Siddharth Agrawal, Additional Professor, Department of Ophthalmology of this University via letter no.325/OPH/2020 dated 1st July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • This is an observational study planned any details available patient registry at Department. • There are no patient available as recordwise be studied retrospectively. **EC Decision:** Please clarify, if cases were reviewed with that time. ***Ref. code: 103rdECM IIA/P3*** ***(Primary Reviewer: Dr. Amita Jain)***
4.	Research proposal entitled **"*Role of prostate tumor over expression1 (PTOV1) in horizontal transfer of bioactive molecules via exosomes in breast cancer cells and its clinical implications*"** submitted by Dr. Kul Ranjan Singh, Associate Professor, Department of Endocrine Surgery of this University via letter no .END/206/2020 dated 30th June, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References • CV of Dr. Yuba Raj Pokharel, Assistant Professor, Cancer Biology Laboratory, Faculty of Life Sciences and Biothechnology, South s Asian University, South Asia University, New Delhi, (India)

Chairperson, IEC
King George's Medical
U.P., Lucknow

	• CV of Prof. Senthil Kumar Venugopal, Dean FLSB, SAU **EC Decision:** Approved ***Ref. code: 103rd ECM IIA/P4*** ***(Primary Reviewer: Dr. Rajiv Garg)***
5.	Research proposal entitled "***Workplace violence against obstetric health care personnel in North India: A multicentric survey***" submitted by Dr. Smriti Agarwal, Additional Professor, Department of Obstetrics and Gynaecology of this University via letter no. nil dated 7th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM IIA/P5*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
6.	Research proposal entitled "***A retrospective demographic analysis of oral cancer and oral epihelial dysplasia in a tertiary care institution: A database study***" submitted by Dr. Fahad Mansoor Samadi, Associate Professor, Department of Oral Pathology & Microbiology Faculty of Dental Sciences of this University via letter no. 1070/OP/2020 dated 8th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Waiver form • References **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 103rd ECM IIA/P6
	(Primary Reviewer: Dr. A.A. Sonkar)
7.	Research proposal entitled "***Retrospective data analysis and distribution of odontogenic cysts and tumors in a teaching hospital-based population: A database study with systematic review***" submitted by Dr. Fahad Mansoor Samadi, Associate Professor, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences of this University via letter no. 1068/OP/2020 dated 8th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Waiver form • References **EC Comment:** • Kindly provided sample size and justification. **EC Decision:** Approval subject to justification ***Ref. code: 103rd ECM IIA/P7*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
8.	Research proposal entitled "***Spectrum of ectopic pregnancies at tertiary care centre of northern India***" submitted by Dr. Manju Lata Verma, Associate Professor, Department of Obstetrics & Gynaecology of this University via letter no. 1664/2020 dated 9th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Waiver form • References **EC Decision:** • Waiver Granted ***Ref. code: 103rd ECM IIA/P8***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Preeti Agarwal)
9.	Research proposal entitled ***"Analysis of radiological and functional outcome in non-union tibia managed by osteoperiosteal decortications flap technique "*** submitted by Prof. Ajai Singh, Head, Department of Paediatric Orthopedics of this University via letter no. 481/Paed Ortho/2020 dated 27th June, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Waiver form • References • CV of Dr. Vineet Kumar, Associate Professor, Department of Orthopaedic Surgery, RMLIMS, Lucknow • Dr. Pankaj Aggarwal, Department of Orthopaedic Surgery, RMLIMS, Lucknow **EC Decision:** Waiver granted Ensure that data is anonymized ***Ref. code: 103rd ECM IIA/P9*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
10.	Research proposal entitled ***"Improving recovery outcome for burns survivors in India: A systems approach"*** sponsored by ICMR New Delhi submitted by Prof. Brijesh Mishra, Head, Department of Plastic surgery of this University via letter no. 653/2020 dated 13rd July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Waiver form • Hindi & English ICF • CV of Dr. Amit Goel, Additional Officer, Department of Gastroenterology, SGPGIMS, Lucknow • References

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment: • Detailed methodology including Study design , Inclusion and Exclusion criteria not submitted (Protocol missing, only brief detail in summary is given) • Sample size calculation not given • Patient information sheet not submitted **EC Decision:** Approval after justification ***Ref. code: 103rdECM IIA/P10*** ***(Primary Reviewer: Dr. Rajendra Nath)***
11.	Research proposal entitled "***Incidence of intrahepatic cholestasis of pregnancy in pregnant Indian women***" submitted by Dr. Manju Lata Verma, Associate Professor, Department of Obstetrics and Gynaecology of this University via letter no. 1663/2020 dated 9thJuly, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • CV of Dr. Amit Goel, Additional Officer, Department of Gastroenterology, SGPGIMS, Lucknow • References **EC Comment:** • This is a grossly incomplete project. There is no clarity on methods, data recording, inclusion, justification and analysis. **EC Decision:** Re-submit ***Ref. code: 103rdECM IIA/P11*** ***(Primary Reviewer: Dr. Amita Jain)***
12.	Research proposal entitled "***Role of Wnt/β-catenin signaling in stroma-mediated chemoresistance of acute myeloid leukemia***" sponsored by Science & Engineering Research Board, DST submitted by Prof. R.N Srivastava, Department of Orthopaedic Surgery of this University via letter no. 107/POS/2020 dated 14th July, 2020. ***The following documents were reviewed in the EC Meeting:***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • CV of Dr. Neeraj K Satija,Senior Scientist, CSIR, IITR Mahatma Gandhi Marg, Lucknow • References **EC Comment:** • This is a grossly incomplete project. There is no clarity on methods, data recording, inclusion, justification and analysis. **EC Decision:** Re-submit ***Ref. code: 103rdECM IIA/P12*** ***(Primary Reviewer: Dr. Rajiv Garg)***
13.	Research proposal entitled "***Impact and stakeholders' perspective of the new MCI/NMC MBBS curriculum on undergraduate Medical education: the KGMedEd cohort study***" submitted by Prof. Anita Rani, Department of Anatomy of this University via letter no. 133/ANAT/2020 dated 16th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • Flowchart of KGMedED Cohort Study and Data Collection • References **EC Decision:** Approved ***Ref. code: 103rdECM IIA/P13*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
14.	Research proposal entitled "***Efficacy of platysma myocutaneous flap in oral defects: A retrospective study***" submitted by Prof. Uma Shanker Pal, Department of Oral and Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. 454/OMSO/2020 dated 25th July, 2020.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	The following documents were reviewed in the EC Meeting: • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • Flowchart of KGMedED Cohort Study and Data Collection • References **EC Comment:** • Please give study design? Clarify in details, has the data been acquiesced? **EC Decision:** Approval after justification ***Ref. code: 103rd ECM IIA/P14*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
15.	Research proposal entitled ***"Cluster randomised trial of sterile glove and instrument change at the time of wound closure to reduce surgical site infection (ChEETAh Protocol)"*** sponsored by Birgit Whitman Research Governance Team submitted by Dr. Shiv Rajan, Assistant Professor, Department of Surgical Oncology of this University via letter no. 824/2020 dated 23rd July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • ChEETAh Protocol- version 2.0 dated 09.07.2019 • ChEETAh case report forms (30-day verbal consent) Version 1.0 dated 21-Aug-2019 • ChEETAh case report forms (30-daywritten consent) Version 1.0 dated 21-Aug-2019 • CTRI registration, registration no: CTRI/2020/02/023606 • References **EC Decision:** Approved ***Ref. code: 103rd ECM IIA/P15***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Smriti Bhadouria)
16.	Research proposal entitled **"*Analysis of impact of lockdown on head injury patients admitted at trauma centre KGMU during corona pandemic*"** submitted by Dr. Somil Jaiswal, Associate Professor Department of Neurosurgery of this University via letter no. 1022/2020 dated 7th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • Case Record Form **EC Decision:** Approved ***Ref. code: 103rdECM IIA/P16*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
17.	Research proposal entitled **"*Endoscopic transcortical transventricular management of cystic craniopharyngioma: outcome analysis of 32 cases at a tertiary care center*"** submitted by Dr. Somil Jaiswal, Associate Professor, Department of Neurosurgery of this University via letter no. NS/1010/2020 dated 8th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • Case Record Form **EC Comment:** • This seems to be retrospective data collection.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Rewrite & Re-submit ***Ref. code: 103rd ECM IIA/P17*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
18.	Research proposal entitled ***"Endoscopic removal of spinal intradural extramedullary tumors and dural repair with clips: analysis of first 20 cases"*** submitted by Dr. Somil Jaiswal, Associate Professor, Department of Neurosurgery of this University via letter no. NS/1033/2020 dated 11th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • Case Record Form **EC Comment:** • Sample size not calculated (PI is taking first come 20 pts) • Study designed not mentioned **EC Decision:** Approval after justification ***Ref. code: 103rd ECM IIA/P18*** ***(Primary Reviewer: Dr. Rajendra Nath)***
19.	Research proposal entitled ***"Incidence of skin necrosis using cold knife or electrocautery for elevating skin flaps during inguinal lymph node dissection- a pilot study"*** submitted by Dr. Shiv Rajan, Assistant Professor, Department of Surgical Oncology of this University via letter no. nil dated 2nd August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • Case Record Form **EC Comment:** • The ICF used is the older version, new form should be prepared & submitted

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Only information which will be available at the end of study is no. of persons developing necrosis 25 cases undergone process. **EC Decision:** Revise ***Ref. code: 103rd ECM IIA/P19*** ***(Primary Reviewer: Dr. Amita Jain)***
20.	Research proposal entitled "***Effect of yogic practices and pumpkin seed supplementation as adjuvants in "Type 2 diabetes mellitus***" sponsored by Biotechnobgy submitted by Prof. Neena Srivastava, Department of Physiology of this University via letter no. 1954/PHY/2020 dated 17th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF **EC Comment:** • Kindly provide the detailed proposal alongwith scientific basic of use of Pumpkin seeds. **EC Decision:** Approval subject to justification ***Ref. code: 103rd ECM IIA/P20*** ***(Primary Reviewer: Dr. Rajiv Garg)***
21.	Research proposal entitled "***Hot spot mapping and analysis of primary surgeon related factors in post cholecystectomy bile duct injury***" submitted by Prof. Abhijit Chandra, Department of Surgical Gastroenterology of this University via letter no. 406/2020 dated 18th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • BDI mapping performa **EC Comment:**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• It is a retrograde study, so question of consent will arise, so P.I. needs to clarify about consent issue. **EC Decision:** Approval subject to justification ***Ref. code: 103rd ECM IIA/P21*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
22.	Research proposal entitled "***Placement of vascularised fibrofatty tissue in empty scrotum as provisional testicular implant after high orchidectomy for testicular tumor***" submitted by Prof. S.N Kureel, Head, Department of Pediatric Surgery of this University via letter no.492/Ped Sy/2020 dated 18th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Hindi & English ICF **EC Comment:** • No review of Litrature **EC Decision:** Re-submit ***Ref. code: 103rd ECM IIA/P22*** ***(Primary Reviewer: Dr. A.A.Sonkar)***
23.	Research proposal entitled "***Deciphering FLT3-ITD elicited signaling pathways in AML cell growth and block in differentiation: hunt for therapeutic targets and inhibitors for mutant FLT3 proteins***" submitted by Prof. M.L.B. Bhatt, Ex-Hon'ble Vice Chancellor & Department of Radiotherapy of this University via letter no. 475/RT/2020 dated 1st September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Hindi & English ICF • CV of Dr. Arun K Trivedi, Principal-Scientist, CSIR-CDRI, Lucknow **EC Decision:** Approved ***Ref. code: 103rd ECM IIA/P23***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Smriti Bhadauria)
24.	Research proposal entitled "***A randomized study of consolidation chemoradiation versus observation after first line chemotherapy in locally advanced carcinoma gallbladder***" submitted by Prof. Kirti Srivastava, Department of Radiotherapy of this University via letter no. 427/RT/2020 dated 13th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • CV of Prof. Sushma Agrawal, SGPGIMS, Lucknow **EC Decision:** Approved ***Ref. code: 103rdECM IIA/P24*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
25.	Research proposal entitled "***Perioperative outcome of head and neck cancer surgery in COVID pandemic***" submitted by Dr. Naseem Akhtar, Department of Surgical Oncology of this University via letter no. nil dated 9th September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF **EC Comment:** • **PI plans to do a prospective study to evaluate the outcome of head and neck cancer surgery during the covid times. There are several issues with the study methods:** • The study duration is not defined. How the PI is going to define "COVID times" prospectively. • The sample size is not calculated. Please calculate the sample size. • The study will be of no meaning if the PI does not compare the outcome of

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	head and neck cancer surgery from pre or post-COVID times. Since the **"POST-COVID times"** are difficult to define, the PI can only compare the outcome of their patients from "PRE-COVID" outcome data. Does the PI have pre-covid outcome data of his head and neck cancer surgery patients? • Inclusion criteria are not properly defined. Will the PI include susceptible population? **EC Comment:** Kindly resubmit with revised methodology ***Ref. code: 103rd ECM IIA/P25*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
26.	Research proposal entitled ***"Analysis of COL9A1 gene polymorphism in paediatric population with Club foot: A case-parent dyad study"*** sponsored by UP.CST, Lucknow submitted by Prof. Ajai Singh, Head, Department of Paediatric Orthopaedics of this University via letter no. 538/Paed.Orth/2020 dated 14th September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Proposal • Undertaking by the P.I. • Hindi & English ICF • Patient Data Sheet **EC Decision:** Approved ***Ref. code: 103rd ECM IIA/P26*** ***(Primary Reviewer: Dr. Rajendra Nath)***
27.	Research proposal entitled ***"An international, cluster randomized-sequence study of a 'safe-anastomosis' quality improvement intervention to reduce anastomotic leak following right colectomy and ileocaecal resection"*** sponsored by Birgit Whitman Research Governance submitted by Dr. Shiv Rajan, Assistant Professor, Department of Surgical Oncology of this University via letter no. nil dated 18th September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list

Chairperson, IEC
King George's Medical

	• Protocol synopsis version0.21, 18th September, 2019 • EAGLE Case report form version0.21, 18th September, 2019 • Undertaking by the P.I. • Hindi & English ICF **EC Decision:** Approved ***Ref. code: 103rd ECM IIA/P27*** ***(Primary Reviewer: Dr. Amita Jain)***
28.	Research proposal entitled ***"Impact of audio-visual 3D animation in understanding the spread of infection in maxillofacial region"*** submitted by Prof. Divya Mehrotra, Department of Oral and Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. OMSD/RP/218/2020 dated 9th September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Proposal • Undertaking by the P.I. • Hindi & English ICF • CV of Dr. Pankhuri Mehrotra, BDS student, Babu Banarsi Das College of Dental Sciences, Lucknow, India. **EC Comment:** • It is a very good proposal where the investigations wish to develop 3-D animation video for BDA IV year student which can be used on digital platform. • There is no mention of the monetary benefit if it occurs by de elopement of this tool (edutainment), what would be the share of Institute. This needs to be addressed. • Rest is ok • What will be source of funding • Will this education tool be patented? **EC Decision:** Approval subject to Modification ***Ref. code: 103rd ECM IIA/P28*** ***(Primary Reviewer: Dr. Rajiv Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. IIB
New Thesis

K.G's Medical University U.P., Lucknow

II B	New Thesis-Resident
1.	Research proposal entitled ***"Comparative study of perioperative multimodal analgesia versus epidural analgesia in lower abdominal surgeries"*** submitted by Dr. Jagriti, JRI, Department of Anaesthesiology of this University via letter no. Anes/300/2020 dated 12th March, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • The aim of this study is to compare the perioperative multimodal analgesia using pregabalin, nefopam hydrochloride and paracetamol versus epidural analgesia in lower abdominal surgeries • Pregabalin is a gabapentin derivative and Nefopam hydrochloride is a non steroidal, non opioid centrally acting analgesic • Sample size is 35 in each group; statistically derived • Inclusion and exclusion criteria are defined • Consent form in 2 languages has been provided • Visual Analog Scale pain score and post operative diaclofenac requirement will be monitored for comparison. • Data collection sheet is missing **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P1*** ***(Primary Reviewer:Dr. Surajit Bhattacharya)***
2.	Research proposal entitled ***"Comparison of effect of dexmedetomidine versus fentanyl to assess neuroendocrine stress response in laparoscopic cholecystectomy in non-diabetic patients"*** submitted by Dr. Indu Singh, JRI, Department of Anaesthesiology of this University via letter no. Anes/164/2020 dated 10th February, 2020. ***The following documents were reviewed in the EC Meeting:***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • As it is a RCT, so, P.I. needs to follow the CONSORT guidelines, hence advised to revise accordingly. **EC Decision:** Re-submit ***Ref. code: 103rd ECM II B-Thesis/P2*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
3.	Research proposal entitled ***"A prospective study of Ca prostate with development of a lookup table for the prediction of metastatic prostate cancer according to prostatic-specific antigen value, clinical tumor stage, and gleason grade groups"*** submitted by Dr. Sashiraj Singh, SRI, Department of Urology of this University via letter no. 302/URO/2020 dated 2nd July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rdECM II B-Thesis/P3*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
4.	Research proposal entitled ***"A study of resources and radiation equipment utilization of radiotherapy Department in a tertiary care Government Hospital"*** submitted by Dr. Supriya Singh, JRII, Department of Hospital Administration of this University via letter no. HA/299/2020 dated 30th June, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Summary • Undertaking by the P.I. • Waiver • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P4*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
5.	Research proposal entitled ***"Assessment of effects of subgingival boric acid irrigation as an adjunct in chronic periodontitis patients- A clinic-microbiological study"*** submitted by Dr. Jaya Agrawal, JRI, Department of Periodontology, Faculty of Dental Sciences of this University via letter no. 2050/2020 dated 3rd July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P5*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
6.	Research proposal entitled ***"A retrospective data analysis of Hepatitis B in teaching Hospital-based population in past 1.5 years- A database study"*** submitted by Dr. Jaya Singh, SRII, Department of Oral Pathology Microbiology, Faculty of Dental Sciences of this University via letter no. 1069/OP/2020 dated 8th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Waiver **EC Comment:** **PI wants to know the prevalence of Hepatitis B in patients visiting the**

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	department of oral and maxillofacial surgery department of KGMU. There are issues with this study: • This is not much of a study. The research question is not defined and the background of the study is not adequately discussed. • The topic of the study does not reflect that the prevalence will be studied retrospectively and only among the patients visiting the oral and maxillofacial surgery department. **EC Decision:** Please resubmit with clear background for the study, convincing research question and appropriate methods to answer the research question. ***Ref. code: 103rd ECM II B-Thesis/P6*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
7.	Research proposal entitled ***"Demographic profile & different treatment outcome of urothelial carcinoma at a tertiary care centre in northern India : A retrospective & prospective study"*** submitted by Dr. Ravi Prakash Mishra, SR, Department of Urology of this University via letter no. 325/URO/2020 dated 10th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • CRF • References **EC Comment:** • Methodology has not been discussed in detail only summary given • Inclusion / Exclusion criteria- not mentioned • Sample size (Only number is given) calculation not done **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P7***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Rajendra Nath)
8.	Research proposal entitled ***"Prone vs supine position percutaneous nephrolithotomy: A prospective comparative study"*** submitted by Dr. Sahil Kapoor, SR, Department of Urology of this University via letter no. 316/URO/2020 dated 7th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • CRF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P8*** ***(Primary Reviewer: Dr. Amita Jain)***
9.	Research proposal entitled ***"Assessment of Psychological impact on Dental Health professionals during COVID-19 outbreak"*** submitted by Dr. Shruti Singh, SRIII, Department of Oral Pathology & Microbiology Faculty of Dental Sciences of this University via letter no. 1075/OP/2020 dated 10thJuly, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Waiver • References **EC Comment:** • Kindly clarify Exclusion criteria. In inclusion criteria all dental undergraduate and PGs included and in exclusion criteria-2-Dental students who are pursuing then study will be excluded, By this what actually do we understand has all the students are here to pursue their studies, Please clarify this. **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P9***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Rajiv Garg)
10.	Research proposal entitled ***"A retrospective data analysis of hepatitis C in Teaching Hospital-based population in past 1.5 years-A database study"*** submitted by Dr. Jaya Singh, SR, Department of Oral Pathology & Microbiology Faculty of Dental Sciences of this University via letter no. 1074/OP/2020 dated 10th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Waiver • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P10*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
11.	Research proposal entitled ***"Invincible against the invisible; anexploratory study on the knowledge, attitude and practice of COVID-19 amongst the vulnerable frontline non-healthcare workers"*** submitted by Dr. Jaya Singh, SR, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences of this University via letter no. 1073/OP/2020 dated 10th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Waiver • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P11*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
12.	Research proposal entitled ***"Study of muscle bleeds, nerve impingement, joint dysfunction and functional disability in Hemophilia patients: A cross sectional study in a tertiary care center in North India"*** submitted by Ms. Geeta Suri, Physiotherapist, Department of Clinical

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Hematology of this University via letter no. 344/CH/2020 dated 16th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P12*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
13.	Research proposal entitled ***"Critical analysis of peripartum Hysterectomies at tertiary care centre of Northern India"*** submitted by Dr. Sonia Prasad, SRII, Department of Obstetrics and Gynaecology of this University via letter no. OG/1825/2020 dated 21st July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Waiver • References **EC Decision:** Waiver granted ***Ref. code: 103rd ECM II B-Thesis/P13*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
14.	Research proposal entitled ***"A study of peri-operative arterial lactate, CRP, neutrophil count and neutrophil to lymphocyte ratio in patients undergoing surgery with cardiopulmonary bypass"*** submitted by Dr. Mohammad Zeeshan Hakim, SRI, Department of Cardiovascular and Thoracic Surgery of this University via letter no. CVTS/202/2020 dated 16th March, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• References **EC Comment:** **This is a prospective study to evaluate the role of several acute blood parameters in determining their prognostic role for sepsis and shock. There are some issues:** • The study can only commence after obtaining the ethical clearance. The duration of study is written as January 2020 to June 2021. Needs to be redefined. • The sample size has to be statistically determined. **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P14*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
15.	Research proposal entitled ***"To study the association of serum homocysteine, C-reactive protein, uric acid & pro-brain natriuretic peptide (PRO-BNP) in patients with ischemic stroke at a tertiary care centre in northern India"*** submitted by Dr. Himanshu Chauhan, JR, Department of Medicine of this University via letter no. 389/Med/2020 dated 20th March, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • Sample size calculation is not done **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P15*** ***(Primary Reviewer: Dr. Rajendra Nath)***
16.	Research proposal entitled ***"Evaluation of ocular surface (Conjunctiva and Cornea) in***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	patients with thyroid associated Ophthalmopathy" submitted by Dr. Ashutosh Maharana, JRI, Department of Ophthalmology of this University via letter no. 2336/OPH/2020 dated 18thMarch, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rdECM II B-Thesis/P16*** ***(Primary Reviewer: Dr. Amita Jain)***
17.	Research proposal entitled ***"Sentinel lymph node evaluation in modified inguinal lymph node dissection in patients of carcinoma penis using indocyanin green dye"*** submitted by Dr. Rachit Nigam, JRI, Department of General Surgery of this University via letter no. 580/2020 dated 21stMarch, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rdECM II B-Thesis/P17*** ***(Primary Reviewer: Dr. Rajiv Garg)***
18.	Research proposal entitled ***"Prospective evaluation of eversion of sac and aspiration sclerotherapy in management of vaginal hydrocele"*** submitted by Dr. Akshat Agarwal, JRI, Department of General Surgery of this University via letter no. 577/2020 dated 16thMarch, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P18*** ***(Primary Reviewer: Dr.Anoop Kumar Verma)***
19.	Research proposal entitled ***"The relationship between pre and post-operative c-reactive protein (CRP), neutrophil to lymphocyte ratio (NLR) and platelet to lymphocyte ratio (PLR) with post-operative pain after total hip and knee arthroplasty"*** submitted by Dr. Akshay Rathee, JRI, Department of Anaesthesiology of this University via letter no. Anaes/225/2020 dated 20th February, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P19*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
20.	Research proposal entitled ***"Comparison of EQ 5D 5L score and oxford hip score in patients undergoing total hip arthroplasty"*** submitted by Dr. Santosh Kumar Sharma, JRI, Department of Orthopaedics of this University via letter no. 1346/OS/2020 dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 103rd ECM II B-Thesis/P20
	(Primary Reviewer: Dr. Preeti Agarwal)
21.	Research proposal entitled ***"A comparative study of novel fibrosis index and transient elastography for predicting fibrosis in patients of chronic liver disease"*** submitted by Dr. Kaustubh Singh, JR, Department of Medicine of this University via letter no. 1943/MED/2020 dated 4th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • Is NFI entirely new index developed by PI? • Aim and objectives: there seems an impression that NFI will give all answers. Looks like element of bias? • They should rewrite and add if NFI proved good there. Secondary objectives would be reviewed. **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P21*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
22.	Research proposal entitled ***"Perioperative trigemino cardiac reflex in patients undergoing surgical treatment of tm joint ankylosis – A study"*** submitted by Dr. Harshita Maurya, JRIII, Department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences of this University via letter no. 479/OMSO/2020 dated 30th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment: • The PI wishes to study the incidence of trigemino cardiac reflex in patients undergoing surgical treatment of TM joint ankylosis under GA. Background of the study is well described. Inclusion/exclusion criteria are well laid down. Sample size is calculated. • **The phrase " a study" from the title may be removed** • **Ethical clearance may be granted Spectrum of lung cancer diagnostic** • PI wishes to study the various factors responsible for delay in the diagnosis of lung cancer. There are several issues: • Please define the type of study – prospective or retrospective. • Define the study duration appropriately as per the study type. • Re-write the methodology of the study as per the study type. The PI is written as if they want to do this study retrospectively from May 2019 to April 2020. Then, in methods, the PI writes that "all undiagnosed/suspected lung cancer patients will be subjected to relevant investigations for the diagnostic work up." A study cannot be retrospective as well as prospective. **EC Decision:** Re-submit ***Ref. code: 103rd ECM II B-Thesis/P22*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
23.	Research proposal entitled ***"Triphala, an Indian traditional herbal formulation mouth wash for the treatment of chronic periodontitis, A randomized controlled clinical trial"*** submitted by Dr. Archana Chaurasia, JRI, Department of Periodontology Faculty of Dental Sciences of this University via letter no. 3024/2020 dated 6th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Hindi & English ICF • References **EC Comment:** • Procurement of Triphala powder + literature of TRP for other uses and safety literature not given. **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P23*** ***(Primary Reviewer: Dr. Rajendra Nath)***
24.	Research proposal entitled ***"Health related quality of life and depression in older adults with knee osteoarthritis pain- cross-sectional telephonic survey in COVID-19 pandemic"*** submitted by Dr. Nimitha K.J, SRII, Department of Geriatric Mental Health of this University via letter no. 578/DGMH/2020 dated 14th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P24*** ***(Primary Reviewer: Dr. Amita Jain)***
25.	Research proposal entitled ***"Left ventricular systolic function assessment during various stages of pump assisted beating heart coronary artery bypass surgery"*** submitted by Dr. Ajith Bhat M, JRI, Department of Anaesthesiology of this University via letter no. 275/Anaes/2020 dated 4th March, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Hindi & English ICF • References **EC Comment:** • Procurement of Triphala powder + literature of TRP for other uses and safety literature not given. **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P23*** ***(Primary Reviewer: Dr. Rajendra Nath)***
24.	Research proposal entitled ***"Health related quality of life and depression in older adults with knee osteoarthritis pain- cross-sectional telephonic survey in COVID-19 pandemic"*** submitted by Dr. Nimitha K.J, SRII, Department of Geriatric Mental Health of this University via letter no. 578/DGMH/2020 dated 14th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rdECM II B-Thesis/P24*** ***(Primary Reviewer: Dr. Amita Jain)***
25.	Research proposal entitled ***"Left ventricular systolic function assessment during various stages of pump assisted beating heart coronary artery bypass surgery"*** submitted by Dr. Ajith Bhat M, JRI, Department of Anaesthesiology of this University via letter no. 275/Anaes/2020 dated 4th March, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P25*** ***(Primary Reviewer: Dr. Rajiv Garg)***
26.	Research proposal entitled ***"Assessment of perceived stress and coping strategies on telephone among elderly with depressive disorder during COCID-19 pandemic"*** submitted by Dr. Ambrish Kumar Mishra, SRII, Department of Geriatric Mental Health of this University via letter no. 577/DGMH/2020 dated 14th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P26*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
27.	Research proposal entitled ***"AGE and SEX estimation based on pulp cavity volume using cone beam computed tomography"*** submitted by Dr. Sanad Khandelwal, JR, Department of Oral Medicine and Radiology Faculty of Dental Sciences of this University via letter no. 643/OMR/2020 dated 24th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P27*** ***(Primary Reviewer: Dr. A.A. Sonkar)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

28.	Research proposal entitled ***"Clinico-pathological relevance of expression of PD-L1 and HER 2 in carcinoma gall bladder: A potential target for therapy:- prospective observational study"*** submitted by Dr. Vikram Singh Sodha, SR, Department of Surgical Gastroenterology of this University via letter no. 430/2020 dated 8th September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • The basis for sample size and statistical analysis for calculating sample size is not presented in proposal. **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P28*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
29.	Research proposal entitled ***"A study on serum Vitamin D level in patients suffering from various pulmonary disorders"*** submitted by Dr. Sapna Dixit, JR, Department of Respiratory Medicine of this University via letter no. 897/2020 dated 15thSeptember, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • Kindly commit regarding the type of study. It can either be a prospective study or a retrospective study. A retrospective study cannot have a prospective follow-up. It can be a prospective study on patients who received treatment of the said

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	condition in the concerned department to assess the functional and radiological outcome. • Define the time duration of study (from ---- to -------) in either case of retrospective or prospective study. • Patient's data sheet is not attached • Sample size not provided • What is the Methodology? • Include someone from biochemistry/Pathology Department where Vitamin-D levels will be performed. • Who os going to pay for Vitamin-D measurement cost, patient or Investigator? If Patient, will it be relevant for him/her. • How is it a cross section study? • Include a control group for relevance **EC Comment:** Revise & Re-submit ***Ref. code: 103rd ECM II B-Thesis/P29*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
30.	Research proposal entitled ***"Spectrum of lung cancer diagnostic delays at a tertiary care centre"*** submitted by Dr. Shekhar Singh, JR, Department of Respiratory Medicine of this University via letter no. 896/2020 dated 15th September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Ref. code: 103rd ECM II B-Thesis/P30*** ***(Primary Reviewer: Dr. Rajiv Garg)***
31.	Research proposal entitled ***"Efficacy and safety of fluorescein green dye imaging in assessing intra-operative viability of parathyroid gland vascularity and predicting post-thyroidectomy hypocalcaemia- A retrospective study"*** submitted by Dr. Loreno. E. Enny, SRIII, Department of Endocrine Surgery of this University via letter no. EndosSurg/286/2020 dated 15th September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • Sample size calculation is not done **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P31*** ***(Primary Reviewer: Dr. Rajendra Nath)***
32.	Research proposal entitled ***"Results of pancreaticogastrostomy in high risk pancreatoduodenectomy cases-observational study"*** submitted by Dr. Pratik Shah, SR, Department of Surgical Gastroenterology of this University via letter no. SG/455/2020 dated 16th September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • Protocol is too brief & not clear.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Revise & Re-submit and send through his guide ***Ref. code: 103rd ECM II B-Thesis/P32*** ***(Primary Reviewer: Dr. Amita Jain)***
33.	Research proposal entitled ***"To analyze the role of pral alendronate on clinic radiological short term outcome of LEGG CALVE's Perthes disease"*** submitted by Dr. Muhammad Shahid Raza, JRI, Department of Orthopaedics Surgery of this University via letter no. 1351/OS/2020 dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rdECM II B-Thesis/P33*** ***(Primary Reviewer: Dr. Rajiv Garg)***
34.	Research proposal entitled ***"Modified baumann;s angle: A comparative study between dominant and non dominant limb in paediatric age group"*** submitted by Dr. Rajnish Kumar, JRI, Department of Orthopaedics Surgery of this University via letter no. 1352/OS/2020 dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rdECM II B-Thesis/P34*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
35.	Research proposal entitled ***"An analytical study of factors associated with carrying angle of the human elbow in paediatric age group"*** submitted by Dr. Yashvardhan

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Sharma, JRI, Department of Orthopaedics Surgery of this University via letter no. 1353/OS/2020 dated 17thFebruary, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P35*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
36.	Research proposal entitled ***"Comparative analysis of reconstruction of ACL tear with quadruple hamstring graft and quadruple hamstring graft internally brace with fibertape: A prospective comparative randomized study"*** submitted by Dr. Devendra Sharma, JRI, Department of Orthopaedics Surgery of this University via letter no. 1354/OS/2020 dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P36*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
37.	Research proposal entitled ***"Effect of kinesiophobia on early functional outcome following total knee arthroplasty"*** submitted by Dr. Yuvraj Vimal, JRI, Department of Orthopaedics Surgery of this University via letter no. 1356/OS/2020 dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P37*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
38.	Research proposal entitled ***"Kinesiophobia in young adults after anterior crutiate ligament reconstruction in a tertiary care centre of north India: A descriptive study"*** submitted by Dr. Pranjal Gupta, JRI, Department of Orthopaedics Surgery of this University via letter no. 1357/OS/2020 dated 17th February, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • In the Title 'North India' should be changed to 'Northern India' • The aim of the study is to ascertain the prevalence of post operative kinesiophobia among patients undergoing ACL reconstruction and identifying the risk factors associated with kinesiophobia • Sample size is 90. Statistically calculated. • Kinesiophobia will be measured by Tampa Scale of Kinesiophobia. This scale ranges from 17 to 68 with higher score indicating stronger level of kinesiophobia • Pain intensity will be measured by Numeric Pain Intensity Rating Scale and Wong Baker Free Pain Rating Scale • At which post operative days will the scales be applied? • How many times post operatively will this be repeated and on which all post operative days? • The case sheet has only demographic details. Where is the date of operation and

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	where are the three mentioned scales and the monitoring schedule? **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P38*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
39.	Research proposal entitled ***"Evaluation of clinical and radiological results of surgical treatment of acetabular fractures using modified stoppa approach"*** submitted by Dr. Balwinder Singh, JRI, Department of Orthopaedics Surgery of this University via letter no. 1435/OS/2020 dated 27th February, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • Kindly commit regarding the type of study. It can either be a prospective study or a retrospective study. A retrospective study cannot have a prospective follow-up. It can be a prospective study on patients who received treatment of the said condition in the concerned department to assess the functional and radiological outcome. • Define the time duration of study (from ---- to -------) in either case of retrospective or prospective study. • Please submit patient's data sheet. **EC Decision:** Re-submit ***Ref. code: 103rd ECM II B-Thesis/P39*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
40.	Research proposal entitled ***"A comparison of harris hip score and oxford hip score in patients undergoing primary total hip arthroplasty"*** submitted by Dr. Priyank Pratap, JRI, Department of Orthopaedics Surgery of this University via letter no. 1345/OS/2020 dated 17th February,

Chairperson IEC
King George's Medical University
U.P., Lucknow

	2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P40*** ***(Primary Reviewer: Dr. Rajendra Nath)***
41.	Research proposal entitled ***"Changes in endothelial cell count after desk for corneal endothelial cell disorder"*** submitted by Dr. Surya Prakash Shukla, JRI, Department of Ophthalmology of this University via letter no. 539/OPH/2020 dated 13th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P41*** ***(Primary Reviewer: Dr. Amita Jain)***
42.	Research proposal entitled ***"Smart phone photography for screening ocular morbidity in School Children- A pilot study"*** submitted by Dr. Suchi Verma, JRI, Department of Ophthalmology of this University via letter no. 540/OPH/2020 dated 13th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved ***Prof. Shally Awasthi did not take part in the decision.*** ***Ref. code: 103rd ECM II B-Thesis/P42*** ***(Primary Reviewer: Dr. Rajiv Garg)***
43.	Research proposal entitled ***"Study on changes in retinoblastoma biomarkers in aqueous humor and their correlation with tumor activity in eyes undergoing local therapy"*** submitted by Dr. Reena Bharti, JRI, Department of Ophthalmology of this University via letter no. 551/OPH/2020 dated 14th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P43*** ***(Primary Reviewer: Dr. Dr. Anoop Kumar Verma)***
44.	Research proposal entitled ***"To study the role of urinary neutrophil gelatinase-associated lipocalin as biomarker of acute kidney injury in liver cirrhosis patients"*** submitted by Dr. Anurag Chaudhary, JRI, Department of Medicine of this University via letter no. 2205/MED/2020 dated 2nd September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • uNGAL is a polypeptide that is upregulated and secreted in Acute Kidney Injury(AKI). It can differentiate between Acute Tubular Necrosis(ATN),

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Hepato Renal Syndrome(HRS) and Prerenal Azotemia • The aim of this study is to evaluate renal dysfunction in liver cirrhosis, cut off level of uNGAL to diagnose AKI, whether its levels have any relation to the outcome of AKI and whether it can be used as a biomarker of AKI • It is a prospective observational study • Sample size is 250. How was it calculated? • Inclusion and exclusion criteria are defined • Consent form in 2 languages has been provided • 5 ml early morning urine sample while fasting will be collected. • The study design has been shown in a flow-chart. • Data collection sheet is attached but it does not have any mention of uNGAL estimation values. **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P44*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
45.	Research proposal entitled ***"Evaluation of postoperative outcome and survival of multiorgan resection on locally advanced carcinoma gall bladder"*** submitted by Dr. Neha Yadav, JRI, Department of General Surgery of this University via letter no. 606/2020 dated 19th March, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P45*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
46.	Research proposal entitled ***"Co- relation between ABO blood grouping and allergic rhinosinusitis with roll of TNF alpha in allergic rhinosinusitis with and without polyposis"*** submitted by Dr. Shilpi Sujata, JRI, Department of OTO-Rhino-Laryngology & Head & Neck

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Surgery of this University via letter no. 168/ENT/2020 dated 16th June, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P46*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
47.	Research proposal entitled ***"Prospective randomized control trial of decompressive craniectomy withoutduralclosure vs decompressive craniectomy withdural closure intraumatic brain injury"*** submitted by Dr. Pankaj Kumar, SR-I, Department of Neurosurgery of this University via letter no. 959 dated 24th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P47*** ***(Primary Reviewer: Dr. Anoop Kumar)***
48.	Research proposal entitled ***"Comparision of transdermal fentanyl and transdermal buprenorphine patchk as post operative analgesia in oatients undergoing lower limb surgery"*** submitted by Dr. Dr. Logesh A, JR-I, Department of Anaesthesiologyof this University via letter no. 931 dated 11th September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Hindi & English ICF • References **EC Comment:** • Sample size calculations not mentioned. • How figure of 25 in each gp reached. • Why RCT and comparative study in one? Which study type is it? • If it is RCT has it been registered with CTRI? **EC Decision:** Approval after justification ***Ref. code: 103rd ECM II B-Thesis/P48*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
49	Research proposal entitled ***"A comparision of the effect of two different doses of oral melatonin on post-operative cognitive dysfunction in elderly patients after surgery under regional anaesthesia: A randomized controlled double blinded study"*** submitted by Dr. Kalpesh Kheni, JR-I, Department of Neurosurgery of this University via letter no. 926 dated 10th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P49*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
50	Research proposal entitled ***"Application of DTI ink intra-axial neoplastic and infective brain lesions-A Comparative study"*** submitted by Dr. Kalpesh Kheni, JR-I, Department of Radiodiagnosis of this University via letter no. 482/RD/2020 dated 3rd September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I.

Chairperson IEC
King George's Medical University
U.P. Lucknow

	• Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P50*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
51	Research proposal entitled ***"Study to demonstrate the role of ultrasonography in evaluation of callus formation in diaphyseal fracture of long bones"*** submitted by Dr. Reetinder Pal Kaur, JR-I, Department of Radiodiagnosis of this University via letter no. 483/RD/2020 dated 3rd September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Comment:** • Kindly modify the date of study. The study can only commence after obtaining the ethical clearance. **EC Decision:** Provisionally approved ***Ref. code: 103rd ECM II B-Thesis/P50*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. IIB
New Ph.D.

K.G's Medical University U.P., Lucknow

II-B	New Thesis-Ph. D. Scholar
1.	Research proposal entitled "***Challenges in implementation of the multi-sectoral action plan for prevention and control of common noncommunicable diseases in the state of Uttar Pradesh***" submitted by Dr. Abhishek Tiwari, Ph.D. 2018 Scholar, under the guidance Prof. S.K Singh, Department of Community Medicine of this University via letter no. 154/CM/2020 dated 9th July, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References • CV of Prof. Uday Mohan, Department of Community Medicine, ERA's Lucknow Medical College and Hospital, Lucknow. **EC Decision:** Approved ***Ref. code: 103rdECM II B-Ph.D/P1*** ***(Primary Reviewer: Dr. Rajendra Nath)***
2.	Research proposal entitled "***To elucidate the role of WWOX (WW domain-containing oxidoreductase) and RUNX2 gene in osteosarcoma subjects in North Indian population***" submitted by Ms. Priyanka Sharma, Ph.D Scholar under the guidance Dr. Wahid Ali, Additional Professor, Department of Pathology of this University via letter no. 963/2020 dated 19th August, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	• CV of Dr. Pradeep Kumar Sharma, Scientist, Food, Drug and Chemical Toxicology Group, CSIR-Indian Institute of Toxicology Research, Lucknow. **EC Comment:** • This is a proposal for Ph.D. too sketchy • A detailed project to be submitted **EC Decision:** Re-submit ***Ref. code: 103rdECM II B-Ph.D/P2*** ***(Primary Reviewer: Dr.Amita Jain)***
3.	Research proposal entitled "***Forensic 3D craniofacial reconstruction using facial anthropometry and soft tissue thickness in India***" submitted by Mr. Anurag Dubey, Ph.D. Scholar, 2019 Batch, under the guidance Prof. Anoop Kumar Verma, Head, Department of Forensic Medicine & Toxicology of this University via letter no. 456/FMT/2020 dated 15th September, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References • CV of Mr. Rakesh Bisht, CFSL, CBI, New Delhi • CV of Mr. Ashutosh Deo Tiwari, CFSL, CBI, New Delhi. • CV of Dr. Vibhavari Singh, Assistant Professor, Sculpture Department, University of Lucknow, Lucknow. **EC Decision:** Approved ***Ref. code: 103rdECM II B-Ph.D/P3*** ***(Primary Reviewer: Dr.Rajiv Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. IIB
MBBS students

K.G's Medical University U.P., Lucknow

II-B	MBBS- Student
1.	Research proposal entitled ***"Effects of diet components on the sleep quality of first year medical students"*** sponsored by ICMR New Delhi submitted by Mr. Shubhajeet Roy, MBBS 2019 Through his Mentor Prof. Archna Ghildiyal, Department of Physiology of this University this University via letter no. 1869/PHY/2020 dated 22nd June, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rdECMIIBMBBS/P1*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
2.	Research proposal entitled ***"A study to assess awareness about COVID-19 pandemic, its perceived impact on education, symptoms of depression, anxiety and stress among the undergraduate students of Medical Colleges in India"*** sponsored by KGMU submitted by Mr. Prateek Kumar Dinkar, MBBS 2016 Through his Mentor Dr. Pawan Kumar Gupta, Associate Professor, Department of Psychiatry of this University this University via letter no. 2735/Psy/2020 dated 24th June, 2020. ***The following documents were reviewed in the EC Meeting:*** • Check list • Summary • Undertaking by the P.I. • Hindi & English ICF • References **EC Decision:** Approved ***Ref. code: 103rdECMIIBMBBS/P2*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
U.P. Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. IIC
New Trials

K.G's Medical University U.P., Lucknow

IIC	Review of New Drug Trial
1.	Research Protocol no. BIS/ED/K19CT001entitled "***A randomized, double blind, parallel design, placebo controlled phase IV study to evaluate the safety and efficacy of bismozyme (nux vomica, Aluminium Citrate, Bismuth Citrate, Dill Oil, Chloroform) in patients with symptomatic gastrointestinal motility disorder***" sponsored by Eastern Drug, 119/E Mancheswar Industrial Estate Bhubaneswar Ltd. submitted by Prof. Sandeep Tiwari, Head, Department of Trauma Surgery of this University via letter no. TS/455/2020 dated 8th July, 2020. **EC Comment:** • CTRI missing • Budget not finalized **EC Decision:** Approval after justification ***Ref. code: 103rdECMIIC/P1*** ***(Primary Reviewer: Dr. Rajendra Nath)***
2.	Research Protocol no.LRP/LUBT/010/2016/008 entitled "***A phase III, comparative, double blind, randomized, multi-centric study to compare the efficacy, safety and immunogenicity of sun's ranibizumab with reference biologic in patients with neovascular age-related macular degeneration (wet AMD)***" sponsored by Sun Pharmaceutical Industries Limited submitted by Prof. Sandeep Saxena, Department of Ophthalmology of this University via letter no. nil dated 1st September, 2020. ***The following documents were reviewed in the Meeting:-***

Sl. No.	Details of document
1	Information Brochure
2	Clinical Study Protocol and Appendices
3	Case Record Form and Unscheduled booklet with its Amendment History
4	Information Brochure

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	5	Patient Information Sheet and Informed Consent form in English and Hindi language
	6	Translation and Back-Translation certificate for Site Specific Patient Information Sheet and Informed Consent form in Hindi language
	7	DCGI CTNOC
	8	Insurance Policy
	9	Draft Clinical Trial Agreement
	10	CTRI
	11	Investigator Undertaking (Protocol Version 1.2, Dated 29/SEP/2020)
	12	CV and MRC certificate of PI

EC Decision: Approval after subject to fulfillment & Administrative Formalities.

Ref. code: 103rdECMIIC/P2

(Primary Reviewer: Dr. Amita Jain)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. III
Adverse Drug Event

K.G's Medical University U.P., Lucknow

III	Adverse Drug Event
1.	ADE Research Protocol version no. 3.4 dated 18th May, 2020 entitled ***"A Randomized, open label, parallel efficacy, active control, multicentre esploratory drug trial to evaluate efficacy and safety of an Ayurvedic Formulation (AYUSH-64) a adjunct treatment to standard of care for the management of mild to moderate COVID-19 patients"*** submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine of this University via letter no. nil dated 25th August, 2020. **Patient ID: 02030A** **Initial: D-S** **Patient report:** ***The above subject discharged from COVID Ward-S3 on 20th July, 2020, experienced and adverse event unrelated consequence to the study drug being administered. Upon telephonic contact on 23rd August, 2020 at 1.00 PM for progress report as per the study protocol, patient explained the adverse event experienced by him 7 days back. Patient suffered from severe diarrhoeal episodes with complaint of abdominal discomfort, weakness and breathlessness for which he seeked medical advice at a nearby local hospital, who advised following medications Tab, Sompra-D 1 B.D, Syp. Mucaine Gel 10 ml H.S. all for 3 days, Patient gradually recovered and is asymptotically for health review and progress report. Any further worsening in condition shall be reported.*** **EC Decision:** Reviewed ***Ref. code: IVECM IB-COVID-19/P9*** ***(Primary Reviewer: Dr. Rajendra Nath)***
2.	ADE research protocol no. SER/01/2016 entitled ***"Efficacy and tolerability of fixed dose combination of perindopril + indapamide + amlodipine in patients with grade II/III hypertension"*** sponsored by M/s Serdia Pharmaceuticals (India)

Chairperson, IEC
King George's Medical University
U.P., Lucknow

Ltd., submitted by Dr. Gaurav Chaudhary, Assistant Professor, Department of Cardiology of this University via letter no. 94/Cardio/Res/18 dated 16th November, 2018, 111/Cardio/Res/18 dated 3rd December, 2018 & 114/Cardio/Res/18 dated 12th December, 2018.

Subject no: 0607

Subject Initial: A-K-S

Enrollment date: 16th May, 2018

SAE Description:

Subject visited our hospital Emergency on 14th November, 2018, His ECG and Trop T was done. Subject is diagnosed with NSTEMI.

The above Patient had an unscheduled visit to hospital on 14th November, 2018 complaining of chest pain which later diagnosed as NDTEMI with the reports from laboratory showing high Troponin values. Patient was hospitalized in the Emergency room on 14th November, 2018. PI started Ecosprin & other medication for the treatment. PI also suggested PCI but due to patient's disagreement he was discharged on the 14th November, 2018. As per PI's desecration study drug was stopped and other Anti-hypertensive treatment started patient does not have any other associated disease. Follow up is planned in the next week.

On 15th November, 2018 Subject came to us and informed about the event. Then PI evaluated and advise for Ango and + PCI but subject refuse for intervention. So medicine was advised and subject was sent back to home.

Patient enrolled under Triplaxam study. Subject visited to his local hospital with the complaint of dry cough similar 16th November, 2018 there he was evaluated and referred to us.

Call was made to subject on 20th November, 2018 and he informed us. He is feeling better and continuing same drug and not willing for any procedure.

An objection letter received from CDSCO, Mr. Navneet Pratap Singjh, Assistant Drugs Controller (I) has objected that due analysis report of the SAE (Injury) **'Hospitalization due to NSTEMI, Kindly provide the opinion as to whether the SAE (Injury) is related/non related to the Investigational product/Clinical trial of the said SAE (Injury) to this office at earliest for further necessary action.**

Chairperson, IEC
King George's Medical University

	EC Decision: The above Matter was discussed in the Committee, the opinion was the EC Committee that this SAE is not related to investigational drug. ***Ref. code: 89th ECM IIC /P4*** ***(Previous Primary Reviewer: Dr. Surajit Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. IV
Extension of previously approved trial

K.G's Medical University U.P., Lucknow

IV	Extension of previously approved trial
1.	Extension of research protocol no. I6T-MC-AMAP. entitled ***"A phase 3, multicenter, Open-label extension study to evaluate the long-term efficacy and safety of mirikizumab in patients with moderately to severely active ulcerative colitis LUCENT 3"*** sponsored by M/S Eli Lilly, USA submitted by Prof. Abhijit Chandra, Department of Surgical Gastroenterology this University via letter no. nil. Dated 15th June, 2020. **EC Comment:** • What changes are suggested to ensure enrollment? **EC Decision:** Approval after justification ***Ref. code: 95th ECM IIC/P10*** ***(Primary Reviewer: Dr. Amita Jain)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. V
Modification

K.G's Medical University U.P., Lucknow

V-	Modification
1.	Modification of research proposal entitled ***"To assess the usefulness of peak expiratory flow rate on monitoring the level of control of asthma in children"*** submitted by Dr. Shabnam, JR-II, Department of Paediatrics of this University via letter no.1394/Ped/2020 dated 29th June, 2020. **EC Decision:** Reviewed ***Ref.code:97th ECMIIThesis/P126*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
2.	Modification of Research protocol no. ***GS-US-417-0304*** entitled ***"A multicenter, double- blind, long term extension study to assess the safety and efficacy of filgotinib in subjects with rheumatoid arthritis"*** submitted by Dr. Puneet Kumar, Department of Rheumatology of this University via letter no. CT/87/2020 dated 30th July, 2020. **EC Decision:** Approved ***Ref.code:86th ECMIIE/P1*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. VI
Annual Progress Reports

K.G's Medical University U.P., Lucknow

VI-	Annual Progress Reports
1.	Annual Progress Report of research protocol no.PMZ—1620/CLINICAL-2.3/2018;DCGI CT NOC no. CT/ND/18/2018 entitled ***"A prospective, multicentric, randomized, double blind, saline controlled phase II clinical study to compare the safety and efficacy of PMZ1620 therapy along with standard supportive care in patients of acute spinal cord injury"*** sponsored by M/s Pharmazz India Pvt. Ltd. submitted by Dr. Shah Waliullah, Assistant Professor, Department of Orthopaedic Surgery of this University via letter no. nil Dated 24th June, 2020. **EC Decision:** Noted ***Ref. code: 93rdECMIIC/P12*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
2.	Annual Progress Report of research protocol no.***GS-US-417-0304 "A multicenter, double- blind, long term extension study to assess the safety and efficacy of filgotinib in subjects with rheumatoid arthritis"*** submitted by Dr. Puneet Kumar, Department of Rheumatology of this University via letter no. Rh/CT/78/2020 Dated 19th June, 2020. **EC Decision:** Noted ***Ref. code: 86thECMIIE/P1*** ***(Primary Reviewer: Dr.Preeti Agarwal)***
3.	Annual Progress Report of research protocol no. EFC14875- Sotagliflozin entitled ***"A randomized double-blind, placebo- controlled, parallel –group, multicenter study to demonstrate the effects of sotagliflozin on cardiovascular and renal events in patients with type 2 diabetes, cardiovascular risk factors and moderately impaired renal function the scored trial"*** sponsored by M/s Sanofi Ltd. submitted by Dr. Virendra Atam, Head, Department of Endocrinology of this University via letter no. nil Dated 8th June, 2020. **EC Comment:** • The ethical clearance of the study was granted on 27th November, 2018. • As on 27th December, 2019, no participant has been included in the study. No data after Dec 2019 is provided by the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Kindly submit response to comments. ***Ref. code: 90th ECMIIC/P4*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
4.	Annual Progress Report of research protocol no. 20170199 entitled ***"A multicenter, open-label, single-arm, study to evaluate safety and tolerability of Repatha in patients with homozygous familial hypercholesterolemia (HoFH) in India"*** sponsored by Amgen Technology Pvt. Ltd submitted by Dr. Virendra Atam, Head, Department of Endocrinology of this University via letter no. nil Dated 8th June, 2020. **EC Decision:** Reviewed ***Ref. code: 93rd ECMIIC/P1*** ***(Primary Reviewer: Dr. Rajendra Nath)***
5.	Annual Progress Report of research protocol no. Bio Mime Branch-1 entitled ***"A prospective, active control, open- label, multi- centre, randomized clinical trial comparing BioMime Branch- sirolimus eluting coronary side branch stent system vs. xience family of everolimus eluting coronary stent system to evaluate safety and performance in patients with de novo coronary bifurcation lesions"*** sponsored by M/s Meril life Sciences Private Ltd. submitted by Dr. Sharad Chandra, Department of Cardiology of this University via letter no. 830/Cardio/2020 Dated 5th March, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 90th ECMIIC/P7*** ***(Primary Reviewer: Dr. Amita Jain)***
6.	Annual Progress Report of research protocol entitled ***"Identification and validation of gene signature profile to predict the recurrence and progression of urothelial cancer: a cohort study"*** sponsored by ICMR, New Delhi submitted by Dr. Vishwajeet Singh, Department of Urology of this University via letter no. 348/URO/2020 Dated 18th July, 2020. **EC Comment:** 1. The project was returned back to ICMR on 14.02.2020. 2. Why it was returned is not mentioned **EC Decision:** Kindly submit response to comments. ***Ref. code: 96th ECMIIA/P18***

Chairperson IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer: Dr. Surajit Bhattacharya)
7.	Annual Progress Report of research protocol entitled ***"A novel and cost effective technique for tricuspid annuloplasty"*** submitted by Prof. Sushil Kumar Singh, Department of Cardiovascular & Thoracic Surgery of this University via letter no. 1074/CVTS/2020 Dated 20th July, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 95th ECMIIA/P16*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
8.	Annual Progress Report of research protocol entitled ***"A post market registry of Abluminus sirolimus eluting coronary stent system for percutaneous intervention in patients with diabetes mellitus"*** sponsored by M/S Envision Scientific, Surat submitted by Dr. Akshyaya Pradhan, Department of Cardiology of this University via letter no. 1013/Cardio/Res/2020 Dated 20th July, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 95th ECMIIC/P12*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
9.	Annual Progress Report of research protocol entitled ***"A study on association of exposure to particulate matter and susceptibility to cardiovascular diseases in North Indian population"*** sponsored by CSIR-IITR, Lucknow submitted by Prof. S.K. Dwivedi, Department of Cardiology of this University via letter no. 1012/Cardio/Res/2020 Dated 20th July, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 97th ECMIIA/P18*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
10.	Annual Progress Report of research protocol no. K-877-302 version V2.0-27-Mar-2017 entitled ***"PROMINENT: pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes"*** sponsored by M/s KOWA Research Institute submitted by Prof. S.K. Dwivedi, Department of Cardiology of this University via letter no. 1010/Cardio/Res/2020 Dated 20th July, 2020. **EC Decision:** Reviewed & noted

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 96th ECMIIC/Pa2
	(Primary Reviewer: Dr. Surajit Bhattacharya)
11.	Annual Progress Report of research protocol no.CTQJ230A12001entitled ***"Multi-centre cross- sectional epidemiological study to characterize the prevalence and distribution of lipoprotein(a) levels among patients with established cardiovascular disease"*** sponsored by M/s Novartis Pvt. Ltd. submitted by Prof. S.K. Dwivedi, Department of Cardiology of this University via letter no. 1011/Cardio/Res/2020 Dated 20th July, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 96th ECMIIC/Pb2*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
12.	Annual Progress Report of research protocol entitled ***"Characterization of miRNAs modulating the response to chemotherapeutic drugs in triple negative breast cancer patients and study of PARP inhibitor therapy in triple negative breast cancer cells"*** sponsored by Indian Council of Medical Research, New Delhi submitted by Dr. Sameer Gupta, Department of Surgical Oncology of this University via letter no. SONC/816/2020 Dated 21st July, 2020. **EC Comment:** • Proposal could not be initiated **EC Decision:** Noted ***Ref. code: 96th ECMIIA/P4*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
13.	Annual Progress Report of research protocol entitled ***"Neo Vasectomy"*** sponsored by Indian Council of Medical Research, New Delhi submitted by Dr. N. S. Dasila, Department of Urology of this University via letter no. 353/URO/2020 Dated 21st July, 2020. **EC Comment:** • Project will get completed in next 2 months • Serious adverse side effects – none • How many patients treated so far is not mentioned. **EC Decision:** Noted

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Ref. code: 95th ECMIIA/P12 ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
14.	Annual Progress Report of research protocol entitled ***"Metabolomic study of pancreatic cancer by ^{1}H NMR for early detection"*** sponsored by ICMR submitted by Dr. Dilutpal Sharma, Associate Professor, Department of Biochemistry of this University via letter no. nil Dated nil. **EC Comment:** • Study already underway. **EC Decision:** Reviewed & noted ***Ref. code: 96th ECMIIA/P44*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
15.	Annual Progress Report of research protocol entitled ***"Evaluation of nutritional intervention with L arginine, vit B6, B12 and vit D for neurological recovery in acute spinal cord injury (ASCI) subjects; A Randomized Control Trial (RCT)"*** sponsored by ICMR, New Delhi submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 113/OS/2020 Dated 25th July, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 96th ECMIIA/P48*** ***(Primary Reviewer: Dr. Smriti Bhadauria)***
16.	Annual Progress Report of research protocol entitled "***Association of methylenetetrahydrofolate reductase (MTHFR) C677T polymorphism in isolated hypospadias in eastern Uttar Pradesh population***" submitted by Dr. Archika Gupta, Associate Professor, Department of Pediatric Surgery of this University via letter no. 486/Ped Sy/2020 Dated 29th July, 2020. **EC Decision:** Reviewed & noted ***Ref. code: 97th ECMIIA/P16*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
17.	Annual Progress Report of research protocol entitled "***Genetic and epigenetic***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	alterations: correlation to treatment outcome of antidiabetics in type2 diabetes mellitus" sponsored by ICMR, New Delhi submitted by Prof. Kauser Usman, Department of Medicine of this University via letter no. nil Dated 30th July, 2020. **EC Comment:** • Literature survey completed • Subject selection and sample collection started • In-Silico Premierdesigning of candidate gene variant done • Details od genes and their primers obtained • Sample collection hampered by CORONA pandemic • 1 presentation in International Congress of Lipid & Atherosclerosis in Seoul, South Korea. **EC Decision:** Noted ***Ref. code: 96th ECMIIA/P23*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Minutes of 103rd "Institutional Ethics Committee" Meeting held on 27th November, 2020

Item no. VII
Other Matter

K.G's Medical University U.P., Lucknow

VII	Any Other Matter (With the permission of Chair)
1-	Request for permission to add the following 3 Co-P.Is of research proposal entitled ***"GlobalSurg-CovidSurg week: Determining the optimal timing for surgery following SARS-CoV-2 infection"*** submitted by Dr. Shiv Rajan, Assistant Professor, Department of Surgical Oncology of this University via letter no.nil dated 20th August, 2020. 1-Prof. S.K. Singh, Department of Cardiovascular & Thoracic Surgery of the University. 2-Dr.Vivek Tewarson, Associate Professor, Department of Cardiovascular & Thoracic Surgery of the University. 3-Prof. Apjit Kaur, Department of Ophthalmology of the University. **EC Decision:** Approved ***Ref. code: Vth ECMIB-COVID-19/P22***
2-	Due to COVID-19 pandemic the OPD were closed so the number of cases PI wanted to enroll the PIs study were not achieved due to the inclusion of only 2 diseaases in her topic so the request for permission to change the topic of the research proposal entitled ***"Spectrum of Aspergillus species causing Pulmonary aspergillosis in Patients with pulmonary diseases"*** in place of ***"Spectrum of aspergillus species causing pulmonary aspergillosis in COPD and POST- TB patients-A descriptive study"*** submitted by Dr. Deepika, JRI, Department of Microbiology of this University via letter no. 755/2020 dated 3rd February, 2020. **EC Decision:** Approved ***Ref. code: 101stECM II B-Thesis/P33***
3-	Due to retairment of Prof. Vinia Das, Head, Department of Obst. & Gynaecology has superannuated and Prof. Uma Singh has taken over as the Head in the same Department so according tho ICMR, NIRRH, Department of Health Research, Ministry of Health and Family Welfare, Govt. of India want to grant the approval for the amended protocol under the research proposal entitled ***"Clinical phenotypes and***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	genetic regulation of endometriosis in Indian women*"** sponsored by Wellcome Trust DBT India Alliance. **This proposal was alreadedy approved in the 98th EC Meeting was held on 6th September, 2019.** **EC Decision:** Approved ***Ref. code: 98th ECM II A/P11
4-	According to M/s JPN Apex Trauma Centre, AIIMS, New Delhi, as per own decision the proposal has been extended for 1 year from 30th September, 2020 to 29th September, 2021 so, Prof. Vimala Venkatsh, Department of Microbiology of this University she has wanted to request from EC for Re-approval via letter no. 2020/10/CB-117 dated 9th October, 2020 under the research proposal entitled ***"Capacity buiding and strengthening of hospital infection control to detect and prevent antimicrobial resistance in India".*** **EC Decision:** Approved
5.	Reg. Revised timeline for completion of INVICTUS study under supervision of Prof. Rishi Sethi, Prinicipal-Investigator, Department of Cardiology of this University via his letter no. 1093/Cardi/Res/2020 dated 16th September, 2020. **EC Decision:** Noted ***Ref. code: 83rd ECM II C/P6***
6.	Reg. permission to currently enrolled 272 patients to use in the ongoing research proposal entitled ***"Role of different triggers in precipitation of first ST segment elevation myocardial infarction: A case-crossover study"*** under supervision Prof. S.K. Dwivedi, Department of Cardiology of this University via letter no.1180/Cardio/Res/2020 dated 12th October, 2020. **EC Decision:** Approved ***Ref. code: 97th ECM II A/P30***

The Next Meeting will be scheduled on 22nd January, 2020

Chairperson, IEC
King George's Medical University
U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 105th ECM held on 19th Februrary, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Minutes of the Institutional Ethics Committee Meeting held on **19th February, 2021 from 2.00 PM 4.30 PM** in the **'Board Room'** Office of the Vice Chancellor, Administrative Block of this University.

Minutes of the Institutional Ethics Committee Meeting was held on **19th February, 2020 from 2.30 p.m.** in the **'Board Room'** Office of the Vice Chancellor, Administrative Block of this University.

The Following Members were present in the EC Meeting:

1. Prof. S.P.S. Gaur -Chairman
2. Hon'ble Justice Vishnu Sahai -Member
3. Dr. Manju Agarwal -Member
4. Mr. Yogesh Mishra -Member
5. Dr. Surajit Bhattacharya -Member
6. Dr. Vimal Kumar Paliwal -Member
7. Dr. Smriti Bhadauria -Member
8. Dr. Anoop Kumar Verma -Member
9. Dr. Rajendra Nath -Member
10. Dr. Rajiv Garg -Member
11. Dr. Preeti Agarwal -Member
12. Dr. Shally Awasthi -Member-Secretary, ex-officio

13. The following Members were not present in the EC Meeting:-

14. 1-Dr. Amita Jain -Send her Comment
15. 2-Dr. A.A. Sonkar -He has not given his comment

IA	Action Taken
1	Clarification of research proposal entitled ***"A pilot study of compulsions and obsessions after sixty years (COSY)"*** submitted by Dr. Shrikant Srivastava, Head and Associate Professor, Department of G.M.H. this University via letter no. nil dated 4th April, 2019. ***P.I. has given his reponce which was reviewed by the Member-Secretary.*** **Action Taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 96thECM II A/ P39*** ***(Primary Reviewer: Dr. Rajendra Nath)***
2	Clarification of research proposal entitled ***"A study of handwriting sample in geriatric population with cognitive impairment"*** submitted by Dr. H.V. Suresh, SR-I, Department of G.M.H. of this University via letter no. 875/DGMH dated 8th February, 2021. ***P.I. has given his reponce which was reviewed by the Member-Secretary.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Action Taken: Provisionally approved **EC Decision:** Approved ***Ref. code: 100th ECM II B-Thesis/P17*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
3	Clarification of research proposal entitled ***"Etiology of acute meningoencephalities in children less than 5 years of age in North India"*** sponsored by Health Research, New Delhi submitted by Prof. Amita Jain, Department of Microbiology of this University via letter no. 644/2021 dated 17th February, 2021. ***The P.I. has given her reply.*** **EC Decision:** Approved ***Ref. code: 101st ECM II A/P11*** ***(Primary Reviewer: Dr. Rajendra Nath)***
4	Clarification of research proposal entitled ***"Serum visfatin levels for mortality prediction in critically ill paediatric intensive care unit patients"*** submitted by Dr. Gaurav Singh, JRI, Department of Pediatrics of this University via letter no. 417/Ped/2021 dated 18th February, 2021. ***The P.I. has given his reply & approved by the Member-Secretary.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P31*** ***(Primary Reviewer: Dr.Rajiv Garg)***
5	Clarification of research proposal entitled ***"A comparative study on cognitive functions in late life depression"*** submitted by Dr. Ambrish Kumar Mishra, SRII, Department of Geriatric Mental Health of this University via letter no. 870/DGMH dated 6th February, 2021. ***P.I. has given his reponce which was reviewed by the Member-Secretary.*** **Action taken :** Provisionally approved **EC Decision:** Approved ***Ref. code: 101st ECM II B-Thesis/P59*** ***(Primary Reviewer : Dr. Amita Jain)***
6	Clarification of research proposal entitled ***"Retrospective data analysis and distribution of odontogenic cysts and tumors in a teaching hospital-based population: A database study with systematic review"*** submitted by Dr. Fahad Mansoor Samadi, Associate Professor, Department of Oral Pathology &

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Microbiology, Faculty of Dental Sciences of this University via letter no. 1257/OP/2020 dated 14th January, 2021. ***P.I. has given his reponce which was reviewed by the Member-Secretary.*** **Action taken :** Provisionally approved **EC Decision:** Approved ***Ref. code: 103rd ECM IIA/P7*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
7	Clarification of research proposal entitled ***"Improving recovery outcome for burns survivors in India: A systems approach"*** sponsored by ICMR New Delhi submitted by Prof. Brijesh Mishra, Head, Department of Plastic surgery of this University via letter no. 142 dated 3rd February, 2021. ***The P.I. has given his reply & approved by the Primary reviewer.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 103rdECM IIA/P10*** ***(Primary Reviewer: Dr. Rajendra Nath)***
8	Clarification of research proposal entitled ***"Efficacy of platysma myocutaneous flap in oral defects: A retrospective study"*** submitted by Prof. Uma Shanker Pal, Department of Oral and Maxillofacial Surgery Faculty of Dental Sciences of this University via letter no. 195/OMFS/21 dated 6th March, 2021. ***The P.I. has given her reply & approved by the Member-Secretary.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 103rdECM IIA/P14*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
9	Clarification of research proposal entitled ***"Incidence of skin necrosis using cold knife or electrocautery for elevating skin flaps during inguinal lymph node dissection-a pilot study"*** submitted by Dr. Shiv Rajan, Assistant Professor, Department of Surgical Oncology of this University via letter dated 28th January, 2021. ***The P.I. has given his reply & approved by the Primary reviewer.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 103rdECM IIA/P19*** ***(Primary Reviewer: Dr. Smriti Bhadouria)***
10	Clarification of research proposal entitled ***"A retrospective data analysis of***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Hepatitis B in teaching Hospital-based population in past 1.5 years- A database study" submitted by Dr. Jaya Singh, SRII, Department of Oral Pathology Microbiology, Faculty of Dental Sciences of this University via letter no. 1294/OP/2021 dated 9th February, 2021. ***The P.I. has given her reply & approved by the Primary reviewer.*** **Action taken:** Provisionally approved **EC Decision:** ***Ref. code: 103rd ECM II B-Thesis/P6*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
11	Clarification of research proposal entitled ***"To study the association of serum homocysteine, C-reactive protein, uric acid & pro-brain natriuretic peptide (PRO-BNP) in patients with ischemic stroke at a tertiary care centre in northern India"*** submitted by Dr. Himanshu Chauhan, JR, Department of Medicine of this University via letter no. 372/Med/2021 dated 19th February, 2021. ***The P.I. has given his reply & approved by the Member-Secretary.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P15*** ***(Primary Reviewer: Dr. Rajendra Nath)***
12	Clarification of research proposal entitled ***"A comparative study of novel fibrosis index and transient elastography for predicting fibrosis in patients of chronic liver disease"*** submitted by Dr. Kaustubh Singh, JR, Department of Medicine of this University via letter no. 319/MED/2021 dated 12th February, 2021. ***P.I. has given his reponce which was reviewed by the Member-Secretary.*** **Action taken :** Provisionally approved **EC Decision:** Approved ***Ref. code: 103rd ECM II B-Thesis/P21*** ***(Primary Reviewer: Dr. A.A. Sonkar)***
13	Clarification of research proposal entitled ***"To study the role of urinary neutrophil gelatinase-associated lipocalin as biomarker of acute kidney injury in liver cirrhosis patients"*** submitted by Dr. Anurag Chaudhary, JRI, Department of Medicine of this University via letter no. nil dated nil. ***The P.I. has given his reply & approved by the Member-Secretary.*** **Action taken:** Provisionally approved **EC Decision:** Approved

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	Ref. code: 103rd ECM II B-Thesis/P44 ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
14	Clarification of research proposal entitled "***Abnormal uterine bleeding classified on the basis of FIGO-PALM COEIN system with histopathological correlation***" submitted by Dr. Shalini Bhalla, Associate Professor, Department of Pathology of this University via letter no.1760 dated 24th February, 2021. ***The P.I. has given her reply & approved by the Member-Secretary.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 104th ECM IIA/P6*** ***(Primary Reviewer:Dr. Dr. Smriti Bhadauria)***
15	Clarification of research proposal entitled "***A study of pattern of certification for psychiatric disability & need, perception, and barriers faced by families of persons with psychiatric disability in availing welfare benefits***" submitted by Dr. Adarsh Tripathi, Additional Professor, Department of Psychiatry of this University via letter no.3550/Psy/2020 dated 25th November, 2020. ***P.I. has given his reponce which was reviewed by the Member-Secretary.*** **Action taken :** Provisionally approved **EC Decision:** Approved ***Ref. code: 104th ECM IIA/P22*** ***(Primary Reviewer: Dr. Rajendra Nath)***
16	Clarification of research proposal entitled "***Study on Phyto based dental filling material***" submitted by Prof. Jitendra Rao, Department of Prosthodontics, Faculty of Dental Sciences of this University via letter no.219/2021 dated 12th February, 2021. ***The P.I. has given his reply & approved by the Primary Reviewer.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 104th ECM IIA/P25*** ***(Primary Reviewer: Dr. Preeti Agarwal)***
17	Clarification of research proposal entitled "***CRISPR/Cas9 and Rad51-single strand oligodeoxynucleotides (Rad51-ssODNS0 mediated correction of IVS 1-5 (G-C) mutation in thalassemia***" sponsored by DHR MRU submitted by Dr. Nitu Nigam, Assistant Professor, Department of CFAR of this University via letter no.31/CFAR/2021 dated 11th February, 2021. ***P.I. has given his reponce which was reviewed by the Member-Secretary.***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Action taken : Provisionally approved **EC Decision:** Approved ***Ref. code: 104th ECM IIA/P27*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
18	Clarification of research proposal entitled ***"Development of primary human microglial/astrocyte cell-based model for neurodegenerative diseases"*** sponsored by ICMR submitted by Prof. Shailendra Kumar Saxena, Head, Department of Centre for Advance Research of this University via letter no.35/CFAR dated 12th February, 2021. ***P.I. has given his reponce which was reviewed by the Member-Secretary.*** **Action taken :** Provisionally approved **EC Decision:** Waiver granted ***Ref. code: 104th ECM IIA/P31*** ***(Primary Reviewer:Dr. Vimal Kumar Paliwal)***
19	Clarification of research proposal entitled ***"Intratumoral histological variation in juvenile nasopharyngeal angiofibroma and preliminary observation of molecular cytogenetics"*** submitted by Dr. Rohit Verma, JRI, Department of OTO-Rhino-Laryngology & Head & Neck Surgery of this University via letter no. 876/ENT dated 4th March, 2021. ***The P.I. has given his reply & approved by the Member-Secretary.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 104th ECM II B-Thesis/P2*** ***(Primary Reviewer: Dr. Rajendra Nath)***
20	Clarification of research proposal entitled ***"Outcome analysis of intradural extramedullary spinal tumors-A 10 yrs retrospective study"*** submitted by Dr. Dinesh Singh, SRI, Department of Neurosurgery of this University via letter no. NS/1954 dated 27th February, 2021. ***The P.I. has given his reply & approved by the Member-Secretary.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 104th ECM II B-Thesis/P20*** ***((Primary Reviewer: Dr. Preeti Agarwal)***
21	Clarification of research proposal entitled ***"Evaluation of perioperative and quality of life outcomes along with cost effectiveness in laparoscopic tarm repair (Transabdominal retro-muscular) for ventral hernia, A prospective***

Chairperson, IEC
King George's Medical University

	observational study" submitted by Dr. Almas Fatma, JRI, Department of General Surgery of this University via letter no. 298 dated 16th February, 2021. ***The P.I. has given his reply & approved by the Primary reviewer.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 104th ECM II B-Thesis/P33*** ***(Primary Reviewer: Dr. Rajendra Nath)***
22	Clarification of research proposal entitled ***"A retrospective study to evaluate clinical and radiological results of surgical treatment of acetabular fractures using modified stoppa approach"*** submitted by Dr. Balwinder Singh, JRII, Department of Orthopaedics of this University via letter no. 246/OS/21 dated 16th February, 2021. ***The P.I. has given her reply which was reviewed by the Member-Secretary.*** **EC Comment:** • Kindly provide Waiver form **EC Decision:** Approved for waiver ***Ref. code: 104th ECM II B-Thesis/P55*** ***(Primary Reviewer:Dr.Preeti Agarwal)***
23	clarification of research proposal entitled ***"Association of chronic periodontitis in broad spectrum of cardio-metabolic syndrome"*** submitted by Dr. Shilpi Gupta, Ph.D. scholar batch 2018 under the guidance Prof. Nand Lal, Head, Department of Periodontology, Faculty of Dental Sciences of this University via letter no. 1561/2021 dated 12th February, 2021. ***P.I. has given his reponce which was reviewed by the Member-Secretary.*** **Action taken :** Provisionally approved ***Ref. code: 104th ECM II B-Ph.D/P1*** ***(Primary Reviewer:Dr. Rajendra Nath)***
24	Clarification of research protocol entitled ***"A prospective, multicentre, randomized, double blind, phase III study to compare the efficacy and safety of ENZ129 with HUMIRA® (Adalimumab) injection in subjects with active ankylosing spondylitis (AS)"*** sponsored by Alkem Laboratories Ltd. submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery of this University via letter no. 273/OS/2021 dated 20th February, 2021. ***The P.I. has given his reply & approved by the Member-Secretary.*** **Action taken:** Provisionally approved

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Approved *Ref. code: 104th ECMIIC/P3* ***(Primary Reviewer: Dr. Surajit Bhattacharya)***
	Minutes of the meeting of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** will be held on 19th February, 2021 from 2.00 of King George's Medical University U.P, Lucknow.(DCGI) • The following members were present in the Meeting:- • Hon'ble Justice Vishnu Sahai -Chairman • Dr. Rajiv Garg - Member • Dr. Rajendra Nath - Member • Dr. Manju Agrawal -Member • Mr. Yogesh Mishra -Member • Dr. Shally Awasthi -Member Secretary, ex-officio
I- a	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology of this University via letter no. 1316/Cardio/Res/2020 dated 28th December, 2020. **Death** **Subject ID no. 010-0001** **Subject Initial:** R B S **SAE term:** Death on 25-09-2020 **Causality:** Cardiac Arrest **Gender:** M **Age:** 48 yrs old **Weight:** 67 KG **Height:** 170 CM **Start Date:** 14-06-2017 **Subject History:** ***Site made a call subject# 010-0001 for 42nd month follow-up visit, his LAR said that he passed away on 25th September, 2020 at 9:15 PM in the hospital. He was taken to the local hospital and primary treatment was given, but could not survived and due to cardiac arrest he died. No autopsy was done and no other medical documents provided.*** **ADR-sub-Committee decision:** **Since a perusal of papers sows that there was no nexus between the death of the subject and the study drug (Warfarin) administered to him, no documents pertaining to is death have**

Chairperson, IEC
King George's Medical University

	been provided by the LAR and no autopsy was done no case for compensation arises.
b	**Death** **Subject ID no.:** 010-00038 **Subject Initial:** R--- **SAE term:** Death on 24-11-2020 **Causality:** Unknown **Gender:** F **Age:** 55 yrs old **Weight:** 67 KG **Height:** 160 CM **Start Date:** 01-02-2018 **Subject History:** Site made a call to the subject ID # 010-0038 for 36th month follow-up visit. His LAR said that he passed away on 24th November, 2020 at 11:15 PM at home. Local practitioner was called and declared him dead. No autopsy was done and death certificate provided. (By village Pradhan authority) **ADR-sub-Committee decision:** Since a perusal of papers shows that there was no nexus between the death of the subject and the study drug (Rivaroxaban) administered to the subject, the local doctor on being called reported that the subject was dead and no autopsy on the corpse of the subject was done any case for compensation arises. ***Ref. code: 83rd ECM IIC/P6***
IB	**Expedited review**
1	Expedited review of research proposal entitled ***"A prospective observational study comparing the effect of epidural analgesia withk intravenous analgesia in blunt trauma chest patients managed by non invasive ventilation"*** submitted by Dr. Abhishek Bhaskar, JR, Department of Anaesthesiology of this University via letter no. Anaes/16/2021 dated 6th January, 2021. ***The above proposal forwarded to Dr. Preeti Agarwal & Dr. Rajendra Nath for review.*** ***Ref. code: 105th ECM IB/P1*** **Action taken:** Provisionally approved **EC Decision:** Approved

Chairperson, IEC
King George's Medical University

II-A	New Proposal
1.	Research proposal entitled ***"A survey on awareness of breast cancer and detection of blood and urine based biomarkers among the patients and their family members at King Georges' Medical University, Lucknow"*** sponsored by CSIR-CDRI submitted by Dr. Pooja Ramakant, Additional Professor, Department of Endocrine Surgery of this University via letter no. SURG/10/2021 dated 7th January, 2021. ***The following doucuments were reviewed in the Meeting:-*** • Report of Scientifec review • Check List • Breif summary • Undertaking by the P.I. • CV of Dr. Dibyendu Banarjee, Senior Scientist, CSIR-CDRI, Lucknow, India • Dr. Monika Sachdev, Prinicipal Scientist, CSIR-CDRI, Lucknow, India • Dr. Ravi Sankar Ampapathi, Sr. Prinicpal Scientist, CSIR-CDRI, Lucknow, India • Dr. Khushboo Sinha, CSIR, Senior Research Fellow, CSIR-CDRI, Lucknow, India • Dr. Akansha Vyas, Senior Research Fellow, CSIR-CDRI, Lucknow, India • Executive Summary • Informed Consent form Hindi & English • References **EC Comment:** • The aim of this study is to determine the knowledge and awareness of CA Breast in Indian society by a questionnaire based study. • The study also wants to find out some blood or urine based biomarkers for diagnosing and prognosticating the outcome of Breast cancer. • Regarding the 1st aim the researchers have not provided the quintessential questionnaire. 4. Regarding the 2and aim all we know is 5 to 10ml of blood and 10 to 5p ml of urine will be taken as sample but what will be tested in them we do not know as that has not been mentioned. • Sample size is 200. How was this calculated? We need a statistical review.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• 100 patients will be of CA Breast and 100 normal. Now who are these normal females? Are they relatives of the patients, then her immediate blood relatives cannot be considered as normal as they are too genetically prone to Breast cancer. Are they from the population attending OPD and not related to the patients? We need clarity in this. • A blanket ethical clearance is being saught for patient photography and videography. This is not possible. I would request the investigators to kindly read the following article and construct a proper consent form for Clinical photography and videography. **EC Decision:** Approval after justification ***Ref. code: 105th ECM IIA/P1*** ***(Primary Reviewer : Dr. Surajit Bhattacharya)***
2.	Research proposal entitled "***Assessment of quality of life outcomes with prophylactic placement of permanent synthetic mesh at the time of enterostomy closure-a prospective observational study***" submitted by Dr. Ajay Kumar Pal, Associate Professor, Department of Surgery General of this University via letter no. 133/2021 dated 21st January, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Check List • Breif summary • Undertaking by the P.I. • Study proforma • Questionnair Hindi & English • Executive Summary • Informed Consent form Hindi & English • References **EC Comment:** • Inclusion/ Exclusion criteria are not clear. While patients with follow up of atleast 3 month are to be included, the exclusion criteria states that patients with less than 6 months of follow up will be excluded. The inclusion criteria are in contradiction with exclusion criteria. **EC Decision:** Approval after justification ***Ref. code: 105th ECM IIA/P2***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	(Primary Reviewer : Dr. Smriti Bhadauria)
3.	Research proposal entitled **"*Low back pain and work absenteeism: a cross sectional study from king george's Medical University, Lucknow, India*"** submitted by Dr. Sudhir R Mishra, Associate Professor, Department of PMR of this University via letter no. DPMR/3523/21 dated 28thJanuary, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Check List • Breif summary • Undertaking by the P.I. • Study proforma • Questionnair Hindi & English • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code: 105thECM IIA/P3*** ***(Primary Reviewer : Dr. Anoop Kumar Verma)***
4.	Research proposal entitled **"*Role of cost effective POP boot traction in post polio residual paralysis (PPRP): A case series*"** submitted by Dr. Sudhir R Mishra, Associate Professor, Department of PMR of this University via letter no. DPMR/3524/21 dated 28thJanuary, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Comment:** • Kindly clarify inclusion & Execlusion Creteria **EC Decision:** Approval after justification ***Ref. code: 105thECM IIA/P4*** ***(Primary Reviewer :Dr. Smriti Bhadauria)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

5.	Research proposal entitled ***"Physiatrist approach in calcaneal osteomyelitis management: A case series"*** submitted by Dr. Sudhir R Mishra, Associate Professor, Department of PMR of this University via letter no. DPMR/3449/21 dated 22nd December, 2020. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Comment:** • Sample size is clearly stated but basis for the same has not been provided. P.I. may provide statistical analysis in support of sample size. **EC Decision:** Approval after justification ***Ref. code: 105th ECM IIA/P5*** ***(Primary Reviewer : Dr. Smriti Bhadauria)***

Chairperson, IEC
King George's Medical University
U.P. Lucknow

II B	New Thesis
1.	Research proposal entitled ***"To evaluate and compare the effect of hyaluronan and metronidazole gels in the treatment of chronic periodontitis"*** submitted by Dr. Nazia Parveen, JRI, Department of Periodontology Faculty of Dental Sciences of this University via letter no. 1586/P.2021 dated 7thJanuary, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Comment:** 1. The aim of this study is to compare the clinical effects of sub-gingival application of HA gel and MTZ gel as an adjunct to root surface debridement (RSD) in patients of Ch. Periodontitis and to do immunoassay of human Beta Defencin-2 (hBD-2) gingival cervicular fluid (GCF) after 3 months of therapy in these 2 sets of patients. 2. The accompanying Review of Literature is adequate 3. A study design flow chart has been provided 4. Sample size in 75, 25 in each of the three groups – Control in which only RSD will be offered and 2 Study groups in which either HA-gel od MTZ-gel will be added as an adjunct to RSD. This is supported by statistics. 5. Randomization will be done by a computer generated random allocation programme 6. A detailed Case Data Collection Sheet is provided 7. Inclusion and exclusion criteria are satisfactory 8. A bilingual consent form is provided **EC Decision:** Approved ***Ref. code: 105thECM II B-Thesis/P1*** ***(Primary Reviewer: Dr. Surajit Bhattacharya)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

IIB	New Ph. D. Scholar
1.	Research proposal entitled **"*Identification and classification of metabolic pathway associated with COVID-19 induced acute kidney injury*"** submitted by Mr. Mukul Kumar Singh, Ph.D. 2019 Scholar under the guidance Prof. Vishwajeet Singh, Department of Urology of this University via letter no. 57/URO/21 dated 4th February 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code: 105thECM II B-Ph.D/P1*** ***(Primary Reviewer : Dr. Rajiv Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

IIC	Review of New Drug Trial
1.	Research Protocol no.LRP/LUBT010/2016/008 entitled "***A global, phaseIII, double blind, randomized controlled study to compare the efficacy, safety & immunogenicity of LUBT010 with lucentis® in patients with neovascular age-related macular degeneration***" sponsored by Lupin Limited (Biotechnology Division) submitted by Prof. Sandeep Saxena, Department of Ophthalmology of this University via letter no. OPh/01/CT dated 7th November, 2020. The following documents were examined and discussed in the meeting 1. Protocol India Version No. 1.1, Dated 20 Jan 2020 2. Appendix A for India Ver. No. 1.1_20 Jan 2020-Final 3. Appendix B for India Ver. No 1.1_20 Jan 2020-Final 4. Appendix C for India Ver. No 1.1_20 Jan 2020-Final 5. Appendix D for India Ver. No 1.1_20 Jan 2020-Final 6. Protocol India Version No. 2.0, Dated 22 Jul 2020 7. Signed Protocol Signature Page_Dr. Sandeep Saxena dated 21 Aug 2020 8. Signed Protocol Signature Page_Dr. Sandeep Saxena dated 14 Oct 2020 9. Investigator Brochure - Edition: 1.2, Dated 03 Mar 2020 10. Main_V1.3IND(en)1.0A_(15Apr2020) Site 10523 11. Translation of Main_V1.3IND(hi)1.0A_(15Apr2020) Site 10523 12. Back Translation of Main_V1.3IND(hi)1.0A_(15Apr2020) Site 10523 13. Translation and Back translation Certificate Hindi Main ICFdated 17 Dec 2020 14. Main_V2.0IND(en)1.0_(04Aug2020) Site 10523 15. Translation of Main_V2.0IND(hi)1.0_(04Aug2020) Site 10523 16. Back Translation of Main_V2.0IND(hi)1.0_(04Aug2020) Site 10523 17. Translation and Back translation Certificate of Hindi Main ICF dated 01Oct2020 18. AV ICF/Other_V7.0IND(en)1.0 (25Feb2020) Site 10523 19. Translation of AV ICF/Other_V7.0IND(hi)1.0 (25Feb2020) Site 10523 20. Back Translation of AV ICF/Other_V7.0IND(hi)1.0 (25Feb2020) Site 10523 21. Translation and Back translation certificate of Hindi AV ICF/OtherICF dated 01Oct2020 22. Audio Visual (A-V) Recording Declaration V4.0IND(en)1.0(19Mar2020) Site 10523 23. Patient ID card, 18 Feb 2020_ [V01 IND(en)] 24. Patient ID card, 18 Feb 2020_ [V01 IND(hi)] 25. Translation certificate of Patient ID card dated 03 Mar 2020 26. NEI-VFQ25-IA_AU1.0_eng-US 27. NEI-VFQ25-IA_AU1.0_hin-IN - 23 Jul 07 28. Translation certificate of Hindi NEI-VFQ-25-IA

Chairperson, IEC
King George's Medical University
Lucknow

29. Insurance certificate dated 03 Sep 2020
30. DCGI approval letter for Protocol version 1.0 dated 15 Dec 2017
31. DCGI approval extension letter dated 27 Dec 2019
32. Import License dated 07 Jan 2020
33. DCGI Cover Letter and Notification dated 31 Jan 2020 for Protocol 1.1
34. DCGI Cover Letter and Notification dated 22 Jun 2020 for IB Ed 1.2 and ICF V 1.3
35. DCGI Cover Letter and Notification_PA v2.0 dated 04 Aug 2020
36. CTRI Registration No. CTRI/2020/09/027776
37. CV_Dr. Sandeep Saxenadated 21Aug 2020
38. MRC_Dr. Sandeep Saxena
39. GCP Certificate_Dr. Sandeep Saxena dated 26Jul 2019
40. Investigators Undertaking (IU)_Dr.Sandeep Saxena dated 21Aug 2020
41. Annotated Study Book for Study Design: LRP/LUBT010/2016/008, V2.0 dated 29Jun2020
42. Draft CTA Template_ FINAL version_18Mar2020

EC Decision: Approval after fulfillment of Administrative Formalities

Ref. code: 105thECMIIC/P1

(Primary Reviewer : Dr. Rajiv Garg)

Chairperson, IEC
King George's Medical University
U.P. Lucknow

IID	Nurses-Students
1.	Research proposal entitled ***"Assess the knowledge and expressed practice regarding temporary contraceptive methods among young women in selected urban slums"*** submitted by Miss. Anjali Baghel, Through his Mentor Mr. Rohitash Kumar, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January , 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P1*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
2.	Research proposal entitled ***"Effectiveness of planned teaching programme on knowledge regarding dengue fever & preventive measures among adult population in selected urban slums"*** submitted by Miss. Rupali Singh, Through his Mentor Mr. Rohitash Kumar, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January , 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P2*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

3.	Research proposal entitled ***"Effectiveness of structured teaching programme on knowledge among mothers of under five children regarding acute respiratory tract infections in selected rural area"*** submitted by Miss. Sujata, Through his Mentor Mr. Rohitash Kumar, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P3*** ***(Primary Reviewer: Dr. Vimal Kumar Paliwal)***
4.	Research proposal entitled ***"Effectiveness of thirst intervention package on thirst intensity and thirst distress among patients of heart failure with fluid restriction admitted in Lari cardiology, KGMU"*** submitted by Ms. Farah Naaz, Through his Mentor Dr. Suchana Roy Bhowmik, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.2089/X51 dated 9th December, 2020. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P4*** ***(Primary Reviewer: Dr. Rajendra Nath)***
5.	Research proposal entitled ***"Effectiveness of coma arousal techniques to improve the sensory stimulation in unconscious patient patient admitted in ICU"*** submitted by Ms. Geeta Kushwaha, Through his Mentor Mr. Subin Sudarsanan, Assistant

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P5*** ***(Primary Reviewer: Dr. Rajendra Nath)***
6.	Research proposal entitled ***"A cross sectional study to assess quality of sleep, self-esteem and life style among patient with depression"*** submitted by Ms. Shashi Chauhan, Through his Mentor Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P6*** ***(Primary Reviewer: Dr. Rajendra Nath)***
7.	Research proposal entitled ***"Effectiveness of self instructional module on knowledge regarding dietary management of iron deficiency anemia among pregnant women attending OPD"*** submitted by Mr. Ramesh Singh Chauhan, Through his Mentor Mrs. Rashmi P. John, Department of KGMU College of Nursing of this University via letter no nil dated 18th January, 2021. ***The following documents were reviewed in the Meeting:-***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Comment:** • Study involves pregnant women. On page 5 they have marked both sites (Probably inadvertently) to be corrected. • Thay hav marked "No" for vulnerable group to be corrected **EC Decision:** Approval after justification ***Ref. code:105th ECM IID/P7*** ***(Primary Reviewer: Dr. Amita Jain)***
8.	Research proposal entitled ***"Effectiveness of BUERGER ALLEN's exercise on foot perfusion among type2 diabetes mellitus patients"*** submitted by Ms. Jyoti Srivastava, Through his Mentor Mrs. Rashmi P. John, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P8*** ***(Primary Reviewer: Dr. Amita Jain)***
9.	Research proposal entitled ***"Effectiveness of structured teaching programme on knowledge and attitude regarding cervical cancer screening among women attending OPD in the Department of OBG, KGMU, Lucknow"*** submitted by Ms. Ramakanti, Through his Mentor Mrs. Rashmi P. John, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. ***The following documents were reviewed in the Meeting:-***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P9*** ***(Primary Reviewer: Dr. Amita Jain)***
10.	Research proposal entitled ***"Hydrotherapy versus land-based exercises on pain and quality of life (Qol) among patient with rheumatoid arthritis"*** submitted by Mr. Rajendra Kumar Jinjwaria, Through his Mentor Mrs. Rashmi P. John, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P10*** ***(Primary Reviewer: Dr.Amita Jain)***
11.	Research proposal entitled ***"Effectiveness of educational intervention on knowledge regarding iron deficiency anemia among adolescent girls residing in urban slums"*** submitted by Ms. Nidhi Shukla, Through his Mentor Mr. Rohitash Kumar, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P11*** ***(Primary Reviewer: Dr.Vimal Kumar Paliwal)***
12.	Research proposal entitled ***"Effectiveness of self-instructional module on knowledge regarding sexually transmitted disease and its prevention among adolescents in selected urban area of Lucknow, U.P."*** submitted by Mr. Ankur Kumar Singh, Through his Mentor Mr. Rohitash Kumar, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P12*** ***(Primary Reviewer: Dr.Vimal Kumar Paliwal)***
13.	Research proposal entitled ***"Effectiveness of video assisted kegel exercise and abdominal muscle exercises on involution of uterus and perineal pain among postnatal mothers"*** submitted by Miss. Neha Singh, Through his Mentor Mrs. Rashmi P. John, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P13*** ***(Primary Reviewer: Dr.Amita Jain)***
14.	Research proposal entitled ***"A study on the psychological and behavioral issues during COVID-19 pandemic on children and adolescent with attention deficit hyperactivity disorder"*** submitted by Ms. Monika Pal, Through his Mentor Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English • References **EC Decision:** Approved ***Ref. code:105th ECM IID/P14*** ***(Primary Reviewer: Dr. Rajendra Nath)***
15	Research proposal entitled "Early identification of hypertensive patients apparently asymptomatic cohort and risk stratification as per new AHA guidelines (2017) among non –teaching employee of KGMU, Lucknow" submitted by Mr. Devi Sahay Kumawat, Through his Mentor Dr. Suchana Roy Bhowmik, Associate Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. ***The following documents were reviewed in the Meeting:-*** • Report of Scientifec review • Brief summary • Check List • Undertaking by the P.I. • Executive Summary • Informed Consent form Hindi & English

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• References **EC Decision:** Approved ***Ref. code:105th ECM IID/P15*** ***(Primary Reviewer: Dr. Rajendra Nath)***

Chairperson, IEC
King George's Medical University

III	Adverse Drug Event
1.	ADE Research Protocol no EX9536-4388 SELECT entitled ***"Semaglutide effects on cardiovascular outcomes in people with overweight or obesity"*** sponsored by M/s Novo Nordisk Ltd. submitted by Dr. Rishi Sethi, Department of Cardiology of this University via letter no. 1315/Cardio/Res/2020 dated 28th December, 2020. **Subject ID no. 253747** **Subject Initial:** M H **Gender:** M **Age:** 55 yrs old **Weight:** 86 KG **Height:** 109 CM **Start Date:** 10-12-2020 **Subject History:** ***Subject called on 21st December, 2020 at 6:30 and informed site staff that he developed chest pain on 20th December, 2020 at nightly and he came to hospital emergency on 21st December, 2020 there his TropT was done at 9:10 AM and repeated 6 hourly tropT at 13:50 so he was admitted on 21st December, 2020 and NSTMI is diagnosed subject underwent PCI on 22nd December, 2020, his procedure was done successfully and he is still hospitalized. Subject discharged on 23rd December, 2020.*** **EC Decision:** Noted ***Ref. code: 92nd ECM IIC/P1*** ***(Primary Reviewer : Dr. Rajiv Garg)***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

III	Modification
1.	Modification of Research protocol entitled ***"Effect of priming on adjunctive repetitive trans cranial magnetic stimulation in the treatment of late life depression, and associated quantitative EEG changes: A prospective randomized sham controlled study"*** submitted by Dr. Vidya K.L, SR, Department of Geriatric Mental Health this University via letter no.828/DGMH dated 15th January, 2021. ***The following documents were reviewed in the Meeting:-*** **EC Decision:** Approved ***Ref.code:101stECMIBThesis/P2*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
2.	Modification of Research protocol no. CTQJ230A12301entitled ***"A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease"*** sponsored by Novartis Health Care Pvt. Ltd. submitted by Prof. S.K. Dwivedi, Department of Cardiology this University via letter no.1356/Cardio/21 dated 16th January, 2021. The following documents were examined and discussed in the meeting 1. Clinical trials protocol (Version Number: 02, dated 20th April, 2020 2. Patient information and informed consent form (Version 2.0 dated 14th May, 2020) 3. Patient information and informed consent form (Version 2.0 dated 14th May, 2020) translated from English to Hindi on 15th May, 2020. 4. Patient information and informed consent form (Version 2.0 dated 14th May, 2020) back translated from Hindi to English on 18th May, 2020. 5. Translation and back translation certificate for patient information and informed consent form (Version 2.0 dated 14th May, 2020): Hindi. **EC Decision:** Approved ***Ref.code:101stECMIIC/P18*** ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
3.	Modification of Research protocol no. CTQJ230A12301entitled ***"A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease*"** sponsored by Novartis Health Care Pvt. Ltd. submitted by Prof. S.K. Dwivedi, Department of Cardiology this University via letter no.1355/Cardio/21 dated 16th January, 2021. The following documents were examined and discussed in the meeting:- 1- Patient information and informed consent form (Version 3.0, Dated 17 July 2020) 2- Patient information and informed consent form (Version 3.0, Dated 17 July 2020) translated from English to Hindi on 15th May, 2020. 3- Patient information and informed consent form (Version 3.0, Dated 17 July 2020) back translated from Hindi to English on 21 July 2020. 4- Translation and back translation certificate for Patient Information and Informed Consent Form (Version 3.0, Dated 17 July 2020):Hindi **EC Decision:** Approved ***Ref.code:101stECMIIC/P18 ***(Primary Reviewer: Dr. Anoop Kumar Verma)***
4.	Modification of Research protocol no. RI-01-006 entitled ***"A randomized, double-blind, parallel- group, phase III study to compare the efficacy, safety, and immunogenicity of proposed rituximab biosimilar (DRL- RI) with MAB THERA® in subjects with previously untreated, stage II- IV, cluster of differentiation (CD) 20- positive, low tumour burden follicular lymphoma"*** sponsored by Reddy's Laboratories S.A. submitted by Dr. Sudhir Singh, Department of Radiotherapy this University via letter no. RT/30/21 dated 30th January, 2021. The following documents were examined and discussed in the meeting ❖ Protocol RI-01-006 version 4 dated 04 Nov 2020 ❖ INVESTIGATOR BROCHURE; Version 8, 10 September 2020 ❖ Summary of changes IB V 8.0 **Main ICF:** • 242435_RI_01_006_India Dr. Sudhir Singh Main ICF_English_Version 3.0_25 Nov 2020 Based on Protocol RI_01_006_Model ICF Version 5.0_12 Nov 2020 • 242435_RI_01_006_India Dr. Sudhir Singh Main ICF_Hindi_Version 3.0_25 Nov 2020

Chairperson, IEC
King George's Medical University
U.P., Lucknow

Based on Protocol RI_01_006_Model ICF_Version 5.0_12 Nov 2020

Translated from English to Hindi on 08 Dec 2020

- 16. 242435_RI_01_006_India Dr. Sudhir Singh Main ICF_Hindi to English_Version 3.0_25 Nov 2020
  Based on Protocol RI_01_006_Model ICF_Version 5.0_12 Nov 2020

  Back Translated from Hindi toEnglish on 08 Dec 2020

- Translation and back translation validations are attached with respective ICF

Other documents:

- COVID19 Guidance v2 dated 12 Nov 2020
- COVID-19 Guidance Document to Sites_V2.0 dated 30 Oct2020
- Physician Letter V3.0 English dated 01 April 2020
- Ring of Resources V2.0 English dated 01 April 2020
- Screening Procedure Site Poster V2.0 English dated 01 April 2020
- Screening Procedure Site Poster V2.0 Hindi dated 01 April 2020
- Annotated Blank CRF_RR03_11 Sep 2020
- CRF v4.0 dated 11 Sep 2020 with summary of changes
- Hepatitis B Post End of Study Follow-Up Reporting dated 23 Nov 2020
- Patient Info getter V2.0 dated 27 Nov 2019 English
- Patient Info getter V2.0 English dated 27 Nov 2019 Hindi

EC Decision: Approved

Ref.code:101st ECMIIC/P2

(Primary Reviewer: Dr. Preeti Agarwal)

Chairperson, IEC
King George's Medical University

IV	Other Matter
1-	Reg. permission to discontinue project of Dr. Rasmi Ranjan Sahoo who has resigned from the Department Research proposal entitled ***"Clinical characteristics and outcomes of macrophage activation syndrome among patients attending a rheumatology tertiary care centre in North India"*** send by Prof. Urmila Dhakad, Head, Department of Rheumatology of this University via letter no.Rh/110/21 dated 3rd February, 2021. **EC Decision:** Discontineu the project ***Ref.code:104th ECMIIB-Thesis/P28***
2-	Reg. request for ethical waiver of the research proposal entitled ***"Expression of podoplanin in oral squamous cell carcinoma and it's correlation with clinicopathological parameters",*** due to the current Covid 19 pandemic it will be difficult for P.I. to complete a sample size of 110 as he is not receiving enough surgically resected specimen of oral squamous cell carcinoma in the department for histopathological examiniation. The P.I. want to allow using the tissue blocks of some retrospective cases in his study. The P.I. will use tissue blocks only after proper reporting and dispatch of the report of the received sample. P.I. will maintain anonymity of data so that the data cannot be linked with identifiable human subject submitted by Dr. Deval Brajesh Dubey, JR, Department of Pathology of this University via letter no. 1523 dated 15th February, 2021. **EC Decision:** Approved ***Ref.code:102nd ECMIIB-Thesis/P30***
3-	Due to the retirement of Prof. P.K. Dalal, the all responsibilities of the research proposal entitled ***"Open-label, flexible-dose of Vortioxetine in patient with Major Depressive Disorder in Inida"*** to Dr. Adarsh Tripathi, Additional Officer is already a part of the state as a sub-investigator, Department of Psychiatry of this University via letter no.46/Psy dated 9th January, 2021. **EC Decision:** Permission granted.

The End

Chairperson, IEC
King George's Medical University

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 107th Institutional Ethics Committee Meeting held on 16th April, 2021.

K.G's Medical University U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 107th Institutional Ethics Committee Meeting held on 16th April, 2021.

Attendance

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 107th ECM held on 16th April, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Minutes of the Institutional Ethics Committee Meeting held on **16th April, 2021 (Friday) from 2.00 P.M. till 4.00 P.M.** in the **'Board Room'** Office of the Vice Chancellor, Administrative Block of this University.

The following Members were present in the virtual Meeting:

1. Dr.Alok Dhawan -Chairman
2. Dr. Shobha Phadke -Member
3. Dr. Akash Agarwal -Member
4. Dr. G.G. Agarwal -Member
5. Mrs. Akansha Dubey -Member
6. Sri Ujjawal Krishna -Member
7. Dr. A.A. Mahdi -Member
8. Dr. Rajendra Nath -Member
9. Dr. Anita Rani Singh -Member
10. Dr. Shally Awasthi -Member-Secretary, Ex-officio

The following Members could not attend:-

1. Dr. K.K. Yadav -Due to Covid duty
2. Dr. D.N. Upadhayaya -Due to Covid duty
3. Dr. Anupam Mishra
4. Mrs. Vasundhara Kumari

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 107th Institutional Ethics Committee Meeting held on 16th April, 2021.

Minutes item no. I

Brought to Ethics Committee after 1st Post Graduate Theses Sub Committee

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 107th ECM held on 16th April, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

I	**Brought to Ethics Committee after 1st PGTSC held on 13th April, 2021**
1.	Research proposal entitled ***"Randomised, single blind, control trial of transcranial direct current stimulation in adolescents with obsessive compulsive disorder as early augmentation"*** submitted by Dr. Aditya Agrawal, JRI, Department of Psychiatry of this University via letter no. 459/Psy/21 dated 8th March, 2021. **PGTSC Comment:** • Sample size calculation is not done **EC Comment:** • Re-write as a comparative study **EC Decision:** Re-submit ***Ref. code: 107th ECM II B-Thesis/P16***
2.	Research proposal entitled ***"Randomised controlled single blind trial of transcranial direct current stimulation (tDCS) as early augmentation in major depressive disorder"*** submitted by Dr. Babli Kumari, JR, Department of Psychiatry of this University via letter no. 522/Psy/21 dated 18th March, 2021. **PGTSC Comment:** • Sample size is not clear. • Fundamental of RC Trial are not followed • Kindly provide CTRI registration **PGTSC Decision:** To be kept in full committee **EC Comment:** Rewrite as a comparative study **EC Decision:**Re-submit ***Ref. code: 107th ECM II B-Thesis/P53***
3.	Research proposal entitled ***"Mindfulness, experiential avoidance, attachment and neurocognition in obsessive compulsive disorder"*** submitted by Ms. Divya Kansal, II Year under the guidance Dr. Shweta Singh, Additional Professor, Department of Psychiatry of this University via letter no. 437/Psy/21 dated 3rd March, 2021. **PGTSC Comment:** • Specify from where the controls will be selected? **EC Decision:** Approval subject to modification ***Ref. code: 107th ECM IIB M. Phil/P1***

Member Secretary
Institutional Ethics Committee
King George's Medical University, U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 107th Institutional Ethics Committee Meeting held on 16th April, 2021.

Minutes item no. IIA

New Proposals

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 107th ECM held on 16th April, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

II-A	New Proposal
1.	Research proposal entitled ***"Epidemiology of pancreatitis and major gastrointestinal disorders: A nationwide multi-center study across India"*** submitted by Dr. Sumit Rungta, Associate Professor & Head, Department of Medical Gastroenterology of this University via letter no.1092/MedGastro/21 dated 4th January, 2021. **EC Comment:** • What is the source of the funding? • Which is the Co-ordinating Centre? • Who are in the Investigators from other Institutions? • What are the roles of Co-investigators from KGMU? Specify for each. **EC Comment:** Approval subject to modification ***Ref. code: 107th ECM IIA/P1***
2.	Research proposal entitled ***"Assessment of tumor budding in Oral cavity squamous cell carcinoma undergoing primary resection and its correlation with clinical outcome parameters"*** submitted by Dr. Shalini Bhalla, Associate Professor, Department of Pathology of this University via letter no.1655/2021 dated 4th February, 2021. **EC Decision:** Defer for the next Meeting ***Ref. code: 107th ECM IIA/P2***
3.	Research proposal entitled ***"Primary extra nodal non HODGKIN's lymphoma: An observational study at a tertiary care teaching centre in North India"*** submitted by Dr. Shivanjali Raghuvanshi, Associate Professor, Department of Pathology of this University via letter no.1661/2021 dated 5th February, 2021. **EC Comment:** 1.Are retired faculty allowed to be investigators? 2. Section 4: The Dawson Criteria is used only for gastrointestinal extranodal NHLs. However, nowhere in the title, methodology, etc is it mentioned that the investigators are trying to look only for this specific subgroup of extranodal NHLs. Need to have clarity of subsites, if any. 3. Section 4: The Dawson Criteria needs information, which is not generally available in the Pathology Department records. Would like to have clarity on this. 4. Section 4: For IHC in patients whose panel is incomplete, please mention source of funding. 5. Section 4: Statistical analysis: Explicitly state the statistical tests planned to be used. SPSS is a tool to compute, it doesn't decide the test.

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	6. Section 7(iv) Use of pre-existing samples is marked 'NO'. Please clarify this. 7. Section 10(iii) Explain how the patient will directly benefit? 8. Checklist: Copy of protocol is not attached, contrary to what has been stated. 9. Has this study already been done as a PG Thesis? 10. Aims and objectives have to be defined, they have been mixed into one. 11. This study is unlikely to provide with prevalence of this disease, can only point towards incidence (that too with many conditions attached). 12. Study Design: Retrospective/ Audit should be enough. These are supposed to be observational. 13. Significance and Rationale: Please provide reference to the statement that the prevalence of this disease is increasing in India, else, remove this. **EC Decision:** Approval subject to modification ***Ref. code: 107th ECM IIA/P3***
4.	Research proposal entitled ***"Academic clinical trial of safety, pharmacokinetics and early measurement of drug activity of CENTINHALE dry powder inhalation"*** sponsored by CSIR-Central Drug Research Institute submitted by Prof. Rajiv Garg, Department of Respiratory Medicine of this University via letter no.1339/RESP/2021 dated 10th February, 2021. **EC Decision:** Defer for the next Meeeting ***Ref. code: 107th ECM IIA/P4***
5.	Research proposal entitled ***"To study the histopathological features in renal biopsy (post-mortem) of critically ill COVID-19 positive patients with renal dysfunction"*** submitted by Dr. Medhavi Gautam, Assistant Professor, Department of Medicine of this University via letter no.343/MED/21dated 15th February, 2021. **EC Comment:** • Patients with renal illness may have preexisting histopathological changes. Mention clearly how would you differentiate changes due to COVID 19 from those already present as there is no control to compare. • Elaborate the parameters to be observed by LM, IHC and EM. **EC Decision:** Approval subject to modification ***Ref. code: 107th ECM IIA/P5***

Member Secretary
Institutional Ethics Committee

Chairperson, IEC
King George's Medical University
U.P., Lucknow

6.	Research proposal entitled **"*Retrospective analysis of a methanol intoxication outbreak in Lucknow district and nearby areas in 2019*"** submitted by Dr. Medhavi Gautam, Assistant Professor, Department of Medicine of this University via letter no.344/MED/21dated 15th February, 2021. **Methodology:** • All criteria not mentioned in text as per the case report form • Case report form to include full forms of the abbreviation, hence revise accordingly **Background information and data:** • Should also include the background literature relevant to proposed objectives **Inclusion criteria:** • If only those cases with positive family history of methanol intake are to be included, then incorporating signs of intoxication and that too based on suspicion seems confusing in this section. Hence revise. **Sufficient number of participants:** • Not specified • Additional Co-PI from TVU and Critical care medicine may be considered since the cases are to be recruited from these dept. as well • Justify inclusion of to Co-Investigators **EC Decision:** Re-submit ***Ref. code: 107th ECM IIA/P6***
7.	Research proposal entitled **"*Photobiostimulation (Low Level laser Therapy) as a non-invasive therapeutic adjunct for non-surgical management of periapical bone defects during COVID-19 pandemic*"** sponsored by UPCST Lucknow submitted by Dr. Rhythm, Department of Conservative Dentistry & Endodontics of this University via letter no.428/2020dated 29th December, 2020.

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment: • Sponsor Information: UPCST is State, not Institutional • Budget is not mentioned-Needs itemized budget • Needs patient information sheet/brochure in English and Hindi • Needs Case Report Form. • Hypothesis: need to differentiate between a research hypothesis and null hypothesis. • Study design: What type of randomization and why? • Will RCT be done in all patients? If yes- mention it, if no: correct consent form. • What type of statistics will be used? Please mention detailed statistical plan. • What are the endpoints and how will they be assessed / measured? • Sample size: explain calculation, effect size and baseline efficacy. • Consent form: There is a risk of using non standard treatment, should be mentioned. **EC Decision:** Re-submit after modification ***Ref. code: 107th ECM IIA/P7***
8.	Research proposal entitled ***"Pilot study to testify the role of antifibrotic drugs (PIRFENIDONE and NINDETANIB) as a probable therapy for patients of post COVID pulmonary fibrosis"*** submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine of this University via letter no.1172/2020dated 22nd December, 2020. **EC Comment:** • Give a detailed Budget. **EC Decision:** Approval subject to modification ***Ref. code: 107th ECM IIA/P8***
9.	Research proposal entitled ***"A ten year retrospective study of clinicoradiological and histopathological profile of lung cancer and its outcome in a tertiary care Hospital"*** submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine of this University via letter no.1510/2021 dated 15th March, 2021. **EC Decision:** Defer for the next Meeting ***Ref. code: 107th ECM IIA/P9***

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

10-	Research proposal entitled **"*Genetic polymorphism of TCF7L2 in type 2 diabetes mellitus*"** submitted by Dr. G.K. Sonkar, Additional Professor, Department of Biochemistry of this University via letter no. Bio/2021/668 dated 24th February, 2021. **EC Decision:** Approved ***Ref. code: 107th ECM IIA/P10***
11	Research proposal entitled ***"Thrombocytosis, hemorrhagic pleural effusion and fibro infiltrative patches with cavitary lesion in lungs of COVID- 19 positive Child"*** submitted by Dr. Ankit Pachauri, JR, Department of Pediatrics of this University via letter no. 598/Ped/21 dated 12th March, 2021. **EC Comment:** • As it is a Single Case Study with no Research Component **EC Decision:** Approved ***Ref. code: 107th ECM IIA/P11***
12	Research proposal entitled ***"International snapshot study on the outcomes of Pancreatic Surgery pancreasGroup.org"*** submitted by Dr. Naseem Akhtar, Additional Professor, Department of Surgical Oncology of this University via letter no. SONC/262/21 dated 17th March, 2021. **EC Comment:** • Collaborators: University College London Hospitals, Massachusetts General Hospital. • Eligibility of Surgeon – Any Surgeon worldwide performing pancreatic surgery is eligible to participate in PancreasGroup.org • Study duration- 12 month frame (Jan-Dec2021) • Working proforma of PancreasGroup.org attached. • Summary of proposal needed. **EC Decision:** Approval subject to modification ***Ref. code: 107th ECM IIA/P12***

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 107th Institutional Ethics Committee Meeting held on 16th April, 2021.

Minutes item no. IIB

Ph.D. Scholars & Fellowship

K.G's Medical University U.P., Lucknow

IIB	New Ph.D Scholar
1.	Research proposal entitled **"*Formulation, optimization and evaluation of apigenin and cardamom essential oil based emulgel for mitigation of oral submucous fibrosis*"** sponsored by ICMR submitted by Ms. Sarita Pal, Ph.D Scholar 2019, under the guidance Dr. N.P. Yadav & Co-PI U.S. Pal, Department of Oral and Maxillofacial Surgery of this University via letter no. 59/OMFS/21 dated 22nd January, 2021. **EC Comment:** • 1-Section 5: This project is an in-vitro study: what is the need for subjects? • 2. Section 5: Many vulnerable subjects have been ticked: why? • Section 6: Privacy statement: not checked • Section 7: Organs and body fluids are being used: wrongly checked. • Section 8: All studies involving patient recruitment need a patient information sheet. • Section 8: Who administers the consent? • Section 10: Give details of interim data analysis points. • Biopsy is an invasive procedure: can have complications, can't be risk free. • Consent form and patient information sheet should be separate. • Why will oral cancer cell lines be used? The study is of OSMF, not cancer. • Objectives: Procurement of buccal mucosa cannot be an objective, at least for this study. • Please provide the Ayurvedic Text which tells about areca nut causing OSF. • Please provide itemized budget. **EC Decision:** Final observation: Needs major modifications, resubmit as fresh proposal. ***Ref. code: 107th ECM II B-Ph.D/P1***
2.	Research proposal entitled **"*Molecular and metabolic profiling of obstructive sleep apnea in North Indian population*"** submitted by Mr. Mohit, Ph.D Scholar 2018, under the guidance Prof. Pooran Chand, Head, Department of Prosthodontics Faculty of Dental Sciences of this University via letter no. 990/2021 dated 4th February, 2021.

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	C Comment: • Justify role of each guide. • How will north Indian population be defined? **Methodology:** • Needs to be elaborated with flow chart(s) • What are those 'following criteria' for subject collection? **Inclusion criteria:** • Need refinement and all criteria to be consolidated at one place **Control arm:** • Mention the source of controls • What will be the consent procedure for controls and specially for obtaining the blood sample? **ICF:** • Study procedure section of informed consent document should be more understandable to the patient • BUT Study procedure section of informed consent document should be elaborated. • Include an Investigator from Respiratory Medicine. • Give budget & Source of funding **EC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Ph.D/P2***
3.	Research proposal entitled **"*Clinical study of compliance and therapeutic adherence in patients of type-2 diabetes mellitus and hypertension and assessment of quality of life in tertiary Hospital*"** submitted by Mr. Indrashis Mukherjee, Ph.D Scholar 2019, under the guidance Prof. Amod Kumar Sachan, Head, Department of Pharmacology & Therapeutics of this University via letter no. 265/Pharma/2021 dated 29th January, 2021. **EC Comment:** Defer for next Meeting. ***Ref. code: 107th ECM II B-Ph.D/P3***

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
Lucknow

IIB	Fellowship
1.	Research proposal entitled ***"miRNA profiling of pre-cancer and cancer of breast to unravel potential novel biomarkers: prognostic and therapeutic implications"*** sponsored by ICMR & DHR submitted by Dr. Richa Singh, under the guidance Prof. M.L.B. Bhatt, Department of Radiotherapy of this University via letter no.614/RT/2020 dated 20th November, 2020. **EC Comment:** • Write that no Surgical intervention will be done for research. • Along with Hindi words write English words in brackets. • This may be taken as a pilot study. • A few selected mRNA to be studied and their list given. Limit only cancer cases to have homegenous group. • Sample size should be feasible and acceptable. **EC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-FS/P1***

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 107th Institutional Ethics Committee Meeting held on 16th April, 2021.

Minutes item no. IIC

New Trial

K.G's Medical University U.P., Lucknow

II C	Review of New Drug Trial
1.	Research Protocol no. CROSSLINKED-HA entitled "***A prospective, rendomized, comparative, clinical study to assess the safety and performance of cross-linked hyaluronic acid-dermal filler in people with all skin types, who need lip enhancement, cheek bone augmentation and nasolabial fold improvement***" sponsored by Biotech Vision CARE Pvt. Ltd. submitted by Prof. Apjit Kaur Chhabra, Department of Ophthalmology of this University via letter no. 1354/OPH/2021 dated 19th January, 2021. **EC Comment:** • Budget: 30,000/subject. Give detailed budget • All tools & scales are attached, undertaking by PI and declaration of conflict of interest statement attached. • CTRI & CT Agreement attached • Comments: 1. Insurance policy paper is attached but expired (16-07-2019 to 15-07-2020) • DCGI approval is awaited • Justify the role of each investigator and whether they have been trained for this work. **EC Decision:** Approval subject to modification & fulfillment administrative formalities. ***Ref. code: 107th ECMIIC/P1***

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 107th Institutional Ethics Committee Meeting held on 16th April, 2021.

Minutes item no. III

Modification

K.G's Medical University U.P., Lucknow

III	Modification
1.	Modification of Research protocol entitled ***"Effect of yoga- based cardiac rehabilitation programme (Yoga-Care) on cardiovascular health: a clinical trial (India) and mechanistic study (UK)"*** submitted by Prof. Sharad Chandra, Department of Cardiology this University via letter no.1393/Cardio/Res/21 dated 5th February, 2021. **EC Comment:** • Give approval from funding agency for extension. **EC Decision:** Approval subject to modification ***Ref.code:74th ECMIIA/P11***
2.	Modification of Research protocol no. ATLAS-OLE: entitled ***"An Open label long term safety and efficacy study of fitusiran in patients with hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX"*** submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology this University via letter no.51/CH/21 dated 6th February, 2021. **EC Decision:** Approved ***Ref.code:90th ECM II C/P1***
3.	Modification for increasing scope of surveillance activity under project entitled ***"Capacity building and strengthening of Hospital Infection Control to detect and prevent antimicrobial resistance in India"*** submitted by Prof. Vimala Venkatesh Department of Microbiology of this University via letter no. 2021/02/CB-131 dated 5th February, 2021 2021/02/CB-132 dated 27th February, 2021. **EC Decision:** Defer for the next Meeting ***Ref. code: 84th ECM II A/P29***
4.	Modification of Research proposal entitled ***"A survey on awareness of breast cancer and detection of blood and urine based biomarkers among the patients and their family members at King Georges' Medical University, Lucknow"*** sponsored by CSIR-CDRI submitted by Dr. Pooja Ramakant, Additional Professor, Department of Endocrine Surgery of this University via letter no. SURG/10/2021 dated 7th January, 2021.

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Comment: • Give role of CSIR-CDRI • Give approval of CSIR-CDRI • Where will funds come for work in CSIR-CDRI ? • Who will administor the questionnaire • Give details in Methodology **EC Decision:** Re-submit with only one arm ***Ref. code: 105th ECM IIA/P1***

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 107th Institutional Ethics Committee Meeting held on 16th April, 2021.

Minutes item no. IV

Annual Progress Reports

K.G's Medical University U.P., Lucknow

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 107th ECM held on 16th April, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

IV	Annual Progress Report
1.	Annual Progress Report of research protocol entitled ***"CETP and SRBI gene polymorphism on lipid subtypes of LDL and dysfunctional HDL in patient with type II diabetes mellitus"*** sponsored by CST-UP submitted by Dr. Wahid Ali, Additional Professor, Department of Pathology of this University via letter no. 1677/2021 Dated 9th February, 2021. **EC Comment:** • How as done work done prior of approved by EC? **EC Decision:** Approval subject to modification ***Ref. code: 98th ECMIIA/P4***
2.	Annual Progress Report of research protocol entitled ***"Newborn screening programme"*** sponsored by U.P NHM submitted by Dr. Wahid Ali, Additional Professor, Department of Pathology of this University via letter no. 1678/2021 Dated 9th February, 2021. **EC Decision:** Defer for the next Meeting ***Ref. code: 99th ECMIIA/P3***
3.	Annual Progress Report of research protocol no.KCP-330-023entitled: ***"BOSTON- A phase 3 randomized, controlled, open-label study of selinexor, bortezomib and dexamethasone (SVD) versus borterzomib and dexamethasone (Vd) in patients with relaplsed or refractory multiple myeloma (RRMM)"*** sponsored by M/s Excel Life Sciences Pvt. Ltd. submitted by Dr. Shailendra Prasad Verma, Assistant Professor, Department of Clinical Heamatology of this University via letter no. 637/CH/2021 Dated 12th January, 2021. **EC Comment:** • How many patterns were supposed to be recruited share approved documents. **EC Decision:** Approval subject to modification ***Ref. code: 87th ECMIIC/P4***
4.	Annual Progress Report of research protocol entitled ***"Elucidate the epigenetic pathways in type 2 diabetes and its associated nephropathy: a case control study"*** sponsored by SERB New Delhi submitted by Dr. Gyanendra Kumar Sonkar, Department of Biochemistry of this University via letter no. Bio/616/2021 Dated 10th February, 2021.

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	EC Decision: Reviewed ***Ref. code: 100th ECM II A/P5***
5.	Annual Progress Report of research protocol entitled ***"Surveillance of scrub typhus infection by serological and molecular testing by DHR- virus diagnostic laboratories across the country"*** sponsored by Health Research, New Delhi submitted by Prof. Amita Jain, Department of Microbiology of this University via letter no. 633/2021 Dated 16th February, 2021. **EC Decision:** Reviewed ***Ref. code: 99th ECM II A/P2***
6.	Annual Progress Report of research protocol entitled ***"Strain parameters at rest and after exercise in symptomatically stable patients with improved heart failure-STRESS-HF"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology of this University via letter no. 1406/Cardio/Res/2021 Dated 16th February, 2021. **EC Comment:** • Send detailed report alongwith details of funding in the EC format. **EC Decision:** Approval subject to modification ***Ref. code: 100th ECM II A/P1***
7.	Annual Progress Report of research protocol entitled ***"Follow up of the Lucknow elderly study (LES) in ageing and geriatric mental health as well as development of human resources and service pathways for mentally ill aging population"*** submitted by Dr. Nisha M Pandey, Associate Professor, Department of Geriatric Mental Health of this University via letter no. 890/DGMH/2021 Dated 20th February, 2021. **EC Decision:** Noted ***Ref. code: 98th ECM II A/P7***
8.	Annual Progress Report of research protocol entitled ***"Clinical phenotypes and genetic regulation of endometriosis in Indian women"*** sponsored by Wellcome Trust DBT India Alliance submitted by Dr. Uma Singh, Department of Obstetrics & Gynaecology of this University via letter no. 169/HRRCLko/2021 Dated 24th February, 2021. **EC Decision:** Reviewed ***Ref. code: 98th ECM II A/P11***
9.	Annual Progress Report of research protocol no. EX9536-4388 SELECT entitled ***"Semaglutide effects on cardiovascular outcomes in people with***

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	overweight or obesity" sponsored by M/s Novo Nordisk Ltd. submitted by Dr. Rishi Sethi, Department of Cardiology of this University via letter no. 1444/Cardio/Res/2021 Dated 4th March, 2021. **EC Comment:** • What numbers were expected to be enrolled? • How many were enrolled? • How will be deficit be made up? **EC Decision:** Resend in the approved format ***Ref. code: 92th ECM II C/P1***

Member Secretary
Institutional Ethics Committee
King George's Medical University
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

K.G's Medical University U.P., Lucknow

Office of the Ethics Committee

Minutes of 107th Institutional Ethics Committee Meeting held on 16th April, 2021.

Minutes item no. V

Minutes of I-PG theses Sub Committee Ratified

K.G's Medical University U.P., Lucknow

V	Minutes of PG theses Sub Committee Ratified
	Attendance of PGTSC Members
	Minutes of "PG Thesis sub Committee" of "Institutional Ethics Committee" Meeting held on 13th April, 2021 from 12.00 P.M. till 1.20 P.M. in the 'Department of Medical Education" Office of the Vice Chancellor, Administrative Block of this University. ***The following Members were present in the PGTSC Meeting:*** **1. Dr. A.A. Mahdi -Member (Online present)** **2. Dr. G.G. Agrwal -Member (Online present)** **3. Dr. Rajendra Nath -Member (Online present)** **4. Dr. Anita Rani Singh -Member (Online present)** **5. Dr. Shally Awasthi -Convenor** **Due to COVID-19 duty, Dr. D.N. Upadhyaya is could not attend.**
	Theses
1.	Research proposal entitled ***"Relation of serum troponin in moderate to severe COVID-19 disease"*** submitted by Dr. Naveen Kumar, JRII, Department of Medicine of this University via letter no. 3144/Med/2020 dated 26th December, 2020. **PGTSC Comment:** • Detailed methodology/technique along with reference needed. A co-guide from investigating department may be included. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P1***
2.	Research proposal entitled ***"Role of respiratory biofeedback in improving pulmonary function and quality of life in stable C.O.P.D. patients: A randomized controlled trial"*** submitted by Dr. Mohd Rashid, JRI, Department of Physical Medicine & Rehabilitation of this University via letter no. 3537/2021 dated 30th January, 2021. **PGTSC Comment:** • If it is a trial then CTRI registration will be needed.

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	PGTSC Decision: Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P2***
3.	Research proposal entitled ***"Quality of life in people with unilateral lower limb amputation-at a tertiary rehabilitation centre in northern India: A cross sectional study"*** submitted by Dr. Deepak k, JRI, Department of Physical Medicine & Rehabilitation of this University via letter no. 3534/2021 dated 30th January, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P3***
4.	Research proposal entitled ***"Role of asymmetrical dimethyl arginine in type II diabetes mellitus in relation to coronary artery disease and chronic kidney disease"*** submitted by Dr. Jyoti Verma, JRI, Department of Medicine of this University via letter no. 2850/MED/2020 dated 20th November, 2020. **PGTSC Comment:** • Methodology needs to be checked and corrected (instead of past tense it shall be future tense). Number of subjects varies, Sample size mentioned is 120, and in methodology it is written 177 out of 200. • How ADMA will be measured? Method? Reference? **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P4***
5.	Research proposal entitled ***"Feasibility of ultrasound guided suprascapular nerve block in improving shoulder motion and pain post surgery in breast cancer survivors: A prospectiverandomised controlled trial"*** submitted by Dr. Laxmi Prajapati, JRI, Department of Physical Medicine & Rehabilitation of this University via letter no. 3535/2020 dated 30th January, 2021. **PGTSC Comment:** • If it is a trial then CTRI will be needed. • In inclusion criteria it is mentioned that patients undergoing surgery will be included. Is it correct?? • In the consent form permission for intervention shall be taken. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P5***
6.	Research proposal entitled ***"Efficacy of dry needling versus transcutaneous electrical nerve stimulation in patients with neck pain due to myofascial trigger***

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P. Lucknow

	points: A randomized control trial" submitted by Dr. Anjana G, JRI, Department of Physical Medicine & Rehabilitation of this University via letter no. 3536/2021 dated 30thJanuary, 2021. **PGTSC Comment:** • If it is a trial then CTRI registration will be needed. • In the consent form permission for intervention shall be taken. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P6***
7.	Research proposal entitled ***"Assessment of reasons of default in treatment of lung cancer in COVID-19 era at a tertiary care centre"*** submitted by Dr. Anmary Royson, JRII, Department of Respiratory Medicine of this University via letter no. 1332/21 dated 8th February, 2021. **PGTSC Comment:** • Incomplete, neither number of subjects, inclusion of exclusion/criteria provided. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P7***
8.	Research proposal entitled ***"A study to estimate levels of oxidative stress biomarkers in post COVID patients (pilot study)"*** submitted by Dr. Nandini Dikshit, JR, Department of Respiratory Medicine of this University via letter no. 1173/2020 dated 22nd December, 2020. **PGTSC Comment:** • Is the study already completed?? As duration of study is mentioned as April 2020 to April 2021. • Sample collection details shall be provided. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P8***
9.	Research proposal entitled ***"An observational study to assess the treatment outcome and adverse effect profile of patients of multidrug resistant pulmonary tuberculosis put on shorter MDR regimen under PMDT"*** submitted by Dr. Sandeep Kumar, JRII, Department of Respiratory Medicine of this University via letter no. 1365/Res/21 dated 15th February, 2021. **PGTSC Comment:** • Is the study already completed?? As duration mentioned is Dec 2019 to

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Dec 2020. • Needs revision and methodology unclear, sample size not mentioned. **PGTSC Decision:** Approval subject to modification
	Ref. code: 107th ECM II B-Thesis/P9
10.	Research proposal entitled ***"Expression of CD24 in gall bladder cancer"*** submitted by Dr. Devanshi Brajesh Dubey, JRI, Department of Pathology of this University via letter no. 1775/21 dated 27th February, 2021. **PGTSC Comment:** • Reference for methodology needed. **PGTSC Decision:** Approval subject to modification
	Ref. code: 107th ECM II B-Thesis/P10
11.	Research proposal entitled ***"To assess thrombocytopenia as a prognostic marker in patients with acute encephalitis at a tertiary care centre in northern India"*** submitted by Dr. Akriti Bhardwaj, JRI, Department of Medicine of this University via letter no. 2994/MED/2020 dated 19th December, 2020. **PGTSC Comment:** • Reference for methodology needed. A co-guide from investigating department may be included **PGTSC Decision:** Approval subject to modification
	Ref. code: 107th ECM II B-Thesis/P11
12.	Research proposal entitled ***"Role of WWOX gene polymorphism in development of cervical cancer"*** submitted by Dr. Gulshan Kumar, JRI, Department of Pathology of this University via letter no. 1758/21 dated 24th February, 2021. **PGTSC Comment:** • Controls not mentioned. What will be the inclusion and exclusion criteria? **PGTSC Decision:** Approval subject to modification
	Ref. code: 107th ECM II B-Thesis/P12
13.	Research proposal entitled ***"An observational study on patterns of POST-COVID fibrosis on high resolution computed tomography thorax at a tertiary care centre"*** submitted by Dr. Richa Tyagi, SRI, Department of Respiratory Medicine of this University via letter no. 1452/21 dated 4th March, 2021. **PGTSC Decision:** Approved
	Ref. code: 107th ECM II B-Thesis/P13
14.	Research proposal entitled ***"Etiology and diagnosis of bacterial meningitis in neonates: an observational study at a University Hospital"*** submitted by Dr. Amber Azim, SRI, Department of Microbiology of this University via letter no.

Member Secretary
Institutional Ethics Committee
King George's Medical University, U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	795/21 dated 12th March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P14***
15.	Research proposal entitled ***"COVID-19 and severity of Co-infections with influenza and other respiratory viruses"*** submitted by Dr. Kalpana Kuntal, JRI, Department of Microbiology of this University via letter no. 803/21 dated 15th March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P15***
16.	Research proposal entitled ***"Randomised, single blind, control trial of transcranial direct current stimulation in adolescents with obsessive compulsive disorder as early augmentation"*** submitted by Dr. , JRI, Department of Psychiatry of this University via letter no. 459/Psy/21 dated 8th March, 2021. **PGTSC Comment:** • Sample size calculation is not done **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P16***
17.	Research proposal entitled ***"International ovarian tumor analysis (IOTA) scoring system versus risk of ovarian malignancy algorithm (ROMA) for prediction of malignancy in adnexal masses"*** submitted by Dr. Natasha Sharma, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/483/21 dated 16th March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P17***
18.	Research proposal entitled ***"A study of determinants of pulmonary fibrosis in COVID-19 survivors"*** submitted by Dr. Raj Kumar, JR, Department of Respiratory Medicine of this University via letter no. 1519/21 dated 16th March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P18***
19.	Research proposal entitled ***"Evaluation of pro-BNP and troponin I in cases of placenta accrete spectrum (PAS) disorders and in cases of placenta previa"*** submitted by Dr. K. Sushma Samy, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/473/21 dated 16th March, 2021.

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	PGTSC Decision: Approved
	Ref. code: 107th ECM II B-Thesis/P19
20.	Research proposal entitled ***"Efficacy of INJ. Ferric carboxy maltose for treatment of anaemia in pregnant women in a tertiary care centre"*** submitted by Dr. Pooja Yadav, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/481/21 dated 16th March, 2021. **PGTSC Decision:** Approved
	Ref. code: 107th ECM II B-Thesis/P20
21.	Research proposal entitled ***"A study of feto-maternal outcome in women with term prelabor rupture of membranes"*** submitted by Dr. Anjali Verma, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/513/21 dated 5th March, 2021. **PGTSC Decision:** Approved
	Ref. code: 107th ECM II B-Thesis/P21
22.	Research proposal entitled ***"Correlation of intrapartum Chlamydia trachomatis infection with obstetric and perinatal outcome"*** submitted by Dr. Tripti Kumari, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/472/21 dated 16th March, 2021. **PGTSC Comment:** • Methodology details are missing **PGTSC Decision:** Approval subject to modification
	Ref. code: 107th ECM II B-Thesis/P22
23.	Research proposal entitled ***"Maternal ophthalmic artery Doppler in normal pregnancy and pre eclampsia and its association with pregnancy outcome"*** submitted by Dr. Khyati Bhatia, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/487/21 dated 17th March, 2021. **PGTSC Decision:** Approved
	Ref. code: 107th ECM II B-Thesis/P23
24.	Research proposal entitled ***"Estimation of vitamin D levels in women with obstetric cholestasis and normal pregnant women and its association with perinatal outcome"*** submitted by Dr. Riya Agrawal, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/488/21 dated 17th March, 2021. **PGTSC Decision:** Approved
	Ref. code: 107th ECM II B-Thesis/P24

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

25.	Research proposal entitled ***"Tolerance and compliance of weekly paclitaxel therapy for epithelial ovarian cancer"*** submitted by Dr. Aparna Kumari, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/523/21 dated 18th March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P25***
26.	Research proposal entitled ***"Study of endocrine disrupting chemicals in women with diminished ovarian reserve"*** submitted by Dr. Amisha Ved, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/524/21 dated 18th March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P26***
27.	Research proposal entitled ***"Expression of ALDH1A1 in gall bladder carcinoma and its correlation with clinicopathological profile"*** submitted by Dr. Prashant Verma, JRI, Department of Pathology of this University via letter no. 1861/21 dated 13rd February, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P27***
28.	Research proposal entitled ***"A study of uterine flora at caesarean section and its association with puerperal infections"*** submitted by Dr. Swapnil Golus, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/489/21 dated 17th March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P28***
29.	Research proposal entitled ***"Comparison of two weaning methods, T-piece method vs continuous positive airway pressure (CPAP) methods, in mechanically ventilated patients admitted to a paediatric intensive care unit department of Paediatrics of a medical university in northern India"*** submitted by Dr. Dhirendra Pratap Yadav, JRI, Department of Paediatrics of this University via letter no. 603/Ped/21 dated 12th March, 2021. **PGTSC Comment:** • Please clarify the role of Dr. Devina Singh in the present study. Clarify the time of inclusion of subjects 24 hrs or 48 hrs after following invasive ventilation. Statistical Analysis part states comparison of controlled and

Chairperson, IEC
King George's Medical University

Member Secretary
Institutional Ethics Committee
King George's Medical University, U.P
Lucknow

	uncontrolled asthma patients kindly give correlation with study. IFC: Study Procedure: explain the procedure to patient's Guardian. **PGTSC Decision:** Approval after justification ***Ref. code: 107th ECM II B-Thesis/P29***
30.	Research proposal entitled ***"Prevalence of hypoxic ischemic encephalopathy and multiorgan dysfunction in late preterm and term infants receiving resuscitation beyond initial steps at birth: A prospective observational study"*** submitted by Dr. Kumari Parul Sohane, JRI, Department of Paediatrics of this University via letter no. 602/Ped/21 dated 12th March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P30***
31.	Research proposal entitled ***"Prospective and retrospective analysis of management and outcome of endometrial carcinoma over a period of 10 Years"*** submitted by Dr. Sapna Jugran, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/525/21 dated 18th March, 2021. **PGTSC Comment:** • ICF : Explain the procedure to patient in easy to understand language. • What would be the follow-up period for patients enrolled in 2021. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P31***
32.	Research proposal entitled ***"Study of pregnancy specific dermatoses and others dermatological lesions in pregnant and postpartum women"*** submitted by Dr. Shweta Mishra, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/533/21 dated 19th March, 2021. **PGTSC Comment:** • Revise ICF , mention study procedure which shall be explained to the patient **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P32***
33.	Research proposal entitled ***"A comparative study of stigma and its correlates in caregivers and patients of bipolar affective disorder and schizophrenia currently in remission"*** submitted by Dr. Sahil Jamal, JRI, Department of Psychiatry of this University via letter no. 528/Psy/21 dated 18th March, 2021.

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	PGTSC Comment: • Kindly revise ICF: Contact details of investigator not provided. Study Procedure: Provide the procedure which will be explained to the patient. Point 9: suggest alternative as Yes/No **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P33***
34.	Research proposal entitled ***"Study of tumor microenvironment at the advancing edge of oral squamous cell carcinoma"*** submitted by Dr. Nida Shabbir, JRI, Department of Pathology of this University via letter no. 1866/21 dated 15th March, 2021. **PGTSC Comment:** • Revise the ICF : kindly explain the study procedure to patient in easy language instead of telling him "observational Study". **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P34***
35.	Research proposal entitled ***"Correlation between serum corin and plasma N-terminal pro-atrial natriuretic peptide with fetomaternal outcomes in Hypertensive disorders of pregnancy"*** submitted by Dr. Rupali Nayak, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/538/21 dated 19th March, 2021. **PGTSC Comment:** • Is it a routine investigation? If case not, who will bear the cost of investigations of control group? Consent form: In study Procedure cross sectional Study is written. Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. Use proper understandable Hindi language. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P35***
36.	Research proposal entitled ***"Comparison of neoadjuvant chemoradiotherapy and neoajuvant chemotherapy in unresectable non-metastatic locally advanced cancers of gall bladder"*** submitted by Dr. Jasmeet Singh Tuteja, JRI, Department of Radiotherapy of this University via letter no. 110/RT/21 dated 5th February, 2021.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

	PGTSC Comment: • Sample size calculation or justification is not provided. • Study duration is not clear. State the follow up plan. • Consent form : In study Procedure Prospective Comparative Study is written. Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. Use proper understandable and proper Hindi language. Pitta Mutrashay is Pittashay. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P36***
37.	Research proposal entitled ***"Association of genetic polymorphism in cytochrome P450 2A6 with treatment outcome in patients of locally advanced inoperable head and neck squamous cell carcinomas treated with concurrent chemoradiotherapy"*** submitted by Dr. Deepak Shakya, JRI, Department of Radiotherapy of this University via letter no. 113/RT/21 dated 5th February, 2021. **PGTSC Comment:** • State the benefits of the study. • Consent form: In study Procedure Prospective Study is written. Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. • Use proper understandable Hindi language. Who among the investigators will perform Genomic DNA analysis? **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P37***
38.	Research proposal entitled ***"Total neoadjuvant therapy in locally advanced rectal cancer"*** submitted by Dr. Ankita Mallick, JRI, Department of Radiotherapy of this University via letter no. 111/RT/21 dated 5th February, 2021. **PGTSC Comment:** • Is it a Pilot study? • State risks and benefits of the study. • Sample size calculation or justification is not provided. • Explain in details the parameters or scale against which outcomes will be compared. • How would you rate success of therapy? • Study duration is not specified. Is there any plan for follow-up?

Member Secretary
Institutional Ethics Committee
K. George's Medical University, U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	• Consent form: In study Procedure Tertiary care hospital based Study is written. • Kindly explain the study procedure, the way you will elaborate or tell the patient about process of treatment. Use proper understandable Hindi language. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P38***
39.	Research proposal entitled ***"Induction therapy in locally advanced borderline or unresectable or Oral cavity carcinoma"*** submitted by Dr. Divya Kukreja, JRI, Department of Radiotherapy of this University via letter no. 112/RT/21 dated 5th February, 2021. **PGTSC Comment:** • Title of study does not clarify the Research Question. • Sample size calculation or justification is not provided. • Study duration is not clear. As the follow up is planned every month for three months and then every 3 monthly. • Consent form: In study Procedure Prospective Comparative Study is written. Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. Use proper understandable Hindi language. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P39***
40.	Research proposal entitled ***"Outcome of hypofractionated radiotherapy versus conventional fractionated radiotherapy with concurrent temozolamide for elderly of younger low performance status patients of gliblastoma multiforms: a prospective randomized study"*** submitted by Dr. Manas Mani Agrawal, JRI, Department of Radiotherapy of this University via letter no. 114/RT/21 dated 5th February, 2021. **PGTSC Comment:** • Explain the method used for randomization of patients in 2 groups. • Consent form: In study Procedure Prospective Randamized Study is written. • Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done.

Chairperson, IEC
King George's Medical University
U.P., Lucknow

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

	• Use proper understandable Hindi language in consent form. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P40***
41.	Research proposal entitled ***"Conventional four field radiotherapy versus computed tomography based radiotherapy in cancer cervix: dosimetric study and its clinical correlation"*** submitted by Dr. Jagrati Yadav, JRI, Department of Radiotherapy of this University via letter no. 109/RT/21 dated 5th February, 2021. **PGTSC Comment:** • Justify the sample size. • Consent form: In study Procedure Prospective Comparative Study is written. • Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. • Use proper Hindi Language. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P41***
42.	Research proposal entitled ***"Plasma creatinine phosphokinase level for assessment of success of methotrexate therapy in unruptured ectopic pregnancy"*** submitted by Dr. Akanksha Dwivedi, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/564/21 dated 20th March, 2021. **PGTSC Decision:** • Consent form: In study Procedure Prospective Cohort Study is written. Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P42***
43.	Research proposal entitled ***"Association of maternal lipid profile in pregnancy with fetomaternal outcomes"*** submitted by Dr. Vallina Narang, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/545/21 dated 20th March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P43***

Chairperson, IEC
King George's Medical University
U.P., Lucknow

Member Secretary
Institutional Ethics Committee
King George's Medical University, U.P
Lucknow

44.	Research proposal entitled ***"Incidence and antenatal risk factors for postpartum diabetes among women with gestational diabetes mellitus"*** submitted by Dr. Naghma Jasmeen, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/546/21 dated 20th March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P44***
45.	Research proposal entitled ***"Study of serum placental growth factor (PIGF) level in women of preeclampsia and its correlation with fetomaternal outcome"*** submitted by Dr. Kiran Arya, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/541/21 dated 19th March, 2021. **PGTSC Comment:** • Study design and sample size calculation need clarification and modification. **PGTSC Decision:** Approval after modification ***Ref. code: 107th ECM II B-Thesis/P45***
46.	Research proposal entitled ***"Study of serum HE-4 and IL-6 levels in women with endometriosis"*** submitted by Dr. Nikita Gupta, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/540/21 dated 19th March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P46***
47.	Research proposal entitled ***"Role of amniotic fluid to umbilical cerebral ratio (AUCR) for prediction of adverse perinatal outcome in fetuses"*** submitted by Dr. Hina Prakash, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/566/21 dated 23rd March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P47***
48.	Research proposal entitled ***"Randomised controlled trial for comparison of efficacy and safety of dinoprostone gel alone with dinoprostone gel and mechanical cervical dilatation together for pre-induction cervical ripening"*** submitted by Dr. Neelansha Varshney, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/542/21 dated 19th March, 2021. **PGTSC Comment:** • CTRI registration is required **PGTSC Decision:** Approval after justification ***Ref. code: 107th ECM II B-Thesis/P48***

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P.
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

49.	Research proposal entitled ***"Randomised control trial of 12 hours versus 24 hours of zuspan regimen of magnesium sulfate therapy for maintenance therapy in women with severe pre eclampsia and eclampsia"*** submitted by Dr. Divyangi Pandey, JRI, Department of Obstetrics & Gynaecology of this University via letter no. OG/482/21 dated 16th March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P49***
50.	Research proposal entitled ***"Analysis and relevance of single or combination mutations of BRAF, TERT, and NRAS genes and their clinic-pathologic relationship in papillary thyroid carcinoma: a study using sanger sequencing"*** submitted by Dr. Isha Makker, JRI, Department of Pathology of this University via letter no. 1830/21 dated 20th March, 2021. **PGTSC Comment:** • Sample size calculation and methodology is not clear. **PGTSC Decision:** Approval after modification ***Ref. code: 107th ECM II B-Thesis/P50***
51.	Research proposal entitled ***"A study of structural and resting state MRI in adolescents with schizophrenia"*** submitted by Dr. Vikash Raj Bharti, JRI, Department of Psychiatry of this University via letter no. 485/Psy/21 dated 10th March, 2021. **PGTSC Comment:** • Study design mentioned is "Cross-sectional but in study sample" it seems to be mentioned case control study. • Sample size calculation is not clear. **PGTSC Decision:** Approval after modification ***Ref. code: 107th ECM II B-Thesis/P51***
52.	Research proposal entitled ***"To study the profile of empyema thorasis at a tertiary care center"*** submitted by Dr. Amit Kumar, JR, Department of Respiratory Medicine of this University via letter no. 1373/Resp/21 dated 13th February, 2021. **PGTSC Comment:** • Sample size calculation is not clear. **PGTSC Decision:** Approval after modification ***Ref. code: 107th ECM II B-Thesis/P52***
53.	Research proposal entitled ***"Randomised controlled single blind trial of transcranial direct current stimulation (tDCS) as early augmentation in major***

Chairperson, IEC
King George's Medical University

Member Secretary
Institutional Ethics Committee
King George's Medical University, U.P
Lucknow

	depressive disorder" submitted by Dr. Babli Kumari, JR, Department of Psychiatry of this University via letter no. 522/Psy/21 dated 18th March, 2021. **PGTSC Comment:** • Sample size is not clear. • Fundamental of RC Trial are not followed • Kindly provide CTRI registration **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P53***
54.	Research proposal entitled ***"To study the pathogens of purulent conjunctivitis in patients attending tertiary care Hospital"*** submitted by Dr. Mohd Saqib Hasan, JRI, Department of Microbiology of this University via letter no. 981/21 dated 23rd March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P54***

Member Secretary
Institutional Ethics Committee
King George's Medical University, U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

II-B	**IMR-Resiedent**
1-	Research proposal entitled ***"Effect of subgingival boric acid irrigation as an adjunctive treatment in patients with chronic periodontitis"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Jaya Agrawal, JRI, Department of Periodontology, Faculty of Dental Sciences this University via letter no. 1644/21 dated 22nd March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B IMR-R/P1***
IIB	**M. Phil Course**
1.	Research proposal entitled ***"Mindfulness, experiential avoidance, attachment and neurocognition in obsessive compulsive disorder"*** submitted by Ms. Divya Kansal, II Year under the guidance Dr. Shweta Singh, Additional Professor, Department of Psychiatry of this University via letter no. 437/Psy/21 dated 3rd March, 2021. **PGTSC Comment:** • Specify from where the controls will be selected. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM IIB M. Phil/P1***
2.	Research proposal entitled ***"A study on effect of brief mindfulness based cognitive therapy on mindfulness, Illness perception and quality of life on medically stable patients with acute myocardial infarction"*** submitted by Ms. Sulakshana Kashyap, II Year under the guidance Dr. Shweta Singh, Additional Professor, Department of Psychiatry of this University via letter no. 430/Psy/21 dated 2nd March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM IIB M. Phil/P2***
3.	Research proposal entitled ***"A study of brief metacognitive therapy as an augmentation to treatment as usual for the management of obsessive compulsive disorder"*** submitted by Ms. Sheeba Parveen, II Year under the guidance Dr. Shweta Singh, Additional Professor, Department of Psychiatry of this University via letter no. 429/Psy/21 dated 2nd March, 2021. **PGTSC Decision:** Approved ***Ref. code: 107th ECM IIB M. Phil/P3***
4.	Research proposal entitled ***"Acceptance and commitment therapy as Psychosocial supportive care in patients with Head and Neck Cancer"*** submitted by Ms. Pooja Varshney, II Year under the guidance Dr. Pooja Mahour,

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	Additional Professor, Department of Psychiatry of this University via letter no. 502/Psy/21 dated 16th March, 2021. **PGTSC Comment:** • Remove patient identifiers from case record form. **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM IIB M. Phil/P4***
5.	Research proposal entitled ***"A study of psychosocial correlates of infertility in women at a tertiary care Hospital"*** submitted by Ms. Ginni Sharma, II Year under the guidance Dr. Pooja Mahour, Additional Professor, Department of Psychiatry of this University via letter no. 503/Psy/21 dated 16thMarch, 2021. **PGTSC Comment:** • Remove patient identifiers from case record form **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM IIB M. Phil/P5***
6.	Research proposal entitled ***"A study of Character strengths, psychological well-being, anger rumination and self-harm in BPD patients"*** submitted by Ms. Shruti Yadav, II Year under the guidance Dr. Pooja Mahour, Additional Professor, Department of Psychiatry of this University via letter no. 504/Psy/21 dated 16th March, 2021. **PGTSC Comment:** • Remove patient identifiers from case record form **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM IIB M. Phil/P6***
7.	Research proposal entitled ***"Childhood trauma experiences, mentalized affectivity, empathy and experiential avoidance in adults with dissociative disorders"*** submitted by Ms. Gunjan Joshi, II Year under the guidance Dr. Shweta Singh, Additional Professor, Department of Psychiatry of this University via letter no. 436/Psy/21 dated 3rd March, 2021. **PGTSC Comment:** • Remove patient identifiers from case record form **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM IIB M. Phil/P7***

Member Secretary
Institutional Ethics Committee
King George's Medical University, U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 107th ECM held on 16th April, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

II-D	Nursing KGMU Institute
1.	Research proposal entitled ***"A comparative cross sectional study to assess knowledge regarding rights of mentally ill between patients with severe mental illness and people without mental illness"*** submitted by Miss. Rashmi Rawat, Through her guidance Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. **PGTSC Comment:** • Severely mentally ill patients have **diminished** autonomy. Who will consent for their participation? • Since cognition of such patients is **diminished** what will be the reliability of their responses. • There is no co-investigator from the Department of Neurology. **PGTSC Decision:** Re-submit ***Ref. code:107th ECM IID/P1***
2.	Research proposal entitled ***"Effectiveness of educational nurturing regarding birth preparedness on knowledge and application among primi mothers & their caregiver during hospitalization for delivery"*** submitted by Miss. Vandna, Through her guidance Dr. Suchana Roy Bhowmik, Associate Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. **PGTSC Decision:** Approved ***Ref. code:107th ECM IID/P2***
3.	Research proposal entitled ***"Effectiveness of Telephonic Adherence Programme' on diet and lifestyle modification on metabolic control in type2 diabetes mellitus patients"*** submitted by Ms. Neha Singh, Through her Mentor Mr. Subin Sudarsanan, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. **PGTSC Comment:** • Mention how effectiveness will be monitored? By glycemic control only? • Will patients be allocated to two groups? **PGTSC Decision:** Approval subject to modification ***Ref. code:107th ECM IID/P3***
4.	Research proposal entitled ***"Effectiveness of breast massage on amount of milk production in mothers who are not actively breast feeding preterm babies"*** submitted by Miss. Pooja Patel, Through her guidance Dr. Suchana Roy

Chairperson, IEC
King George's Medical University

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

	Bhowmik, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. **PGTSC Decision:** Approved ***Ref. code:107th ECM IID/P4***
5.	Research proposal entitled ***"Effectiveness of video assisted teaching on knowledge and practice regarding suctioning of children on mechanical ventilator among nurse working in Paediatric Department"*** submitted by Mr. Anurag Sharma, Through his guidance Mr. Subin Sudarsanan, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. **PGTSC Decision:** Approved ***Ref. code:107th ECM IID/P5***
6.	Research proposal entitled ***"Effectiveness of nesting on posture, stress and self-regulation responses in new born"*** submitted by Miss. Maria Jyoti, Through her guidance Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. **PGTSC Decision:** Approved ***Ref. code:107th ECM IID/P6***
6.	Research proposal entitled ***"Effectiveness of nesting on posture, stress and self-regulation responses in new born"*** submitted by Miss. Maria Jyoti, Through her guidance Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. **PGTSC Decision:** Approved ***Ref. code:107th ECM IID/P6***
7.	Research proposal entitled ***"Effectiveness of discharge guide module on knowledge regarding nephritic syndrome among parents of children with nephritic syndrome"*** submitted by Ms. Anupriya Kushwaha, Through her guidance Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021. **PGTSC Comment:** • Kindly correct the ICF- Parental guardian **PGTSC Decision:** Approval subject to modification ***Ref. code:107th ECM IID/P7***
8.	Research proposal entitled ***"Effectiveness of educational package on parental stress reduction among the parents of low birth weight neonates admitted in NICU"*** submitted by Miss. Pushpa Jaisal, Through her guidance Mr. Subin Sudarsanan, Assistant Professor, Department of KGMU College of Nursing of this University via letter no.nil dated 18th January, 2021.

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University
U.P., Lucknow

	PGTSC Comment: • Kindly correct the ICF-Parental guardian **PGTSC Decision:** Approval subject to modification ***Ref. code:107th ECM IID/P8***
9.	Research proposal entitled ***"A comparative study to assess knowledge and attitude related to human milk donation among parous women of selected urban and rural community, Lucknow, U.P., India"*** submitted by Mr. Ankit Kumar Tony Ms. Ankita Yadav Mr. Anoop Shriwastawa Ms. Aparna Pandey Ms. Aradhana Varun Ms. Arpita Samridhi Mr. Ashutosh Singh Ms. Ayesha Sagar Through her guidance Mrs. Roohi Elizabeth Peter & Ms. Amanjeet Kaur, Department of KGMU College of Nursing of this University via letter no.766/X-51 dated 22nd March, 2021. **PGTSC Decision:** Approved ***Ref. code:107th ECM IID/P9***
10.	Research proposal entitled ***"A descriptive study to assess internet addiction and quality of sleep among nursing students at selected College of Nursing, Lucknow, U.P., India"*** submitted by Mr. Ranveer Gautam Ms. Roshani Ms. Ruby Mr. Sachin Kumar Ms. Saher Fatima Mr. Sanjay Kumar Mr. Santosh Kumar Mr. Satyam Dixit Through her guidance Mr. Bhagwant Singh Ms. Loveena Arpita Samuel Ms. Amanjeet Kaur, Department of KGMU College of Nursing of this University via letter no.763/X-51 dated 20th March, 2021. **PGTSC Decision:** Approved ***Ref. code:107th ECM IID/P10***
11.	Research proposal entitled ***"A study to assess the relationship between blood pressure, body mass index, social support, physical activity, and eating habits among nursing students at selected College of Nursing, Lucknow, U.P., India"*** submitted by Ms. Dipanshi Verma Ms. Divyanshi Verma Ms. Garima Maurya Mr. Girish Chandra Shukla Ms. Gunjan Kumari Ms. Jyoti Gautam Ms. Jyoti Verma Ms. Kamini Singh Through her guidance Mr. Bhagwant Singh, Department of KGMU College of Nursing of this University via letter no.764/X-51 dated 20th March, 2021. **PGTSC Decision:** Approved ***Ref. code:107th ECM IID/P11***
12.	Research proposal entitled ***"A study to assess the risk of venous thromboembolism (VTE) among pre-operative patient admitted in department of cardiology at tertiary care centre in India"*** submitted by Ms. Mayankita Mr. Nagendra Kumar Ms. Neetu Devi Ms. Neha Gautam Mr. Pankaj Kumar Sharma Mr. Pintu Kumar Ms. Preeti Ms. Priyanka Mishra Through her guidance Mr.

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Chairperson, IEC
King George's Medical University

	Sachin Dwivedi Ms. Aditi MeCarty, Department of KGMU College of Nursing of this University via letter no.767/X-51 dated 22nd March, 2021. **PGTSC Decision:** Approved ***Ref. code:107th ECM IID/P12***
13.	Research proposal entitled ***"A study to assess knowledge of mothers regarding child abuse in the selected rural and urban areas in Lucknow with a view to develop information by providing booklet"*** submitted by Ms. K.M. Pallavi Ms. Kritika Kanojia Ms. Km. Anjali Mr Lalit Kumar Verma Ms. Layka Katiyaar Ms. M Uma Devi Mr. Madhusudan Singh Ms. Mantsha Naz Through her guidance Ms. Manisha Anand Ms. Jaya Sharma, Department of KGMU College of Nursing of this University via letter no.738/X-51 dated 23rd March, 2021. **PGTSC Decision:** Approved ***Ref. code:107th ECM IID/P13***
VII	**Other Matter-PGTSC**
1-	Clarification of research proposal entitled ***"Evaluation of 3D scanning over 2D photography in forensic analysis"*** submitted by Mr. Rohit Kumar Singh, Ph.D 2018 Scholar under the guidance Prof. Anoop Kumar Verma, Head, Department of Forensic Medicine & Toxicology of this University via letter no. 481/FMT/2020 dated 8th October, 2020. **PGTSC Decision:** Approved **EC Decision:** Approved ***Ref. code: 104th ECM II B-Ph.D/P2***
2-	Clarification of research proposal entitled ***"Telephonic follow up of patients who could not attend geriatric mental health OPD during the lockdown periods"*** submitted by Dr. Vidya K.L, JR, Department of Geriatric Mental Health of this University via letter no. 956/DGMH/2020 dated 26th March, 2021. **PGTSC Decision:** Approved **EC Decision:** Approved ***Ref. code: 104th ECM II B-Thesis/P35***
3-	Clarification of research proposal entitled ***"Optical coherence tomography findings in tubercular meningitis patients and its relation with visual function and its outcome"*** submitted by Dr. Deepika Verma, JRI, Department of Ophthalmology of this University via letter no. 711/OPH/2020 dated 19th September, 2020. **PGTSC Decision:** Approved **EC Decision:** Approved ***Ref. code: 104th ECM II B-Thesis/P27***
4-	Clarification of research proposal entitled ***"An epidemiological study of***

Member Secretary
Institutional Ethics Committee
King George's Medical University, U.P
Lucknow

Chairperson, IEC
King George's Medical University

	orthopaedic admissions in KGMU trauma centre and the status of bone specific alkaline phosphatase in these subjects" submitted by Dr. Nayank Gautam, JRII, Department of Orthopaedics of this University via letter no. 2467/2020 dated 10th December, 2020. **PGTSC Comment:** Give details of study methods **PGTSC Decision:** Approval subject to modification **EC Decision:** Approval subject to modification ***Ref. code: 104th ECM II B-Thesis/P56***
5-	Clarification of research proposal entitled ***"Evaluation of Immuno-Modulatory subject and frontline healthcare workers in COVID-19 care centre"*** submitted by Dr. S.K. Singh, Associate Professor, Department of CFAR of this University via letter no. nil dated nil. **EC Decision:** Approved ***Ref. Code: 107th ECM IIA/P13***

- Principal-Investigator to prepare 5 slides send in advance and give a 2-3 minutes presentation, if feasible, in light of COVID situation.
- Progress reports must be in the approved format only.
- The next Meeting will be held on 22nd May, 2021 from 11.00 A.M.

Member Secretary
Institutional Ethics Committee
King George's Medical University
Lucknow

Chairperson, IEC
King George's Medical University

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 108th ECM held on 22nd May, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19

Minutes of the **"Institutional Ethics Committee"** Meeting ***virtually*** held on **22nd May, 2021 (Saturday) from 10.30 A.M.**

The following Members were present in the Meeting:-

1. Dr. Alok Dhawan -Chairman
2. Dr. Shobha Phadke -Member
3. Dr. Akash Agarwal -Member
4. Dr. G.G. Agarwal -Member
5. Dr. K.K. Yadav -Member
6. Mrs. Akansha Dubey -Member
7. Sri Ujjawal Krishna -Member
8. Dr. A.A. Mahdi -Member
9. Dr. Rajendra Nath -Member
10. Dr. D.N. Upadhayaya -Member
11. Dr. Anita Rani Singh -Member
12. Dr. Shally Awasthi -Member-Secretary, Ex-officio

The following Members could not attend:-

1. Dr. Anupam Mishra
2. Mrs. Vasundhara Kumari - as she did not get the link to join

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 108th ECM held on 22nd May, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19

IA	Action Taken- 107th ECM held on 16th April, 2021-For faculties
a1	Clarification of research proposal entitled ***"Epidemiology of pancreatitis and major gastrointestinal disorders: A nationwide multi-center study across India"*** submitted by Dr. Sumit Rungta, Associate Professor & Head, Department of Medical Gastroenterology, KGMU via letter no.1092/MedGastro/21 dated 4th January, 2021. **Previous EC Comment:** • What is the source of the funding? • Which is the Co-ordinating Centre? • Who are in the Investigators from other Institutions? • What are the roles of Co-investigators from KGMU? Specify for each. **Previous EC Decision:** Approval subject to modification **Final EC Decision:** Approved ***Ref. code: 107th ECM IIA/P1***
a2-	Clarification of research proposal entitled ***"To study the histopathological features in renal biopsy (post-mortem) of critically ill COVID-19 positive patients with renal dysfunction"*** submitted by Dr. Medhavi Gautam, Assistant Professor, Department of Medicine, KGMU via letter no.1054/MED/21 dated 10th May, 2021. **Previous EC Comment on 16th April, 2021:** • What is the source of the funding? • Which is the Co-ordinating Centre? • Who are in the Investigators from other Institutions? • What are the roles of Co-investigators from KGMU? Specify for each. **Previous EC Decision on 16th April, 2021:** Approval subject to modification ***The above comment forwarded to Primary Reviewer.*** **Final EC Decision:** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 107th ECM IIA/P5
a3-	Clarification of research proposal entitled ***"International snapshot study on the outcomes of Pancreatic Surgery pancreasGroup.org"*** submitted by Dr. Naseem Akhtar, Additional Professor, Department of Surgical Oncology, KGMU via letter no. SONC/262/21 dated 17th March, 2021. **Previous EC Comment:** • Collaborators: University College London Hospitals, Massachusetts General Hospital. • Eligibility of Surgeon – Any Surgeon worldwide performing pancreatic surgery is eligible to participate in PancreasGroup.org • Study duration-12 months (Jan-Dec 2021) • Working proforma of PancreasGroup.org attached. • Summary of proposal needed. **Previous EC Decision:** Approval subject to modification ***The above comment forwarded to Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **Final EC Decision:** Approval ratified ***Ref. code: 107th ECM IIA/P12***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

II-A	New Proposal
1.	Research proposal entitled ***"A study on development of gamma (γ) H2AX expression based screening assay of oral sub mucous fibrosis and oral squamous cell carcinoma"*** sponsored by ICMR submitted by Dr. Kapila Kumar, Research Associate, Department of Oral & Maxillofacial Surgery, KGMU via letter no.DHR/MRU/2010 dated 5th April, 2021. **EC Comment:** • Justify the role of each Co-Investigator • How can research associate and Scientists be Co-Investigators? Who were send as investigators to ICMR? **EC Decision:** Approval after justification ***Ref. code: 108th ECM IIA/P1***
2.	Research proposal entitled ***"Biosurveillance for spillover of henipaviruses and filoviruses in rural communities in India"*** sponsored by Eco Health Alliance, United States submitted by Prof. Amita Jain, Head, Department of Microbiology via letter no.65/21 dated 8th April, 2021. **EC Comment:** • Funded by an International NGO & perhaps the USUHS • Is here G.O.I. approval for Eco Health Alliance, USA to work in the country?. • Is there an agreement between KGMU and NGO? • After submission to H.M.S.C of I.C.M.R. please submit the documents to Ethics Committee • Vulnerable subjects have been checked **NO**, despite including vulnerable subjects-children, illiterate adults • Objective 1: How will this be achieved, not elaborated in text • What is the operational definition of "site"?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• What are the other factors that will be used to select sites? • What is the geographical area that will be included? Whole of UP, part of state? • How will village/clusters be chosen if bat species being looked for are found in more than 4 clusters? • What type of randomization will be done within clusters to ensure 25% representation of children as well as equal participation of both sexes. • What will be done if someone refuses consent? • How has the sample size of 800 calculated? • Is consent for archived samples present? • Who will administer the questionnaire- Self or some project worker, and in what language? • If questionnaire will be administered in Hindi (highly likely), need a TRANSLATED and VALIDATED questionnaire in Hindi language. • While the title refers to rural communities, why take hospital based AES and VHF patients? • Does institution have the required permits/ certification to accept foreign grants-FCRA, etc? • What is the purpose of the NGO and USUHS for funding this study and how will it benefit them? **EC Decision:** Approval after justification ***Ref. code: 108th ECM IIA/P2***
3.	Research proposal entitled "***The incidence of noninvasive follicular neoplasm with papillary like nuclear features: A meta- analysis assessing worldwide impact of the reclassification***" submitted by Dr. Chanchal Rana, Associate Professor, Department of Pathology, KGMU via letter no. 2051/21 dated 1st April, 2021. **EC Comment:** • As this is a Meta-analysis of the published literature, the application for waver from IEC can be approved. The researcher is not going to include the data

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	from their lab or clinical group. • Since Meta-analysis is a specialized area, Co-PI who is knowledgeable in the field must be included if PI has no training. Else the PI may undergo training before undertaking this project. **EC Decision:** Waiver granted subject to the above. ***Ref. code: 108th ECM IIA/P3***
4.	Research proposal entitled **"*The impact of Neoadjuvant chemotherapy on ExtraNodal Extension (NeoENE) in head and neck squamous cell cancers-A prospective, interventional study*"** submitted by Dr. Mranalini Verma, Assistant Professor, Department of Radiotherapy, KGMU via letter no. 324/RT/21 dated 6th April, 2021. **EC Comment:** • This is a pilot study with 50 patients to be recruited. Details of chemotherapy are to be provided in material methods section. Rather altogether this section is sketchy. Moreover, in the informed consent form it is mentioned that there is neither any risk from the study nor there are any expected complications following treatment. Will it be so? Please clarify. **EC Decision:** Re-submit ***Ref. code: 108th ECM IIA/P4***
5.	Research proposal entitled **"*An international snapshot study on the outcomes of pancreatic surgery*"** submitted by Prof. Abhinav Arun Sonkar, Head, Department of General Surgery, KGMU via letter no. 705/21 dated 6th April, 2021. **EC Comment:** • This proposal was submitted by Dr. Naseem Akhtar, Additional Professor, and Department of Surgical Oncology on 17th March, 2021 and has been approved by Ethics Committee. Kindly identify in which objective/s you will be participating. **EC Decision:** Same project cannot be approved twice ***Ref. code: 108th ECM IIA/P5***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

6.	Research proposal entitled ***"IPC capacity building orientation training for COVID-19 preparedness and IPC for healthcare facilities"*** sponsored by BMGF submitted by Prof. Vimala Venkatesh, Department of Microbiology, KGMU via letter no. 55/21 dated 8th April, 2021. **EC Comment:** • This is a training activity, there is no interaction with patient, Human subjects review waiver attached. **EC Decision:** Approval for waiver ***Ref. code: 108th ECM IIA/P6***
7.	Research proposal entitled ***"Detection and comparison of anti-SARS-COV-2 IgG antibodies and T cell immune response among COVID-19 infected and vaccinated, health care workers (HCWs)"*** submitted by Dr. Geeta Yadav, Associate Professor, Department of Pathology, KGMU via letter no. 2117/21 dated 26th April, 2021. **EC Comment:** • Clarification regarding sample size is requested. • Clarify the role of Co-P.Is. • Mention this is a pilot study. **EC Decision:** Approval subject to modification ***Ref. code: 108th ECM IIA/P7***
8.	Research proposal entitled ***"Assessment of psycho-ogical morbidity in parents of children with club foot"*** submitted by Dr. Vikas Verma, Associate Professor, Department of Paediatric Orthopaedics, KGMU via letter no. 2117/21 dated 26th April, 2021. **EC Decision:** Approved ***Ref. code: 108th ECM IIA/P8***

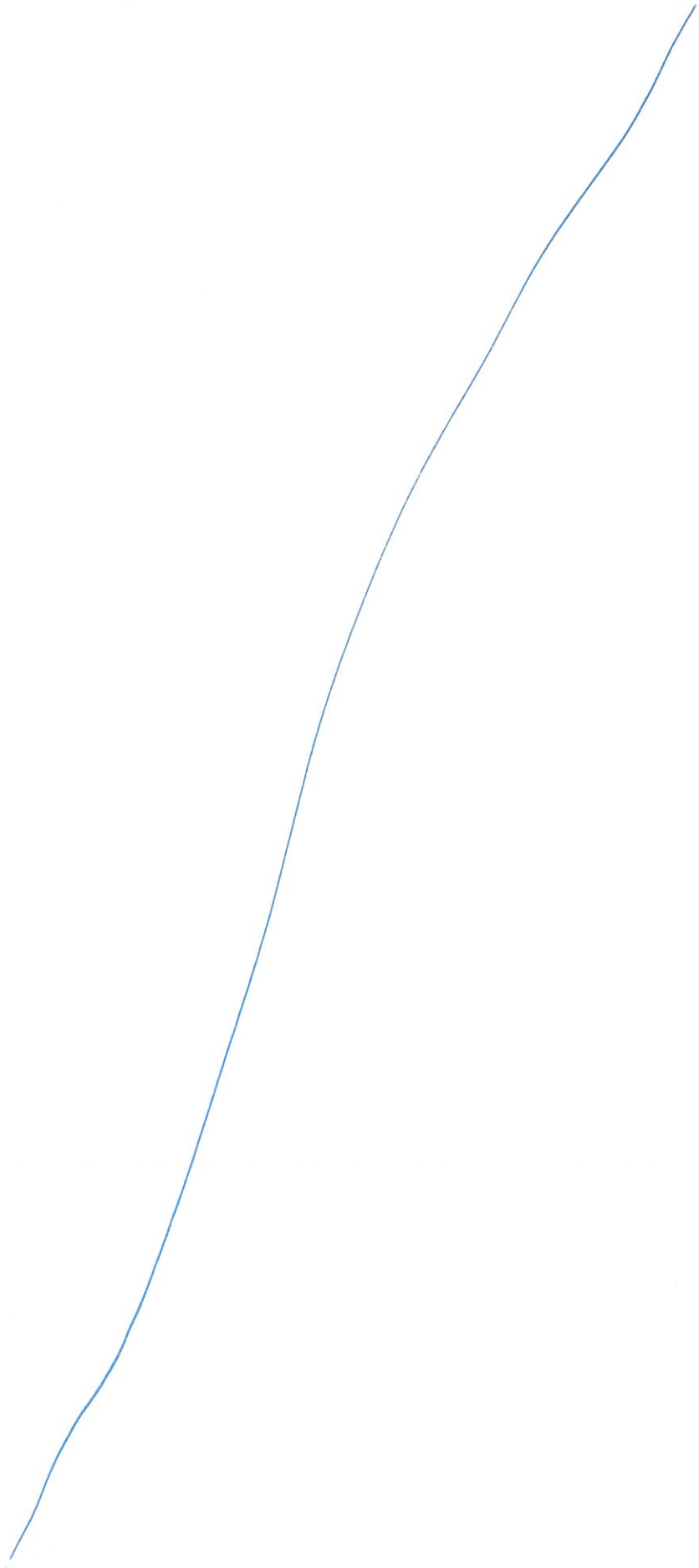
(Shally Awasthi)
Member-Secretary, IEC

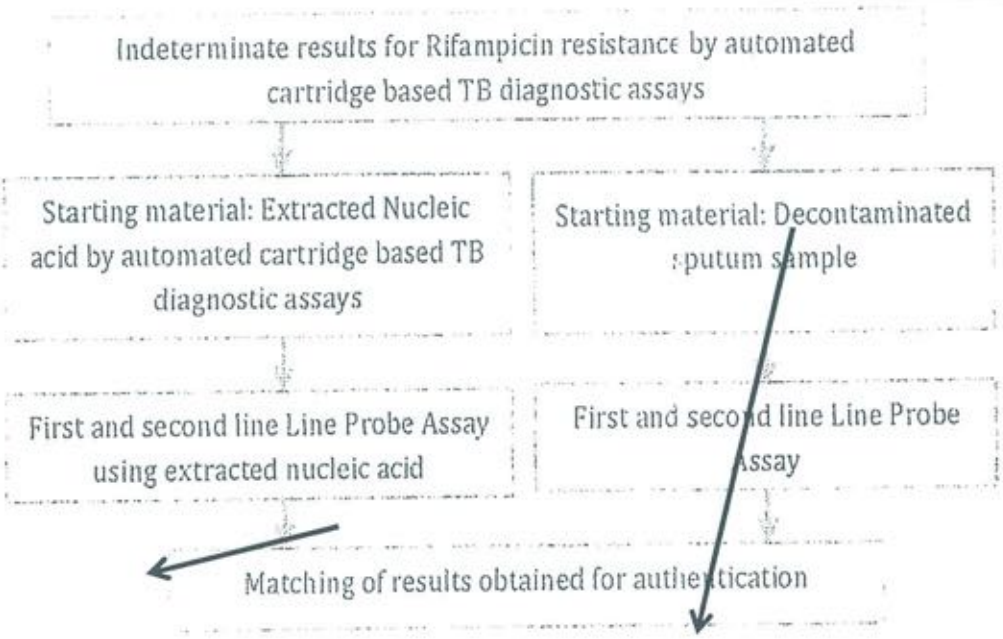
(Alok Dhawan)
Chairman, IEC

11.	Research proposal entitled ***"Interpretation of indeterminate results of automated cartridge based TB diagnostic assays by line probe assay utilizing the already extracted nucleic acid"*** submitted by Dr. Parul Jain, Assistant Professor, Department of Microbiology, KGMU via letter no. 116/2021 dated 13th April, 2021. **EC Comment:** 1. Some fields of form are not filled out: Section 5 (vi), (vii) 2. Aim and objective 1 are same: need to correct it. 3. What is the current standard of testing and treatment for samples that are indeterminate for resistance to rifampicin? 4. Will your objective 1 change or modify treatment? a. If yes: you will need patient consent b. If no: what is the utility of this study 5. What NAAT will be used? From our little understanding, DNA cannot be extracted from cartridge based automated TB assays, only a report is generated. Please shed some light on this.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC





6. Matching results: How? What if discordant?
7. Where does this decontaminated sputum come from? Is it stored? Will storing lead to any changes in the quality of specimen for purpose of results?
8. What are the end points?
9. Is the LPA a one-time purchase or does it need reagents/ consumables. If the latter, needs a source of funding.
10. Sample size calculation is based not only on the prevalence of the condition, but also end points.
11. For objective 2, needs a separate sample size calculation.
12. Similarly, need to define endpoints for objective 2.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	13. What statistical tests will be used- Instant Prism software will not itself choose the test to be used, investigator has to decide. **EC Decision:** Approval subject to modification ***Ref. code: 108th ECM IIA/P11***

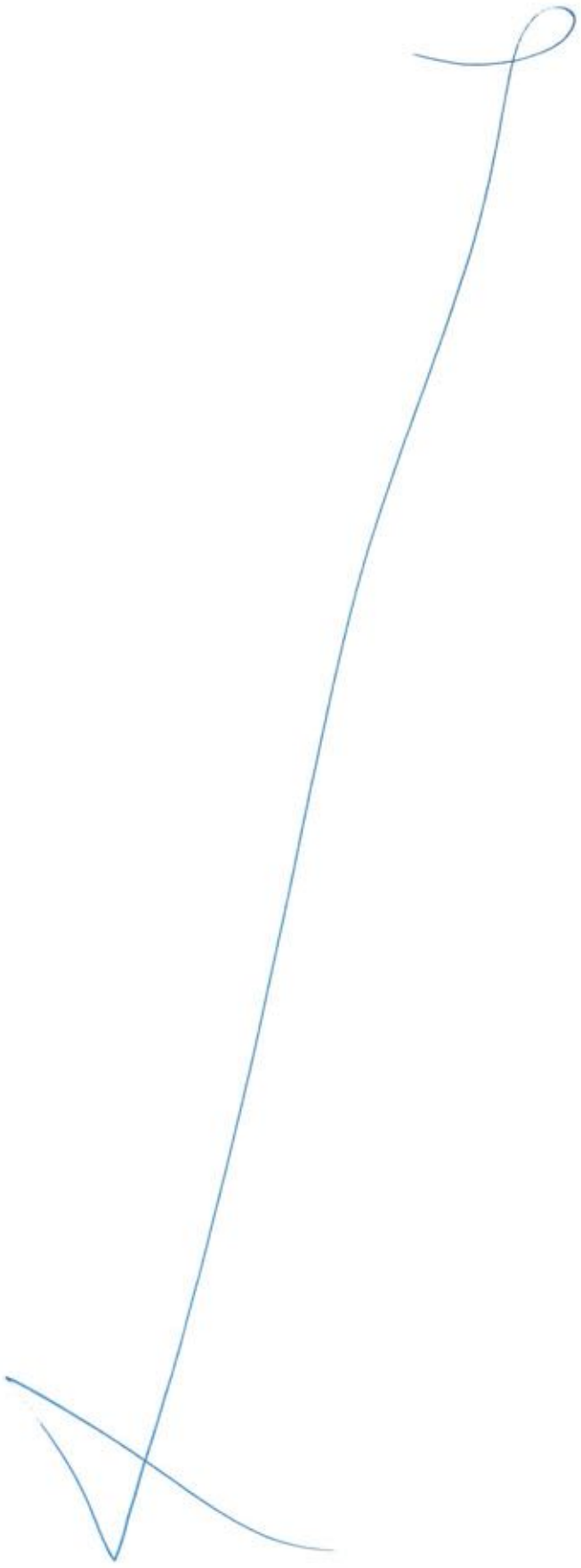
(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

II- B	IMR-Faculty
1.	Research proposal entitled ***"Feasibility study of voluntary breath hold technique in reducing heart toxicity in left breast cancer Radiotherapy in our setup: low-cost substitute for high capital investment (Advanced) technology"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Mranalini Verma, Assistant Professor, Department of Radiotherapy, KGMU via letter no. 325/RT/21 dated 6th April, 2021. **EC Comment:** • Sample size is 30, however, the rationale is not mentioned. If it is a pilot study then it may be mentioned. • Inclusion and exclusion criteria of subjects not clearly mentioned. **EC Decision:** Approval subject to modification ***Ref. code: 108th ECM II B-IMR-F/P1***

(Shally Awasthi)
Member-Secretary, IEC

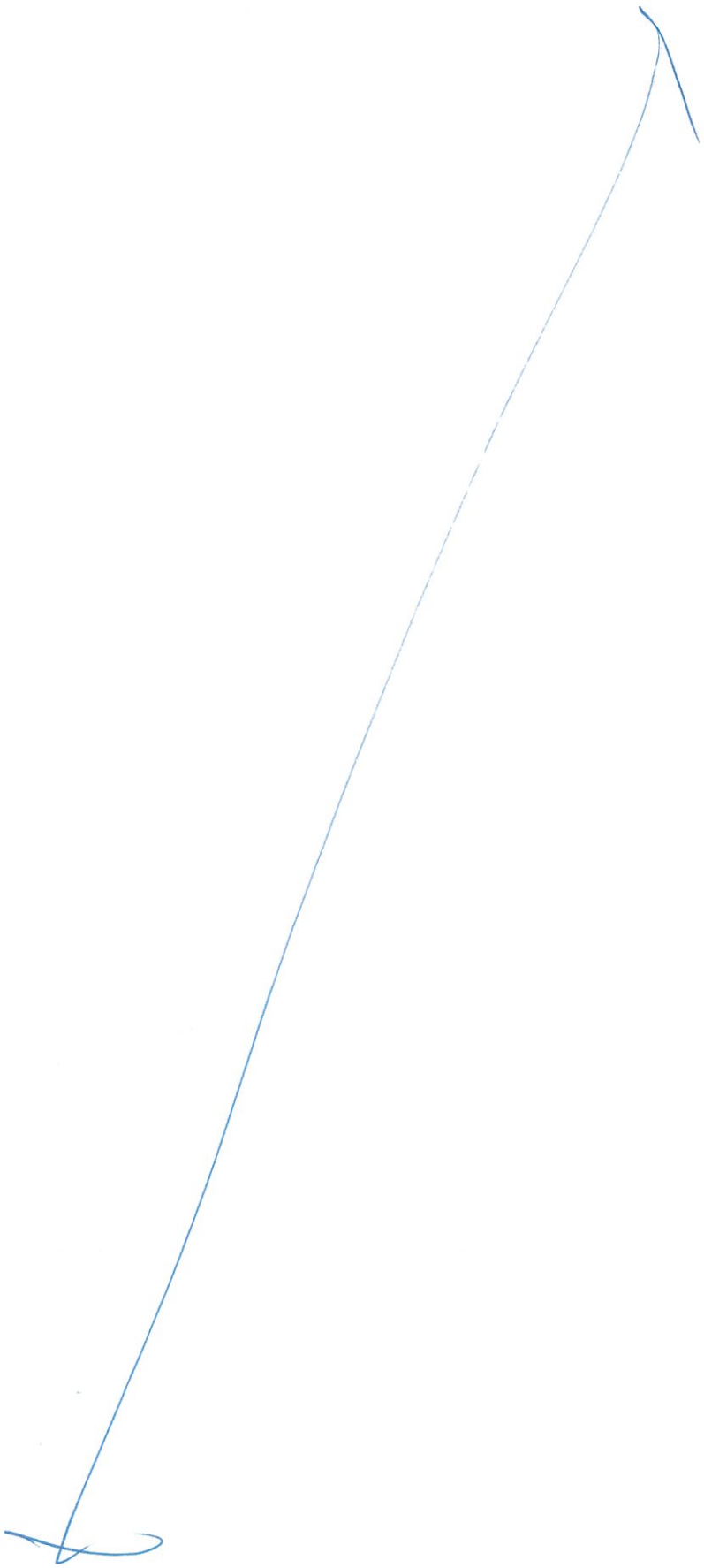
(Alok Dhawan)
Chairman, IEC



IIC	Review of New Drug Trial
1.	Research Protocol no. STS-BDB001-04 entitled "***A multi-centre, open-label, randomized parallel controlled evaluation on the efficacy and safety of BDB-001 injection in the treatment of progressive severe COVID-19 in phase II***" sponsored by Staidson (Beijing) Biopharmaceutical Co. Ltd. submitted by Dr. D. Himanshu, Principal Investigator, Additional Professor, Department of Medicine, KGMU via letter no. MED/CT/25/2021 dated 29th April, 2021. **EC Decision:** Approval after fulfillment of Administrative Formalities. ***Ref. code: 108thECMIIC/P1***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC



King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 108th ECM held on 22nd May, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19

Document of the last 107th Ethics Committee Meeting held on 16th April, 2021	
1-	Research proposal entitled "***Assessment of tumor budding in Oral cavity squamous cell carcinoma undergoing primary resection and its correlation with clinical outcome parameters***" submitted by Dr. Shalini Bhalla, Associate Professor, Department of Pathology, KGMU via letter no.1655/2021 dated 4th February, 2021. **EC Decision:** Defer for the next Meeting **EC Comment:** • Clarity is required on the following issues – • Is this a retrospective study? Will patient consent be required for this? If Yes, how will it be obtained retrospectively? • Does it require patient follow-up for outcome assessment? • What is the policy for funding from Chinese Company? Submit to HMSC, ICMR for approval **EC Decision:** Approval subject to modification ***Ref. code: 107th ECM IIA/P2***
2.	Research proposal entitled "***Academic clinical trial of safety, pharmacokinetics and early measurement of drug activity of CENTINHALE dry powder inhalation***" sponsored by CSIR-Central Drug Research Institute submitted by Prof. Rajiv Garg, Department of Respiratory Medicine, KGMU via letter no.1339/RESP/2021 dated 10th February, 2021. **EC Decision:** A meeting of the Chairman IEC, Secretary IEC with the investigators of CDRI and KGMU to be convened clarify certain points the projects. ***Ref. code: 107th ECM IIA/P4***
3	Research proposal entitled "***A ten year retrospective study of clinicoradiological and histopathological profile of lung cancer and its outcome in a tertiary care Hospital***"

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine-, KGMU via letter no.1510/2021 dated 15th March, 2021. **EC Comment:** • Research question and need of this study to be defined. • What is the lacuna in our understanding of the subject that the study proposes to address? • Is it a retrospective, observational study, or a Cross-sectional study? The terms have been used interchangeably in the proforma. • Unclear. Proforma says yes. Which Vulnerable populations will be studied? • Sample size not calculated. Define 'as per convenient sampling'? • Is informed consent required since it is a retrospective study of patient records? If it is required, how will it be obtained? **EC Decision:** Re-submit ***Ref. code: 107th ECM IIA/P9***
4	Research proposal entitled "***Clinical study of compliance and therapeutic adherence in patients of type-2 diabetes mellitus and hypertension and assessment of quality of life in tertiary Hospital***" submitted by Mr. Indrashis Mukherjee, Ph.D Scholar 2019, under the guidance Prof. Amod Kumar Sachan, Head, Department of Pharmacology & Therapeutics, KGMU via letter no. 265/Pharma/2021 dated 29th January, 2021. **EC Comment:** Defer for next Meeting. **EC Comment:** • Has validated QOL questionnaire been used? **EC Decision:** Approved ***Ref. code: 107th ECM II B-Ph.D/P3***

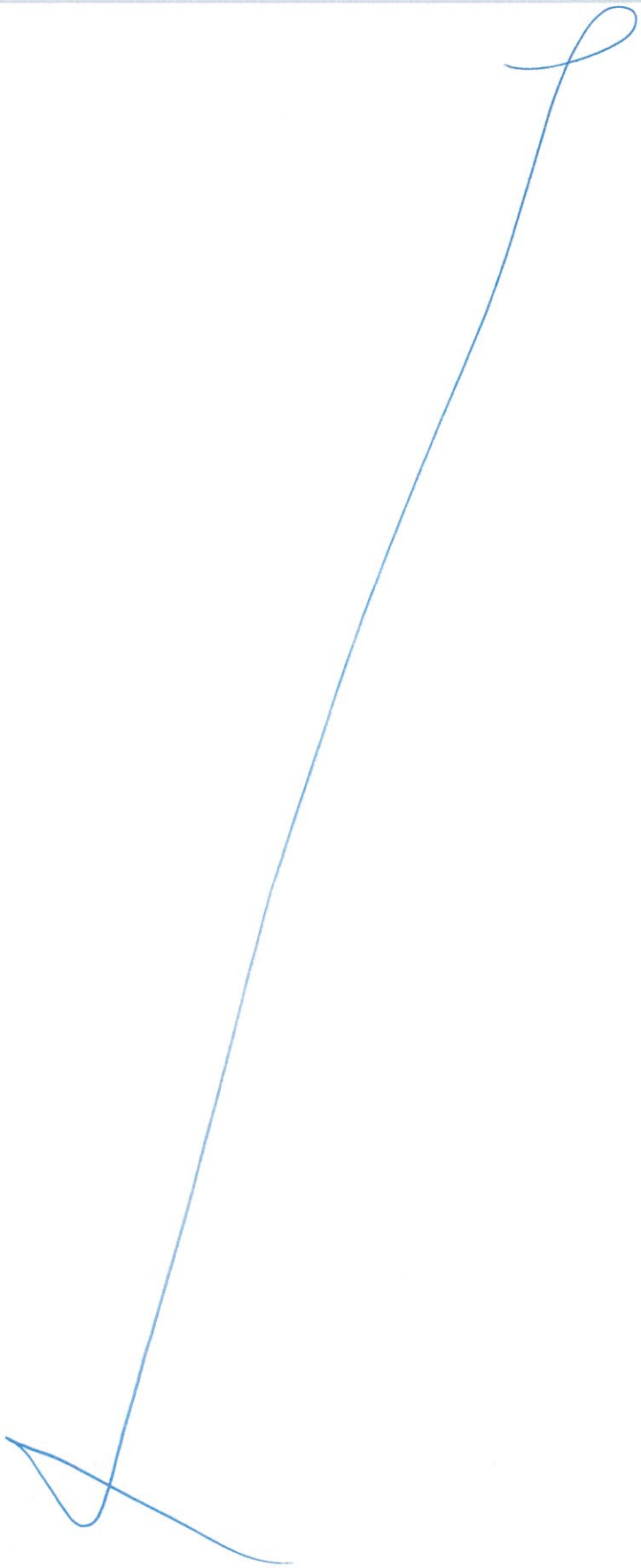
(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

III	Modification
1	Modification for increasing scope of surveillance activity under project entitled ***"Capacity building and strengthening of Hospital Infection Control to detect and prevent antimicrobial resistance in India"*** submitted by Prof. Vimala Venkatesh Department of Microbiology, KGMU via letter no. 2021/02/CB-131 dated 5th February, 2021, 2021/02/CB-132 dated 27th February, 2021. **EC Decision:** Approved ***Ref. code: 84th ECM II A/P29***
2.	Modification of Research protocol entitled ***"Study of clinical and temporal profiles in drug resistant epilepsy patients"*** submitted by Dr. Nikhil Kumar Sahu, SR-I, Department of Neurology, KGMU via letter no.84/Neuro/21 dated 23rd February, 2021. **EC Decision:** Approved ***Ref.code:100th ECM II B-Thesis/P16***
3.	Modification of Research protocol entitled ***"Effect of Vitamin B12 supplementation on late life depression: A randomized controlled trial"*** submitted by Dr. Pooja Misal, JR-II, Department of Geriatric Mental Health this University via letter no.927/DGMH/21 dated 13th March, 2021. **EC Decision:** Approved ***Ref.code:100th ECM II B Thesis/P18***

(Shally Awasthi)
Member-Secretary, IEC

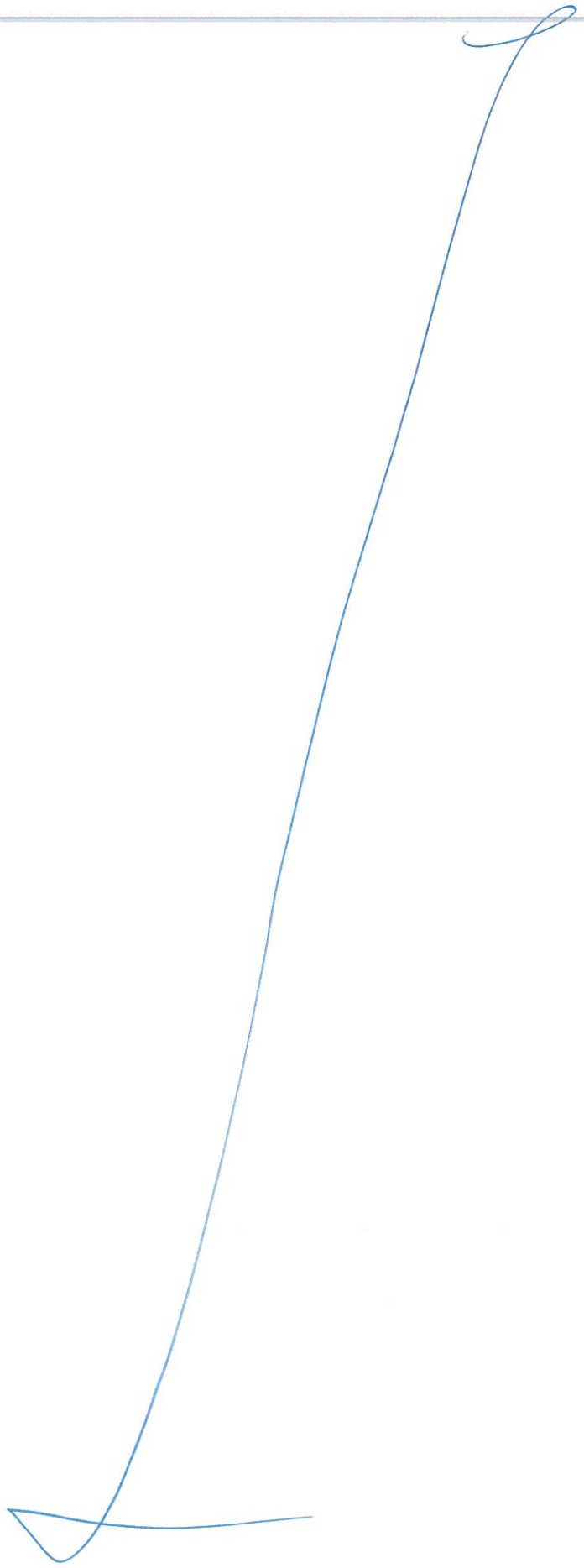
(Alok Dhawan)
Chairman, IEC



IV	Annual Progress Report
1.	Annual Progress Report of research protocol entitled ***"Newborn screening programme"*** sponsored by U.P NHM submitted by Dr. Wahid Ali, Additional Professor, Department of Pathology, KGMU via letter no. 1678/2021 Dated 9th February, 2021. **EC Decision:** Approved ***Ref. code: 99th ECMIIA/P3***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC



King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 108th ECM held on 22nd May, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19

V- **Minutes of PG theses Sub Committee Ratified**

Minutes of **"II Post Graduate Theses Sub Committee"** of the Institutional Ethics Committee Meeting ***virtually*** held on **15th May, 2021 (Saturday) from 11.30 A.M. till 11.50 A.M.**

The following Members were present in the virtual Meeting:

1- Dr. G.G. Agarwal -Member

2- Dr. Rajendra Nath -Member

3- Dr. D.N. Upadhayaya -Member

4- Dr. Shally Awasthi -Member-Secretary, Ex-officio

The following Members could not attend:-

1- Dr. A.A. Mahdi -Member

2. Dr. Anita Rani Singh - Due to COVID duty

I	Action Taken
a	Clarification of research proposal entitled ***"Study of tumor microenvironment at the advancing edge of oral squamous cell carcinoma"*** submitted by Dr. Nida Shabbir, JR, Department of Pathology, KGMU via letter no. 2153 dated 10th May, 2021. **Action Taken:** Approved **PGTSC Decision:** Approval ratified ***Ref. Code no. 107th ECM IIA/P34***
b	Clarification of research proposal entitled ***"A comparative cross sectional study to assess knowledge regarding rights of mentally ill between patients with severe mental***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	illness and people without mental illness" submitted by Miss Rashmi Rawat through her guide Mrs. Sudha Mishra, Assistant Professor, Office of the Dean of Nursing, Kalam Centre, KGMU -via letter no.923/x-51 dated 28th April, 2021. **Action Taken:** Approved **PGTSC Decision:** Approval ratified ***Ref. Code no. 107th ECM IID/P1***
IIA	**PGTSC**
1.	Research proposal entitled ***"A clinical study of executive function deficits, emotional and behavioral problems in adolescents with ADHD with problematic use of internet"*** submitted by Dr. Sauraj Kapoor, JRI, Department of Psychiatry, KGMU via letter no. 548/Psy/21 dated 23rd March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P1***
2.	Research proposal entitled ***"Study of single nucleotide polymorphism in mgmt gene promoter region and correlation with mgmt methylation status and prognosis in glioblastoma"*** submitted by Dr. Krachi Agarwal, JRI, Department of Pathology–, KGMU via letter no. 1832/21 dated 20th March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P2***
3.	Research proposal entitled ***"To study genital tract infections with special focus on Chlamydia trachomatis and neisseria gonorrhoeae in women attending infertility clinic at tertiary care center, Lucknow"*** submitted by Dr. Diksha Shukla, JRI, Department of Microbiology, KGMU via letter no. 989/21 dated 23rd February, 2021. **PGTSC Comment:** • Objectives are not properly defined so as to generate proper "Statistical Hypotheses". Statistical considerations are not mentioned. **PGTSC Decision:** Re-write & Re-submit

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: II-PGTSC-IIA /P3
4.	Research proposal entitled ***"Microbial profiling and IgA/IgG Anti-SARS-CoV-2 in donor human milk: A pilot study at a regional milk bank"*** submitted by Dr. Astha Yadav, JRI, Department of Microbiology, KGMU via letter no. 1004/21 dated 25th March, 2021. **PGTSC Comment:** • Objectives are not well-defined so as to generate proper "Statistical Hypotheses". Sample size is not shown. The methodology is incomplete. **PGTSC Decision:** Re-write & Re-submit
	Ref. code: II-PGTSC-IIA /P4
5.	Research proposal entitled ***"Delta sofa score as a prognostic indicator in women admitted in an obstetric ICU"*** submitted by Dr. Kathipri Nelia, JRI, Department of Obstetrics & Gynaecology, KGMU via letter no. GO/484/21 dated 16th March, 2021. **PGTSC Decision:** Approved
	Ref. code: II-PGTSC-IIA /P5
6.	Research proposal entitled ***"Study to elucidate the risk factors and association of NAD(P)H: quinoneoxidoreductase 1 C609T(NQO1) gene polymorphism with cervical cancer in Indian population"*** submitted by Dr. Sangeeta Kumari, JRI, Department of Obstetrics & Gynaecology, KGMU via letter no. GO/603/21 dated 24th March, 2021. **PGTSC Decision:** Approved
	Ref. code: II-PGTSC-IIA /P6
7.	Research proposal entitled ***"A randomized double blind placebo controlled study of celecoxib ADD-On in obsessive compulsive disorder"*** submitted by Dr. Shivangini Singh, JRI, Department of Psychiatry, KGMU via letter no. 500/Psy/21 dated 16th March, 2021. **PGTSC Comment:** • If it is a trial then CTRI registration will be needed. • In study hypothesis and Objectives, it is mentioned that association of clinical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	and functional outcome will be assessed with serum IL-6 and BDNF levels. Nowhere in the methodology assessment of IL-6 and BDNF levels is mentioned. Please add the methods and cite relevant references. **PGTSC Decision:** Re-write & Re-submit ***Ref. code: II-PGTSC-IIA /P7***
8.	Research proposal entitled ***"A study of female sexual functioning in patients with obsessive compulsive disorder"*** submitted by Dr. Nirupama Jaiswal, JRI, Department of Psychiatry, KGMU via letter no. 488/Psy/21 dated 12th March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P8***
9.	Research proposal entitled ***"Assessment of oral health status before and after oral hygiene interventions in children with leukemia"*** submitted by Ms. Shamakhatoon MDS II Year, under the guidance Dr. Nishant Verma, Associate Professor, Department of Pediatric & Preventive Dentistry Babu Banarasi Das College of Dental Sciences Lucknow, KGMU via letter no. 819/Ped/21 dated 8th April, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P9***
10.	Research proposal entitled ***"Study of sociodemographic and clinical variables including psychiatric comorbidities in patients with irritable bowel syndrome"*** submitted by Dr. Ankita Saroj, JRI, Department of Psychiatry, KGMU via letter no. 612/Psy/21 dated 31st March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P10***
11.	Research proposal entitled ***"A study of adverse childhood experiences (ACE) in patients of opioid use disorder, alcohol use disorder and healthy controls"*** submitted by Dr. Akanksha Shankar, JRI, Department of Psychiatry, KGMU via letter no. 625/Psy/21 dated 31st March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P11***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

12.	Research proposal entitled ***"Correlation of ultrasonographic findings with endoscopic findings in infertile women"*** submitted by Dr. Kirti Yadav, JRI, Department of Obstetrics & Gynaecology, KGMU via letter no. OG/716/21 dated 7th April, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P12***
13.	Research proposal entitled ***"To study the correlation of MTR (A919G) and MTHFR (C677T) gene with endometriosis in women of reproductive age group"*** submitted by Dr. Suman, JRI, Department of Obstetrics & Gynaecology KGMU via letter no. OG/592/21 dated 22nd February, 2021. **PGTSC Comment:** • Introduction is a poor cut-paste job. Argument for the need of the study needs to be made. • Need for a control group to be clearly stated. • Is it a case-control study or an observational study? Is any intervention being done? These need to be looked into and amended. • In Privacy/Confidentiality section of Thesis Proforma the researcher has ticked both 'Direct Identifiers' as well as 'Completely Anonymized'. This needs correction **PGTSC Decision:** Approval subject to modification ***Ref. code: 108th II-PGTSC-IIA /P13***
14.	Research proposal entitled ***"Correlation of fibroblast growth FACTOR-23 levels for acute kidney injury in critically ill obstetrics cases and its association with fetomaternal outcome"*** submitted by Dr. Shruti, JRI, Department of Obstetrics & Gynaecology, KGMU via letter no. OG/606/21 dated 24th March, 2021. **PGTSC Comment:** • Privacy and Confidentiality section in Proforma – Direct Identifiers and Completely Anonymized have both been ticked.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Checkboxes in 'Consent' area of Proforma are not checked. • Checkboxes in Sections 9, 10, 11, and 12 of the Proforma are not checked. 5. In the 'Background and Rationale' the argument for this study has not been made. According to the literature provided by the researcher, FGF-23 is already an established marker for AKI. What then is the rationale of proving and already proven fact? **PGTSC Decision:** Approval subject to modification ***Ref. code: II-PGTSC-IIA /P14***
15.	Research proposal entitled ***"Myocardial functions in predicting the outcome of severe community acquired pneumonia in paediatric population: A prospective observational study"*** submitted by Dr. Adhyati Sachdev, JRI, Department of Paediatrics-, KGMU via letter no. 891/Ped/21 dated 13th April, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P15***
16.	Research proposal entitled ***"Clinical study of sleep disturbance and sleep hygiene in children and adolescents with attention deficit hyperactivity disorder"*** submitted by Dr. Ankita Devrani, JRI, Department of Psychiatry, KGMU via letter no. 473/Psy/21 dated 9th March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P16***
17.	Research proposal entitled ***"Hemophagocytic lymphohistiocytosis in sepsis: A prospective observational study"*** submitted by Dr. Ruovinuo Sachu, JRI, Department of Pathology, KGMU via letter no. 1917/21 dated 18th March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P17***
18.	Research proposal entitled ***"To study serum leptin and serum insulin hormone levels as predictors of obstetrical outcome in women with history of recurrent pregnancy***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	losses (RPL)" submitted by Dr. Anuradha Deol, JRI, Department of Obstetrics & Gynaecology, KGMU via letter no. GO/682/21 dated 3rd April, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P18***
19.	Research proposal entitled ***"An audit of cesarean section using modified ROBSON's criteria"*** submitted by Dr. Anjali Kapoor, JRI, Department of Obstetrics & Gynaecology, KGMU via letter no. GO/543/21 dated 19th March, 2021. **PGTSC Comment:** • Sample size not calculated (only formula is given) **PGTSC Decision:** Approval subject to modification ***Ref. code: II-PGTSC-IIA /P19***
20.	Research proposal entitled ***"Curcumin as an adjunct in treatment of thyroid associated ophthalmopathy: A pilot study"*** submitted by Dr. Swati Goyal, JRI, Department of Ophthalmology, KGMU via letter no. 69/OPH/21 dated 22nd April, 2021. **PGTSC Comment:** • No Ayurvedic (AYUSH) Consultant as Co-investigator included • No literature showing correlation of Curcumin and treatment of TAO given • The source of curcumin not mentioned • Which placebo is used - not given • How the groups 1 and 2 will be divided then how Group 2 into mild, moderate and severe is not mentioned, so detailed methodology should be submitted. **PGTSC Comment:** Re-write & Decision ***Ref. code: II-PGTSC-IIA /P20***
21.	Research proposal entitled ***"A hospital based observational study on HIV-TB coinfection"*** submitted by Dr. Akansha Soni, JRI, Department of Microbiology, KGMU via letter no. 183/21 dated 27th April, 2021. **PGTSC Comment:** • Objectives not defined • Methodology section incomplete

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Sample size calculation is not shown. Statistical considerations are to be mentioned. **PGTSC Comment:** Re-write & Decision` ***Ref. code: II-PGTSC-IIA /P21***
22.	Research proposal entitled ***"Assessment of psychological disorders and quality of life in women with polycystic overian syndorm"*** submitted by Dr. Neha Gupta, JRI, Department of Obst. & Gynecology, KGMU via letter no. OG/700/21 dated 30th March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P22***
23.	Research proposal entitled ***"Randomized, single blind, controlled trial of transcranial direct current stimulation (TDCS) on craving in alcohol use disorder"*** submitted by Dr. Arundhati Gairola, JRI, Department of Psychiatry, KGMU via letter no. 638/Psy dated 28th April, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P23***
24.	Research proposal entitled ***"A study of the characteristics of donor mothers and recipient neonates of the first human mild bank in Uttar Pradesh"*** submitted by Altaf Ahmad, JRI, Department of Paediatrics, KGMU via letter no. 1034/Ped/2021 dated 30th April, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P24***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

IIB	Nursing KGMU Institute
1.	Research proposal entitled ***"A study to assess the knowledge regarding problem faced during breastfeeding and its management among postnatal caesarean mothers in Queen Mary Hospital KGMU, Lucknow U.P"*** submitted by Mr. Idrees Akbar, Ms. Shivangi Singh, Ms. Parul Verma, Ms. Madhu, Ms. Pragati Patel, Ms. Shashi Prabha, Ms. Sugandha Singh, Mr. Hari Shankar Mishra, Mr. Vikash Chand Dubey, under the guidance Mrs. Sarla Singh & Miss. Monica Nancy Lal, Department of KGMU College of Nursing, KGMU via letter no.804/21 dated 25th March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIB /P1***
2.	Research proposal entitled ***"A study to assess the knowledge regarding osteoporosis, its preventive measures and home management among perimenopausal women visiting in the OPD of Queen Mary Hospital, KGMU, Lucknow with a view to develop patient information pamphlet"*** submitted by Mr. Sudhakar Bind, Mr. Sudhir Goswami, Mr. Sudhanshu Ranjan, Ms. Supriya Singh, Ms. Swapnil Chandel, Ms. Tanisha Singh, Ms. Tanya Maurya, Mr. Vishnuwendra Datt Mishra, Ms. Zeenat Parveen, under the guidance Mrs. Juhi G Nair & Mrs. Kumkum Yadav, Department of KGMU College of Nursing, KGMU via letter no.798/21 dated 25th March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIB /P2***
3.	Research proposal entitled ***"A study to assess the work stress regarding COVID 19 duties among health care professionals in selected departments of KGMU Lucknow"*** submitted by Miss. Purnima Tadav, Miss. Ranjana Kumari, Mr. Ratnesh Mishra, Mr. Ravi Ranjan Kumar, Miss. Reesma Maurya, Miss. Rina Kumari, Miss. Rinki Sonkar, Miss. Ruchika Singh, under the guidance Mrs. Supriya Singh & Mrs. Ankita Abiel, Department of KGMU College of Nursing, KGMU via letter no.800/21 dated 25th March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIB /P3***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

4.	Research proposal entitled ***"A study to assess the knowledge and attitude regarding hand washing among mothers of under five children in pediatric ward, KGMU"*** submitted by Ms. Shalini Chaudhary, Ms. Shalini Maurya, Ms. Sharon Tressler, Ms. Shefali Gautam, Ms. Shikha Gupta, Ms. Shivani Yadav, Ms. Shreya Bajpai, Ms. Shreya Mishra, under the guidance Mr. Nayan Paul & Mrs. Versha Rani Verma, Department of KGMU College of Nursing, KGMU via letter no.758/21 dated 25th March, 2021. **PGTSC Comment:** • Content and tool validation certificate -without signature attached • Why content and tool validation certificate -without signature is attached **PGTSC Decision:** Approval subject to modification ***Ref. code: II-PGTSC-IIB /P4***
5.	Research proposal entitled ***"A study to assess the knowledge, attitude and practice regarding COVID 19 and its preventive measures among rural population at selected area, Kucknow"*** submitted by Mr. Abhai Pratap Singh, Mr. Abhay Singh, Mr. Abhishek Anand, Mr. Alok Mishra, Mr. Aman Parihar, Ms. Anjali, Ms. Anjali Bhaskar, Ms. Anjali Pandey, under the guidance Mrs. Priyanka Singh & Ms. Loveena Arpita Samuel, Department of KGMU College of Nursing, KGMU via letter no.803/21 dated 25th March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIB /P5***
6.	Research proposal entitled ***"A study to assess impact of mobile phone use on dimensions of student life among nursing students at KGMU, College of Nursing, Lucknow, U.P. with a view to develop informational pamphlet"*** submitted by Ms. Sakshi Mishra, Ms. Sadhna Kaushal, Ms. Shweta Shukla, Mr. Saurabh Sharma, Mr. Saurabh Verma, Ms. Seema Parveen, Ms. Shaifali Gupta, Mr. Shailendra Kumar, under the guidance Mr. Migron Rubin & Mr. Ankit Raj, Department of KGMU College of Nursing, KGMU via letter no.799/21 dated 25th March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIB /P6***
7.	Research proposal entitled ***"A descriptive study to assess daily routine activities and perceived level of stress among students of B.Sc. nursing at KGMU, Lucknow"*** submitted

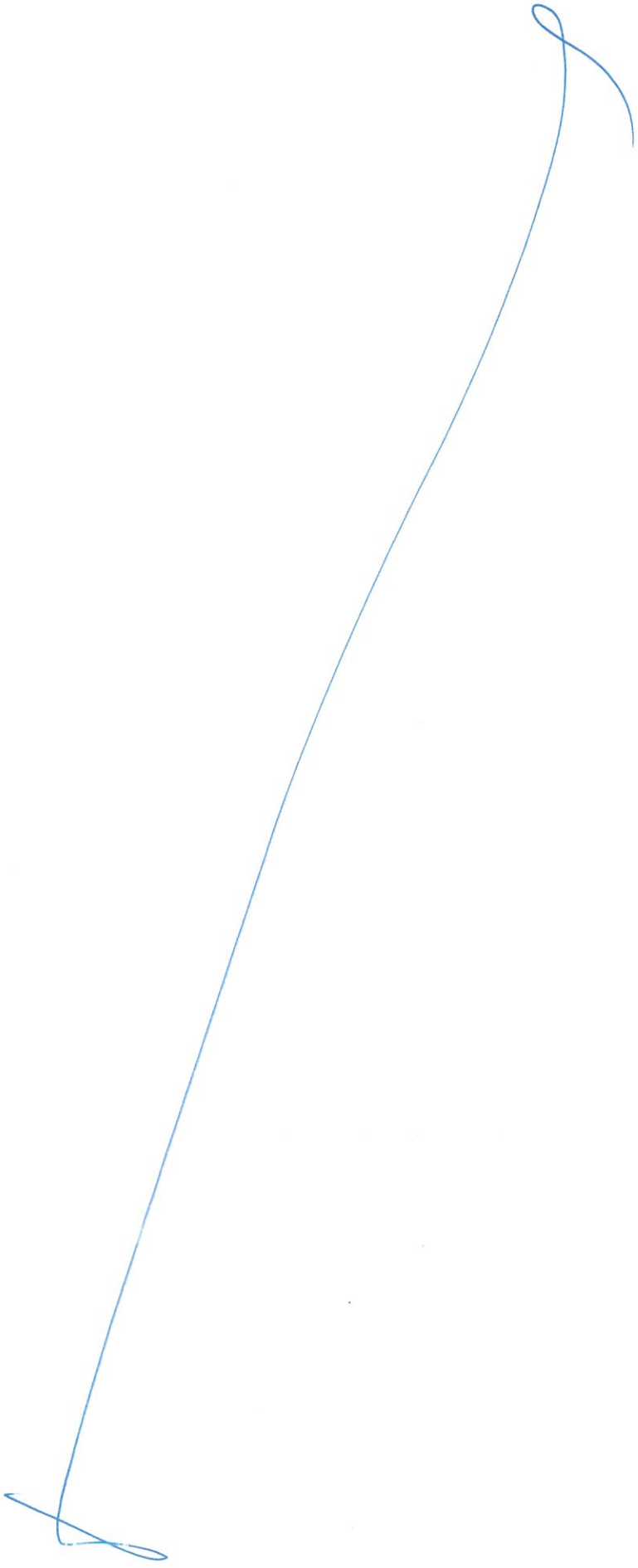
(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	by Mr. Shubham Gupta, Mr. Shubham Singh, Mr. Shubham Singh, Mr. Shubham Singh, Mr. Shubham Yadav, Ms. Shubhangi Chandra, Ms. Srestha Cahndra, Mr. Subhash Shukla, under the guidance Mr. Om Prakash Veragi & Mrs. Hina Singh, Department of KGMU College of Nursing, KGMU via letter no.784/21 dated 23rd March, 2021. **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIB /P7***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC



VI	Other Matter with the permission of Chair
1.	Clarification of research proposal entitled ***"Assessment of quality of life outcomes with prophylactic placement of permanent synthetic mesh at the time of enterostomy closure-a prospective observational study"*** submitted by Dr. Ajay Kumar Pal, Associate Professor, Department of Surgery General, KGMU via letter no. nil dated nil. **Action taken:** Send all documents to DNU for review ***Ref. code: 105th ECMIIA/P2***
2.	Clarification of research proposal entitled ***" Role of cost effective POP boot traction in post polio residual paralysis (PPRP): A case series"*** submitted by Dr. Sudhir R Mishra, Associate Professor, Department of PMR, KGMU via letter no. DPMR/3640/21 dated 6th March, 2021, **Action taken:** Send all documents to DNU for review ***Ref. code: 105th ECMIIA/P4***
3.	Clarification of research proposal entitled ***"Physiatrist approach in calcaneal osteomyelitis management: A case series"*** submitted by Dr. Sudhir R Mishra, Associate Professor, Department of PMR, KGMU via letter no. DPMR/3639/21 dated 6th March, 2021, **Action taken:** Send all documents to AR for review ***Ref. code: 105th ECMIIA/P5***
VI	**Other Matter with the permission of Chair**
1.	Clarification of the research proposal entitled ***"Effect of food grade pure flaxseed oil intake on tobacco craving in tobacco Dependent patients: A randomized double-blind placebo-controlled study"*** submitted by Ms. Anjali Singh, PhD Scholar, via his

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Mentor Prof. Narsingh Verma, Department of Physiology KGMU via letter no. 2353/PHY/21 dated 17th March, 2021. **Decision:** Approved ***Ref. code: 102th ECM II B-Ph.D/P2***
2.	Clarification of the research proposal entitled ***"Perioperative trigemino cardiac reflex in patients undergoing surgical treatment of tm joint ankylosis–A study"*** submitted by Dr. Harshita Maurya, JRIII, Department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences KGMU via letter no. Anaes/253/21 dated 16th March, 2021. **Decision :** Approved ***Ref. code: 103rd ECM II B-Thesis/P22***
3.	Clarification of the research proposal entitled ***"Comparision of transdermal fentanyl and transdermal buprenorphine patchk as post operative analgesia in patients undergoing lower limb surgery"*** submitted by Dr. Logesh A, JR-I, Department of Anaesthesiology KGMU via letter no. Anaes/253/21 dated 16th March, 2021. **Decision :** Approved ***Ref. code:103rd ECM IIB Thesis/P48***
4.	Clarification of the research proposal entitled ***"Impact of intense life style modification on changes in cardiovascular risk status as predicted by novel "Artificial intelligence based" cardiovascular disease (CVD) risk prediction score in individuals at high risk for CVD"*** submitted by Dr. Virendra Kumar Yadav, SRI, Department of Cardiology KGMU via letter no. 1633/Cardio/2021 dated 12th April, 2021. **Decision:** Approved ***Ref. code: 104th ECM II B-Thesis/P3***
5.	Clarification of the research proposal entitled ***"Gall bladder perforation: management and outcomes: A single centre experience"*** submitted by Dr. Bharat Sangal, SRI, Department of Surgical Gastroenterology KGMU via letter no. SG/134/21 dated 10th March, 2021. **Decision:** Approved

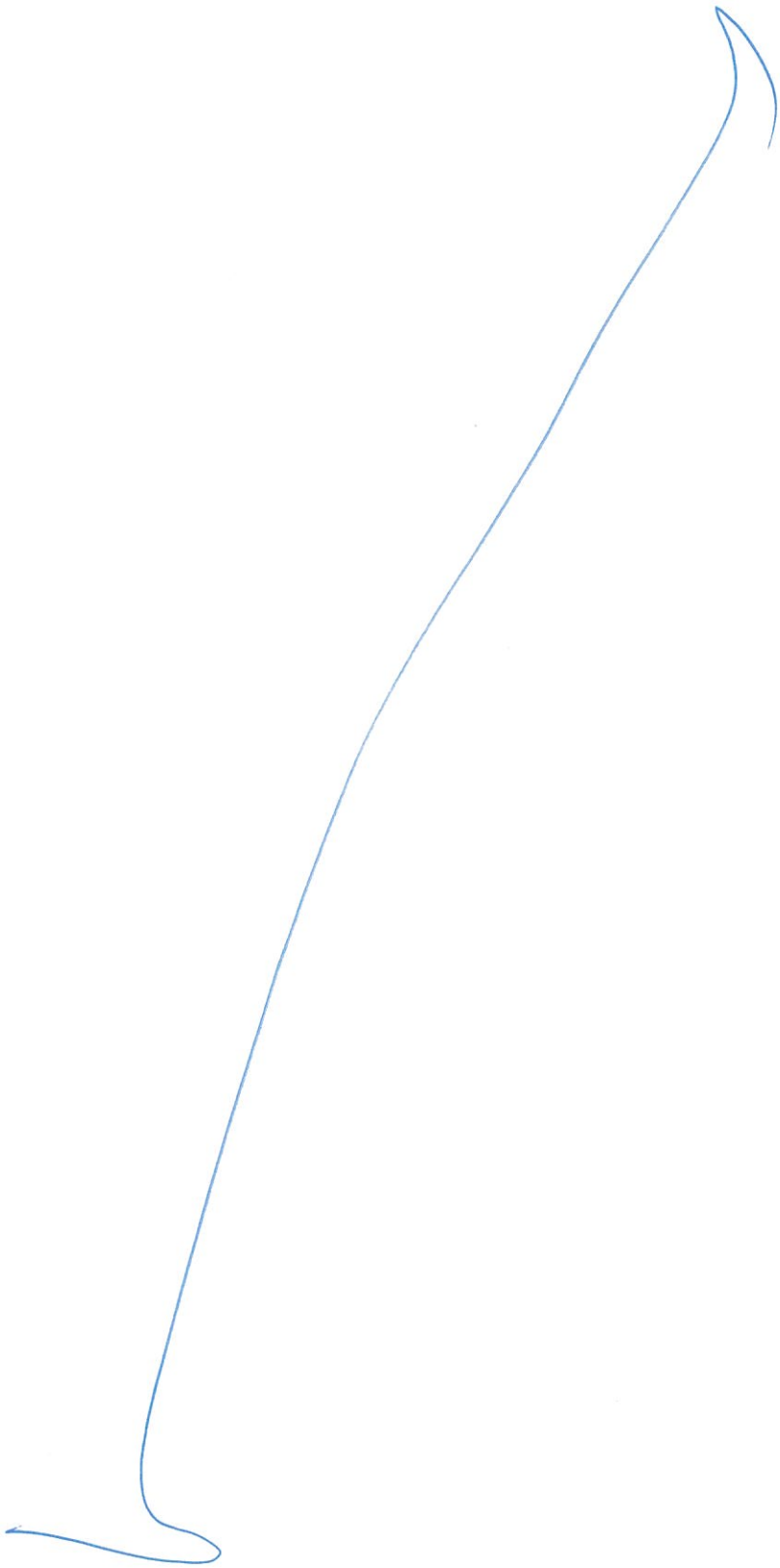
(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code:104th ECM IIB Thesis/P17
6.	Clarification of the research proposal entitled ***"Study of coronary culprit lesion characteristics by optical coherence tomography in young patients presenting with acute coronary syndrome"*** submitted by Dr. Arvind Kumar Jaiswal, SRI, Department of Cardiology KGMU via letter no. 1542/Cardio/2021 dated 26th March, 2021. **Decision:** Approved ***Ref. code: 104th ECM II B-Thesis/P21***
7.	Clarification of the research proposal entitled ***"Proton NMR metabolic profiling of small molecule metabolites and lipoproteins in serum of gall bladder cancer patients"*** submitted by Dr. Alok Kumar, JRI, Department of General Surgery KGMU via letter no. 377/21 dated 27th February, 2021. **Decision:** Approved ***Ref. code:104th ECM IIB Thesis/P***
8.	Clarification of the research proposal entitled ***"Effect of Ramucirumab (vegf2 inhibitor) on 6 months progression free survival (PFS) and quality of life (QOL) on metastatic drug resistant nsclc: A pilot study"*** submitted by Dr. Neelam Kumari, JRI, Department of General Surgery KGMU via letter no. 489/21 dated 12th March, 2021. **Decision:** Approved ***Ref. code:104th ECM IIB Thesis/P30***
9.	Clarification of the research proposal entitled ***"Effectiveness of self instructional module on knowledge regarding dietary management of iron deficiency anemia among pregnant women attending OPD"*** submitted by Mr. Ramesh Singh Chauhan, Through his Mentor Mrs. Rashmi P. John, Department of KGMU College of Nursing KGMU via letter no. 632/X.51/21 dated 3rd March, 2021. **Decision:** Approved ***Ref. code:105th ECM IID/P7***

(Shally Awasthi)
Member-Secretary, IEC

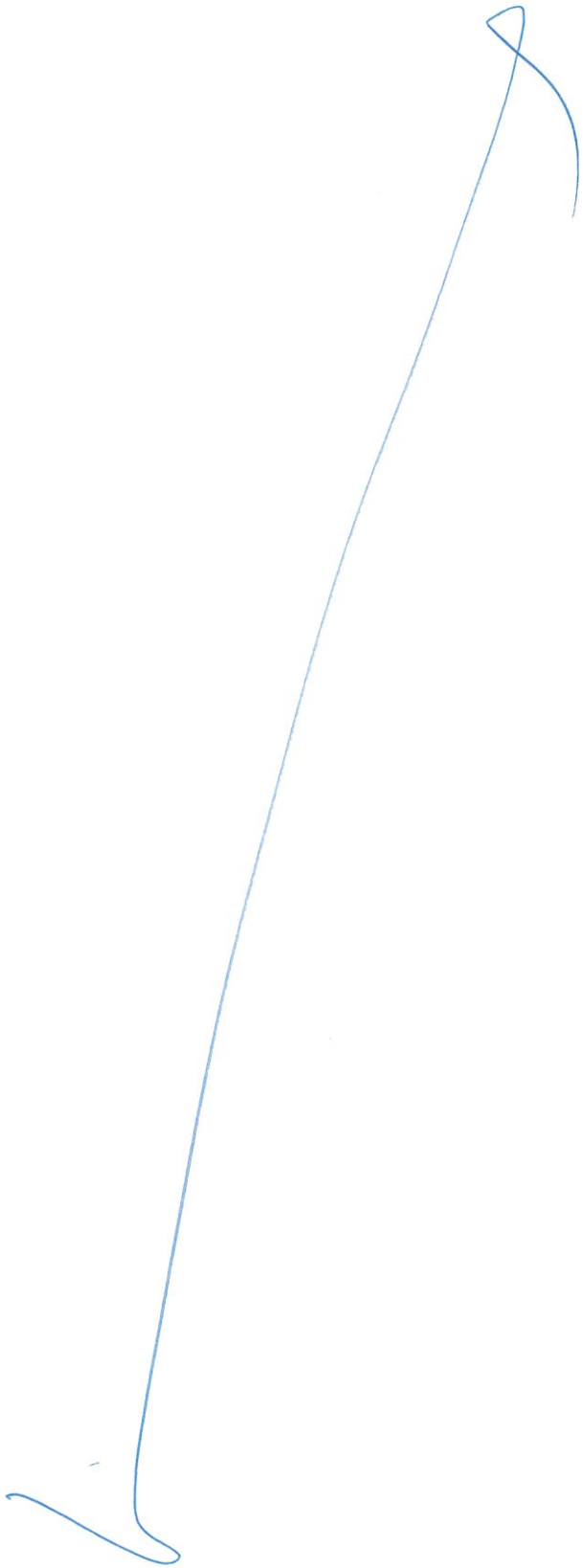
(Alok Dhawan)
Chairman, IEC



VII	Corrigendum
1.	There is a typo error in the protocol title. Inadvertently we had written title ***GS-US-417-0304: "A Multicentre, double-blind, long-term extension study to assess the safety and efficacy of filgotinib in subjects with Rheumatoid arthritis"*** **in place of** **GS-US-417-304:** ***"A Multicentre, open label, long-term extension study to assess the safety and efficacy of Filgotinib in subjects with Rheumatoid Arthritis"*** submitted by Prof. Puneet Kumar, Department of Rheumatology via letter no.RH/CT/16/21 dated 16th March, 2021. **EC Comment:** • Kindly clarify current status of the project ***Ref. code: 86thECMIIE/P1***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC



King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 108th ECM held on 22nd May, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19

	Other Matter with the permission of Chair-PGTSC
1.	Clarification of the research proposal entitled ***"Effect of food grade pure flaxseed oil intake on tobacco craving in tobacco Dependent patients: A randomized double-blind placebo-controlled study"*** submitted by Ms. Anjali Singh, PhD Scholar, via his Mentor Prof. Narsingh Verma, Department of Physiology KGMU via letter no. 2353/PHY/21 dated 17th March, 2021. **Decision:** Approved ***Ref. code: 102th ECM II B-Ph.D/P2***
2.	Clarification of the research proposal entitled ***"Perioperative trigemino cardiac reflex in patients undergoing surgical treatment of tm joint ankylosis–A study"*** submitted by Dr. Harshita Maurya, JRIII, Department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences KGMU via letter no. Anaes/253/21 dated 16th March, 2021. **Decision :** Approved ***Ref. code: 103rd ECM II B-Thesis/P22***
3.	Clarification of the research proposal entitled ***"Comparision of transdermal fentanyl and transdermal buprenorphine patchk as post operative analgesia in patients undergoing lower limb surgery"*** submitted by Dr. Dr. Logesh A, JR-I, Department of Anaesthesiology KGMU via letter no. Anaes/253/21 dated 16th March, 2021. **Decision :** Approved ***Ref. code:103rd ECM IIB Thesis/P48***
4.	Clarification of the research proposal entitled ***"Impact of intense life style modification on changes in cardiovascular risk status as predicted by novel "Artificial intelligence based" cardiovascular disease (CVD) risk prediction score in individuals at high risk for CVD"*** submitted by Dr. Virendra Kumar Yadav, SRI, Department of Cardiology KGMU via letter no. 1633/Cardio/2021 dated 12th April, 2021. **Decision:** Approved ***Ref. code: 104th ECM II B-Thesis/P3***
5.	Clarification of the research proposal entitled ***"Gall bladder perforation: management and outcomes: A single centre experience"*** submitted by Dr. Bharat Sangal, SRI, Department of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Surgical Gastroenterology KGMU via letter no. SG/134/21 dated 10th March, 2021. **Decision:** Approved ***Ref. code:104th ECM IIB Thesis/P17***
6.	Clarification of the research proposal entitled ***"Study of coronary culprit lesion characteristics by optical coherence tomography in young patients presenting with acute coronary syndrome"*** submitted by Dr. Arvind Kumar Jaiswal, SRI, Department of Cardiology KGMU via letter no. 1542/Cardio/2021 dated 26th March, 2021. **Decision:** Approved ***Ref. code: 104th ECM II B-Thesis/P21***
7.	Clarification of the research proposal entitled ***"Proton NMR metabolic profiling of small molecule metabolites and lipoproteins in serum of gall bladder cancer patients"*** submitted by Dr. Alok Kumar, JRI, Department of General Surgery KGMU via letter no. 377/21 dated 27th February, 2021. **Decision:** Approved ***Ref. code:104th ECM IIB Thesis/P29***
8.	Clarification of the research proposal entitled ***"Effect of Ramucirumab (vegf2 inhibitor) on 6 months progression free survival (PFS) and quality of life (QOL) on metastatic drug resistant nsclc: A pilot study"*** submitted by Dr. Neelam Kumari, JRI, Department of General Surgery KGMU via letter no. 489/21 dated 12th March, 2021. **Decision:** Approved ***Ref. code:104th ECM IIB Thesis/P30***
9.	Clarification of the research proposal entitled ***"Effectiveness of self instructional module on knowledge regarding dietary management of iron deficiency anemia among pregnant women attending OPD"*** submitted by Mr. Ramesh Singh Chauhan, Through his Mentor Mrs. Rashmi P. John, Department of KGMU College of Nursing KGMU via letter no. 632/X.51/21 dated 3rd March, 2021. **Decision:** Approved ***Ref. code:105th ECM IID/P7***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- In all submission, the role of Investigators and Co-Investigators has to be clearly mentioned.

Next Meeting will be held on 26th June, 2021 at 10.30 A.M.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 109th ECM held on 26th June, 2021

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of 109th Institutional Ethics Committee Meeting *virtually* held on **26th June, 2021** from 10.30 AM.

The following Members were present in the Meeting:-

1. Dr.Alok Dhawan -Chairman
2. Dr. Shubha R Phadke -Member
3. Dr. Akash Agarwal -Member
4. Dr. G.G. Agarwal -Member
5. Dr. K.K. Yadav -Member
6. Mrs. Akansha Dubey -Member
7. Sri Ujjawal Krishna -Member
8. Dr. A.A. Mahdi -Member
9. Dr. Rajendra Nath -Member
10. Dr. Anita Rani Singh -Member
11. Mrs. Vasundhara Kumari -Member
12. Dr.Shally Awasthi -Member-Secretary, Ex-officio

The following Members could not attend:-

1. Dr. Anupam Mishra -
2. Dr. D.N. Upadhayaya -

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

IA	Action Taken
1.	Clarification of research proposal entitled ***"Assessment of quality of life outcomes with prophylactic placement of permanent synthetic mesh at the time of enterostomy closure- a prospective observational study"*** submitted byDr. Ajay Kumar Pal, Associate Professor, Department of Surgery General, King George's Medical University U.P., Lucknow vide letter no. 133/2021 dated 21st January, 2021. **Previous EC Comment:** • Inclusion/ Exclusion criteria are not clear. While patients with follow up of at least 3 month are to be included, the exclusion criteria states that patients with less than 6 months of follow up will be excluded. The inclusion criteria are in contradiction with exclusion criteria. **Previous EC Decision:** Approval after justification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Primary Reviewer recommendation:** **Comment:** • A prospective observational study using a questionnaire for assessing the QOL after a surgical procedure. **Decision:** Approved **EC Decision:** Approval ratified ***Ref. code: 105th ECM IIA/P2***
2.	Clarification of research proposal entitled ***"Role of cost effective POP boot traction in post polio residual paralysis (PPRP): A case series"*** submitted by Dr. Sudhir R. Mishra, Associate Professor, Department of PMR, King George's Medical University U.P., Lucknow vide letter no. DPMR-3524 dated 28th January, 2021. **Previous EC Comment:** • Kindly clarify inclusion & Exclusion Criteria **Previous EC Decision:** Approval after justification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Primary Reviewer recommendation:** **Comment:** Retrospective review of patient data- **Decision:** Approved **EC Decision:** Approval ratified ***Ref. code: 105th ECM IIA/P4***

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

3.	Clarification of research proposal entitled "***Detection and comparison of anti-SARS-COV2IgG antibodies and T cell immune response among COVID-19 infected and vaccinated,health care workers (HCWs)***"submitted by Dr. Geeta Yadav, Associate Professor, Department of Pathology, King George's Medical University U.P., Lucknow vide letter no. nil dated 7th June, 2021. ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Previous EC Comment:** • Clarification regarding sample size is requested. • Clarify the role of Co-P.I. • Mention this is a pilot study **Previous EC Decision:** Mention this is a pilot study. **Primary Reviewer recommendation:** **Comment:** • A prospective observational study using a questionnaire for assessing the QOL after a surgical procedure. **Decision:** Approved **EC Decision:** Approval ratified ***Ref. code: 108thECM IIA/P7***
4.	Clarification of research proposal entitled "***Retrospective analysis of a methanol intoxication outbreak in Lucknow district and nearby areas in 2019***" submitted by Dr. Medhavi Gautam, Assistant Professor, Department of Medicine, King George's Medical University U.P., Lucknow vide letter no.1269/MED/21dated 10thJune, 2021. **Previous Comment:** **<u>Methodology:</u>** • All criteria not mentioned in text as per the case report form • Case report form to include full forms of the abbreviation, hence revise accordingly **Background information and data:** • Should also include the background literature relevant to proposed objectives **Inclusion criteria:** • If only those cases with positive family history of methanol intake are to be included, then incorporating signs of intoxication and that too based on suspicion seems confusing in this section. Hence revise.

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	Sufficient number of participants: • Not specified • Additional Co-PI from TVU and Critical care medicine may be considered since the cases are to be recruited from these dept. as well • Justify inclusion of to Co-Investigators **Previous EC Decision:** Re-submit ***The above comment forwarded to the Primary reviewer.*** ***Recommendation of the Primary reviewer:*** Pending **EC Decision:**Since Dr. Anupam Mishra family issued to be forwarded to Prof. A.A. Mahdi ***Ref. code: 107th ECM IIA/P6***
	Minutes of Meeting
6	A meeting held on 09.06.2021 to review the following proposal which was put-up in the Ethics Committee Meeting held on 22nd May, 2021.
7	Research proposal entitled ***"Academic clinical trial of safety, pharmacokinetics and early measurement of drug activity of CENTINHALE dry powder inhalation"*** sponsored by CSIR-Central Drug Research Institute submitted by Prof. Rajiv Garg, Department of Respiratory Medicine KGMU via letter no.1339/RESP/2021 dated 10th February, 2021. The Following were present in the Meeting: 1. Dr. Alok Dhawan, Chairperson, Ethics Committee 2. Dr. Rajiv Garg, P.I. of the proposal Senior Principal Scientist and Professor, Department of Pulmonary Medicine, KGMU 3. Dr. Amit Mishra, Senior Scientist, CDRI, Lucknow 4. Dr. Shally Awasthi, Member Secretary, Ethics Committee Prof. Alok Dhawan went point by point through the protocol with the investigators and highlighted areas which needed clarity and revision. He also asked the Principal Investigator to incorporate a work flow chart. It was agreed that the above proposal will be considered in the scheduled Ethics Committee meeting to be held on 26.06.2021.

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	The revised protocol would be submitted by the Principal investigator on 16.06.2021.
IB	**Expedited review**
1.	Expedited review of research proposal entitled "***Advanced mycology diagnostic and research centre at the Department of Microbiology, KGMU Lucknow***"sponsored by ICMR New Delhisubmitted by Prof. Prashant Gupta, Department of Microbiology, King George's Medical University U.P., Lucknow vide letter no.321/21 dated 31st May, 2021.**Comment:** • "Since this proposal is for establishing an advanced mycology diagnostic and research center facility in the Department of Microbiology in KGMU, it is being approved; however separate approval must be taken for research project. **Decision:** Approved **EC Decision:** Approval ratified ***Ref. code: 109th ECM IB/P1***
2.	Expedited review of research proposal entitled "***A prospective evaluation of patients with CNS involvement in mucormycosis***" submitted by Dr. Shweta Pandey, Associate Professor, Department of Neurology, King George's Medical University U.P., Lucknow vide letter no.163/Neuro/21 dated 2nd June, 2021. **Decision:** Approved **EC Decision:** Approval ratified ***Ref. code: 109th ECM IB/P2***
3.	Expedited review of research proposal entitled "***Spectrum and management of mucormycosis during COVID-19 pandemic***" submitted by Prof. Hardeep Singh Malhotra, Department of Neurology, King George's Medical University U.P., Lucknow vide letter no.1194/Med/21 dated 3rdJune, 2021. **Decision:** Approved **EC Decision:** Approval ratified ***Ref. code: 109th ECM IB/P3***
4.	Expedited review of research proposal entitled "***Understanding the seroprevalence in general population aged 5 and above across 75 districts, selected urban slum and studying seroconversion among COVID positive patients in Uttar Pradesh, India***"sponsored by Swasthya NH mission and IDSP, UP submitted by Dr. Suruchi Shukla, Assistant Professor, Department of Microbiology, King George's Medical University U.P., Lucknow vide letter no.356/21 dated 7thJune, 2021. **Decision:** Approved **EC Decision:** Approval ratified ***Ref. code: 109th ECM IB/P4***
5.	Expedited review of research proposal entitled "***Risk factors and effect on inflammatory markers in Fungal infections during Covid-19 pandemic: A pilot study***" submitted by Dr. Atin Singhai, Additional Professor, Department of Pathology, King George's Medical

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	University U.P., Lucknow vide letter no. 2792 dated 11th June, 2021. **EC Decision:** Awaited ***Ref. code: 109th ECM IB/P5***
6.	Expedited review of research proposal entitled "***To assess spectrum of multi-system inflammatory syndrome inchildren hospital in certain hospitals in Norther India: Prospective case series***" submitted by Prof. Shally Awasthi, Department of Pediatrics, King George's Medial University, U.P., Lucknow vide letter no. MIS/608/2021dated 21stJune, 2021. **EC Decision:** Approved ***Prof. Shally Awasthi did not participate in the discussion &decision making process.*** ***Ref. code: 109th ECM IB/P6***
7.	Expedited review of research proposal entitled "***Evaluate the effectiveness, safety and tolerability of various doses of linezolid in combination with bedaquiline and pretomanid in adults with extensively drug-resistant (XDR),MDR with additional resistance to fluroquinolones or second line injectables, intolerant/non-responsive multidrug-resistant (MDR) pulmonary tuberculosis in India***" submitted by Prof. Surya Kant, Department of Respiratory Medicine, King George's Medial University, U.P., Lucknow vide letter no. 1820/2021 dated 21stJune, 2021. **EC Decision:** Approved ***Ref. code: 109th ECM IB/P7***
II-A	**New Proposal**
1.	Research proposal entitled "***Impact of COVID-19 and lockdown in India on mortality***"submitted byDr. Shiuli, Assistant Professor, Department of Forensic Medicine & Toxicology, King George's Medical University U.P., Lucknow vide letter no.302/FMT/2021 dated 7thMay, 2021. **EC Comment:** • What is the role of Co-P.I. from Australia? • Give details of number of autopsies/day. • Will a meaningful inference be possible **EC Decision:** Approval subject to modification ***Ref. code: 109th ECM IIA/P1***
2.	Research proposal entitled "***To evaluate the role of RBP 4 as pediatric acute liver failure prognostic biomarker***" sponsored byCSIRsubmitted byDr. Sanjeev Kumar Verma, Associate Professor, Department of Pediatrics,King George's Medical University U.P., Lucknow vide letter no.1151/Ped/2021 dated 13thMay, 2021. **EC Comment:** • The aim is to study the biomarker as a prognostic tool. However, nowhere in the proposal, any reference to the prognosis of ALF has been made. • Why include a control group in this study? • No statistical plan has been given. • Flowchart is incomplete

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	• Inclusion criteria: How will the fact that 'PT-INR >2 is of hepatic origin' will be ascertained? • Sec 5: Why include "institutionalized" subjects? • Sec 6: Why use direct identifiers? • Sec 7 is left blank, needs to be completed. • Sec10: If risk is not reasonable to anticipated benefit, why do the study? • Blank fields in benefit section need to be filled. **EC Decision:** Approval subject to modification ***Ref. code: 109th ECM IIA/P2***
3.	Research proposal entitled ***"Operative management of early gallbladder cancer (OMEGA)-an analysis of management and outcomes in gallbladder cancer surgery"***submitted byProf. Abhinav Arun Sonkar, Head, Department of General Surgery, King George's Medical University U.P., Lucknow vide letter no.1038/2021 dated 25thMay, 2021. **Primary reviewer recommendation:** • The proposed study seems to be interesting and important. • It consists of prospective as well as retrospective study design. • The outcome variables for both the designs should be identified separately. They have mentioned these to be in Appendix I, but this is missing. • It would be helpful if research hypotheses for both parts should be stated clearly in terms of the terms of variables and associated parameters. It would be required for sample size calculations also. • The Sample size is mentioned to be 2500. How this figure is achieved? • Unless proper hypotheses are defined, the appropriate statistical analysis can not be performed. • Several study centers shall be involved, so multi-centric considerations have to be taken into accountat every stage including statistical analysis. The analysis procedures shall be different for retrospective and prospective designs. • The statistical analysis section should be rewritten in view of above comments. • The patient information sheet is not attached. • Who will be funding the study? • Give a list of collaborators from Institute uptil date. • Kindly follow National guidelines for date sharing. **EC Decision:**Approval subject to modification ***Ref. code: 109th ECM IIA/P3***
4.	Research proposal entitled ***"Evaluation of relation between mercury concentration in saliva and blood with number and surface of class I amalgam restorations"***submitted byDr. Diksha Singh, Associate Professor, Department of Oral Pathology &Microbiology,

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	King George's Medical University, U.P., Lucknow vide letter no.1345/OP/21 dated 1st March, 2021. **EC Comment:** • Only the background and rationale is given. No other details provided. Cannot comment. **EC Decision:** Re-submit with details ***Ref. code: 109th ECM IIA/P4***
5.	Research proposal entitled "***Feasibility of truenat assay in detecting mycobacterium tuberculosis in stool, gastric aspirate and extrapulmonary samples***" sponsored byICMR, New Delhi submitted byDr. Parul Jain, Assistant Professor, Department of Microbiology, King George's Medical University U.P., Lucknow vide letter no.254/21 dated 15th March, 2021. **Primary reviewer Comment:** • Budget- Rs 31,45,800 (Breakup –not mentioned)-From ICMR-New Delhi • Patient information sheet-submitted only English version (Hindi version missing) • Study design mentioned as Experimental? what type of experimental-details not mentioned • ICF- ICF-English attached but Guardian and Assent form missing-ICF-Hindi-Incomplete. **EC Decision:** Approval subject to modification ***Ref. code: 109th ECM IIA/P5***
6.	Research proposal entitled "***Experience of botulinum toxin type a in patients with movement disorders at tertiary care center India***"submitted byDr. Shweta Pandey, Associate Professor, Department of Neurology, King George's Medical University U.P., Lucknow vide letter no.162/Neuro/21 dated 2nd June, 2021. **EC Comment:** • How researchers calculated sample size is not mentioned. • They are using various scales to understand the level of improvement and in statistical analysis, they did mention about the statistical tests for scales or scores. How will they prevent biases? They did not mention. • Consent form-Patient information sheet is incorrect. • Clarify duration of follow-up **EC Decision:** Approval subject to modification ***Ref. code: 109th ECM IIA/P6***
7.	Research proposal entitled "***Attitude towards post exposure prophylaxis for contacts and disease disclosure among leprosy patients in India: A multicentric study***" submitted byDr. Swastika Suvirya, Additional Professor, Head, Department of Dermatology, Venereology and Leprosy, King George's Medical University U.P., Lucknow vide letter no.98/SKIN/21 dated 21st May, 2021. **Primary reviewer recommendation:** Approved

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	EC Decision: Approved ***Ref. code: 109th ECM IIA/P7***
8.	Research proposal entitled ***"Cellular fibroadenoma versus phyllodes tumors: A pre-operative diagnostic approach based on radiological and cytological features"***submitted byDr. Chanchal Rana, Associate Professor,Department of Pathology, King George's Medical University U.P., Lucknow vide letter no. 2769/21 dated 7thJune, 2021. **EC Comment:** • How will you get clinical data? • From where will you get the consent as patients may not be traceable? • Senior resident should not be included as Co-Investigators **EC Decision:** Approval subject to modification ***Ref. code: 109th ECM IIA/P8***
9.	Research proposal entitled ***"To conduct pilot testing of pre-service competency-based training tools for undergraduate medical students (interns) and provide feedback on the content, duration and training methods"***sponsored by W.H.O., New Delhi submitted byProf. Uma Singh, Department of Obst. & Gynaecology, King George's Medical University U.P., Lucknow vide letter no. OG/819/21 dated 9thJune, 2021. **EC Comment:** • Since this is a training project no ethical issues are involved **EC Decision:** Approved ***Ref. code: 109th ECM IIA/P9***
IIC	**Review of New Drug Trial**
1.	ResearchProtocol no.HCR/III/TENESTEMI/08/2020. Version: 1.0;Dated:05 Aug, 2020 entitled ***"A prospective, multicenter, randomized, comparative, parallel group clinical study to compare the efficacy, pharmacokinetics, pharmacodynamics, immunogenicity and safety of intravenous injection of tenecteplase (Hetero Biopharma Limited) and reference medicinal product (RMP Tenecteplase, BoehringerIngelheim) in adults for the thrombolyic treatment of suspected myocardial infarction with persistent ST elevation"*** sponsored by M/s Hetero Biopharma Ltd submitted by Dr. Akhil Sharma, Associate Professor, Department of Cardiology, King George's Medical University U.P., Lucknow vide letter no. 1540/Cardio/Res/2021 dated 1stMay, 2021. **Primary reviewer Recommendation:** • Budget- approx..-Rs 179550/ per complete pt visit (Breakup not given) • Test drug / Ref. drug will be given as single dose -50 mg IV with in 6 hrs of onset of symptoms – Hospitalization –for 48 hrs- follow up- up to 30th day (90 min, 24 hr, 48 hr , 7th , 14th and 30th day) – what does this comment mean?? • DCGI submission letter –attached – Permission letter – Awaited • Clinical Trial Registry document not given. **EC Decision:** Approval subject to modification & fulfillment of Administrative formalities.

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	Ref. code: 109th ECMIIC/P1
2.	Research Protocol no. GENESIS II entitled "***A clinical evaluation of the HYDRA self expanding transcatheter aortic valve***" sponsored by M/s Vascular Concepts Ltd. submitted by Prof. Sharad Chandra, Department of Cardiology, King George's Medical University U.P., Lucknow vide letter no. 1558/Cardio/Res/2021 dated 11thMay, 2021. **EC Comment:** • Section 4: not attached. • Section 5: Inclusion criteria are >65 years: These are vulnerable subjects. Not checked. • Duration is not 6 months for the study, it's for each subject. • Section 6: Why will direct identifiers be used? • Budget: Funding documents to be attached. **EC Decision:** Clarification & additional information is needed. ***Ref. code: 109th ECMIIC/P2***
3.	Research Protocol no. E7080-M091-511entitled "***A prospective, multicenter, post-marketing phase IV study to Assess the safety and efficacy of lenvatinib as first-line treatment in patients with unresectable hepatocellular carcinoma (HCC)***" sponsored by M/s Eisai Pharmaceuticals India Pvt. Ltd. submitted by Prof. Vijay Kumar, Department of Surgical Oncology, King George's Medical University U.P., Lucknow vide letter no. SONC/414.2021 dated 15thMay, 2021. **EC Comment:** • Departmental Review Committee comments to be send. • University proforma not filled **EC Decision:** Approval subject to modification ***Ref. code: 109th ECMIIC/P3***
III	**Modification**
1.	Modification of Research protocol no. CTQJ230A12301entitled "***Arandomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with pelacarsen (TQJ230) on major cardiovascular events in patients with established cardiovascular disease***" sponsored by Novartis Health Care Pvt. Ltdsubmitted by Prof. S.K. Dwivedi, Department of Cardiology,King George's Medical University U.P., Lucknowvide letter no.1555/Cardio/Res/2021 dated 7th May, 2021. **EC Comment:** • Can be approved with a remark that adverse events are reported to EC as and when they occur. **EC Decision:** Approved ***Ref.code:101st ECMIIC/P18***

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

2.	Modification of Research protocolno. ATLAS-A/Bentitled ***"A phase 3 study to evaluate the efficacy and safety of fitusiran in patients with hemophilia A or B, without inhibitory antibodies to factor VIII or IX"*** sponsored by M/s Bajaj Allianz Generali Insurance Co Ltd. Ltd. submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology, King George's Medical University U.P., Lucknowvide letter no.243/CH/21 dated 3rd June, 2021. **EC Comment:** The SAE of severe types have been reported. These include very high transaminases and 6 cases with thrombosis. One of them was fatal. The reason given for fatality is that probable misdiagnosis of intracranial bleed while the patient had sinus thrombosis. The total number of cases enrolled in various parts of the previous studies is not clear, but the incidence rate [page 97] is 5.91 and 1.49 [of vascular thrombosis events per 100 patients years for AT levels of <10% and 10 to 20% respectively). Comment on whether this risk is acceptable for patients with hemophilia without inhibitors? Currently the hemophilia patients in India do not have access to prophylaxis [mostly] but they have access to on demand therapy and serious bleeds are managed successfully for the cases who are not on prophylaxis. For the cases with inhibitors, the management of serious bleeds is not easy and they also do not have access to prophylaxis - Hence, they may be better group for trial. But this trial has excluded them. I on review of data from other countries where trial on cases without inhibitors is going on this it was stopped after fatal SAE. Kindly confirm. To compare with efficacy, the previous studies have shown average ABR [annual bleed rate] on drug as 3 to 5. (can it be considered very effective? [2] The amendment is basically to incorporate the findings that the ABR is related to AT levels and they decided to mitigate the risk of vascular thrombosis event while maintaining a favourable benefit risk balance to change the dose from 80 mg per month to 50 mg every 2 months. This appears logical. But the patient information brochures in Hindi and English mention the dose as 80mg per 28 days. This needs verification / clarification. Most importantly this document does not contain the protocol of the study to verify the dose planned and how many time AT levels will be measured and based on those if the drug levels will be modified. Kindly submit a detailed report of recruitment at our site and their outcomes. **EC Decision:** Pending review of clarifications

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	Ref.code:90th ECMIIC/P2
IV	**Annual Progress Reports**
1.	Annual Progress Report of research protocol entitled ***"Analogue of prothrombin time: identification and assay development of novel non-invasive and surrogate indicator of blood coagulopathy"*** sponsored by ICMR New Delhi submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University U.P., Lucknow vide letter no. 1600/Cardio/Res/2021 Dated 7th June, 2021. **EC Decision:** Reviewed ***Ref. code: 101st ECM IIA/P5***
2.	Annual Progress Report of research protocol entitled ***"Impact of COVID-19 on quality of life among health care professional of selected hospital in U.P."*** submitted by Mr. Rohitash Kumar, Assistant Professor, KGMU College of Nursing, King George's Medical University U.P., Lucknow vide letter no. 793/21 Dated 8th June, 2021. **EC Decision:** Reviewed ***Ref. code: IIIrd ECM COVID-19 IB/P4***
V	**Other Matter with the permission of chair**
1.	Due to quorum is incomplete in the EC Meeting held on 22nd May, 2021, the research Protocol no. STS-BDB001-04 entitled ***"A multi-centre, open-label, randomized parallel controlled evaluation on the efficacy and safety of BDB-001 injection in the treatment of progressive severe COVID-19 in phase II"*** sponsored by Staidson (Beijing) Biopharmaceutical Co. Ltd. submitted by Dr. D. Himanshu, Principal Investigator, Additional Professor, Department of Medicine, King George's Medical University U.P., Lucknow vide letter no. MED/CT/25/2021 dated 29th April, 2021. **Previous Primary reviewer recommendation:** Approval after fulfillment of Administrative Formalities. **EC Decision:** Approved ***Ref. code: 108th ECMIIC/P1***
2.	Due to quorum was incomplete in the EC Meeting held on 16th April, 2021. This modification under the research protocol no. ATLAS-OLE: entitled ***"An Open label long term safety and efficacy study of fitusiran in patients with hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX"*** submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology King George's Medical University U.P., Lucknow vide letter no.51/CH/21 dated 6th February, 2021. **Previous Primary reviewer recommendation:** Approved **EC Comment:** • See comments to letter no. 243/CH/21 dated 3rd June, 2021. **EC Decision:** Pending ***Ref.code:90th ECM II C/P1***

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

3.	Due to the name of Sponsor Company is changed from Sanofi-Synthelabo (India) Pvt. Ltd. to Sanofi Healthcare India Private Limited (SHIPL) under the protocol no. TERIFL08918 entitled ***"A single arm phase IV clinical trial to describe the safety and efficacy of TeriflunomidE in patients with relapsing forms of multiple scierosis (SAFE trial)"***sponsored by M/s SANOFI submitted by Prof. Hardeep Singh Malhotra, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 147/Neuro/21 dated 17th June, 2021. **EC Decision:** Reviewed ***Ref.code:93rd ECM II C/P11***
4-	As per request of the student Ms. Geeta Kushwaha, M.Sc. Nursing student under the guidance of Mr. Subin S., Assistant Professor, KGMU College of Nursing, ***a Co-guide add in the study Prof. Avinash Agarwal, Head Department of Critical Care Medicine, King George's Medical University, U.P. Lucknow"*** under the research proposal entitled ***"Effectiveness of coma arousal technique to improve sensory stimulation in unconscious patients"*** vide letter no.746 dated 21st May, 2021. **EC Decision:** Approved ***Ref.code:105th ECM II D/P5***
V	**Corrigendum**
5-	There is a typo error in the protocol title. Inadvertently written title is incorrect from this office "Evaluation of Immuno-Modulatory potential of selected Ayurvedic Formulations in high risk quarantined subjects and frontline healthcare workers in COVID-19 care center" instead of "Evaluation of immune-modulatory subject and frontline healthcare workers in COVID-19 care centre" submitted by Prof. S.K. Singh, Associate Professor, Department of CFAR, King George's Medical University, U.P., Lucknow vide letter no. nil dated 18th June, 2021. **EC Decision:** Approved ***Ref.code:107th ECM II A/P13***
IV	**Annual Progress Reports**
1.	Annual Progress Report of research protocolentitled ***"Analogue of prothrombin time: identification and assay development of novel non-invasive and surrogate indicator of blood coagulopathy"*** sponsored by ICMR New Delhi submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University U.P., Lucknow vide letter no. 1600/Cardio/Res/2021 Dated 7th June, 2021. **EC Decision:** Reviewed ***Ref. code: 101st ECM IIA/P5***
2.	Annual Progress Report of research protocol entitled***"Impact of COVID-19 on quality of life among health care professional of selected hospital in U.P."*** submitted by Mr. Rohitash Kumar, Assistant Professor, KGMU College of Nursing, King George's Medical University U.P., Lucknow vide letter no. 793/21 Dated 8th June, 2021.

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	EC Decision: Reviewed ***Ref. code: IIIrd ECM COVID-19 IB/P4***
V	**Other Matter with the permission of chair**
1.	Due to qouram is incomplete in the EC Meeting held on 22nd May, 2021, the researchProtocol no. STS-BDB001-04 entitled ***"A multi-centre, open-label, randomized parallel controlled evaluation on the efficacy and safety of BDB-001 injection in the treatment of progressive severe COVID-19 in phaseII"*** sponsored by Staidson (Beijing) Biopharmaceutical Co. Ltd. submitted by Dr. D. Himanshu, Principal Investigator, Additional Professor, Department of Medicine, King George's Medical University U.P., Lucknow vide letter no. MED/CT/25/2021 dated 29th April, 2021. **Previous Primary reviewer recommendation:** Approval after fulfillment of Administrative Formalities. **EC Decision:** Approved ***Ref. code: 108th ECMIIC/P1***
3.	Due to the name of Sponsor Company is changed from Sanofi-Synthelabo (India) Pvt. Ltd. to Sanofi Healthcare India Private Limited (SHIPL) under the protocol no. TERIFL08918 entitled ***"A single arm phase IV clinical trial to describe the safety and efficacy of TeriflunomidE in patients with relapsing forms of multiple sclerosis (SAFE trial)"***sponsored by M/s SANOFI submitted by Prof. Hardeep Singh Malhotra, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 147/Neuro/21 dated 17th June, 2021. **EC Decision:** Reviewed ***Ref.code:93rd ECM II C/P11***
4-	As per request of the student Ms. Geeta Kushwaha, M.Sc. Nursing student under the guidance of Mr. Subin S., Assistant Professor, KGMU College of Nursing, ***a Co-guide add in the study Prof. Avinash Agarwal, Head Department of Critical Care Medicine, King George's Medical University, U.P. Lucknow"*** under the research proposal entitled ***"Effectiveness of coma arousal technique to improve sensory stimulation in unconscious patients"*** vide letter no.746 dated 21st May, 2021. **EC Decision:** Approved ***Ref.code:105th ECM II D/P5***
V	**Corrigendum**
5-	There is a typo error in the protocol title. Inadvertently written title is incorrect from this office ***"Evaluation of Immuno-Modulatory potential of selected Ayurvedic Formulations in high risk quarantined subjects and frontline healthcare workers in COVID-19 care center"*** instead of ***"Evaluation of immune-modulatory subject and frontline healthcare workers in COVID-19 care centre"*** submitted by Prof. S.K. Singh, Associate Professor, Department of CFAR, King George's Medical University, U.P., Lucknow vide letter no. nil dated 18th June, 2021. **EC Decision:** Approved ***Ref.code:107th ECM II A/P13***

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

Minutes of **"III PG Thesis sub Committee"** of **"Institutional Ethics Committee"** Meeting ***virtually*** will be held on 19th June, 2021 from 11.30.

The following Members were present in the Meeting:-

1. Prof. G.G. Agarwal -Member
2. Prof. Rajendra Nath -Member
3. Prof. A.A. Mahdi -Member
4. Prof. Anita Rani -Member
5. Dr. D.N. Upadhyaya -Member
6. Prof. Shally Awasthi -Convener

IA	Action Taken
1.	Clarification of research proposal entitled ***"Evaluation of magnetic nanoparticles as pulpotomy medicament in primary teeth: randomized control trial"*** submitted by Dr. KumariCharul, JRI, Department of Paediatric& Preventive Dentistry Faculty of Dental Sciences,King George's Medical University, U.P., Lucknow vide letter no. Pado/399/21 dated 25th May, 2021. **PGTSC Comment:** 1. The aim is to evaluate the effectiveness of magnetic nanoparticles (MNPs) as a pulpotomy medicament in primary molars and to compare its effectiveness to MTA 2. Inclusion and exclusion criteria are clearly defined 3. Two groups – study group will receive MNPs and control group will get MTA. Rest of the treatment will be the same 4. Sample size 24 in each group. Statistically derived 5. Randomization will be computer generated 6. Bilingual consent form is provided. 7. What will be observed and when? 8. A data collection sheet is missing 9. If it is a RCT then we need Consort guidelines **PGTSC Decision:** Approval after justification ***The above comment forwarded to the P.I., Reply has given by P.I. which was forwarded to the Primary reviewer.*** **PGTSC Decision:** Approved ***Ref. code: 102nd ECM II B-Thesis/P59***

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

2.	Clarification of research proposal entitled ***"Comparative study of role of indocyanine green combined with methylene blue dye versus methylene blue dye alone in sentinel lymph node biopsy in post nact breast cancer patients"*** submitted by Dr. Gowri CharanDharmalingam, JRI, Department of General Surgery,King George's Medical University, U.P., Lucknow vide letter no. 1080/21 dated 4thJune, 2021. **EC Comment:** • As per the aim PI is comparing 2 methods for diagnosing/ detecting LN. • Study design, can not be cross sectional. It should be designed for evaluation of diagnostic test" Sample size, +ve& -ve cases to calculate sensitivity/speciality/ PPV/NPV/LR should be planned. • Case record form/questionnaire shall be attached. **EC Comment:** Approval after justification ***The above comment forwarded to the P.I. Reply given by P.I. was reviewed by the Member-Secretary, IEC & approved it.*** **PGTSC Decision:**Approved ***Ref. code: 104th ECM II B-Thesis/P31***
3.	Clarification of research proposal entitled ***"An epidemiological study of orthopaedic admissions in KGMU trauma centre and the status of bone specific alkaline phosphatase in these subjects"*** submitted by Dr. Nayank Gautam, JRII, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 650/OS/21 dated 29thMay, 2021. **EC Comment:** • Kindly Rewrite Hindi Consent form (Google translation is not allowed). **EC Decision:** Approval after justification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Primary Reviewer recommendation:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: 104th ECM II B-Thesis/P56***
4.	Clarification of research proposal entitled ***"Relation of serum troponin in moderate to severe COVID-19 disease"*** submitted by Dr. Naveen Kumar, JRII, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1133/Med/2021 dated 24th May, 2021. **PGTSC Comment on 13th April, 2021:** • Detailed methodology/technique along with reference needed. A co-guide from investigating department may be included. **PGTSC Decision on 13th April, 2021:** Approval subject to modification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	Ref. code: 107th ECM II B-Thesis/P1
5.	Clarification of research proposal entitled ***"Role of asymmetrical dimethyl arginine in type II diabetes mellitus in relation to coronary artery disease and chronic kidney disease"*** submitted by Dr. Jyoti Verma, JRI, Department of Medicine,King George's Medical University, U.P., Lucknow vide letter no. 1196/Med/2021 dated 3rd June, 2021. **PGTSC Comment on 13th April, 2021:** • Methodology needs to be checked and corrected (instead of past tense it shall be future tense). Number of subjects varies, Sample size mentioned is 120 and in methodology it is written 177 out of 200. • How ADMA will be measured? Method? Reference? **PGTSC Decision on 13th April, 2021:** Approval subject to modification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P4***
6.	Clarification of research proposal entitled ***"To assess thrombocytopenia as a prognostic marker in patients with acute encephalitis at a tertiary care centre in northern India"*** submitted by Dr. Akriti Bhardwaj, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1094/MED/2021 dated 15thMay, 2021. **PGTSC Comment:** • Reference for methodology needed. A co-guide from investigating department may be included **PGTSC Decision:** Approval subject to modification ***The above comment forwarded to the P.I., Reply given by P.I. which was forwarded to the Primary reviewer.*** **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P11***
7.	Clarification of research proposal entitled ***"Role of WWOX gene polymorphism in development of cervical cancer"*** submitted by Dr. Gulshan Kumar, JRI, Department of Pathology,King George's Medical University, U.P., Lucknow vide letter no. 2746/21 dated 4th June, 2021. **PGTSC Comment:** • Controls not mentioned. What will be the inclusion and exclusion criteria? **PGTSC Decision:** Approval subject to modification ***The above comment forwarded to the P.I., Reply given by P.I. which was forwarded to the Primary reviewer.*** **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P12***

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

8.	Clarification of research proposal entitled ***"Randomised, single blind, control trial of transcranial direct current stimulation in adolescents with obsessive compulsive disorder as early augmentation"*** submitted by Dr. Aditya Agrawal, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 784/Psy dated 21st May, 2021. **PGTSC Comment on 13th April, 2021:** • Sample size calculation is not done **PGTSC Decision on 13th April, 2021:** Approval subject to modification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P16***
9.	Clarification of research proposal entitled ***"Correlation of intrapartum Chlamydia trachomatis infection with obstetric and perinatal outcome"*** submitted by Dr. TriptiKumari, JRI, Department of Obstetrics &Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/655/21 dated 19th May, 2021. **PGTSC Comment on 13th April, 2021:** • Methodology details are missing **PGTSC Decision on 13th April, 2021:** Approval subject to modification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** ***Primary reviewer Recommendation:*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P22***
10.	Clarification of research proposal entitled ***"Prospective and retrospective analysis of management and outcome of endometrial carcinoma over a period of 10 Years"*** submitted by Dr. Sapna Jugran, JRI, Department of Obstetrics &Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG794/21 dated 7th June, 2021. **PGTSC Comment:** • ICF : Explain the procedure to patient in easy to understand language. • What would be the follow-up period for patients enrolled in 2021. **PGTSC Decision:** Approval subject to modification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** ***Primary reviewer Recommendation:*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P31***

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

11.	Clarification of research proposal entitled ***"Study of pregnancy specific dermatoses and others dermatological lesions in pregnant and postpartum women"*** submitted by Dr. Shweta Mishra, JRI, Department of Obstetrics &Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/636/21 dated 15th May, 2021. **PGTSC Comment on 13th April, 2021:** • Revise ICF, mention study procedure which shall be explained to the patient **PGTSC Decision on 13th April, 2021:** Approval subject to modification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** ***Primary reviewer Recommendation:*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P32***
12.	Clarification of research proposal entitled ***"Correlation between serum corin and plasma N-terminal pro-a trial natriuretic peptide with fetomaternal outcomes in Hypertensive disorders of pregnancy"*** submitted by Dr. Rupali Nayak, JRI, Department of Obstetrics &Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/771/21 dated 3rd June, 2021. **PGTSC Comment on 13th April, 2021:** • Is it a routine investigation? If case not, who will bear the cost of investigations of control group? Consent form: In study Procedure cross sectional Study is written. Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. Use proper understandable Hindi language. **PGTSC Decision on 13th April, 2021:** Approval subject to modification ***The above comment forwarded to the P.I., Reply has given by P.I. which was forwarded to the Primary reviewer.*** **Comment:** • The cost of additional investigation will be borne by investigator. Study procedure to be explained to the patient has been. ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** ***Primary reviewer Recommendation:*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P35***
13.	Clarification of research proposal entitled ***"Study of serum placental growth factor (PIGF) level in women of preeclampsia and its correlation with fetomaternal outcome"*** submitted by Dr. Kiran Arya, JRI, Department of Obstetrics &Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/725/21 dated 26th May, 2021. **PGTSC Comment:** • Study design and sample size calculation need clarification and modification.

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	PGTSC Decision: Approval after modification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** ***Primary reviewer Recommendation:*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P45***
14.	Clarification of research proposal entitled ***"Randomised controlled trial for comparison of efficacy and safety of dinoprostone gel alone with dinoprostone gel and mechanical cervical dilatation together for pre-induction cervical ripening"*** submitted by Dr. Neelansha Varshney, JRI, Department of Obstetrics &Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/674/21 dated 21st May, 2021. **PGTSC Comment:** • CTRI registration is required **PGTSC Decision:** Approval after justification ***The above comment reviewed by the Member-Secretary, IEC.*** ***Member-Secretary Recommendation:*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P48***
15.	Clarification of research proposal entitled ***"Analysis and relevance of single or combination mutations of BRAF, TERT, and NRAS genes and their clinic-pathologic relationship in papillary thyroid carcinoma: a study using sanger sequencing"*** submitted by Dr. IshaMakker, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 2778/21 dated 9th June, 2021. **PGTSC Comment:** • Sample size calculation and methodology is not clear. **PGTSC Decision:** Approval after modification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** ***Primary reviewer Recommendation:*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P50***
16.	Clarification of research proposal entitled ***"Curcumin as an adjunct in treatment of thyroid associated ophthalmopathy: A pilot study"*** submitted by Dr. Swati Goyal, JRI, Department of Ophthalmology King George's Medical University, U.P., Lucknow vide letter no. 253/OPH/21 dated 11th June, 2021. **Previous PGTSC Comment:** • No Ayurvedic (AYUSH) Consultant as Co-investigator included • No literature showing correlation of Curcumin and treatment of TAO given • The source of curcumin not mentioned • Which placebo is used -not given • How the groups 1 and 2 will be divided then how Group 2 into mild,moderate

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	and severe is not mentioned,so detailed methodology should be submitted. **Previous PGTSC Comment:** Re-write & Decision ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **PGTSC Comment:** **PI has included Ayush consultant as Co-guide** **-But other quarries still to be resolved** 1. PI mentioned two groups - Standard treatment gp (control) + Standard treatment + Curcumin gp (cases) . What placebo will be used is not clear 2. Study design -Mentioned as Prospective interventional placebo based study, but PI written that Randomisation of patients will be done ? 3. PI did not answer that from where he will procure Curcumin as active ingredient of Curcumin longa plant. 4.PI has written in summary of clarification that mild,moderate and severe cases will be divided according to EUGOGO classification,but he did not mentioned it in methodology part (EUGOGO classification not attached). **PGTSC Decision:** Approval after justification ***Ref. code: II-PGTSC-IIA/P20***
17.	Clarification of research proposal entitled ***"Feasibility of ultrasound guided suprascapular nerve block in improving shoulder motion and pain post surgery in breast cancer survivors: A prospectiverandomised controlled trial"*** submitted by Dr. Laxmi Prajapati, JRI, Department of Physical Medicine & Rehabilitation King George's Medical University, U.P., Lucknow vide letter no. 3535/2020 dated 30th January, 2021. ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **PGTSC Decision:** • If it is a trial then CTRI will be needed. • In inclusion criteria it is mentioned that patients undergoing surgery will be included. Is it correct?? • In the consent form permission for intervention shall be taken. • Rest things taken care but consent form for intervention is in English, what about its Hindi version????? **PGTSC Decision:**Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P5***
18.	Clarification of research proposal entitled ***"Efficacy of dry needling versus transcutaneous electrical nerve stimulation in patients with neck pain due to myofascial trigger points: A randomized control trial"*** submitted by Dr. Anjana G, JRI, Department of Physical Medicine & Rehabilitation,King George's Medical University,

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	U.P., Lucknow vide letter no. 3536/2021 dated 30thJanuary, 2021. ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** ***Primary reviewer Recommendation:*** • If it is a trial then CTRI registration will be needed. It is fine now • In the consent form permission for intervention shall be taken. • Rest things taken care but consent form for intervention is in English, what about its Hindi version????? **PGTSC Decision:**Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P6***
19.	Research proposal entitled ***"A comparative study of stigma and its correlates in caregivers and patients of bipolar affective disorder and schizophrenia currently in remission"*** submitted by Dr. Sahil Jamal, JRI, Department of Psychiatry,King George's Medical University, U.P., Lucknow vide letter no. 528/Psy/21 dated 18th March, 2021. **PGTSC Comment:** • Kindly revise ICF: Contact details of investigator not provided. Study Procedure: Provide the procedure which will be explained to the patient. Point 9: suggest alternative as Yes/No **PGTSC Decision:** Approval subject to modification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to Dr. Anita Rani.*** **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P33***
20-	Research proposal entitled ***"Randomised controlled single blind trial of transcranial direct current stimulation (tDCS) as early augmentation in major depressive disorder"*** submitted by Dr. BabliKumari, JR, Department of Psychiatry,King George's Medical University, U.P., Lucknow vide letter no. 522/Psy/21 dated 18th March, 2021. **PGTSC Comment:** • Sample size is not clear. • Fundamental of RC Trial are not followed • Kindly provide CTRI registration **PGTSC Decision:** Approval subject to modification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to Dr. G.G. Agarwal.***

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	PGTSC Comment: Approved ***Ref. code: 107th ECM II B-Thesis/P53***
21.	Clarification of research proposal entitled ***"A retrospective study to evaluate clinical and radiological results of surgical treatment of acetabular fractures using modified stoppa approach"*** submitted by Dr. Balwinder Singh, JRII, Department of Orthopaedics,King George's Medical University, U.P., Lucknow vide letter no. 2468/2020 dated 10th December, 2020. **EC Comment:** • As per Aims and objective and methodology the management has already been proformed in the study subjects, PI only intends to study the outcome, advantages and disadvantages of the Stoppa approach. • Will there be a comparison group of any other approach, if yes please clarify **EC Decision:** Approval after justification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to Dr. Anita Rani Singh.*** ***Recommendation:*** Waiver granted **PGTSC Decision:**Approved-Waiver granted ***Ref. code: 104th ECM II B-Thesis/P55***

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

II-A	New Thesis-Resident
1.	Research proposal entitled ***"A study of olfactory functioning in patients of depression"*** submitted by Dr. Aniruddh Kumar Gupta, JRI, Department of Physiology, King George's Medical University, U.P., Lucknowvide letter no. 2408/PHY/21 dated 28th April, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P1***
2.	Research proposal entitled ***"Initial laboratory findings useful for predicting the diagnosis of immune thrombocytopenic purpura"*** submitted by Dr. Mithilesh, JRI, Department of Pathology, King George's Medical University, U.P., Lucknowvide letter no. 2133/21 dated 4th May, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P2***
3.	Research proposal entitled ***"Study on association of inflammatory and oxidative stress paradox during plaque vulnerability across the spectrum of acute coronary syndrome: A prospective case control study"*** submitted by Dr. Ram Kumar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknowvide letter no. 2127/21 dated 3rd May, 2021. **PGTSC Comment:** • The title is inappropriate. The case control study is retrospective, not prospective. Research hypothesis is not defined (involving parameter, variable, outcome measure etc.) Sample size calculations are not done. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P3***
4.	Research proposal entitled ***"Study of P100 wave latency in prediabetics"*** submitted by Dr. Ruchika Thakur, JRI, Department of Physiology, King George's Medical University, U.P., Lucknowvide letter no. 2412/PHY/21 dated 6th May, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P4***
5.	Research proposal entitled ***"Association of S100 B and CRP levels with delirium in critically ill obstetrics cases"*** submitted by Dr. Monam Solanki, JRI, Department of Obstetrics &Gynaecology, King George's Medical University, U.P., Lucknowvide letter no. OG/555/21 dated 20th March, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P5***

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

6.	Research proposal entitled ***"A study of all-cause and cause-specific mortality in a public sector level III neonatal intensive care unit of a teaching hospital"*** submitted by Dr. Akash Mohan, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknowvide letter no. 1095/Ped/21 dated 8th May, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P6***
7.	Research proposal entitled ***"Comparison of clinic-radiological characteristics of spontaneous intracerebral hemorrhage in patients with and without hypertension and their clinical outcomes"*** submitted by Dr. VikasVittalPrabhu, SRI, Department of Neurology, King George's Medical University, U.P., Lucknowvide letter no. 100/NEURO/21 dated 8th April, 2021. **PGTSC Comment:** • Research hypothesis is not properly defined. It is a comparative study involving two groups. Accordingly, study design should be defined. There are no sample size calculations. Statistical Analysis section is very general and is not in line with the objective of the study. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P7***
8.	Research proposal entitled ***"New onset seizures in tuberculous meningitis: A 6 Months follow up study"*** submitted by Dr. Roopesh Singh Kirar, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 98/NEURO/21 dated 8th April, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P8***
9.	Research proposal entitled ***"Effect of advanced age on bioactive factors (IL-6 & TGF-ß) in colostrum"*** submitted by Dr. Shivani, JRI, Department of Physiology, KGMUvide letter no. 2425/PHY/21 dated 17th May, 2021. **PGTSC Decision:** Approved • Kindly provide details of timing, frequency and procedure for colostrum extraction. Also clarify that if the collection of milk will be till 7th day as written in methods or will be within 72 hrs (according to ICF). According to ROL, TGF and IL are affected by preterm delivery and birth weight. The study needs careful inclusion and exclusion criteria. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P9***
10.	Research proposal entitled ***"Predictors of CSF gene XPERT positivity in patients with tuberculous meningitis"*** submitted by Dr. Priyanka Gupta, SRI, Department of Neurology,King George's Medical University, U.P., Lucknowvide letter no. 101/NEURO/21 dated 8th April, 2021. **PGTSC Decision:** Approved

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	Ref. code: III PGTSC-IIA/P10
11.	Research proposal entitled ***"External validation of "MASH-P" score in patients with tuberculous meningitis- A multicentric analysis"*** submitted by Dr. Pooja Tripathi, SRI, Department of Neurology, King George's Medical University, U.P., Lucknowvide letter no. 99/NEURO/21 dated 8th April, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P11***
12.	Research proposal entitled ***"Clinical trend analysis of orbital cellulitis in a tertiary care institute in northern India: A 15 years experience"*** submitted by Dr. Ashutosh Maharana, JR, Department of Ophthalmology, King George's Medical University, U.P., Lucknowvide letter no. 165/OPH/21 dated 18th May, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P12***
13.	Research proposal entitled ***"Impact of smart phone technology on outcome of management in congenital nasolacrimal duct obstruction (CNLDO)"*** submitted by Dr. ShauryaVerma, SR, Department of Ophthalmology, King George's Medical University, U.P., Lucknowvide letter no. 164/OPH/21 dated 17th May, 2021. **PGTSC Comment:** • Kindly provide primary and secondary objectives of the study. Provide sample size with justification. Provide outcome parameters. Instead of allocating subjects for a year as control and next year with video guidance….alternate allocation will make the efforts more reliable. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P13***
14.	Research proposal entitled ***"Cone beam computed tomographic evaluation of mandible for orthodontic mini-implant placement in different malocclusions"*** submitted by Dr. Babita Yadav, JRII, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dental Sciences,King George's Medical University, U.P., Lucknowvide letter no. 85/21 dated 30th January, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P14***
15.	Research proposal entitled ***"Musculoskeletal complications in patients of type2 diabetes vs. non diabetics"*** submitted by Dr. Nabila Nishat, JRI, Department of Physiology, King George's Medical University, U.P., Lucknowvide letter no. 2427/PHY/21 dated 20th May, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P15***
16.	Research proposal entitled ***"Clinical predictors of neuroimaging findings in patients with subacute sclerosing panencephalitis- ZA prospective evaluation"*** submitted by Dr. Keerthiraj D.B, SRI, Department of Neurology, King George's Medical University, U.P., Lucknowvide letter no. 107/NEURO/21 dated 9th April, 2021.

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	PGTSC Comment: • Kindly provide justification for not calculating or providing sample size. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P16***
17.	Research proposal entitled ***"Gene polymorphism of leukotriene A4 hydrolase among tuberculous meningitis patients in north India and its associations with clinical response: A case control study"*** submitted by Dr. Pragnya Panda, SRI, Department of Neurology,King George's Medical University, U.P., Lucknowvide letter no. 128/NEURO/21 dated 21st May, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P17***
18.	Research proposal entitled ***"Evaluation and categorization of tumour stroma in oral squamous cell carcinoma and its correlation with clinic-pathological parameters"*** submitted by Dr. Ashok Kumar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknowvide letter no. 2024/21 dated 24th March, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P18***
19.	Research proposal entitled ***"Association of central obesity with cardiac autonomic parameters"*** submitted by Dr. Arun Kumar Yadav, JRI, Department of Physiology, King George's Medical University, U.P., Lucknowvide letter no. 2433/PHY/21 dated 25th May, 2021. **PGTSC Comment:** • Get new Guide & Co-guide allotted • Give definition of controls and their inclusion and exclusion and exclusion criteria. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P19***
20.	Research proposal entitled ***"To estimate the prevalence of celiac disease in refractory iron deficiency anemia among children: prospective observational study"*** submitted by Dr. Samrat Chirag Singh, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknowvide letter no. 1056/Ped/21 dated 4th May, 2021. **PGTSC Comment:** • How will be Iron deficiency be assessed. • Where and how will Serum Zinc level be assessed. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P20***
21.	Research proposal entitled ***"Study of complications of therapeutic plasma exchange according to patients demography and variations in procedure"*** submitted by Dr. Jyoti Bharti, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknowvide letter no. 088//21 dated 24th May, 2021.

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	PGTSC Comment: This is a prospective observational pilot study with 60 patients. · Is the study already underway?? · In the informed consent form risks or any expected complications following plasma exchange are not mentioned. · References are incomplete. Most do not have a year of publication and are not properly written e.g. publishers of books and manuals are not mentioned. · When patients height and weight are being noted then BMI may also be included in patient demographic data. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P21***
22.	Research proposal entitled ***"Assessment of knowledge, attitude and awareness of blood donors for promoting their motivation and retention"*** submitted by Dr. Vinay Tiwari, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknowvide letter no. 089/21 dated 25th May, 2021. **PGTSC Comment:** • Theses proforma with details has to be submitted **PGTSC Decision:** Re-submit ***Ref. code: III PGTSC-IIA/P22***
23.	Research proposal entitled ***"Changing etiological profile of paediatric acute liver failure in the era of viral hepatitis immunization in northern India: A prospective observational study"*** submitted by Dr. Stuti Shukla, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknowvide letter no. 1258/Ped/21 dated 29th May, 2021. **PGTSC Comment:** • Lab. Methodology of all parameters has to given. **PGTSC Decision:**Approval subject to modification ***Ref. code: III PGTSC-IIA/P23***
24.	Research proposal entitled ***"Comparison of prognostic value of american joint committee on cancer 8th and 7th edition staging system for gall bladder carcinoma patients undergoing curative surgery: A retrospective study"*** submitted by Dr. Abhishek Kumar Verma, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknowvide letter no. SONC/427/21 dated 29th May, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P24***
25.	Research proposal entitled ***"Survival outcomes of patients with early oral squamous cell carcinoma (pT1-T2pN0) undergoing a curative-intent surgery"*** submitted by Dr. Mamidipalli S Siddhartha, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknowvide letter no. SONC/428/21 dated 29th May, 2021. **PGTSC Comment:** • Study design mentioned a Retrospective, descriptive case series study, but

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	mentioned that Patients will be followed up for 18 months and ICF is submitted, the study design should be modified. • Sample size calculation has not done. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P25***
26.	Research proposal entitled ***"Clinical outcomes of interval cytoreduction in patients with stage III epithelial ovarian cancer-A tertiary care centre experience"*** submitted by Dr. Rohit Kashyap, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/426/21 dated 29th May, 2021. **PGTSC Comment:** • Sample size no. 60 (Treatment naïve Stage III epithelial ovaria cancer patients underwent interval cytoreduction surgery during the period Jan, 2015-2020 and will be followed up for 2 years) Not calculated. • Study design mentioned as Retrospective case series study, but Principal-Investigator mentioned that patients will be followed up for 2 years or till death whichever is earlier and ICF is submitted, So the study design should be modified. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P25***
27.	Research proposal entitled ***"A study of the clinic-biochemical parameters as prognostic markers for pneumonia among hospitalized elderly patients"*** submitted by Dr. Rajat Chaudhary, JRI, Department of Medicine, King George's Medical University, U.P., Lucknowvide letter no. 1161/MED/21 dated 29th May, 2021. **PGTSC Decision:**Approved ***Ref. code: III PGTSC-IIA/P27***
28.	Research proposal entitled ***"Zinc alpha2 glycoprotein as an early biomarker of diabetic nephropathy in patients with type2 diabetes mellitus"*** submitted by Dr. Akash Gupta, JRI, Department of Medicine, King George's Medical University, U.P., Lucknowvide letter no. 1162/MED/21 dated 29th May, 2021. **PGTSC Comment:** • Data collection sheet to be inserted. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P28***
29.	Research proposal entitled ***"A study of the association between serum ferritin levels and microalbuminuria in patients of type2 diabetes mellitus"*** submitted by Dr. Kinjalk Dubey, JRI, Department of Medicine, King George's Medical University, U.P., Lucknowvide letter no. 1156/MED/21 dated 28th May, 2021. **PGTSC Comment:** • Standard Questionnaire format not submitted **PGTSC Decision:** Approval subject to modification

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	Ref. code: III PGTSC-IIA/P29
30.	Research proposal entitled ***"To assess the nutritional status and determinants of underweight among pediatric tuberculosis patients"*** submitted by Dr. Ashvini Rana, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknowvide letter no. 1215/Ped/21 dated 24th May, 2021. **PGTSC Comment:** • Study design:- • Principal-Investigator mentioned study design as Prospective observational study, but in setting part of summary he has mentioned it as Randomized prospective double blind clinical trial. This is making confusion. Actually the study design is Prospective Observational case control study. **PGTSC Decision:** Approval subject to modification
	Ref. code: III PGTSC-IIA/P30
31.	Research proposal entitled ***"To assess the role of VITAMIN D levels as a risk factor and prognostic marker in patients of acute ischemic stroke at a tertiary care centre in northern India"*** submitted by Dr. Kislaya Kamal, JRI, Department of Medicine, King George's Medical University, U.P., Lucknowvide letter no. 1186/MED/21 dated 2nd June, 2021. **PGTSC Comment:** • Patient record form needed **PGTSC Decision:** Approval subject to modification
	Ref. code: III PGTSC-IIA/P31
32.	Research proposal entitled ***"Study of pattern and outcome of acute poisoning cases at tertiary care Hospital in North India"*** submitted by Dr. Naman Aggarwal, JRI, Department of Medicine, King George's Medical University, U.P., Lucknowvide letter no. 1178/MED/21 dated 31st May, 2021. **PGTSC Comment:** • Patient record form needed (Structured Proforma) • Sample size not given **PGTSC Decision:** Approval subject to modification
	Ref. code: III PGTSC-IIA/P32
33.	Research proposal entitled ***"Evaluation of changes in ultrasonographic optic nerve sheath diameter as a useful point of care tool to supplement invasive intracranial pressure measurement in Paediatric patients with hydrocephalus undergoing neurosurgical intervention"*** submitted by Dr. Malika Dhawal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknowvide letter no. Anaes/440/21 dated 3rd June, 2021. **PGTSC Comment:** • **<u>Suggest changing the title:</u>** Ultrasonographic evaluation of changes in optic nerve sheath diameter as a useful point of care tool to supplement invasive intracranial pressure

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	measurement in pediatric patents with hydrocephalus undergoing neurosurgical intervention" • Subject selection, Privacy and Confidentiality and Consent Sections of Proforma incompletely filled. • No co-supervisor/Co-PI from Radiology Department is there. Who will do the ultrasound? Does the person doing the ultrasound? Does the person doing the ultrasound have PCPNDT registration? • According to the PI, ONSD is already an established method of detecting raised intracranial pressure. What is the rationale behind this study then?? What is the research question? Also, please mention role of each member of the team of researchers. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P33***
34.	Research proposal entitled ***"Effect of non-surgical periodontal therapy on salivary and gingival crevicular fluid concentration of visfatin in periodontal health and disease"*** submitted by Dr. Hira Ismail, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknowvide letter no. 1582/P/21 dated 23rd February, 2021. **PGTSC Comment:** • According to the PI role of Visfatin as an inflammatory marker in periodontal disease is already established. What is the needkl for this study? • Proforma says the study I NOT a clinical trial. However, the PI says the study will be registered with clinical trial Registry of India. This is conflicting. • Role of everyone participating in the study needs to be defined. Is it a trial? Research question needs to be defined. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P34***
35.	Research proposal entitled ***"To evaluate the effect of oral zinc supplementation on salivary MMP-8 levels in chronic periodontitis"*** submitted by Dr. Vishakha Gupta, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknowvide letter no. 1581/P/21 dated 23rd February, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P35***
36.	Research proposal entitled ***"To evaluate and assess association of ABO phenotype and rhesus factor with oral hygiene status and severity of periodontitis"*** submitted by Dr. Mohd. Aamir Khan, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknowvide letter no. 1585/P/21 dated 23rd February, 2021. **PGTSC Comment:** • According to the literature provided by the PI several such studies have already been done all over the world in the past. What is the rationale for another such

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	study then? What is the research question? • Define 'Other blood parameters' mentioned in Aims of the study • Justify use of 'Other blood parameters'. • Research question needs to be formulated. • Role of all investigators needs to define. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P36***
37.	Research proposal entitled ***"Evaluation of periodontal health status in patients with lung cancer in north Indian population: A case-control study"*** submitted by Dr. Pooja Singh, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknowvide letter no. 1583/P/21 dated 23rd February, 2021. **PGTSC Comment:** • Periodontontal health and HBD-2 have already been linked to cancers in previous studies. Please argue the need for another study on the same subject. • Besides the PI there are seven Co-PI. Please define the role of every Co-PI. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P37***
38.	Research proposal entitled ***"Effect of antioxidant therapy in periodontal disease: A clinical study"*** submitted by Dr. Sakeena Tariq, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknowvide letter no. 1586/P/21 dated 23rd February, 2021. **PGTSC Comment:** • Role of antioxidants in reducing oxidative damage in periodontal disease has already been established. What new aspect do the investigators want to research? **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P38***
39.	Research proposal entitled ***"Impact of oil pulling on periodontitis in patients with and without type2 diabetes mellitus-A randomized controlled trial"*** submitted by Dr. Nehil Saran, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknowvide letter no. 1584/P/21 dated 23rd February, 2021. **PGTSC Comment:** • Objectives of studying the efficacy of an Ayurvedic procedure in a modern medicine University by a person not trained in Ayurveda amounts to malpractice. • PI not trained in Ayurvedic sciences, thus cannot act as PI. • The PI and all exact one Co-PIs are not trained in Ayurveda • KGMU is a University imparting training in Modern Medicine. Research in subject pertaining to Ayurveda involving patients will be malpractice. • Patient has to be informed that they are being treated by an Ayurvedic method by a person not trained in Ayurveda.

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	• Research on an Ayurvedic medication/Ayurvedic treatment/procedure cannot be conducted by a person not trained in Ayurvedic sciences and in a non-Ayurvedic University. This amounts to Malpractice. Suggest rethinking of the research topic on a subject from Modern Medicine. • Mention the compensation of oil to be used. • How will the oil be Standardized? • Justify the role of Co-PIs. • Include a Doctor Ayush working in KGMU. **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P39***
40.	Research proposal entitled ***"Incidence, etiological profile and outcome of ventilator associated pneumonia (VAP) in pediatric intensive care unit (PICU)"*** submitted by Dr. Naresh Kumar, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknowvide letter no. 13322/Ped/21 dated 5th June, 2021. **PGTSC Comment:** • The study is prospective. Observational However, the PI has filled the Risk and benefit section in the proforma. In and non-interventional study there is no risk for the patient except form the disease. • The 'Background and review of Literature' mentions KGMU as a Central Government hospital, which it is not. This should be corrected. **PGTSC Decision:**Approved ***Ref. code: III PGTSC-IIA/P40***
II-B	**IMR-Resident**
1-	Research proposal entitled ***"Analysis of efficacy of elastography in comparison to dynamic renal nuclear scintigraphy in diagnosis of unilateral pelvi-ureteric junction obstruction"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Nirpex Tyagi, SRII, through his Mentor Prof. Anand Pandey, Associate Professor, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknowvide letter no. 184/Ped Sy/21 dated 12thMay,2021. **PGTSC Comment:** • Age of PIs included to be given? • Complications of Radionuclide to be described **PGTSC Decision:** Approval subject to modification ***Ref. code: IIIPGTSC-II B IMR-R/P1***
2.	Research proposal entitled ***"Clinical and radiographic assessment of the efficacy of three different materials used as pulpotomy medicaments in primary teeth: A randomized control trial"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Gunna Madhuri, JRII, through his Mentor Prof. Afro Alam Ansari, Department of Paediatric and Preventive Dentistry, Faculty of Dental Sciences,King George's Medical University, U.P., Lucknowvide letter no. Pedo/382/21 dated 15thMay,2021.

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

	PGTSC Comment: • The Principal-Investigator mentions that there is risk to the patients, but there are no plans for reporting of adverse events or provision of compensation. This is probably a mistake in filling the proforma. Please have it checked and edited. **PGTSC Decision:** Approval subject to modification ***Ref. code: IIIPGTSC-II B IMR-R/P2***
3.	Research proposal entitled "***A randomized clinical trial on comparative evaluation of intranasal combinations of midazolam-ketamine, dexmedetomidine ketamine, midazolam-fentanyl and dexmedetomidine-fentanyl for procedural sedation and analgesiainpaediatric dental patients***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Agarwal AbhilashaKishanlal, JRII, through her Mentor Prof. Rakesh Kumar Chak, Head, Department of Paediatric and Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknowvide letter no. Pedo/387/21 dated 15thMay,2021. **PGTSC Comment:** • The PI mentions that the risk is not reasonable compared to anticipated benefits. Please correct this is it is a mistake in the proforma. • Privacy & Confidentiality is not mentioned in the proforma. • The PI mentions that there is risk to the patient, but there are no plans for reporting of adverse events or provisions of compensation. This is probably a mistake in filling the proforma. Please have it checked and edited. **PGTSC Decision:** Approval subject to modification ***Ref. code: IIIPGTSC-II B IMR-R/P3***
	MBBS-Student
1	Research proposal entitled "***Clinical outcomes of deep brain stimulation (DBS) under Microelectrode recording***"submitted by Mr. Ahmad Ozair, MBBS Student under the guidance of Dr. Ankur Bajaj, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/229 dated 14th June,2021. **PGTSC Comment:** • The study involves no human subjects • It is a Retrospective data analysis of records **PGTSC Decision:** Approval subject to modification ***Ref. code: IIIPGTSC-II B student/P1***

Next Meeting will be held on 1st Saturday, 7th August, 2021 from 10.30 A.M.

(Shally Awasthi)
Member Secretary-IEC

(Alok Dhawan)
Chairman-IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 110th ECM held on 7th August, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Minutes of 110th Institutional Ethics Committee Meeting ***virtually*** held on **7th August, 2021** from 10.30 AM.

The following Members were present in its Meeting:

- Prof. Alok Dhawan -Chairman
- Prof. G.G. Agarwal -Member
- Prof. Shubha R Phadke -Member
- Mrs. Akansha Dubey -Member
- Mrs.Vasundhara Kumari -Member
- Mr. Ujjawal Krishna -Member
- Dr. Akash Agarwal -Member
- Dr. K.K. Yadav -Member
- Prof. A.A. Mahdi -Member
- Prof. Rajednra Nath -Member
- Prof. Anupam Mishra -Member
- Prof. Anita Rani Singh -Member
- Dr. D.N. Upadhyaya -Member
- Prof. Shally Awasthi -Member-Secretary, IEC

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 110th ECM held on 7th August, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

IA	Action taken
1.	Clarification of research proposal entitled "***Metabolic and transcriptomic pattern as potential biomarkers for breast cancer patients***" submitted by Prof. Anand Kumar Mishra, Head, Department of Endocrine Surgery, King George's Medical University U.P., Lucknow vide letter no. ENDOSURG/2021/2/93 dated 17th March, 2021. **Previous EC Comment:** • Kindly provide Data collection sheet. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Member-Secretary, IEC & Provisionally approved.*** **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 104th ECM IIA/P23***
2.	Clarification of research proposal entitled "***Assessment of tumor budding in Oral cavity Squamous cell carcinoma undergoing primary resection and its correlation with clinical outcome parameters***" submitted by Dr. Shalini Bhalla, Associate Professor, Department of Pathology, King George's Medical University U.P., Lucknow vide letter no. 2877 dated 2nd July, 2021. **Previous EC Comment:** • Clarity is required on the following issues – • Is this a retrospective study? • Will patient consent be required for this? If Yes, how will it be obtained retrospectively? Does it require patient follow-up for outcome assessment? • What is the policy for funding from Chinese Company? Submit to HMSC, ICMR for approval ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 107th ECM IIA/P2***
3.	Clarification of research proposal entitled "***Phase I academic clinical trial of safety,***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	pharmacokinetics and early measurement of drug activity of CENTINHALE dry powder inhalation" submitted by Prof. Rajiv Garg, Department of Respiratory Medicine, King George's Medical University U.P., Lucknow vide letter no. 1909/21 dated 14th July, 2021. ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to Secondary reviewer, Prof. A.A.Mahdi.*** **EC Decision:** Approved ***Ref. code: 107th ECM IIA/P4***
4.	Clarification of research proposal entitled ***"Retrospective analysis of a methanol outbreak in Lucknow district nearby areas in 2019 (prospective)"*** submitted by Dr. Medhavi Gautam, Assistant Professor, Department of Medicine, King George's Medical University U.P., Lucknow vide letter no. 1269/MED/2021 dated 10th June, 2021. **Previous EC Comment:** • Kindly provide the Methodology ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 107th ECM IIA/P6***
5.	Clarification of research proposal entitled ***"Pilot study to testify the role of antibifrotic drugs (Pirfenidone and ninterdanib) as a probable therapy for patients of post COVID pulmonary fibrosis"*** submitted by Dr. Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University U.P., Lucknow vide letter no. 1814/21 dated 19th June, 2021. **Previous EC Comment:** • Give a detailed Budget ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **Action taken:** Provisionally approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Approved ***Ref. code: 107th ECM IIA/P8***
6.	Clarification of research proposal entitled "***Severity of COVID-19 disease in vaccinated and non-vaccinated patients: An experience from a tertiary care centre***" submitted by Dr. Ajay Kumar Patwa Professor Jr. Grade, Department of Medicine, King George's Medical University U.P., Lucknow vide letter no. 1436/MED/2021 dated 2nd July, 2021. **Previous EC Comment:** • Third objective: To determine mortality rate and discharge rate in vaccinated and non-vaccinated patients. • Study Design: This study should be planned as case-control (retrospective) study with case (Vaccinated) and control (Non-vaccinated). The case and control can be matched either 1:1 or 1:k, depending on the availability of patients in the two groups. • The sample size calculations are not shown. If different parameters are not available, it can be made a pilot study. • Data Analysis section should be more precise. What is the need of "Shapiro-Will" test or "Mann-Whitney test"? • Define vaccinated & unvaccinated strains • Write role of each investigator • Parentally inclusion of serial no. 6 ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **Action taken:** Provisionally approved **EC Comment:** • Assent form-ICF (For Children above 8 years) still not attached separately **EC Decision:** Approval subject to modification ***Ref. code: 108th ECM IIA/P9***
7.	Clarification of research proposal entitled "***Biosurveillance for spillover of henipaviruses and filoviruses in rural communities in India***" sponsored by Eco Health Alliance, United States submitted by Prof. Amita Jain, Head, Department of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Microbiology, King George's Medical University U.P., Lucknow vide letter no.427/2021 dated 22nd June, 2021.

Previous EC Comment:

- Funded by an International NGO & perhaps the USUHS
- Is here G.O.I. approval for Eco Health Alliance, USA to work in the country?.
- Is there an agreement between KGMU and NGO?
- After submission to H.M.S.C of I.C.M.R. please submit the documents to Ethics Committee
- Vulnerable subjects have been checked **NO**, despite including vulnerable subjects- children, illiterate adults
- Objective 1: How will this be achieved, not elaborated in text
- What is the operational definition of "site"?
- What are the other factors that will be used to select sites?
- What is the geographical area that will be included? Whole of UP, part of state?
- How will village/clusters be chosen if bat species being looked for are found in more than 4 clusters?
- What type of randomization will be done within clusters to ensure 25% representation of children as well as equal participation of both sexes.
- What will be done if someone refuses consent?
- How has the sample size of 800 calculated?
- Is consent for archived samples present?
- Who will administer the questionnaire- Self or some project worker, and in what language?
- If questionnaire will be administered in Hindi (highly likely), need a TRANSLATED and VALIDATED questionnaire in Hindi language.
- While the title refers to rural communities, why take hospital based AES and VHF patients?
- Does institution have the required permits/ certification to accept foreign grants- FCRA, etc?
- What is the purpose of the NGO and USUHS for funding this study

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	and how will it benefit them? ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** **Comment:** The investigators have, in the covering letter, acknowledged that the study which they have submitted previously was incomplete and have now attached a complete proposal. In view of modifications by the investigator, should be resubmitted as a fresh proposal. Also, I am not sure who will arrange for clarification for point no. 18 from the Finance Officer, KGMU- the ethics committee or the PI. Prof. Alok Dhawan, Chairman, IEC has responded by e-mail dated 14th July, 2021 with following comments: ***"Since the project involves two foreign organization (an NGO and Uniformed Services University of Health Sciences-USUHS) and this components is beyond the scope of the IEC, it is requested that and in principal approval may be taken from the VC, KGMU before approval from, IEC.*** The above comment forwarded to Hon'ble Vice Chancellor, KGMU UP, Lucknow, for approval. The following comments raise by the Hon'ble Vice Chancellor:- • Approved In Principal with following caveats:- • 1- Submit permission from State/Central Govt. authorities. • 2- Agreement with Both US and Indian authorities' permission. The above response forwarded to Prof. Alok Dhawan, Chairman, IEC vide this office letter no. 951/Ethics/2021 dated 3rd August, 2021 by E-mail. **EC Comment:** EC has requested expedited review of the scientific contents of the project by 11th August 2021. Member secretary has sent this for the same on 7th August 2021. ***Reply has given by Dr. Akash Agarwal on 10th August, 2021.*** **Comment:** • Scientific content of the proposal and its ethical implication approved in principal, condition to fulfillment of requirement of the Institution. ***Ref. code: 108th ECM IIA/P2***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

8.	Clarification of research proposal entitled ***"Feasibility study of voluntary breath hold technique in reducing heart toxicity in left breast cancer Radiotherapy in our setup: low-cost substitute for high capital investment (Advanced) technology"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Mranalini Verma, Assistant Professor, Department of Radiotherapy King George's Medical University U.P., Lucknow vide letter no. 583/RT/21 dated 28th July, 2021. **Previous EC Comment:** • Sample size is 30, however, the rationale is not mentioned. If it is a pilot study then it may be mentioned. • Inclusion and exclusion criteria of subjects not clearly mentioned. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Pending **EC Decision:** Approved ***Ref. code: 108th ECM II B-IMR-F/P1***
9.	Clarification of research proposal entitled **"*Impact of COVID-19 and lockdown in India on mortality*"** submitted by Dr. Shiuli, Assistant Professor, Department of Forensic Medicine & Toxicology, King George's Medical University U.P., Lucknow vide letter no.381/FMT/2021 dated 14th July, 2021. **Previous EC Comment:** • What is the role of Co-P.I. from Australia? • Give details of number of autopsies/day. • Will a meaningful inference be possible ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **EC Decision:** Approved ***Ref. code: 109th ECM IIA/P1***
10.	Clarification of research proposal entitled **"*Experience of botulinum toxin type a in patients with movement disorders at tertiary care center India*"**submitted by Dr. Shweta Pandey, Associate Professor, Department of Neurology, King George's Medical University U.P., Lucknow vide letter no.215/Neuro/21 dated 23rd July, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous EC Comment: • How researchers calculated sample size is not mentioned. • They are using various scales to understand the level of improvement and in statistical analysis, they did mention about the statistical tests for scales or scores. How will they prevent biases? They did not mention. • Consent form-Patient information sheet is incorrect. • Clarify duration of follow-up ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **EC Decision:** Approved ***Ref. code: 109th ECM IIA/P6***
11.	Clarification of research Protocol no.HCR/III/TENESTEMI/08/2020. Version: 1.0;Dated:05 Aug, 2020 entitled "***A prospective, multicenter, randomized, comparative, parallel group clinical study to compare the efficacy, pharmacokinetics, pharmacodynamics, immunogenicity and safety of intravenous injection of tenecteplase (Hetero Biopharma Limited) and reference medicinal product (RMP Tenecteplase, BoehringerIngelheim) in adults for the thrombolyic treatment of suspected myocardial infarction with persistent ST elevation***" sponsored by M/s Hetero Biopharma Ltd submitted by Dr. Akhil Sharma, Associate Professor, Department of Cardiology, King George's Medical University U.P., Lucknow vide letter no. 1694/Cardio/Res/2021 dated 22nd July, 2021. **Primary reviewer Recommendation:** • Budget- approx.-Rs 179550/ per complete pt visit (Breakup not given) • Test drug / Ref. drug will be given as single dose -50 mg IV with in 6 hrs of onset of symptoms – Hospitalization –for 48 hrs- follow up- up to 30th day (90 min, 24 hr, 48 hr , 7th , 14th and 30th day) – what does this comment mean?? • DCGI submission letter –attached – Permission letter – Awaited • Clinical Trial Registry document not given. **EC Decision:** Approval subject to modification & fulfillment of Administrative formalities.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer. **Recommendation of Primary reviewer:** Approved **EC Decision:** Approved ***Ref. code: 109th ECMIIC/P1***
12.	Clarification of research protocol no. GENESIS II entitled ***"A clinical evaluation of the HYDRA self expanding transcatheter aortic valve"*** sponsored by M/s Vascular Concepts Ltd. submitted by Prof. Sharad Chandra, Department of Cardiology, King George's Medical University U.P., Lucknow vide letter no. 1693/Cardio/Res/2021 dated 29th July, 2021. **Previous EC Comment:** • Section 4: not attached. • Section 5: Inclusion criteria are >65 years: These are vulnerable subjects. Not checked. • Duration is not 6 months for the study, it's for each subject. • Section 6: Why will direct identifiers be used? • Budget: Funding documents to be attached. ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Recommendation of Primary reviewer:** Pending **EC Decision:** Approved ***Ref. code: 109th ECMIIC/P2***
13.	Clarification of the research protocol no. ATLAS-OLE: entitled ***"An Open label long term safety and efficacy study of fitusiran in patients with hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX"*** submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology King George's Medical University U.P., Lucknow vide letter no.411/CH/21 dated 26th July, 2021. **Previous EC Comment:** • See comments to letter no. 243/CH/21 dated 3rd June, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.

Recommendation of Primary reviewer: Pending

The following documents were reviewed in its Meeting:

Sr. No.	Document	Version & date
1.	Protocol No: LTE15174	Amendment 2.0 dated 25 Nov 2020, version 1.0 (Controlled Copy No: PPD/LTE15174/Protocol Amendment 2.0 dated 25 Nov 2020, version 1.0 015-019) Clean Copy
2.	Protocol No: LTE15174	Amendment 2.0 dated 25 Nov 2020, version 1.0 (Controlled Copy No: PPD/LTE15174/ Protocol Amendment 2.0 dated 25 Nov 2020, version 1.0 015-019) Track change version
3.	Protocol No: LTE15174	Amendment 2.0 dated 25 Nov 2020, version 1.0 (Controlled Copy No: PPD/LTE15174/ Protocol Amendment 2.0 dated 25 Nov 2020, version 1.0 015-019) Summary of Changes
4.	DCGI Acknowledgment for Submission_ Protocol	Cover Letter Dated 03 Dec 2020 E-Mail Acknowledgement dated 03 Dec

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Amendment 2_25 Nov 2020	2020
	5.	DCGI Approval Letter_ Protocol Amendment 2_25 Nov 2020	Application No. GCT/PostAppr/2020/10382 Signed and Dated 28 Dec 2020
	6.	Investigators Brochure	Investigator's brochure Edition 07 Amendment 2 dated 25 November 2020 (Controlled Copy No: PPD/LTE15174/Investigator's Brochure/Edition 07/Dated 25November2020/ 015-019) Clean Copy
	7.	Investigators Brochure	Investigator's brochure Edition 07 Amendment 2 dated 25 November 2020 (Controlled Copy No: PPD/LTE15174/Investigator's Brochure/Edition 07/Dated 25 Nov 2020/ 015-019) Track change version
	8.	Investigators Brochure	Investigator's brochure Edition 07 dated Amendment 2 25 November 2020 (Controlled Copy No: PPD/LTE15174/Investigator's Brochure/Edition 07/Dated 25 Nov 2020/ 015-019) Summary of Changes
	9.	English Participant/ Parental ICF:	LTE15174 India Main ICF English v2.1.0_02 Dec 2020_ Dr Shailendra Verma

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	10.	Hindi Participant/ Parental ICF	LTE15174 India Main ICF Hindi v2.1.0_ 02 Dec 2020_ Dr Shailendra Verma Translation Certificate dated 27 Jan 2021 attached
	11.	Hindi to English Participant/ Parental ICF	LTE15174 India Main ICF Hindi to English v2.1.0_ 02 Dec 2020_ Dr Shailendra Verma Translation Certificate dated 27 Jan2021 attached
	12.	English Assent ICF	LTE15174 India Patient Assent Form English v2.1.0 02 Dec 2020_ Dr Shailendra Verma
	13.	Hindi Assent ICF	LTE15174 India Patient Assent Form Hindi v2.1.0 02 Dec 2020_ Dr Shailendra Verma Translation Certificate dated 27 Jan 2021 attached
	14.	Hindi to English Assent ICF	LTE15174 India Patient Assent Form Hindi to English v2.1.0 02 Dec 2020_ Dr Shailendra Verma Translation Certificate dated 27 Jan 2021 attached
	15.	DCGI Acknowledgment for Submission IB Ed 07 dtd 25Nov2020 and ICF ver 2.1.0_dtd 02 Dec 2020	Cover Letter Dated 07 Dec 2020 E-Mail Acknowledgement dated 07 Dec 2020
	16.	Protocol No: LTE15174	Amendment 3.0 dated 08 Dec 2020, version 1.0 (Controlled Copy No: PPD/LTE15174/Protocol Amendment 3.0

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			dated 08 Dec 2020, version 1.0 015-019) Clean Copy
	17.	Protocol No: LTE15174	Amendment 3.0 dated 08 Dec 2020, version 1.0 (Controlled Copy No: PPD/LTE15174/Protocol Amendment 3.0 dated 08 Dec 2020, version 1.0 / 015-019) Track change version
	18.	Protocol No: LTE15174	Amendment 3.0 dated 08 Dec 2020, version 1.0 (Controlled Copy No: PPD/LTE15174/ Amendment 3.0 dated 08 Dec 2020, version 1.0 /015-019) Summary of changes
	19.	DCGI Acknowledgment for Submission_ Protocol Amendment 3_08 December 2020	Cover Letter Dated 30 Dec 2020 E-Mail Acknowledgement dated 30 Dec 2020
	20.	English eCOA Handheld Bleed Diary	Version 1.00 dated 01-Jul-2020
	21.	English eCOA Handheld Caregiver Quiz	Version 1.00 dated 01-Jul-2020
	22.	English eCOA Handheld Practice Diary	Version 1.00 dated 01-Jul-2020

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

23.	English eCOA Handheld Prophylaxis Diary	Version 1.00 dated 01-Jul-2020
24.	English eCOA Handheld Subject Quiz	Version 1.00 dated 01-Jul-2020
25.	English eCOA Handheld Weekly Diary	Version 1.00 dated 01-Jul-2020
26.	Hindi eCOA Handheld Bleed Diary	Version 1.00 dated 22-Sep-2020 Translation Certificate dated 22-Sep-2020
27.	Hindi eCOA Handheld Caregiver Quiz	Version 1.00 dated 22-Sep-2020 Translation Certificate dated 22-Sep-2020
28.	Hindi eCOA Handheld Practice Diary	Version 1.00 dated 22-Sep-2020 Translation Certificate dated 22-Sep-2020
29.	Hindi eCOA Handheld Prophylaxis Diary	Version 1.00 dated 22-Sep-2020 Translation Certificate dated 22-Sep-2020
30.	Hindi eCOA Handheld Subject Quiz	Version 1.00 dated 22-Sep-2020 Translation Certificate dated 22-Sep-2020
31.	Hindi eCOA Handheld Weekly Diary	Version 1.00 dated 22-Sep-2020 Translation Certificate dated 22-Sep-2020

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	32.	English Patient Dosing Diary	Version 2.0 dated 26 Nov 2020
	33.	Hindi Patient Dosing Diary	Version 2.0 dated 26 Nov 2020 Translation Certificate dated 21 Jan 2021
	34.	English Patient Instructions for Use for Fitusiran Vials	Version 2.0 dated 26 Nov 2020
	35.	Hindi Patient Instructions for Use for Fitusiran Vials	Version 2.0 dated 26 Nov 2020 Translation Certificate dated 21 Jan 2021

EC Decision: Approved

Ref.code:90th ECM II C/P2

14. Clarification of the modification of Research protocol no. ATLAS-A/B entitled ***"A phase 3 study to evaluate the efficacy and safety of fitusiran in patients with hemophilia A or B, without inhibitory antibodies to factor VIII or IX"*** sponsored by M/s Bajaj Allianz Generali Insurance Co Ltd. Ltd. submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology, King George's Medical University U.P., Lucknow vide letter no.410/CH/21 dated 26th July, 2021.

EC Comment:

The SAE of severe types have been reported. These include very high transaminases and 6 cases with thrombosis. One of them was fatal. The reason given for fatality is that probable misdiagnosis of intracranial bleed while the patient had sinus thrombosis. The total number of cases enrolled in various parts of the previous studies is not clear, but the incidence rate [page 97] is 5.91 and 1.49 [of vascular thrombosis events per 100 patients years for AT levels of <10% and 10 to 20% respectively).

Comment on whether this risk is acceptable for patients with hemophilia without inhibitors? Currently the hemophilia patients in India do not have access to prophylaxis [mostly] but they have access to on demand therapy and serious bleeds are managed successfully for the cases who are not on prophylaxis.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	For the cases with inhibitors, the management of serious bleeds is not easy and they also do not have access to prophylaxis - Hence, they may be better group for trial. But this trial has excluded them. As per the reviewer statement from on cases without inhibitors is going on, it was stopped after fatal SAE. Kindly confirm. To compare with efficacy, the previous studies have shown average ABR [annual bleed rate] on drug as 3 to 5. (can it be considered very effective? [2] The amendment is basically to incorporate the findings that the ABR is related to AT levels and they decided to mitigate the risk of vascular thrombosis event while maintaining a favourable benefit risk balance to change the dose from 80 mg per month to 50 mg every 2 months. This appears logical. But the patient information brochures in Hindi and English mention the dose as 80 mg per 28 days. This needs verification / clarification. Most importantly this document does not contain the protocol of the study to verify the dose planned and how many time AT levels will be measured and based on those if the drug levels will be modified. Kindly submit a detailed report of recruitment at our site and their outcomes. **EC Decision:** Pending review of clarifications ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Recommendation of Primary reviewer:** **Comment:** • I did not understand the responses to queries 2 and 3. It says dosing had been stopped from October, 2020 to January, 2021. Does it mean that the drug is not being given to the patients enrolled previously? I did not get the point about the amendment. Some clarity is missing. May be, you should go through it and also talk to Dr. Verma who can clarify the exact status and the amendment.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

EC Comment:

- Is the study continuing?
- In what doses is the drug being given?
- Kindly provide updated information from KGMU site on

EC Decision: Approval after modification

Ref.code:90th ECMIIC/P2

15. Clarification of research Protocol no. E7080-M091-511 entitled "***A prospective, multicenter, post-marketing phase IV study to Assess the safety and efficacy of lenvatinib as first-line treatment in patients with unresectable hepatocellular carcinoma (HCC)***" sponsored by M/s Eisai Pharmaceuticals India Pvt. Ltd. submitted by Prof. Vijay Kumar, Department of Surgical Oncology, King George's Medical University U.P., Lucknow vide letter no. SONC/414.2021 dated 15th May, 2021.

Previous EC Comment:

- Departmental Review Committee comments to be send.
- University proforma not filled

The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.

Recommendation of Primary reviewer: Approved

The following documents were reviewed in its Meeting:

Sr. No	Document	Version	Date
1	Clinical Study Protocol	1.0	19 Sep 2019
2	Protocol Signature Page	1.0	
3	Package Insert_ Lenvima	NA	Jul 2019
4	**English ICF:** Subject Informed Consent Form V1.0 (en)_ (TSN-00008) _Dr.	1.0	11 Aug 2020

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Vijay Kumar dated 11 Aug 2020 adapted from Master Informed Consent Form Version 1.0 (en) dated 19 Sep 2019		
	4.1	**Hindi ICF:** Subject Informed Consent Form V1.0 (hi)_(TSN-00008) _Dr. Vijay Kumar dated 12 Aug 2020 Translated from English (V1.0 dated [11 Aug 2020]) to Hindi	1.0	12 Aug 2020
	4.2	**Hindi BT ICF:** Subject Informed Consent Form V1.0 (hi to en) _(TSN-00008) _Dr. Vijay Kumar dated 12 Aug 2020 Translated from Hindi (V1.0 dated [12 Aug 2020]) to English	1.0	12 Aug 2020
	4.3	**Translation Certificate- ICF** English to Hindi	1.0	12 Aug 2020
	4.4	**Backtranslation Certificate-ICF** Hindi to English	1.0	12 Aug 2020
	5	**English Subject Diary** Subject Diary – V1.0 (en) dated 20 Sep 2019	1.0	20 Sep 2019

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

5.1	**Hindi Subject Diary** Subject Diary – V1.0 (hi) dated 13-Nov-2019 Translated from English (V1.0 dated 20 Sep 2019) to Hindi	1.0	13 Nov 2019
5.2	**Hindi BT Subject Diary** Subject diary V1.0 (hi to en) dated 13-Nov-2019 Back Translated from Hindi (V1.0 dated 13-Nov-2019) to English	1.0	13 Nov 2019
5.3	**Translation Certificate- Diary Card** English to Hindi	1.0	13 Nov 2019
5.4	**Backtranslation Certificate-Diary Card** Hindi to English	1.0	13 Nov 2019
6	Annotated CRF	1.0	20 Sep 2019
7	CV of PI	NA	14 Aug 2020
7.1	MRC of PI	NA	14 Aug 2020
8	Investigator Undertaking	NA	14 Aug 2020

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	9	DCGI NOC	NA	22 Nov 2019
	10	Draft Clinical Trial Agreement (Study Agreement – Quintiles Global template – 15 April 2013 updated 24 Sept 19) IV Interventional Study /India/APICS/PB/ET/JC/29June20	NA	NA
	11	Clinical Trial Registration Certificate (CTRI/2020/08/027136)	NA	14 Aug 2020
	12	Subject Recruitment Methods	[PK1]	

EC Decision: Approved

Ref. code: 109th ECMIIC/P3

Minutes of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting held on 26th June, 2021 from 10.00 AM. **(DCGI)**

The following Members were present in the virtual Meeting:

1. Dr. Alok Dhawan — Chairman
2. Mrs. Akansha Dubey — Member
3. Dr. Rajendra Nath — Member
4. Mr. Ujjawal Krishna — Member
5. Mrs. Vasundhara Kumari — Member

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	6. Dr. Shally Awasthi Member Secretary, IEC ***The following Member could not attend:*** 1-Dr. D.N. Upadhyaya
I-	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1440/Cardio/Res/2021 dated 04th March, 2021. **Death** **Subject ID no. 010-0094** **Subject Initial:** J **SAE term:** Death on 18-06-2020 **Gender:** F **DOB:** 01-01-1958 **Weight:** 64 KG **Height:** 150 CM **Start Date:** 29-05-2019 **Subject History:** *A call was made to the subject #010-0094 for 18th month follow-up visit. His LAR informed that the subject had passed away on 18th June, 2020 at 2:00 PM at home. Local practitioner was called who declared him dead. No autopsy was done and death certificate was provided by Village Pradhan.* **ADR-sub-Committee decision:** SAE (Death) seems to be due to disease outcome and not due to intervention

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	as patient was enrolled on 25th May, 2019 Casual relationship cannot be established as death occurred at home and no autopsy was done. **ADR Sub Committee Decision:** Noted ***Ref. code: 83rd ECM IIC/P6***
2-	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1594/Cardio/Res/21 dated 05th June, 2021. **Death** **Subject ID no. 010-0092** **Subject Initial:** S-D **SAE term:** Death on 30-01-2021 **Gender:** F **Age:** 60 year **Dated of Randomization:** 27-05-2019 **Date of SAE-** 30-01-2021 **Subject History:** Subject was screened in INVICTUS study, A call made to the subject for his scheduled follow up visit (24th Month dated 26th May, 2021), Call was received by LAR on 25th May, 2021. LAR informed to the P.I. that subject developed fever and breathlessness on 29th May, 2021 for which he went to Trauma Emergency but due to non availability of COVID RT-PCR Test report, subject was not hospitalized and passed away on 30th January, 2021 around 2:00 PM. As the subject has not admitted, LAR informed the P.I. that all paper were discarded after death (Cremation), Hence no documents are available.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	No autopsy was done. This SAE is not related to IP. Date of notification of SAE (Death) This is within 24 hours of occurrence of SAE (Death) (to Licensing Authority and Ethics Committee was 29th May, 2021 vide email). **ADR sub Committee Decision:** • SAE (Death) is likely due to disease outcome and not due to intervention (Rivaroxaban /Aspirin) as patient was enrolled almost 1 year 7 months back and taking concomitant treatment. • Causal relationship can not be established as death occurred at home and autopsy was not done and no documents are available as all documents were discarded after death. **ADR Sub Committee Decision:** Noted ***Ref. code: 83rd ECM IIC/P6***
	Minutes of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting held on 26th June, 2021 from 10.30 A.M.**(Non-DCGI)** ***The following Members were present in the virtual Meeting:*** 7. Dr. Alok Dhawan — Chairman 8. Mrs. Akansha Dubey — Member 9. Dr. Rajendra Nath — Member 10. Mr. Ujjawal Krishna — Member 11. Mrs. Vasundhara Kumari — Member 12. Dr. Shally Awasthi — Member Secretary, IEC

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The following Member could not attend:- 1-Dr. D.N. Upadhyaya
1-	ADR of research protocol no. ISCHEMIA: entitled ***"International study of comparative health effectiveness with Medical and Invasive approaches"*** submitted by Prof. S.K. Dwivedi, Head, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1477/Cardio/Res/21 dated 19th March, 2021. **Death** **Subject ID no. 091019-098** **Subject Initial:** M-L **SAE term:** Death on 26-02-2021 **Gender:** M **Age:** 67 yrs old **Weight:** 51 KG **Height:** 162 CM **Start Date:** 22-02-2021 **Subject History:** Subject was randomized in conservative arm. A call was made to the subject for regular follow up. The call was answered by LAR who informed that the subject passed away on 26th February, 2021, after a paralysis attack about 4 days prior to death (date not confirmed) He was treated by a local practitioner. On 26th February, 2021, he was being brought to the Department of Cardiology at KGMU for further treatment but he died on the way before he could reach KGMU. LAR told us that all his papers were destroyed after death, hence no documents are available. No autopsy was done and no hospital records were available as he was not admitted anywhere. He was in follow up in the study since 21st June, 2017. **Primary reviewer recommendation:** As the patient was in conservative arm and in follow-up since 21st June, 2017, the SEA

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	(Death) after paralysis attack is due to disease outcome and not related to any intervention which he was taking for about 4 years. Causal relationship cannot be established as there is no hospital record and no autopsy was done. **ADR Sub Committee Decision:** Noted ***Ref. code: 60th ECM IIA/P1***
2-	ADR of research protocol entitled ***"A post market registry of Abluminus® sirolimus eluting coronary stent system for percutaneous intervention in patient with diabetes mellitus"*** submitted by Dr. Akshyaya Pradhan, Associate Professor & P.I., Department of Cardiology King George's Medical University, U.P., Lucknow vide letter no. 1504/Cardio/Res/21 dated 6th April, 2021. **Death** **Subject ID no.26-011** **Subject Initial:** S-D **Date of death: 03-09-2021** **Gender:** F **Age:** 58 yrs old **Weight:** 59 KG **Height:** 148 cm **Date of Randomization:** 07-01-2020 **Subject History:** During the event track call, we came to know that subject # 26-011 expired on 3rd September, 2020. The Subject developed breathlessness and chest pain and collapsed. He was not taken to hospital. Local physician visited at home and confirmed that subject passed away. Cause

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	of death is unknown. No autopsy was done. **Primary reviewer recommendation:** • SAE (Death) is likely due to disease outcome and not due to intervention (PTCA drug eluted stenting done on 04-01-2020) as patient was enrolled almost 8 months back and taking concomitant treatment from 15-02-2020. • Causal relationship cannot be established as death occurs at home and autopsy was not done and no documents are available. **ADR Sub Committee Decision:** Noted ***Ref. code: 95th ECM IIC/P12***
3-	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1596/Cardio/Res/2021 dated 05th June, 2021. **Death** **Subject ID no. 010-0134** **Subject Initial:** S-J **SAE term:** Death on 30-01-2021 **Gender:** F **Age:** 25 year **Dated of Randomization:** 31-03-2021 **Date of Follow up on site:** 6 weeks/42 days visit Schedule of Follow up: 6th weeks, 6th Month, 12th Month, 18th Month and every 6th Month till 5 years

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Subject History: LAR has informed by the P.I. that subject expired on 13th May, 2021 at around 2:30 AM. She was having breathlessness and hospitalized in District Male hospital Ajodhya on 12th May, 2021. She could not recover and expired in the hospital. No autopsy was done. **Primary reviewer recommendation:** • SAE (Death) is likely due to disease (Recurrent rheumatic fever and Inf. endocarditis causing breathlessness) • Causal relationship cannot be established as death occurred at hospital due to dyspnea with anemia one day after admission and autopsy could not be done. Hospital discharge documents also are not showing any relationship with intervention. **ADR Sub Committee Decision:** Noted ***Ref. code: 83rd ECM IIC/P6***
IB	**Expedited review**
1.	Expedited review of research proposal entitled ***"Covid associated Mucormycosis in India, a case control investigation at the Department of Microbiology, KGMU, Lucknow"*** submitted by Prof. Prashant Gupta, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 391/2021 dated 14th June, 2021. ***The above proposal forwarded to Primary reviewers, for review*** **Recommendation of Primary reviewers:** **Comment:** • The study is recruiting 4 times control subjects as compared to cases. Since there is a decline of covid positive cases it may be difficult to get required number of controls. Therefore, a modification in the criterion for control subjects can be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	considered **Decision:** Approved ***The above comment & decision forwarded to the P.I. vide this office letter no.813/Ethics/2021 dated 12th July, 2021.-Reply Pending from P.I.*** **EC Decision:** Approval subject to modification ***Ref.Code 110th ECM IB/P1***
2.	Expedited review of research proposal ***"Effect of various therapeutic options on the outcome in Indian Children with Multisystem syndrome related to SARS-CoV-2 (MIS-C)"*** submitted by Prof. Shally Awasthi, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 541/2021 dated 17th July, 2021. ***The above proposal forwarded to Primary reviewers, for review.*** **Comment:** **Prof. Shally Awasthi did not participate in the discussion or decision making project.** **EC Decision:** Waiver of consent request approved ***Ref.Code 110th ECM IB/P2***
3.	Expedited review of research proposal ***"Multicenter observational study of candidaemia cases with special reference to candida auris candidaemia among ICU patients in India"*** submitted by Prof. Gopa Banerji, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 541/2021 dated 17th July, 2021. ***The above proposal forwarded to Primary reviewers, for review.*** **EC Decision:** Approved ***Ref.Code 110th ECM IB/P3***
4.	Expedited review of research proposal entitled ***"Assessment of the 4 month moxifloxacin containing daily regimen in the treatment of microbiologically confirmed new pulmonary tuberculosis patients"*** submitted by Prof. Rajiv Garg, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1908/2021 dated 13th July, 2021. ***The above proposal forwarded to Primary reviewers, for review.*** **EC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• In cover letter, the P.I. has ticked it is multinational, kindly correct it. **EC Decision:** Approved ***Ref.Code 110th ECM IB/P4***
IIA	**New Proposal**
1.	Research proposal entitled ***"An ambispective study of hemophagocytic lymphohistiocytosis in COVID-19"*** submitted by Dr. Geeta Yadav, Associate Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.2770/2021 dated 8th June, 2021. **EC Comment:** • Consent waiver for retrospective patients has been mentioned but no consent waiver form is attached for consideration. • Few points in annexure are incomplete: need completion • Informed consent document should be more patient friendly such as in sections of purpose. **EC Decision:** Approval subject to modification ***Ref. code: 110th ECM IIA/P1***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

2.	Research proposal entitled ***"Proteomics and promoter methylation approach for genetic signatures in early detection of lung cancer"*** sponsored by DHR-ICMR submitted by Prof. Santosh Kumar, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no.1783/2021 dated 8th June, 2021. **EC Comment:** • Dr. Santosh Kumar is the P.I; but role is more of investigator Dr. Seema who is listed in first position. Also Dr. Santosh is listed as co-investigator and his CV is submitted at the end. Hence, this needs rectification. • Patient information sheet is not attached but rather only guidelines are attached. Rectification is needed. • Informed consent document should be more patient friendly such as in sections of purpose of study and study procedure. • Study included healthy control subjects from which 6 ml blood samples need to be drawn BUT. a) No consent form for controls is attached. How will same geographical match be done (age/gender wise): Clarification needed? b) How will same geographical match be done (age/gender wise): Clarification needed? c) Inclusion criteria for controls need to be added. d) It would be nice to specify the sample size of controls as well. • Clarify if it is "Sponsored" or submitted **EC Decision:** Approval subject to modification ***Ref. code: 110th ECM IIA/P2***
3.	Research proposal entitled ***"Pediatric thyroid nodules: A multi-institutional study from India"*** submitted by Dr. Chanchal Rana, Associate Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 2807/2021 dated 14th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	June, 2021. **EC Comment:** • It is a retrospective cohort study, for patients undergoing fine needle aspiration cytological assessment. Incomplete Perform, sample size not mentioned. **EC Decision:** Approval subject to modification ***Ref. code: 110th ECM IIA/P3***
4.	Research proposal entitled "***Correlation of last rectal effluent color and quality of bowel preparation: A prospective, cross-sectional, observational study***" submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1296/MED/2021 dated 14th June, 2021. **EC Comment:** • It is prospective, cross-sectional, observational study. Controls are not described and exclusion criteria also not mentioned for subjects. In data collection it is mentioned that contact details of subjects were recorded, it seems as if the study has already been conducted. It needs to be corrected. **EC Decision:** Approval subject to modification ***Ref. code: 110th ECM IIA/P4***
5.	Research proposal entitled "***Incidence of bile leak post liver resection using water jet technology versus harmonic scalpel: A randomized clinical trial***" sponsored by ICMR, New Delhi submitted by Dr. Manish Kumar Agrawal, Additional Professor, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no.1142/2021 dated 15th June, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • Kindly provide Patient Information Sheet. • Specify the source of funding- ICMR or intramural? • Kindly specify, who among the investigators will perform the procedure/ Surgery? None of the investigator is claimed for this role. • The role of various investigators are shown as part of thesis work. Is it a thesis work? • Will the two methods be applied by the same surgeon? • Kindly, specify the experience in years for conducting such surgeries and number too. If the surgeon changes, the results/ incidence may be affected. • ICF: It is unacceptable and highly objectionable that the title in the ICF is not the same as that of the project, with inappropriate information about the principal investigator. • Kindly explain the study procedure to patient in simple language instead of telling him/her that this is a Single blind RCT. **EC Comment:** • Who will be perfumery Surgery? CTRI registration to be done. **EC Decision:** Approval subject to modification ***Ref. code: 110th ECM IIA/P5***
6.	Research proposal entitled ***"Pre-clinical development of CPMD-1049 targeting drug-resistant mycobacterium tuberculosis"*** sponsored by Department of Biotechnology Ministry of Science and Technology Government of India, New Delhi submitted by Prof Rajiv Garg, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no.1844/2021 dated 29th June, 2021. **EC Decision:** Approved ***Ref. code: 110th ECM IIA/P6***
7.	Research proposal entitled ***"A study to assess the compulsive buying behavior and its***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	association with emotional distress, depression and impulsiveness among general population" submitted by Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.796/2021 dated 4th June, 2021. **Recommendation of Primary reviewer:** **Comment:** • Role of PI and Co-PIs are the same. Please edit. **EC Comment:** • As above **EC Decision:** Approved ***Ref. code: 110th ECM IIA/P7***
8.	Research proposal entitled ***"A cross-sectional study of Mental Health of Women in North India"*** sponsored by National Commission for Women; Government of India. submitted by Prof. Vivek Agarwal, Head, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.905/Psy/2021 dated 22nd June, 2021. **Recommendation of Primary reviewer:** **Comment:** • Scientific review Committee has only three members. • There are five (5) Co-PI Role of PI are the same as in the proforma. Please justify. **EC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• As above **EC Decision:** Approval subject to modification ***Ref. code: 110th ECM IIA/P8***
9.	Research proposal entitled ***"A study on burnout and compassion fatigue among nurse working in COVID-19 areas"*** submitted by Mr. G. Srinivasan, Clinical Instructor, Head, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.929/2021 dated 19th June, 2021. **Primary reviewer recommendation:** • Sample size calculated online. • In Questionnaire –Hindi version of some questions are not similar to English version. This needs to be modified. **EC Comment:** • As above **EC Decision:** Approved ***Ref. code: 110th ECM IIA/P9***
10.	Research proposal entitled ***"Association of genetic variations of the TGF alpha and MTHFR genes with non syndromic cleft lip with or without cleft palate in North Indian population"*** submitted by Dr. Juhi Yadav, Department of Dentistry Government allopathic Medical College, Banda, Through under the guidance Dr. Veerendra Prasad, Department of Plastic Suactic, King George's Medical University, U.P., Lucknow vide letter no.572/2021 dated 7th June, 2021. **Primary reviewer recommendation:** • Sample size not has not been calculated and given in protocol separately

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	(Mentioned 100 pt. + 100 control in material method part). • Methodology details not given- study design not mentioned • English & Hindi Informed Consent Form are attached but Ascent form for children no attached. • Scientific review to be done in the Department. **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 110th ECM IIA/P1***
11.	Research proposal entitled ***"Profile of orbital involvement in COVID associated mucormycosis: A tertiary health care center experience"*** submitted by Prof. Apjit Kaur Chhabra, Head, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no.295/OPH/21 dated 23rd June, 2021. **Recommendation of Primary reviewer:** • Profile of orbital involvement in covid associated mucormycosis: a tertiary health care centre experience' • The researchers intend to study the profile of orbital involvement in patients with covid associated mucor mycosis in KGMU. • Is it a Prospective study? Will they include cases admitted earlier also (retrospective)? Will the closed cases [died or cured] included. • As per the proposal the researchers will be enrolling only new cases. This should be confirmed. • The evaluation and management will be done as per the institute protocol and hence, there are no ethics related issues. • Is purpose same as objective of the study?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• APPROVED with the confirmation about enrolment limited to only new cases. • Scientific review to be done in the Department. **EC Comment:** • As above **EC Decision:** Re-submit ***Ref. code: 110th ECM IIA/P11***
12.	Research proposal entitled "***Outcome of transcutaneous retrobulbar amphotericin B (TRAMB) in COVID-19 associated rhino-orbito-cerebral (ROCM) mucormycosis***" submitted by Prof. Apjit Kaur, Head, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no.296/OPH/21 dated 23rd June, 2021. **Recommendation of Primary reviewer:** • This project has a great overlap with the previous project by the same PI. • The PI need to clarify what is different from the previous project on the same area and the similar aspect of the disease in concern. **EC Comment:** • As above **EC Decision:** Re-submit ***Ref. code: 110th ECM IIA/P12***
13.	Research proposal entitled "***Serum ferritin as a biochemical marker of severity for orbital disease in COVID associated mucormycosis***" submitted by Prof. Apjit Kaur, Head, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 3416/OPH/21 dated 3rd July, 2021. **EC Comment:** • Residents can't be co-investigators. • Innumerable deficiencies in Ethics form: a few are pointed below:-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	What is the meaning of "self" in budget: is patients paying of himself/herself Section 5: Incomplete Section 6: all have been ticked Section 7: Isn't blood a body fluid? • There is no methodology section **EC Decision:** Re-submit as fresh proposal ***Ref. code: 110th ECM IIA/P13***
14.	Research proposal entitled ***"COVID IgG spike antibodies detection by ELISA and quantitative chemiluminiscence: A comparative study"*** sponsored by POCT Service, Complete Medical Solution submitted by Prof. Tulika Chandra, Principal Investigator, Head, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no.185/21 dated 3rd July, 2021. **EC Comment:** • Ethics form not filled completely • Budget not specified • Checklist not ticked • No statistical plan given • Sample size calculation no given **EC Decision:** Re-submit as fresh proposal ***Ref. code: 110th ECM IIA/P14***
15.	Research proposal entitled ***"Cutaneous manifestations of mucormycosis during the current severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) pandemic: A retrospective study"*** submitted by Prof. Swastika Suvirya, Principal Investigator, Head, Department of Dermatology, Venereology and Leprosy, King George's Medical University, U.P., Lucknow vide letter no.119/SKIN/21 dated 3rd July, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: • This is a retrospective study based on mucormycosis in Covid patients. One of the primary objectives of the study is to identify and classification of cutaneous mucormycosis for early diagnosis and management. But it is not explained how a retrospective study can fulfill this objective. • Study settings are not well defined like subjects will be recruited from outdoor services or indoor services? • For inclusion criteria- It has mentioned in the proposal that the established diagnosis of the mucormycosis will be included in the study. But which method will be considered for establishing diagnosis eg. mucrobiologically proven mucormycosis or radiologically suspected or both is not clearly mentioned in the proposal. Moreover, the status of RT PCR is also not mentioned- whether it is during active infection or during post covid period. **EC Decision:** Approval subject to modification ***Ref. code: 110th ECM IIA/P15***
16.	Research proposal entitled ***"Study on polio and non-polio enterovirus infections in patients with primary immunodeficiency disorders (PIDs) at multiple medical institutes across India-PHASE II"*** sponsored by WHO & ICMR New Delhi submitted by Prof. Shally Awasthi, Head, Department of Dermatology, Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. IECS/619/21 dated 8th July, 2021. **EC Decision:** Approved ***Dr. Shally Awasthi did not participate in discussion & decision making.*** ***Ref. code: 110th ECM IIA/P16***
17.	Research proposal entitled ***"Substance abuse and mental health issue among the LGBT community in India: A study of inter-relationship between mental health***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

disorders and stress, coping, perceived social support, occupation and religiosity" sponsored by National Human Right's Commission, New Delhi submitted by Prof. Vivek Agarwal, Head, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 974/Psy/21 dated 8th July, 2021.

Recommendation of Primary reviewer:

Comment:

- This seems to be an interesting and very ambitious study as they are trying to cover whole country.
- In this particular study, study design and sampling methods are very important.
- There is no mention of type of study design used.
- Theoretical population (population for generalization), study population (accessible population) and sampling frame are to be properly defined.
- What are the variables and parameters?
- Which sampling method is to be used (Simple random sampling, stratified random sampling, cluster sampling etc.)?
- For stratified sampling, different non-overlapping groups are to be defined.
- There is mention of purposive sampling. This is nonprobabilty sampling. The nonprobability samples cannot depend upon the rationale of probability theory. There will be problem in using the statistical theory (e.g. finding confidence intervals, testing of hypotheses etc.).
- If it is a multi-centric study, all the prerequisite have to be followed.
- The sample size calculation is not clear. Since variables and parameters are not defined.
- Are the instruments used are gold-standard?

EC Comment:

- As above

EC Decision: Approval subject to modification

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 110th ECM IIA/P17
18.	Research proposal entitled "***Assess job satisfaction in nurses and its correlation with experience of working in the COVID-19 Hospital***" submitted by Dr. Suchana Roy Bhowmik, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no. 1189/X.51/21 dated 13th July, 2021. **Recommendation of Primary reviewer:** **Comment:** • There is mention of objectives, research question and hypotheses? It should be replaced by objectives and associated research hypotheses? There should be a main objective and the rest can be secondary objectives. • The sampling method is purposive. This is nonprobabilty sampling. • The nonprobability sample nay not depend upon the rationale of probability theory. There will be problem in using the statistical theory (e.g. finding confidence intervals, testing of hypotheses etc.). • There will be problem in generalization (external validity) also. A threat to external validity is an explanation of how you might be wrong in making a generalization. For instance, you conclude that the results of your study (which was done in a specific place, with certain types of people, and at a specific time) can be generalized to another context (for instance, another place, with slightly different people, at a slightly later time). • The sample size calculations and statistical analysis methods are not clear, since the variables and parameters used in the study are not exclusively defined. **EC Comment:** • As above **EC Decision:** Re-submit ***Ref. code: 110th ECM IIA/P18***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

19.	Research proposal entitled **"*Inter-observer variation in assessing depth of invasion, pattern of invasion and extranodal extension as histological parameters in oral squamous cell carcinoma(OSCC)*"** submitted by Dr. Sumaira Qayooom, Associate Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 2941/21 dated 14th July, 2021. **Recommendation of Primary reviewer:** **Comment:** • This is a retrospective study. The resected specimen has already been collected. • The variables and associated parameters have already been measured. • The study proposes to assess the new variables (Depth of invasion, pattern of invasion, etc.) on the specimen. How shall this be done reliably and precisely? This is a real challenge. • The assessment is to be done by 5 pathologists. There will be 10 possible Kappa coefficients. An statistical test has to be performed on equality of these 10 coefficients. If the hypothesis is rejected, how these coefficients will be interpreted? • The calculation of Kappa coefficients shall depend on the type of the data (categorical, ordinal or ratio). The sample size calculation and statistical analysis will depend on it. • There are some paradoxes associated with Kappa: (i) prevalence effect and (ii) bias effect. If these are present, then prevalence and bias adjusted kappa (PABAK) has to be calculated. **EC Comment:** • Involve a statistician as co-investigator • Remove SR as Co-investigator **EC Decision:** Approval subject to modification

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 110th ECM IIA/P19
20.	Research Protocol entitled "***Impact of COVID-19 on heart failure hospitalization and outcome in India-A Cardiological society of India study (CSI-HF in COVID-19 times study-"The COVID C-HF study)***" sponsored by Cardiological Society of India submitted Dr. Sharad Chandra, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.1653/Cardio/Res/2021 dated 7th July, 2021. ***Recommendation of Primary reviewer:*** • Few entries on page 6 of annexure are incomplete • As per the annexure only oral consent will be obtained (instead of written consent): what is the role of attached informed consent document? Will it be electronically mailed to the participant for signature or will just act as a guide for clarification? • Study timelines dating before March 2021 may be revised **EC Comment:** As above **EC Decision:** Approval subject to modification *Ref. code: 110th ECMIIA/P20*
IIB	**New Ph.D Scholar**
1.	Research proposal entitled "***Study of T regulatory cells, soluble cytotoxic T lymphocyte associated antigen-4 and transforming growth factor-β1 in patients of chronic myeloid leukemia on dasatinib therapy***" sponsored by ICMR submitted by Dr. Akanksha Singh, Ph.D Scholar 2019, under the guidance Prof. Rashmi Kushwaha, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.2808/21 dated 14th June, 2021. **Recommendation of Primary reviewer:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The investigator plans to study biomarkers at the start of treatment and after 3 months in patients with CML on dasatinib. • The consent does not mention how much amount of blood to be collected and how many times. • The patient information in the consent [English] is not appropriate. Benefit should mention the direct or indirect benefits to the patient and then to the medical science. • Hindi consent is a very poor quality translation, incorrect, complex and clumsy. It needs to be rewritten in simplified form by Hindi speaking person. Automatic translation by software is not appropriate. • It need to be confirmed that the decision of giving a particular drug is not dependent on the trial and is independent and before considering the patient for the study. **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 110th ECM II B-Ph.D/P1***
2.	Research proposal entitled ***"Effect of dietary modification and physical activity on blood glucose level of pregnant women with gestational diabetes mellitus: an interventional study"*** sponsored by ICMR submitted by Dr. Mallicka, Ph.D Scholar 2019, under the guidance Prof. Jamal Masood, Head, Department of Community Medicine, King George's Medical University, U.P., Lucknow vide letter no.237/CM/21 dated 17th June, 2021. **Recommendation of Primary reviewer:** • Sample size calculations – not important for Ethics committee • There will be two groups. Group II will get diet plan according to sample meal plan as given in guidelines prescribed by Government of India. Group I cannot be deprived of this management protocol which is approved by government operational guidelines. Also the counseling has to be provided to all women with

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	gestational diabetes as it is an important part of management. • As diet and physical activity are important parts of approved management such two groups with one group deprived of approved management cannot be done. • THE STUDY NOT APPROVE IN THIS FORM. • In addition there are many limitations in the scientific part of the study about documenting and verifying the compliance for the dietary and exercise advices, etc. **EC Comment:** • As above **EC Decision:** Revise & Re-submit ***Ref. code: 110th ECM II B-Ph.D/P2***
3.	Research proposal entitled ***"Postmortem examination of deceased using digital infrared photography"*** submitted by Mr. Anurag Dubey, Ph.D Scholar 2019, under the guidance Prof. Anoop Kumar Verma, Head, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no.378/FMT/21 dated 8th July, 2021. **EC Decision:** Approved ***Ref. code: 110th ECM II B-Ph.D/P3***
4.	Research proposal entitled ***"Metagenomics approach in forensic science for human identification among North Indians"*** submitted by Mr. Sangram Sandhu, Ph.D Scholar 2019, under the guidance Prof. Pooran Chand, Head, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.182/21 dated 9th July, 2021. ***Recommendation of Primary reviewer:*** • It is a multicentric study. Subjects will be recruited at KGMU and DNA extraction and other laboratory work will be done at Birbal Sahni Institute but in the proposal it has been mentioned as a single centre study.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The role of the Ph.D. scholar is not defined in the proposal. His name is neither in PI nor Co-PI list. **EC Comment:** • As above • Mr. Sangram Sandhu's biodata and role in work has to be defined. • Ethical approval from B.S.I has to be taken. • How will the dental guides give scientific inputs for this work which is on metagenomics? **EC Decision:** Approval subject to modification ***Ref. code: 110th ECM II B-Ph.D/P4***
5.	Research proposal entitled "***Efficacy of dietary intervention of flax seeds (Linum usitatissimum) on signs and symptoms associated with perimenopausal syndrome***" submitted by Ms. Rashmi Shrivastava, Ph.D Scholar, under the guidance Prof. Sunita Tiwari, Head, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.2491/PHY/21 dated 28th June, 2021. **EC Comment:** • What is the budget and who is the sponsor • Is it alright to test herbal remedies by Allopathic Physicians • Section 5: Subject participation, type of subjects needs correction • Section 8: Elements need to checked. If not ticked, mention reason CRF not included. • CRF not included Methodology: • There are no references. Has any such study ever been done? If not, how can you do a RCT as the first study? • It's a RCT: Mention all the elements of RCT • Inclusion criteria: Who have not used Vitamin from when to when? • Questionnaire: Where has the questionnaire been validated, in which language? • Sample size calculation: What is the effect size? **EC Decision:** Re-submit as fresh proposal ***Ref. code: 110th ECM II B-Ph.D/P5***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

IIC	Review of New Drug Trial
1.	Research Protocol no.PreQuest-01 entitled "***Prospective, multI-centric, single arm post marketing surveillance of PRISTINE, everolimus eluting cobalt chromium coronary stent system to assess its continued safety and efficacy***" sponsored by Relisys Medicine Devices Ltd. submitted by Prof. Pravesh Vishwakarma, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1624/Cardio/Res/2021 dated 18th June, 2021.

The following documents were reviewed in Its Meeting:-

Sr. No	Document	Version	Date
1	Protocol	4.1	15 Sept 2020
2	CRF	NA	NA
3	ICD Hindi	1.1	23 June 2020
4	ICD Hindi Back translated	1.1	11 Feb 2021
5	Translation Certificate	NA	NA
6	ICD English	1.1	23 June 2020
7	IB	1.1	25 Feb 2020
8	Investigator Undertaking	1.1	NA

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	9	CV GCP MRC of PI and Study Team	NA	NA
	10	CTRI registration certificate	NA	NA
	11	Draft CTA	NA	NA

Primary reviewer recommendation:

Comment:

- Sample size not given in protocol separately and not calculated
- Synopsis summary not given

EC Comment:

As above

EC Decision: Approval subject to modification

Ref. code: 110th ECMIIC/P1

2. Research Protocol no. CIM-MEG19 entitled "***A study to assess efficacy and safety of Ayurvedic formulation (CIM-MEG19) as an add-on therapy to the standard care in mild to moderate COVID-19 positive to combat the severity/recovery of symptoms/disorders***" sponsored by CSIR Central Institute of Medicinal and Aromatic Plants Lucknow submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.MED/CT/99/2021 dated 25th June, 2021.

The following documents were reviewed in Its Meeting:-

Sl. no.	Document	Dated
01	Protocol	NA
02	Investigator brochure	NA
03	Hindi ICF	1.0 Dated 02-06-2021
04	English ICF	1.0 Dated 05-06-2021
05	Translation certificate	Dated 11-06-2021
06	CRF	NA
07	Investigator Undertaking	17-05-2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

08	PI CV,MRC	17-05-2021
09	CTRI	11-05-2021
10	Approval Letter	17-05-2021
11	CTRI	15-05-2021
12	Draft CTA	NA

Primary reviewer recommendation:

Comment:

- Sample size given in but calculation not mentioned
- Insurance and DCGI permission letter (if needed) not submitted
- Methodology –Grouping not clear (in Synopsis -2 groups but in Case Reg Form- 2nd group again divided in two groups)
- Separate brief summary not attached
- Budget not given (only mentioned in CTA but not attached)
- Departmental Scientific review committee report not given
- Work distribution of PI and Co-PI not given

EC Comment:

- Kindly include the Co-P.I. of Ayurvedic

EC Decision: Approval subject to modification

Ref. code: 110th ECMIIC/P2

3. Research Protocol no. Version 2 Dated 29th May, 2021 entitled "The impact of chyawanprash on immunogenicity when administered after COVID-19 vaccination in health care personnel-An open-label, prospective randomized controlled study" sponsored by submitted by Prof. Satyendra Kumar Sonkar, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1410/MED/2021 dated 29th June, 2021.

The following documents were reviewed in Its Meeting:-

Sl. no.	Document	Dated
01	Protocol	Version 2 Dated 29th May 2021
02	ICF English	NA

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	03	Hindi ICF	1.0 Dated 02-06-2021
	04	English ICF	1.0 Dated 05-06-2021
	05	Translation certificate	Dated 11-06-2021
	06	CRF	NA
	07	Investigator Undertaking	17-05-2021
	08	PI CV,MRC	17-05-2021
	09	CTRI	11-05-2021
	10	Approval Letter	17-05-2021
	11	CTRI	15-05-2021
	12	Draft CTA	NA

Primary reviewer recommendation:

Comment:

- Sample size given in but calculation not mentioned
- Insurance and DCGI permission letter (if needed) not submitted
- Methodology –Grouping not clear (in Synopsis -2 groups but in Case Reg Form- 2nd group again divided in two groups)
- Separate brief summary not attached
- Budget not given (only mentioned in CTA but not attached)
- Departmental Scientific review committee report not given
- Work distribution of PI and Co-PI not given

EC Comment:

- Kindly include the Co-P.I. of Ayurvedic

EC Decision: Approval subject to modification

Ref. code: 110th ECMIIC/P2

3.	Research Protocol no. Version 2 Dated 29th May, 2021 entitled "***The impact of chyawanprash on immunogenicity when administered after COVID-19 vaccination in***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

health care personnel-An open-label, prospective randomized controlled study" sponsored by submitted by Prof. Satyendra Kumar Sonkar, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1410/MED/2021 dated 29th June, 2021.

The following documents were reviewed in Its Meeting:-

Sl. no.	Document	Dated
01	Protocol	Version 2 Dated 29th May 2021
02	ICF English	NA
03	ICF Hindi	NA
04	CRF	NA
05	Investigator Undertaking	04-06-2021
06	PI CV,MRC	NA
07	CO-I CV,MRC	NA
08	AYUSH Approval Letter	F. No.3-64/2020-CCRAS/Admn./Hq/Coll/092 dated -11-06-2021
09	Insurance Letter	NA
10	MOU	NA

Recommendation of Primary reviewer:

Comment:

- Study proposes to evaluate role of 'Chyawanprash' and Ayurvedic formulation which is mentioned as a 'drug' at one place in the proforma, as a 'multi-herbal jam' at another place and as a 'Nutraceutical and Functional food' at another place.
- What is it? Food or drug?
- What is its exact composition in w/w or w/v?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- What are its active ingredients?
- Which active ingredient is being tested in this project?
- Is it a trial? What is being tried? The proforma mentions the study as a 'Trial' (interventional RCT)
- 'Background' of the study mentions that 'Chyawanprash strengthens the tracheabronchial tree and hence improves immunity and functioning of the respiratory system'. Such statements have no medical or bio-chemical basis or basis science study supporting the claim. There are other such claims made in the proforma which are untenable and not supported by modern medicine literature. All the references quoted are from journals which cannot be claimed to be mainstream medical journals.
- Can a modern medicine specialist undertake research as PI in a field outside his specialty?
- Departmental Scientific Review Committee has not approved the 'Background and Rationale', Hypothesis, Methodology etc.
- The PI is an expert of Modern Medicine, while the study evaluates the efficacy of an Ayurvedic formulation.
- All Co-PI have been assigned the same role in the proforma
- Direct identifiers are being used. No mention of confidential handling.
- Dr. Sanjay Kumar Singh is mentioned as PI in one place and as Co-PI in another place.
- Project has a Co- PI from Radiotherapy and another from Netra-rog (ophthalmic department). Please mention their roles corresponding to their specialties.

EC Comment:

- As above
- No insurance in the budget

EC Decision: Project not in purview of KGMU ethics committee

Ref. code: 110thECMIIC/P3

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

4.	Research Protocol no.RLS/CNS/2020/01 Version 3.0 Dated 12 Nov,2020, entitled "***A prospective, multi-center, randomized, parallel group, two-arm, active control, open label, clinical study to evaluate efficacy and safety of Tenecteplasr/R-TPR-012(0.25mg/Kg) compared with acute ischemic stroke***" sponsored by Ahirubhai Ambani Life Sciences Centre submitted Dr. Imran Rizvi, Assistant Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no.189/Neuro/2021 dated 7th July, 2021. ***The following documents were reviewed in Its Meeting:-*** 1. Clinical Trial Protocol (Protocol No.: RLS/CNS/2020/01 Version 3.0 Dated 12 Nov 2020) 2. Investigator's Brochure, Edition: 3.0, Release Date: 30 Mar 2020 3. Case Report Form for the study; Version 1.0 Dated 15 Mar 2021 4. DCG (I) Approval letter dated 04 Mar 2021 5. Draft Clinical Trial Agreement 6. Copy of Insurance Policy valid from 30 Aug 2020 to 29 Aug 2021 7. Patient Information Sheet and Informed Consent Form; Version 3.0, Dated 10 Mar 2021 in English 8. Patient Information Sheet and Informed Consent Form (PIS-ICF), Version 3.0, Dated 10 Mar 2021, translated from English to Hindi on 18 Mar 2021 9. Patient Information Sheet and Informed Consent Form (PIS-ICF), Version 3.0, Dated 10 Mar 2021, back translated from Hindi to English on 18 Mar 2021 10. PIS-ICF - Translation Certificate – English to Hindi dated 18 Mar 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

11. PIS-ICF Back Translation Certificate – Hindi to English dated 18 Mar 2021
12. Investigator Study Undertaking Dated: 20 Mar 2021
13. Investigator Consent Letter Dated: 20 Mar 2021
14. Investigator's Curriculum Vitae and Medical Registration Certificate
15. Other documents: STUDY QUESTIONNAIRES:
    a) Alberta stroke program early CT score (ASPECTS); Version 1.0, Dated 22 May 2020
    b) Barthel Index of Activities of Daily Living; Version 1.0, Dated 22 May 2020
    c) Modified Rankin scale (mRS); Version 1.0, Dated 22 May 2020
    d) National Institutes of Health Stroke Scale; Version 1.0 Dated 22 May 2020
    e) SF 36 Questionnaire; Version 1.0 Dated 22 May 2020

Recommendation of Primary reviewer:

Comment:

- Are the active ingredients of Tenecteplase and Tenectase same?
- The control arm also has the same drug (Tenectase). What is being tested, drug efficacy or dosage or new usage?
- The study is supposed to be randomized but in the Methodology the PI states that patients with up to 4.5 hrs of ischemia time will be selected for Tenecteplase group and patients with up to 3 hrs of ischemia time will be selected for both groups. This introduces bias. Please comment.
- Tenecteplase is and established antithrombolytic agent. What is the objective of this study then? Is this a trial to find new usage of the drug?
- Involvement of Vulnerable participants is not mentioned. Please mention in the IEC form.
- Numbers of subjects in IEC form are given as 50 and in the Methodology

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	submitted to Scientific review Committee of the Department it is given as 225. • The parallel arm has the same drug (Tenectase) the justification for which has been asked from the PI. • Study is funded by private, Indian pharmaceutical firm • Informed consent mentions that there is only ONE study group-the one receiving the test drug. This has to be modified. • Not given in consent form. Name and contact details of on-site PI/counselor must be mentioned is Consent form. • Indirect identifiers/Coded in privacy & Confidentiality • Does the study involve a change in use of drug from Acute Stroke? This has not been mentioned in the IEC form. • The CTRI form does not have mention of KGMU site. • Roles of PI and Co-investigators are overlapping. **EC Decision:** Approval subject to modifications/clarifications and fulfillment of administrative formalities ***Ref. code: 110th ECMIIC/P4***
5.	Research Protocol no.VPM1002-HCWentitled ***"A multicenter, phase III, double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of VPM1002 vaccine in the prevention of tuberculosis infection in health care workers"*** sponsored by Serum Institute of India Pvt. Ltd submitted Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.MED/CT/110/2021 dated 7th July, 2021. ***The following documents were reviewed in Its Meeting:-***

Sl. no.	Document	Dated
1.	Protocol with Memo	Protocol Version 2.0, dated 27 Apr 2021; Memo - 01 dated 05 May 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

2.	Protocol Signature Page	Dated 18 Jun 2021
3.	Investigator's Brochure	Version 01 release date 22 May 2020
4.	Case Report Form	Draft dated 15 Jun 2021
5.	Clinical Trial Agreement with budget sheet	Draft dated 18 Jun 2021
6.	Clinical Trial Insurance Policy Certificate	Policy no.:15250036201500000006 Expires on: 28 Feb 2022
7.	Investigator's Current CV and MRC	CV dated: 18 Jun 2021 MRC No: 047302
8.	Investigator Undertaking	Dated 18 Jun 2021
9.	DCGI submission	Dated 22 Jun 2020
	Informed Consent Forms	
10.	Informed Consent Form (English)	ICF_ V2.0, 27Apr 2021/ Dr.D. Himanshu Reddy
	Informed Consent Form (Hindi)	ICF_ V2.0, 27Apr 2021/ Hindi / Dr.D. Himanshu Reddy
	Informed Consent Form (Back Translated Language: Hindi to English)	ICF_ V2.0, 27Apr 2021/ Hindi to English / Dr.D. Himanshu Reddy
Translation Certificates for Informed Consent Forms		
11.	Translation certificate English to Hindi; Version 2.0	
	Back Translation certificate Hindi to English; Version 2.0	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Subject Diary	
	12.	Subject Diary (English)
		Subject Diary (Hindi)
		Subject Diary (Back Translated Language: Hindi to English)
	Translation Certificates for Subject Diary	
	13.	Translation certificate English to Hindi; V1.0 dated 26 May 2020
		Back Translation certificate Hindi to English V1.0 dated 26 May 2020
	14.	Co-Investigator – Dr.V. Atam
	15.	Co-Investigator – Dr. Amit Kumar
	16.	Co-Investigator – Dr. K. K. Sawlani

EC Decision: Approval subject to fulfillment of administrative formalities

Ref. code: 110th ECMIIC/P5

6. Research Protocol no.ET201101 entitled "Assessment of safety and efficacy of SilvoGuard Foley balloon catheter in the prevention of catheter-associated urinary tract infections among Indian population" sponsored by We Innovate Biosolutions Pvt. Ltd submitted Prof. S.N. Sankhwar, Head, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no.URO/CT/10/2021 dated 8th July, 2021.

The following documents were reviewed in Its Meeting:-

Sl. no.	Document	Dated
1	Protocol	(Version 01 dated 30-Jan-2021)
2	Investigator's Brochure.	(Version 01 dated 30-Jan-2021)
3	Case Report Form	(Version 01 dated 30-Jan-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		2021)
4	Informed Consent Form English	(Version 01 dated 30-Jan-2021)
5	Informed Consent Form Hindi	(Version 01 dated 30-Jan-2021)
6	Informed Consent Form Hindi to English Back translation	(Version 01 dated 30-Jan-2021)
7	Translation and Back Certificates (Hindi)	NA
8	Draft Clinical Trial Agreement (CTA)	NA
9	Copy of IU along with CV & MRC of PI	NA
10	Insurance Copy (Awaited from Insurance Company)	NA
11	DCGI Approval letter (Awaited from DCGI due to query raised for submission of EC approval letters, copy of query of same is attached)	NA

EC Decision: Approval subject to fulfillment of administrative formalities

Ref. code: 110th ECMIIC/P6

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

III	Modification
1.	Modification of Research protocol no.I6T-MC-AMBG entitled "***A phase 3 multicenter, randomized, double-blind, parallel-arm, placebo-controlled maintenance study of mirikizumab in patients with moderately to severely active ulcerative colitis***" submitted by Dr. Abhijit Chandra, Principal Investigator, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no.SGE/CT/13/2021 dated 20th April, 2021. **The following documents is attached in above Modification:** 1. I6T-MC-AMBG(16) COVID19 Addendum 11Sep2020 1.1 Protocol Signature Page I6T-MC-AMBG(16)_dated 12Jan2021 2. Summary of changes_ Addendum Consent for I6T-MC-AMBG Study_17Mar2021 2.1 Addendum Consent for I6T-MC-AMBG Study-English_17Mar2021 2.2 Addendum Consent for I6T-MC-AMBG Study. Translated from English to Hindi on 06Apr2021 2.3 Translation certificate of Addendum Consent for I6T-MC-AMBG Study_Hindi_dated06Apr2021 2.4 Addendum Consent for I6T-MC-AMBG Study. Back translated from Hindi to English on 06Apr2021 2.5 Back Translation certificate of Addendum Consent for I6T-MC-AMBG Study _Hindi_dated06Apr2021 3. Summary of changes I6T-MC-AMBG_ India Main_V4.0IND(en)1.0(30Dec2020) 3.1 Main_V4.0IND(en)1.0(30Dec2020) 3.2 Main_V4.0IND(hi)1.0(30Dec2020) 3.3 Translation certificate of Main_V4.0IND(hi)1.0(30Dec2020) dated

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	16Feb2021 3.4 Back Translation of Main_V4.0IND(hi)1.0(30Dec2020) 3.5 Back Translation certificate of Main_V4.0IND(hi)1.0(30Dec2020)dated 16Feb2021 4. I6T-MC-AMBG_Patient Study Drug Self-Administration Log mirikizumab_V1.1_Trans_Paper_English-IN_ dated 17Jul2020 4.1 Translation certificate of Patient Study Drug Self-Administration Log mirikizumab_V1.1_Trans_Paper_English-IN_dated 24Jul2020 4.2 I6T-MC-AMBG_Patient Study Drug Self-Administration Log mirikizumab_V1.1_Trans_Paper_Hindi-IN_ dated 20Jul2020 4.3 Translation certificate of Patient Study Drug Self-Administration Log mirikizumab_V1.1_Trans_Paper_ Hindi-IN_dated 24Jul2020 5. MIRIKIZUMAB-CT-PFS-IFU-AMBG-SELF IN_v1.1_Trans_Paper_English-IN_ dated 23Jul2020 5.1 Translation certificate of MIRIKIZUMAB-CT-PFS-IFU-AMBG-SELF IN_v1.1_Trans_Paper_English-IN_ dated 24Jul2020 5.2 MIRIKIZUMAB-CT-PFS-IFU-AMBG-SELF IN_v1.1_Trans_Paper_Hindi-IN_ dated 29Jun2020 5.3 Translation certificate of MIRIKIZUMAB-CT-PFS-IFU-AMBG-SELF IN_v1.1_Trans_Paper_Hindi-IN_ dated16Jul2020 **Primary reviewer recommendation:** Approved **EC Decision:** Approved ***Ref.code:95th ECMIIC/P11***
2.	Modification of Research protocol entitled ***"Evaluate the effectiveness, safety and***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	tolerability of various doses of linezolid in combination with bedaquiline and pretomanid in adults with extensively drug-resistant (XDR),MDR with additional resistance to fluroquinolones or second line injectables, intolerant/non-responsive multidrug-resistant (MDR) pulmonary tuberculosis in India" submitted by Prof. Surya Kant, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no.1897/Res/2021 dated 9th July, 2021. **Recommendation of Primary reviewer:** • The PI informs that WHO has updated some definitions of extensively drug resistant TB and their outcomes and these have been incorporated in Indian guideline. Due to these the proposal needs amendment to incorporate the modified definitions and labels. • APPROVED AS IT SEEMS NECESSARY AND APPROPRIATE. • Someone involved in treating tuberculosis from Medicine or Pediatrics [Dr Shally herself] please go through the modifications. **EC Decision:** Approved ***Ref.code:109th ECMIB/P7***
3	Modification of research proposal entitled ***Digoxin in patients with rheumatic heart disease- a randomized placebo controlled trial"*** submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.1626/Cardiology/Res/21 dated 18th June, 2021. **EC Comment:** • This project was already approved in 2020 and is now re-submitted with some additions/Clarifications of some procedural details regarding the systems for web-based randomization, data entry, study drug management, SAE reporting and overall trial management. In addition this version has already been approved by AIIMS IEC. • The rationale of this study is to measure in relatively younger RHD patients, the role (including mortality) of inexpensive digoxin that otherwise is known for its mortality in older patients non-valvular AF.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The % of SAE for interim analysis to stop trial has been decided as 50% primary outcomes i.e. 180 deaths. • Since compensation will be included for a mishap, such point should be mentioned in informed consent document as well **EC Decision:** Approval subject to modification ***Ref.code:102nd ECMIIA/P24***
IV	**Brought to Ethics Committee after IV-PGTSC held on 31st July, 2021**
	Minutes of IV PG Thesis sub Committee" of "Institutional Ethics Committee" Meeting ***virtually*** will be held on 31st July, 2021 from 11.30 A.M. ***The following Members were present in the Meeting:*** 1. Prof. G.G. Agarwal — Member 2. Prof. Abbas Ali Mahdi — Member 3. Prof. Rajendra Nath — Member 4. Prof. Anita Rani Singh — Member 5. Dr. D.N. Upadhyaya — Member 6. Prof. Shally Awasthi — Convener
1.	Clarification of research proposal entitled ***"Feasibility of ultrasound guided suprascaplular nerve block in improving shoulder motion and pain post surgery in breast cancer survivors: A randomized controlled trial"*** submitted by Dr. Laxmi Prajapati, JR, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 3867/2021 dated 13th July, 2021. **Previous PGTSC Comment:** • If it is a trial then CTRI will be needed. • In inclusion criteria it is mentioned that patients undergoing surgery will be included. Is it correct?? • In the consent form permission for intervention shall be taken. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approval ratified ***Ref. code:107th ECM IIB-Thesis/P5***
2.	Clarification of research proposal entitled ***"Efficacy of dry needling versus transcutaneous electrical nerve stimulation in patients with neck pain due to myofascial trigger points: A randomized control trial"*** submitted by Dr. Anjana G, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 3859/2021 dated 5th July, 2021. **Previous PGTSC Comment:** • If it is a trial then CTRI registration will be needed. • In the consent form permission for intervention shall be taken. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer: Comment:** Kindly provide CTRI registration **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: 107th ECM II B-Thesis/P6***
3.	Clarification of research proposal entitled ***"Assessment of reasons of default in treatment of lung cancer in COVID-19 era at a tertiary care centre"*** submitted by Dr. Anmary Royson, JRII, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1813/Res/21 dated 19th June, 2021. **Previous PGTSC Comment:** • Incomplete, neither number of subjects, inclusion of exclusion/criteria provided. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: 107th ECM II B-Thesis/P7***
4.	Clarification of research proposal entitled ***"A study to estimate levels of oxidative stress biomarkers in post covid patients (Pilot study)"*** submitted by Dr.Nandini Dikshit, JR-II, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1815/Res/21 dated 19th June, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous PGTSC Comment: • Is the study already completed?? As duration of study is mentioned as April 2020 to April 2021. • Sample collection details shall be provided. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:107th ECM IIB-Thesis/P8***
5.	Clarification of research proposal entitled ***"An observational study to assess the treatment outcome and adverse effect profile of patients of multidrug resistance pulmonary tuberculosis put on shorter MDR regimen under PMDT"*** submitted by Dr.Sandeep Kumar, JR, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1846/Res/21 dated 29th June, 2021. **Previous PGTSC Comment:** • Is the study already completed?? As duration mentioned is Dec 2019 to Dec 2020. • Needs revision and methodology unclear, sample size not mentioned. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:107th ECM IIB-Thesis/P9***
6.	Clarification of research proposal entitled ***"Expression of CD24 in gall bladder cancer"*** submitted by Dr.Devanshi Brajesh Dubey, JR, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 2875/Res/21 dated 1st July, 2021. **Previous PGTSC Comment:** • Reference for methodology needed. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code:107th ECM IIB-Thesis/P10
7.	Clarification of research proposal entitled ***"Comparison of two weaning methods, T-piece method Vs continuous positive airway pressure (CPAP) methods, in mechanically ventilated patients admitted to a paediatric intensive care unit Department of Paediatrics of a Medical University in Northern India"*** submitted by Dr.Dhirendra Pratap Yadav, JR, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1465/Ped/21 dated 19th June, 2021. **Previous PGTSC Comment:** • Please clarify the role of Dr. Devina Singh in the present study. Clarify the time of inclusion of subjects 24 hrs or 48 hrs after following invasive ventilation. Statistical Analysis part states comparison of controlled and uncontrolled asthma patients kindly give correlation with study. IFC: Study Procedure: explain the procedure to patient's Guardian. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:107th ECM IIB-Thesis/P29***
8.	Clarification of research proposal entitled ***"Comparison of neoadjuvant chemoradiotherapy and neoajuvant chemotherapy in unresectable non-metastatic locally advanced cancers of gall bladder"*** submitted by Dr. Jasmeet Singh Tuteja, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 495/RT/21 dated 3rd July, 2021. **Previous PGTSC Comment:** • Sample size calculation or justification is not provided. • Study duration is not clear. State the follow up plan. • Consent form : In study Procedure Prospective Comparative Study is written. Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. Use proper understandable and proper Hindi language. Pitta Mutrashay is Pittashay.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: 107th ECM II B-Thesis/P36***
9.	Clarification of research proposal entitled ***"Association of genetic polymorphism in cytochrome P450 2A6 with treatment outcome in patients of locally advanced inoperable head and neck sqanous cell carcinomas treated with concurrent chemoradiotherapy"*** submitted by Dr.Deepak Shakya, JR, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 496/RT/21 dated 3rd July, 2021. **Previous PGTSC Comment:** • State the benefits of the study. • Consent form: In study Procedure Prospective Study is written. Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. • Use proper understandable Hindi language. Who among the investigators will perform Genomic DNA analysis? **PGTSC Decision:** Approval subject to modification ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:107th ECM IIB-Thesis/P37***
10.	Clarification of research proposal entitled ***"Total neoadjuvant therapy in locally advanced rectal cancer"*** submitted by Dr. Ankita Mallick, JR, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 494/RT/21 dated 3rd July, 2021. **Previous PGTSC Comment:** • Is it a Pilot study? • State risks and benefits of the study. • Sample size calculation or justification is not provided.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Explain in details the parameters or scale against which outcomes will be compared. • How would you rate success of therapy? • Study duration is not specified. Is there any plan for follow-up? • Consent form: In study Procedure Tertiary care hospital based Study is written. • Kindly explain the study procedure, the way you will elaborate or tell the patient about process of treatment. Use proper understandable Hindi language. ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:107th ECM IIB-Thesis/P38***
11.	Clarification of research proposal entitled ***"Induction therapy in locally advanced borderline or unresectable or Oral cavity carcinoma"*** submitted by Dr. Divya Kukreja, JR, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 493/RT/21 dated 3rd July, 2021. **Previous PGTSC Comment:** • Title of study does not clarify the Research Question. • Sample size calculation or justification is not provided. • Study duration is not clear. As the follow up is planned every month for three months and then every 3 monthly. • Consent form: In study Procedure Prospective Comparative Study is written. Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. Use proper understandable Hindi language. ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:107th ECM IIB-Thesis/P39***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

12.	Clarification of research proposal entitled ***"Outcome of hypofractionated radiotherapy versus conventional fractionated radiotherapy with concurrent temozolamide for elderly of younger low performance status patients of gliblastoma multiforms: a respective randomized study"*** submitted by Dr. Manas Agarwal, JR, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 491/RT/21 dated 3rd July, 2021. **Previous PGTSC Comment:** • Explain the method used for randomization of patients in 2 groups. • Consent form: In study Procedure Prospective Randamized Study is written. • Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. • Use proper understandable Hindi language in consent form. ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:107th ECM IIB-Thesis/P40***
13.	Clarification of research proposal entitled ***"Conventional four field radiotherapy versus computed tomography based radiotherapy in cancer cervix: dosimetric study and its clinical correlation"*** submitted by Dr. Jagrati Yadav, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 492/RT/21 dated 3rd July, 2021. **Previous PGTSC Comment:** • Justify the sample size. • Consent form: In study Procedure Prospective Comparative Study is written. • Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. • Use proper Hindi Language. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P41***
14.	Clarification of research proposal entitled ***"Plasma creatinine phosphokinase level for***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	assessment of success of methotrexate therapy in unruptured ectopic pregnancy" submitted by Dr. Akanksha Dwivedi, JR, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. 1026/2021 dated 8th July, 2021. **Previous PGTSC Decision:** • Consent form: In study Procedure Prospective Cohort Study is written. Kindly explain the study procedure, the way you will elaborate or tell the patient about process of investigation or study to be done. ***The above comment forwarded to the P.I., Reply given by P.I. was forwarded to the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:107th ECM IIB-Thesis/P42***
15.	Clarification of research proposal entitled ***"A study of structural and resting state MRI in adolescents with schizophrenia"*** submitted by Dr. Vikash Raj Bharti, JR-I, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 949/Psy dated 2nd July, 2021. **Previous PGTSC Comment:** • Study design mentioned is "Cross-sectional but in study sample" it seems to be mentioned case control study. • Sample size calculation is not clear. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:107th ECM IIB-Thesis/P51***
16.	Clarification of research proposal entitled ***"A randomized double blind placebo controlled study of celecoxib add-on in obsessive compulsive disorder"*** submitted by Dr. Shivangini Singh, JR-I, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 951/Psy dated 2nd July, 2021. **Previous PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• If it is a trial then CTRI registration will be needed. • In study hypothesis and Objectives it is mentioned that association of clinical and functional outcome will be assessed with serum IL-6 and BDNF levels. Nowhere in the methodology assessment of IL-6 and BDNF levels is mentioned. Please add the methods and cite relevant references. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:II PGTSC-IIA/P7***
17.	Clarification of research proposal entitled ***"Correlation of fibroblast growth FACTOR-23 levels for acute kidney injury in critically ill obstetrics cases and its association with fetomaternal outcome"*** submitted by Dr. Shruti, JR, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. 922/21 dated 24th June, 2021. **Previous PGTSC Comment:** • Privacy and Confidentiality section in Proforma – Direct Identifiers and Completely Anonymized have both been ticked. • Checkboxes in 'Consent' area of Proforma are not checked. • Checkboxes in Sections 9, 10, 11, and 12 of the Proforma are not checked. 5. In the 'Background and Rationale' the argument for this study has not been made. According to the literature provided by the researcher, FGF-23 is already an established marker for AKI. What then is the rationale of proving and already proven fact? ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code:II PGTSC-IIA/P14
18.	Clarification of research proposal entitled ***"An audit of cesarean section using modified robson's criteria"*** submitted by Dr. Anjali Kapoor, JR, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. 1027/OG/2021 dated 8th July, 2021. **Previous PGTSC Comment:** • Sample size not calculated (only formula is given) ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:II PGTSC-IIA/P19***
19.	Clarification of research proposal entitled ***"Curcumin as an adjuct in treatment of thyroid associated ophthalmopathy: A pilot study"*** submitted by Dr. Swati Goyal, JR, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 363/OPH dated 9th July, 2021. **Previous PGTSC Comment:** • No Ayurvedic (AYUSH) Consultant as Co-investigator included • No literature showing correlation of Curcumin and treatment of TAO given • The source of curcumin not mentioned • Which placebo is used -not given • How the groups 1 and 2 will be divided then how Group 2 into mild, moderate and severe is not mentioned, so detailed methodology should be submitted. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:II PGTSC-IIA/P20***
20.	Clarification of research proposal entitled ***"Effect of advances age on bioactive factors (IL-6 & TGF-ß) in colostrum"*** submitted by Dr. Shivani, JR, Department of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2505/PHY/2021 dated 7th July, 2021. **Previous PGTSC Comment:** • Kindly provide details of timing, frequency and procedure for colostrum extraction. Also clarify that if the collection of milk will be till 7th day as written in methods or will be within 72 hrs (according to ICF). According to ROL, TGF and IL are affected by preterm delivery and birth weight. The study needs careful inclusion and exclusion criteria. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:III PGTSC-IIA/P9***
21.	Clarification of research proposal entitled ***"Study of complications of therapeuric plasma exchange according to patients demography and variations in procedure"*** submitted by Dr. Jyoti Bharti, JR-I, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 207/2021 dated 12th July, 2021. **Previous PGTSC Comment:** This is a prospective observational pilot study with 60 patients. • Is the study already underway?? • In the informed consent form risks or any expected complications following plasma exchange are not mentioned. • References are incomplete. Most do not have a year of publication and are not properly written e.g. publishers of books and manuals are not mentioned. • When patients' height and weight are being noted then BMI may also be included in patient demographic data. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code:III PGTSC-IIA/P21
22.	Clarification of research proposal entitled ***"Assessment of knowledge, attitude and awareness of blood donor for promoting their motivation and retention"*** submitted by Dr. Vinay Tiwari, JR-I, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 208/2021 dated 12th July, 2021. **Previous PGTSC Comment:** • Theses proforma with details has to be submitted ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:III PGTSC-IIA/P22***
23.	Clarification of research proposal entitled ***"A study of the association between serum ferritin levels and microalbuminuria in patients of type 2 diabetes mellitus"*** submitted by Dr. Kinjalk Dubey, JR-I, Department of Internal, Medicine King George's Medical University, U.P., Lucknow vide letter no. 1478/MED/2021 dated 8th July, 2021. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code:III PGTSC-IIA/P29***
24.	Clarification of research proposal entitled ***"Effect of non-surgical periodontal therapy on salivary and gingival crevicular fluid concentration of visfatin in periodontal health and disease"*** submitted by Dr. Hira Ismail, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1833/P/21 dated 16th July, 2021. **Previous PGTSC Comment:** • According to the PI role of Visfatin as an inflammatory marker in periodontal disease is already established. What is the need for this study? • Proforma says the study I NOT a clinical trial. However, the PI says the study will be registered with clinical trial Registry of India. This is conflicting.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Role of everyone participating in the study needs to be defined. Is it a trial? Research question needs to be defined. **Recommendation of Primary reviewer:** **Comment:** Following this the Primary was reviewer satisfied with the answer to point no. 1 (need for the study) However, points 2 and 3 have not been answered to satisfactorily. **Point no.** 2-The PG thesis is a clinical, interventional study and cannot be considered a 'Trial' which the Principal-Investigator is claiming. However, if the Principal-Investigator insists that this study is indeed a 'Trial',the project be put forward in front of a Full Committee for evaluation. CTRI registration, as claimed by the Principal-Investigator, is not MANDATORY for publication in medical journals. This is an erroneous assumption and false claim by the PI. **Point no.3**-The number of Co-supervisors is untenable. Number of co-supervisors has to be decreased. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: III PGTSC-IIA/P34***
25.	Clarification of research proposal entitled ***"To evaluate and assess association of ABO phenotype and rhesus factor with oral hygiene status and severity of periodontitis"*** submitted by Dr. Mohd. Aamir Khan, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1837/P/21 dated 19th July, 2021. **Previous PGTSC Comment:** • According to the literature provided by the PI several such studies have already been done all over the world in the past. What is the rationale for another such study then? What is the research question? • Define 'Other blood parameters' mentioned in Aims of the study

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Justify use of 'Other blood parameters'. • Research question needs to be formulated. • Role of all investigators needs to define. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P36***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"To study the role of Vitamin D and calcium supplementation on tumor response in patients receiving neoadjuvant chemotherapy for stage II/III breast cancer-A comparative study"*** submitted by Dr. Sukesh K.S., JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1078/21 dated 29th May, 2021. **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P1***
2.	Research proposal entitled ***"To study the role of Vitamin D and calcium supplementation on overall survival in patients receiving palliative chemotherapy for metastatic cancer gallbladder-A pilot study"*** submitted by Dr. Priyanshi Swarup, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no.1079/21 dated 29th May, 2021. **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P2***
3.	Research proposal entitled ***"Comparative study of stress response to COVID-19 and coping in patients of depression and anxiety disorder"*** submitted by Dr. Kritika Chawla, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 752/Psy/21 dated 30th April, 2021. **PGTSC Decision:** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: IV PGTSC-IIA/P3
4.	Research proposal entitled ***"A randomized controlled trial to compare ligation of intersphincteric fistula (LIFT) v/s LIFT plus in complex anal fistula"*** submitted by Dr. Shristi Rathore, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1087/21 dated 5th June, 2021. **Primary reviewer recommendation:** • The fundamentals of performing RCT are not specified: Clinical Trial Registry, method of randomization, blinding, follow-up, outcome event, efficacy or effectiveness trial, statistical and methodology. **PGTSC Decision:** Approval subject to modification
	Ref. code: IV PGTSC-IIA/P4
5.	Research proposal entitled ***"Proliferative and anti-apoptotic indices of ameloblastoma and odontogenic keratocyst"*** submitted by Dr. Eram Khan, JRI, Department of Oral Pathology and Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 34/OP/21 dated 31st May,2021. **Primary reviewer recommendation:** • The study design sample size calculation, methodology etc. need to be specified **PGTSC Decision:** Revise & Re-submit
	Ref. code: IV PGTSC-IIA/P5
6.	Research proposal entitled ***"Immunoexpression of glucocorticoid receptor alpha (GRA) isoform in oral squamous cell carcinoma (OSCC), oral sub mucous fibrosis (OSMF), oral lichen planus and oral epithelial dysplasia"*** submitted by Dr. Kriti Sharma, JRI, Department of Oral Pathology and Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 33/OP/21 dated 31st May, 2021. **PGTSC Decision:** Approved
	Ref. code: IV PGTSC-IIA/P6
7.	Research proposal entitled ***"Expression pattern of muc1 and muc4 in (OPMD) oral premalignant disorders and oral squamous cell carcinoma (OSCC) and normal oral mucosa in an attempt to analyze its role played in oral carcinogenesis"*** submitted by Dr. Sharon John, JRI, Department of Oral Pathology and Microbiology, Faculty of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 32/OP/21 dated 31st May, 2021. **Primary reviewer recommendation:** • Study design, sample size calculation are not mentioned, the aims & objectives do not match with Material and methods. In material & method, the three groups are selected. This is not obvious from aims & objectives. **PGTSC Decision:** Revise & Re-submit ***Ref. code: IV PGTSC-IIA/P7***
8.	Research proposal entitled ***"Overexpression of epstein barr virus encoded latent membrane protein-1 in oral squamous cell carcinoma and oral premalignant disorders"*** submitted by Dr. S. Ramya, JRI, Department of Oral Pathology and Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 35/OP/21 dated 31st May, 2021. **Primary reviewer recommendation:** • Study design, sample size calculation are not mentioned, the aims & objectives do not match with Material and methods. In material & method, the three groups are selected. This is not obvious from aims & objectives. **PGTSC Decision:** Revise & Re-submit ***Ref. code: IV PGTSC-IIA/P8***
9.	Research proposal entitled ***"To compare the effects of paraffin wax and beeswax in impregnation and embedding of oral tissues and subsequent histopathological staining using hematoxylin and eosin stain"*** submitted by Dr. Nikhil Gupta, JRI, Department of Oral Pathology and Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.37/OP/21 dated 31st May, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P9***
10.	Research proposal entitled ***"A study on assessing the effectiveness of stereomicroscope in studying the surface details of the samples in routine grossing and its role in arriving at a final histopathological diagnosis"*** submitted by Dr. Nikhil Gupta, JRI, Department of Oral Pathology and Microbiology, Faculty of Dental Sciences, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. 36/OP/21 dated 31st May, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P10***
11.	Research proposal entitled ***"Non-invasive predictors of oesophageal varices in liver cirrhosis"*** submitted by Dr. R. Sushma Swaraj, JRI, Department of Physiology vide letter no. 2458/PHY/21 dated 7th June, 2021. **PGTSC Comment:** • Kindly provide in ICF clear, understandable description of study procedure in simple language instead of writing study design. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P11***
12.	Research proposal entitled ***"To study soluble transferrin receptor level and serum visfatin level in beta thalassemia"*** submitted by Dr. Himadri Shukla, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter n. 2754/21 dated 7th June, 2021. **PGTSC Comment:** • Define selection criteria for control subjects. • The study title does not address inclusion of patients of Iron deficiency anemia, but objectives of the study state comparison of various parameters between the two. The study topic is not appropriately addressing the objectives so either reconsider the study or modify. • Kindly provide in ICF clear, understandable description of study procedure in simple language instead of writing study design. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P12***
13.	Research proposal entitled ***"Role of impulse oscillometry in diagnosis and assessment of level of control of childhood asthma: A prospective observational study"*** submitted by Dr. Gopaji Saiprasad, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1323/Ped/21 dated 5th June, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approved ***Ref. code: IV PGTSC-IIA/P13***
14.	Research proposal entitled ***"A comparative study of plasma CYSTATIN C with renal resistive index as an early predictor of acute kidney injury in critically ill patients"*** submitted by Dr. Himanshu Mishra, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1215/MED/21 dated 4th June, 2021. **PGTSC Comment:** • Kindly provide in ICF clear, understandable description of study procedure in simple language instead of writing study design. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P14***
15.	Research proposal entitled ***"Predisposing factors for hypotension during prone positioning in patients under general anaesthesia: A prospective observational study"*** submitted by Dr. Anupam Kumar Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/456/21 dated 8th June, 2021. **PGTSC Comment:** • Kindly provide in ICF clear, understandable description of study procedure in simple language instead of writing study design. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P15***
16.	Research proposal entitled ***"Randomized controlled trial for comparing conventional vs wide angle viewing system for sclera buckling surgery"*** submitted by Dr. Ruchi Agarwal, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 1525/OPH/21 dated 19th February, 2021. **PGTSC Comment:** • Kindly explain the procedure for randomization. • Kindly provide in ICF clear, understandable description of study procedure in simple language instead of writing study design. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P16***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

17.	Research proposal entitled ***"A randomized, double blind, controlled study of low dose aripiprazole adjunctive therapy in patients with depression"*** submitted by Dr. Moin Uddin, JRI, Department of Pharmacology and Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 637/Pharma/21 dated 8th June, 2021. **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P17***
18.	Research proposal entitled ***"Association of stress and primary Hypothyroidism"*** submitted by Dr. Monika Singh, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2462/PHY/21 dated 10th June, 2021. **PGTSC Comment:** • Kindly provide clear criteria for enrolling control subjects and the setting from where these controls will be selected. • Kindly provide in ICF clear, understandable description of study procedure in simple language instead of writing study design **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P18***
19.	Research proposal entitled ***"Extragastric manifestations of helicobacter pylori infection with or without ulcer"*** submitted by Dr. Sudipti Yadav, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2463/PHY/21 dated 10th June, 2021. **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P19***
20.	Research proposal entitled ***"Effect of disturbed circadian rhythm on autono.mic function in young healthy adults"*** submitted by Dr. Aparna Yadav, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2464/PHY/21 dated 10th June, 2021. **PGTSC Comment:** • Kindly provide clear criteria for enrolling control subjects and the setting from where these controls will be selected. • Define clearly, the k parameters for selecting healthy controls. • Kindly provide clear criteria for enrolling control subjects and the setting from

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	where these controls will be selected. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P20***
21.	Research proposal entitled ***"Assessment of efficacy of coagulation factors in fresh frozen plasma prepared at different time intervals"*** submitted by Dr. Shubhi Yadav, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. nil dated 9th June, 2021. **Primary reviewer recommendation:** • Incomplete performa, neither methodology, nor sample size mentioned. No reference/bibliography. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P21***
22.	Research proposal entitled ***"Correlation between breath holding time test and 6 minute walk test in apparently healthy individual of North India"*** submitted by Dr. Himani More, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.2465/PHY/21 dated 11th June, 2021. **Primary reviewer recommendation:** • Title may be changed and "A pilot study" may be added to it. **GTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P22***
23.	Research proposal entitled ***"A cross-sectional study of immunophenotypic profile in adult acute lymphoblastic leukaemia and its association with clinic-hematological parameters and treatment response"*** submitted by Dr. Kumar Varunanidhi, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 2789/21 dated 10th June, 2021. **Primary reviewer recommendation:** • Risk association with collection of bone marrow samples may be mentioned in the consent forms. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P23***
24.	Research proposal entitled ***"A study of the clinic-etiological profile of hyponatremia***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	among elderly patients" submitted by Dr. Ravi Shankar Prasad, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1214/MED/21 dated 4th June, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P24***
25.	Research proposal entitled ***"A study of correlation between nafld fibrosis score, transient elastography fibrosis grading with fasting serum insulin levels in patients of non alcoholic steatohepatitis"*** submitted by Dr. Avinash Kumar, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1244/MED/21 dated 8th June, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P25***
26.	Research proposal entitled ***"Nutritional status and dietary practices of adult pulmonary tuberculosis patients in Lucknow district"*** submitted by Dr. Purnoor Kaur, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 218/21 dated 10th June, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P26***
27.	Research proposal entitled ***"Sympathovagal balance in newly diagnosed drug naïve COPD subjects"*** submitted by Dr. Durgesh Kumar Gupta, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2468/PHY/21 dated 14th June, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P27***
28.	Research proposal entitled ***"Comparison of high flow nasal oxygen and conventional oxygen therapy on postoperative atelectasis in obese patients after cardiac surgery with fast track extubation: A randomized control trial"*** submitted by Dr. Aditi Banka, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	vide letter no. Anas/452/21 dated 7th June, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P28***
29.	Research proposal entitled ***"Immunohistochemical expression of IDH1, ATRX and P53 in gliomas and their correlation with clinicopathological parameters"*** submitted by Dr. Shipra Singh, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 2809/21 dated 15th June, 2021. **PGTSC Comment:** • Calculation of sample size to be mentioned as it is not clear as to why 80 subjects will be recruited. Complications/risks associated with the study need to be mentioned in the consent forms. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P29***
30.	Research proposal entitled ***"Histopathological study of liver diseases in unclaimed and claimed dead bodies: A case-control study"*** submitted by Dr. Krishna Nishad, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 350/FMT/21 dated 15th June, 2021. **PGTSC Comment:** Consent forms need to be corrected as a legally acceptable representative will be giving the consent and it is mentioned in point no. 2 that "my participation", similarly in the Investigator's statement "subject" is the dead body so it may be deleted. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P30***
31.	Research proposal entitled ***"Morphology and anatomical relations of the spinal accessory nerves: A cadaveric and surgical neck dissection study"*** submitted by Dr. Surabhi Sachan, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 97/ANAT/21 dated 14th June, 2021. **PGTSC Comment:** • The course, length, and relations of the SAN are well known. What is the need of this study? • Number of patients mentioned is 51 at one place and 60 at another place (20

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	cadavers and 40 patients) • Please argue the need for this study • Discrepancy in numbers within the proforma • The section on Consent is incompletely filled in the proforma • The Yes and No are both ticked in 'Confidential Handling of Data'. Direct Identifiers and Completely Anonymized are both ticked. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P31***
32.	Research proposal entitled ***"Genetic analysis of RB1 gene in retinoblastoma patients"*** submitted by Dr. Honey Zahra, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 94/ANAT/21 dated 14th June, 2021. **PGTSC Comment:** • The study is being conducted in Pediatric patients with retinoblastoma. • How is this appropriate topic for a thesis work of an Anatomy postgraduate? • No anatomical study is being done. • Will encourage reconsidering the project. • Tissue samples are being sent out of the campus while a department of Biochemistry and a CFAR are present in the University. This will be difficult to overlook. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P32***
33.	Research proposal entitled ***"Comparison of laryngeal mask airway proseal and laryngeal mask airway protector in laparoscopic surgery"*** submitted by Dr. Deshraj Verma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anas/471/21 dated 15th June, 2021. **Primary reviewer recommendation:** **Comment:** • In the proforma 'Subject Selection' section it is not mentioned whether the subjects will be patients or volunteers. • Proforma says risk is not reasonable compared to benefits. Please correct this. • Not mentioned in proforma. • Conflicting numbers of subjects given – 60 at one place and 120 at another. Please correct.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Appropriate boxes not ticked in the proforma • Direct Identifiers, Indirect Identifiers and Anonymized are all ticked. Please correct this. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P33***
34.	Research proposal entitled ***"A randomized controlled study comparing videolaryngoscopy to conventional laryngoscopy for intubation in adult patients in intensive care unit"*** submitted by Dr. Ravi Shankar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anas/459/21 dated 10th June, 2021. **PGTSC Comment:** • The answer to 'Risk is reasonable' has been give as 'No'. Please check if this is correct. If the risk is not reasonable the study cannot be approved. • Not specified in proforma • Boxes not checked. Please complete in ICF • Direct identifiers and Completely Anonymized are both ticked. Please correct in privacy & confidentiality. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P34***
35.	Research proposal entitled ***"A comparative morphometric study of lumbosacral spine in normal subjects and patients of spondylolisthesis: A clinic-anatomical perspective using 64-SLICE multidetectoe computed tomography"*** submitted by Dr. Sumbul, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 98/ANAT/21 dated 14th June, 2021. **PGTSC Comment:** • Is the Morphometry of the adult lumbo-sacral spine not known that this study is being undertaken? What new knowledge do the investigators propose to seek from the study? • How will volunteers for the control group be recruited? • Will the two groups be age and sex matched? The vertebral morphology will vary according to age/sex/racial characteristics and other confounding factors like growth disorders. • Sufficient work has already been done on this subject. Why another study? • Risk is not reasonable has been ticked. If this is true study cannot be approved. • Not specified. Please correct this in Voluntary, Non-coercive Recruitment of Participants. • The subject number will go up if the groups are age-sex matched.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Some conditions in the control group may act as confounding factors for eg. Osteopenia? • Informed consent doesn't have any mention of the risk of radiation that the volunteers will be exposed to. • Boxes not ticked. Please correct this in ICF • Direct identifiers, indirect identifiers, and Anonymized are all ticked. Please correct this in Privacy & Confidentiality. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P35***
36.	Research proposal entitled ***"Morphometric analysis of coracoids process, acromion process and glenoid fossa: A computed tomography study"*** submitted by Dr. Akriti Anand, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no.99/ANAT/21 dated 14th June, 2021. **PGTSC Comment:** • PI has answered 'No' to the point 'Is the risk reasonable?' • Number of subjects not mentioned in the Form filled by the PI. • Besides written consent, Oral explanation of the consent also must be done. Not ticked. Consent must also be taken after explaining additional radiation dose • No mention of extra radiation dose that the patient will be subjected to. • Direct identifiers, indirect identifiers, and Anonymized are all ticked. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P36***
37.	Research proposal entitled ***"Effect of surya-namaskar on anthropometric parameters and serotonin level in apparently healthy subjects"*** submitted by Dr. Ajaya Deep Singh, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.2471/PHY/21 dated 16th June, 2021. **PGTSC Comment:** • Does the study also intend to show changes in anthropometric dimensions during the period of study? No such relevant literature has been cited. Why has one particular 'Asana' been chosen? Will it not be better to have a more generic title like 'Effect of exercise/Yoga on Anthropometry and serotonin levels'?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The time period of measurement of serotonin levels is different in Aims and Objectives section from the Methodology section. • No data regarding affect of 'Surya Namaskar' on anthropometric changes has been cited. Will they say changes also occur with any other exercise, such as running, or aerobics? • Is risk reasonable has been answered with 'No'. • No mention has been made in the form. Please correct this in Involvement of Vulnerable Participants. • Volunteers have not been ticked in the form. • Contents not ticked in the form. Please correct this in ICF • How will they monitor adherence? **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P37***
38.	Research proposal entitled ***"Retrospective and prospective outcomes of transarterial chemoembolization in gestational trophoblastic diseases"*** submitted by Dr. Durga Singh, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 1040/RD/21 dated 7th June, 2021. **PGTSC Comment:** • TACE is an already established treatment modality. Why another study? • Risk is not reasonable has been declared in the proforma. Please check this. • Involvement of Vulnerable Participant-Not mentioned in proforma. • Conflict in the number mentioned in the form (100) and in the proforma (32). Please check. • Risks have not been explained in the consent. TACE will have risks of failed embolization, bleeding, hematoma etc. These must be mentioned. • Check boxes in the proforma are not ticked. Please correct in ICF. • Direct identifiers and Completely Anonymized are both ticked. Please correct in Privacy & confidentiality. • Provisions for Medical / Psychosocial Support-Not mentioned • Provisions for Treatment of Study-related injuries-Not mentioned • Provision for Compensation-Not mentioned • The study has eight co-supervisors besides one supervisor. Please mention the role of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	each supervisor in the project or curtail the number of names. **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P38***
39.	Research proposal entitled ***"Utility of lung ultrasono.graphy in the evaluation of ≤34 weeks preterm neonates admitted in a neonatal intensive care unit with clinical suspicion of respiratory distress syndrome within 12 hours of birth"*** submitted by Dr. Shivendra Rai, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.1096/Ped/21 dated 8th May, 2021. **PGTSC Comment:** • 'No' has been ticked in response to 'Reasonable risk' question in form. • Involvement of Vulnerable Participants-Not mentioned • Voluntary, Non-coercive Recruitment of Participants-Not mentioned • Voluntary, Non-coercive Recruitment of Participants-Not mentioned • Direct identifiers and completely anonymized are both ticked **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P39***
40.	Research proposal entitled ***"Effect of dexmedetomidine on elevated blood pressure inside operation theatre: A randomized controlled trial"*** submitted by Dr. Rahul Kumar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/469/21 dated 15th June, 2021. **PGTSC Comment:** • Is it a trial? How will blinding be done? What are two groups? What will be compared between the two groups? • The title labels the study as a 'Trial', but no permission has been sought from DCGI/CTRI. • Dexmedetomidine has already been studied, and its effects proven. Why this study? • Reasonable risk question is answered as 'No' • Both the arms of the study are getting the drug under study? Is the role of drug being assessed or is its dose being studied? • Consent section in the form mentions 'Healthy Volunteers'. Please check • Direct identifiers and completely anonymized are both ticked. Please check

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approval subject to modification ***Ref. code: IV PGTSC-IIA/P40***
41.	Research proposal entitled ***"Effectiveness of intravenous extension tubing in reducing peripheral intravenous catheter failure in children: an open label randomized controlled trial"*** submitted by Dr. Jaya Gupta, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow. **PGTSC Comment:** • **In ICF**-Guardian consent and is assent form are not attached **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P41***
42.	Research proposal entitled ***"Comparison between straight versus curved reinforced tube in video laryngoscope guided intubation in patients undergoing thyroid surgery"*** submitted by Dr. Ayushi Pandey, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/470/21 dated 15th June, 2021. **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P42***
43.	Research proposal entitled ***"Clinico-anatomical study of posterior tibial artery and its perforators"*** submitted by Dr. Saba Anjum, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 104/ANAT/21 dated 15th June, 2021. **PGTSC Comment:** • Study design not mentioned in brief synopsis (given in ICF as Observational cross - sectional study) • Do we need ICF in donated bodies or required Waiver form ,should be discussed in meeting **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P43***
44.	Research proposal entitled ***"Correlation of plasma D-DIMER level with severity of liver cirrhosis: an observational study"*** submitted by Dr. Rituraj Singh, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 230/Med/21 dated 5th June, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: • Cross sectional observational study • All pts of liver cirrhosis of any etiology admitted in Medicine • Case Record Form not submitted **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P44***
45.	Research proposal entitled ***"To study the role and prognostic value of early biomarker of acute kidney injury in patients of chronic liver disease"*** submitted by Dr. Shivani Rani, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 277/Med/21 dated 12th June, 2021. **PGTSC Comment:** • Pt. Case Record Form not submitted • Study design has to be clarified **PGTSC Decision:** Approval subject to modification ***Ref. code: IV PGTSC-IIA/P45***
46.	Research proposal entitled ***"Morphological and morphometric analysis of variations in pelvicalyceal system and its impact on stone formation: A CT urography study"*** submitted by Dr. Anupriya Singh, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 95/ANAT/21 dated 14th June, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P46***
47.	Research proposal entitled ***"Morpphology morphometry and variations of superior and inferior mesenteric vessels: A CT angiographic study"*** submitted by Dr. Mariam Moonis, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 96/ANAT/21 dated 14th June, 2021. **Decision:** Approved ***Ref. code: IV PGTSC-IIA/P47***
48.	Research proposal entitled ***"Assessment of blood supply and demand during COVID-19 pandemic"*** submitted by Dr. Sunil Kumar, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 146/21 dated 17th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	June, 2021. **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P48***
49.	Research proposal entitled ***"To study the knowledge, attitudes, and practices towards COVID-19 among blood donors during the COVID-19 outbreak"*** submitted by Dr. Pradeep Kumar Maurya, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 145/21 dated 17th June, 2021. **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P49***
50.	Research proposal entitled ***"Effect of pulmonary recruitment maneuver and intraperitoneal bupivcaine on postoperative shoulder pain after laparoscopic cholecystectomy: A randomized controlled study"*** submitted by Dr. Sedeyino. Nakhro, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/476/21 dated 16th June, 2021. **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P50***
51-	Research proposal entitled ***"A study of phenomenology of major depressive disorder & its correlation with inflammatory markers among Covid 19 recovered elderly"*** submitted by Dr. Shashank Saurabh Sinha, SR-I, Department of G.M.H., King George's Medical University, U.P., Lucknow vide letter no.1071/DGMH dated 14th July, 2021. **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P51***
II-B	**IMR-Resident**
1.	Research proposal entitled ***"Satisfaction levels in patients after rhinoplasty using outcome evaluation questionnaire"*** sponsored by Research Cell, King George's Medical University, U.P., Lucknow submitted by Dr. Devisha Agarwal, JRI through her Mentor Dr. Manish Chandra, Associate Professor, Department of Otorhinolaryngology & Head Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 111/ENT/21 dated 3rd June, 2021. **PGTSC Comment:** • Justify 6 guides from ENT Department, KGMU as no cases are being recruited

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	from ENT. • What are potential sources of bias? • Will patients operated in 2015 have same response as those operated later? Please Specify the research question/s • Confirm the study design prospective/retrospective. • Ethical clearance is required from SGPGIMS **PGTSC Decision:** Pending till approval granted from SGPGIMS after proposal modified as per comment above. ***Ref. code: IVPGTSC-II B IMR-R/P1***
2.	Research proposal entitled "***Application of Milan system for salivary gland cytology and diagnostic utility of PLAG-1 and SOX-10 immuno.cytochemistry markers in diagnosing salivary gland neoplasms and it's cyto-histological correlation for it's risk stratification*** " sponsored by Research Cell, King George's Medical University, U.P., Lucknow submitted by Dr. Pooja Dwivedi, JRII, through her Mentor Dr. Madhu Kumar, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 2868/21 dated 30th June, 2021. **PGTSC Comment:** • Elaborate Methodology **PGTSC Decision:** Approval subject to modification ***Ref. code: IVPGTSC-II B IMR-R/P2***
III	**Other Matter**
1-	Prof. Anita Rani & Dr. Divya Narain Upadyaya will a take a P.G. lecture on why and how to write on I.C.F. in August, 2021.
	Next EC meeting scheduled on 18th September 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 111th ECM held on 18th September, 2021

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

Minutes of 111th Institutional Ethics Committee Meeting ***virtually*** held on **18th September, 2021** from 10.30 AM.

The following members were present in its Meeting:

1.	Prof. Alok Dhawan	-Chairman
2.	Prof. G.G. Agarwal	-Member
3.	Prof. Shubha R Phadke	-Member
4.	Mrs. Akansha Dubey	-Member
5.	Mr. Ujjawal Krishna	-Member
6.	Dr. Akash Agarwal	-Member
7.	Dr. K.K. Yadav	-Member
8.	Prof. A.A. Mahdi	-Member
9.	Prof. Rajednra Nath	-Member
10.	Prof. Anupam Mishra	-Member
11.	Prof. Anita Rani Singh	-Member
12.	Dr. D.N. Upadhyaya	-Member
13.	Prof. Shally Awasthi	-Member-Secretary, IEC

The following Member could not attend the Meeting:

1. Mrs. Vasundhara Kumar- the Network was not available at her site.

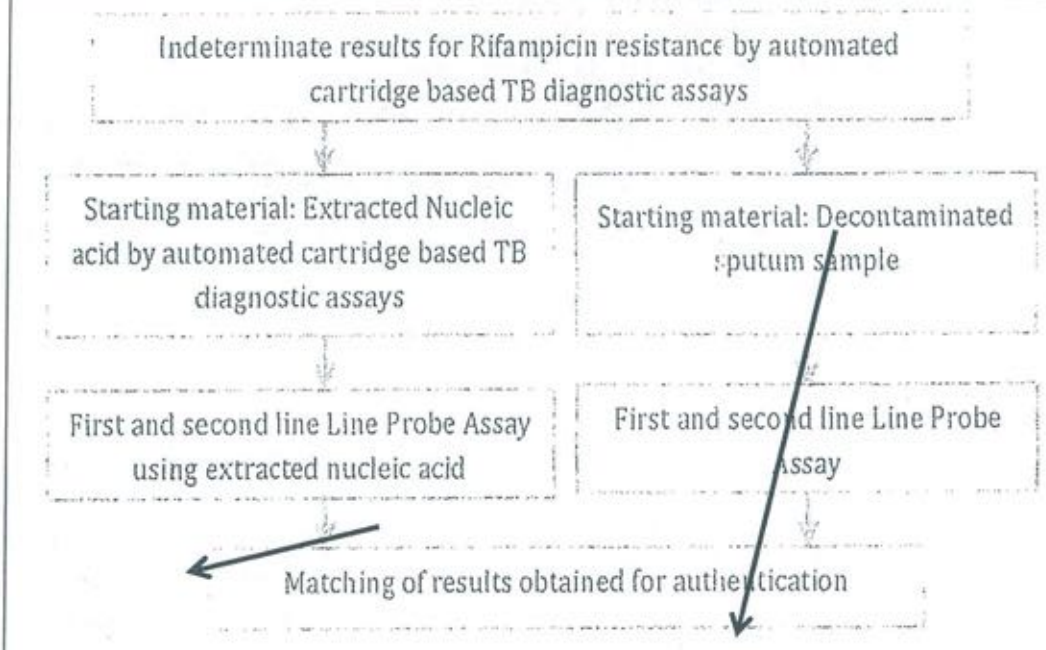
(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

IA	Action taken
1-	Clarification of research proposal entitled "***Interpretation of indeterminate results of automated cartridge based TB diagnostic assays by line probe assay utilizing the already extracted nucleic acid***" submitted by Dr. Parul Jain, Assistant Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 551/2021 dated 22nd July, 2021. **Previous EC Comment:** • Some fields of form are not filled out: Section 5 (vi), (vii) • Aim and objective 1 are same: need to correct it. • What is the current standard of testing and treatment for samples that are indeterminate for resistance to Rifampicin? • Will your objective 1 change or modify treatment? a. If yes: you will need patient consent b. If no: what is the utility of this study • What NAAT will be used? From our little understanding, DNA cannot be extracted from cartridge based automated TB assays, only a report is generated. Please shed some light on this.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC



- Matching results: How? What if discordant?
- Where does this decontaminated sputum come from? Is it stored? Will storing lead to any changes in the quality of specimen for purpose of results?
- What are the end points?
- Is the LPA a one-time purchase or does it need reagents/ consumables. If the latter, needs a source of funding.
- Sample size calculation is based not only on the prevalence of the condition, but also end points.
- For objective 2, needs a separate sample size calculation.
- Similarly, need to define endpoints for objective 2.
- What statistical tests will be used- Instant Prism software will not itself choose the test to be used, investigator has to decide.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • 1-Before embarking on Objective a-It will be prudent to do a study of objective b-If DNA quality is found to be good, then objective 1 should be evaluated. 2-How will discordance between the two techniques be measured? Is there any objective scale or subjective assessment will be done? 3- Sample size calculation for Objective 1 and statistics don't seem to be correct. What one needs to measure are the sensitivity and specificity of the new test with respect to the standard. • Needs consultation from statistician to get a proper sample size and analysis. Cannot be accepted in current form. **EC Comment:** • Response from Principal-Investigator is not received, therefore decision is pending. ***Ref. code: 108th ECM IIA/P11***
2-	Clarification of the research proposal entitled ***"To evaluate the role of RBP 4 as pediatric acute liver failure prognostic biomarker"*** sponsored by CSIR submitted by Dr. Sanjeev Kumar Verma, Associate Professor, Department of Pediatrics, King George's Medical University U.P., Lucknow vide letter no.1951/Ped/2021 dated 6th August, 2021. **Previous EC Comment:** • The aim is to study the biomarker as a prognostic tool. However, nowhere in the proposal, any reference to the prognosis of ALF has been made. • Why include a control group in this study? • No statistical plan has been given. • Flowchart is incomplete • Inclusion criteria: How will the fact that 'PT-INR >2 is of hepatic origin' will be ascertained? • Sec 5: Why include "institutionalized" subjects? • Sec 6: Why use direct identifiers? • Sec 7 is left blank, needs to be completed. • Sec 10: If risk is not reasonable to anticipated benefit, why do the study?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Blank fields in benefit section need to be filled. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer by 13th September, 2021:** 1. Statistical plan is not elaborated: **"appropriate parametric and non-parametric test will be done"** is not a statistical plan. 2. Despite pointing out earlier, researchers have not explained the reason why a control group is being used. 3. The Primary objective is not reflecting the title of the study. 4. Secondary objective is not reflecting in the title of the study. **EC Comment:** • Response from Principal-Investigator is not received, therefore decision is pending. ***Ref. code: 109th ECM IIA/P2***
3-	Clarification of research proposal entitled **"*Operative management of early gallbladder cancer (OMEGA)-an analysis of management and outcomes in gallbladder cancer surgery*"** submitted by Prof. Abhinav Arun Sonkar, Head, Department of General Surgery, King George's Medical University U.P., Lucknow vide letter no.1556/21 dated 25th August, 2021. **Previous EC Comment:** • The proposed study seems to be interesting and important. • It consists of prospective as well as retrospective study design. • The outcome variables for both the designs should be identified separately. They have mentioned these to be in Appendix I, but this is missing. • It would be helpful if research hypotheses for both parts should be stated clearly in terms of the terms of variables and associated parameters. It would be required for sample size calculations also. • The Sample size is mentioned to be 2500. How this figure is achieved? • Unless proper hypotheses are defined, the appropriate statistical analysis can not be performed. • Several study centers shall be involved, so multi-centric considerations have to be taken into accountant every stage including statistical analysis. The analysis procedures shall be different for retrospective and prospective designs.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The statistical analysis section should be rewritten in view of above comments. • The patient information sheet is not attached. • Who will be funding the study? • Give a list of collaborators from Institute uptil date. • Kindly follow National guidelines for date sharing. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 109th ECM IIA/P3***
4-	Clarification of research proposal entitled ***"Feasibility of truenat assay in detecting mycobacterium tuberculosis in stool, gastric aspirate and extrapulmonary samples"*** sponsored by ICMR, New Delhi submitted by Dr. Parul Jain, Assistant Professor, Department of Microbiology, King George's Medical University U.P., Lucknow vide letter no.896/21 dated 18th September, 2021. **Previous EC Comment:** • Budget- Rs 31,45,800 (Breakup –not mentioned)-From ICMR-New Delhi • Patient information sheet-submitted only English version (Hindi version missing) • Study design mentioned as Experimental? what type of experimental-details not mentioned • ICF- ICF-English attached but Guardian and Assent form missing-ICF-Hindi-Incomplete. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** • Assent form-ICF (for children above 8 years) still not attached separately. **Action taken:** As above **EC Decision:** Approved ***Ref. code: 109th ECM IIA/P5***
5-	Clarification of research proposal entitled ***"Covid associated Mucormycosis in India, a case control investigation at the Department of Microbiology, KGMU, Lucknow"***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

submitted by Prof. Prashant Gupta, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter dated 10th September, 2021.

The above proposal forwarded to Primary reviewers, for review

Previous EC Comment:

- The study is recruiting 4 times control subjects as compared to cases. Since there is a decline of covid positive cases it may be difficult to get required number of controls. Therefore, a modification in the criterion for control subjects can be considered

Previous EC Decision: Approved

The above comment forwarded to the P.I., Reply given by P.I. vide letter dated 10th September, 2021:

Response of the PI:

- Controls would be recruited retrospectively from the Department of Medicine.

EC Decision: Approved

Ref.Code 110th ECM IB/P1

Clarification of research proposal entitled ***"Assessment of the 4 month moxifloxacin containing daily regimen in the treatment of microbiologically confirmed new pulmonary tuberculosis patients"*** submitted by Prof. Rajiv Garg, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2045/21 dated 24th August, 2021.

Previous EC Comment:

- In cover letter, the P.I. has ticked it is multinational, kindly correct it.

Previous EC Decision: Approved

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer: Approved

EC Decision: Approved

Ref.Code 110th ECM IB/P4

Clarification of research proposal entitled ***"Correlation of last rectal effluent color and quality of bowel preparation: A prospective, cross-sectional, observational study"*** submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1775/MED/2021 dated

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	1st September, 2021. **Previous EC Comment:** • It is prospective, cross-sectional, observational study. Controls are not described and exclusion criteria also not mentioned for subjects. In data collection it is mentioned that contact details of subjects were recorded, it seems as if the study has already been conducted. It needs to be corrected. **Recommendation of Primary reviewer:** Pending **EC Comment:** Recruitment to be done after date of approval. **EC Decision:** Approved ***Ref. code: 110th ECM IIA/P4***
8.	Clarification of research proposal entitled "***A study to assess the compulsive buying behavior and its association with emotional distress, depression and impulsiveness among general population***" submitted by Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1446/X-51/2021 dated 25th August, 2021. **Previous EC Comment:** • Role of PI and Co-PIs are the same. Please edit. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **Action taken:** Provisionally approved **EC Decision:** Approval ratified ***Ref. code: 110th ECM IIA/P7***
9.	Clarification of research proposal entitled "***A cross-sectional study of Mental Health of Women in North India***" sponsored by National Commission for Women; Government of India. submitted by Prof. Vivek Agarwal, Head, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.1239/Psy/2021 dated 28th August, 2021.

(Shully Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comment:

- Scientific review Committee has only three members.
- There are five (5) Co-PI Role of PI are the same as in the proforma. Please justify.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer:

- The Research proposal still has five Co-PIs, Two from the Department of Community Medicine and three from the Department of Psychiatry. Their roles as mentioned in the attached document are also overlapping. It is strongly suggested to decrease the number of Co-PIs or mention their UNIQUE roles in the study. **Need modification**

Action taken: As above

EC Decision: Response from P.I. is not received, therefore decision is pending.

Ref. code: 110th ECM IIA/P8

10. Clarification of research proposal entitled **"*Cutaneous manifestations of mucormycosis during the current severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) pandemic: A retrospective study*"** submitted by Prof. Swastika Suvirya, Principal Investigator, Head, Department of Dermatology, Venereology and Leprosy, King George's Medical University, U.P., Lucknow vide letter no.167/SKIN/2021 dated 26th August, 2021.

Previous EC Comment:

- This is a retrospective study based on mucormycosis in Covid patients. One of the primary objectives of the study is to identify and classification of cutaneous mucormycosis for early diagnosis and management. But it is not explained how a retrospective study can fulfill this objective.
- Study settings are not well defined like subjects will be recruited from outdoor services or indoor services?
- For inclusion criteria- It has mentioned in the proposal that the established diagnosis of the mucormycosis will be included in the study. But which method will be considered for establishing diagnosis eg. mucrobiologically proven

(Shully Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	mucormycosis or radiologically suspected or both is not clearly mentioned in the proposal. Moreover, the status of RT PCR is also not mentioned- whether it is during active infection or during post covid period. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **Action taken:** Provisionally approved **EC Decision:** Approval ratified ***Ref. code: 110th ECM IIA/P15***
11.	Clarification of research Protocol no.PreQuest-01 entitled ***"Prospective, multi-centric, single arm post marketing surveillance of PRISTINE, everolimus eluting cobalt chromium coronary stent system to assess its continued safety and efficacy"*** sponsored by Relisys Medicine Devices Ltd. submitted by Prof. Pravesh Vishwakarma, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1778/Cardio/Res/2021 dated 1st September 2021. **Previous EC Comment:** • Sample size not given in protocol separately and not calculated • Synopsis summary not given As above ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **Action taken:** Provisionally approved **EC Decision:** Defer for the next Meeting because quorum is incomplete. ***Ref. code: 110th ECMIIC/P1***
12.	Clarification of the modification of Research protocol no. ATLAS-A/B entitled ***"A phase 3 study to evaluate the efficacy and safety of fitusiran in patients with hemophilia A or B, without inhibitory antibodies to factor VIII or IX"*** sponsored by M/s Bajaj Allianz Generali Insurance Co Ltd. Ltd. submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology, King George's Medical University U.P., Lucknow vide letter no.693/CH/21 dated 25th August, 2021.

(Shully Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comment:

- Is the study continuing?
- In what doses is the drug being given?
- Kindly provide updated information from KGMU site

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer: As I understand the study is complete and closes on 31st August, 2021. That's ok.

Action taken: Provisionally approved

EC Decision: Defer for the next Meeting because quorum is incomplete.

Ref.code:90th ECMIIC/P2

13. Clarification of modification of research proposal entitled ***"Digoxin in patients with rheumatic heart disease- a randomized placebo controlled trial"*** submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.1774/Cardi/Res/21 dated 1st September, 2021.

Previous EC Comment:

- This project was already approved in 2020 and is now re-submitted with some additions/Clarifications of some procedural details regarding the systems for web-based randomization, data entry, study drug management, SAE reporting and overall trial management. In addition this version has already been approved by AIIMS IEC.
- The rationale of this study is to measure in relatively younger RHD patients, the role (including mortality) of inexpensive digoxin that otherwise is known for its mortality in older patients non-valvular AF.
- The % of SAE for interim analysis to stop trial has been decided as 50% primary outcomes i.e. 180 deaths.
- Since compensation will be included for a mishap, such point should be mentioned in informed consent document as well

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer: Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Action taken: Provisionally approved **EC Decision:** Approval ratified ***Ref.code:102nd ECMIIA/P24***
IIA	**New Proposal**
1.	Research proposal entitled ***"Impact of institutional refresher course on clinical skills for nurses on knowledge among staff nurses working in Government sector"*** submitted by Mrs. Rashmi P John, Principal Investigator, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1215/X.51/2021 dated 16th July, 2021. **EC Comment:** • As the title says the objective of the proposal says appears to assess the impact of institutional refresher course on clinical skills for nurses on knowledge among staff nurses working in Government sector. However, at the end of background it is written, ' the researcher planned to assess and endeavors to provide a platform for the nurses of GM & AH to refresh and upgrade their knowledge and skills with the aim to improve patient care'. This is entirely different than the one mentioned in the title. • There is no information about the 'Institutional refresher course'. As the covid is here for last more than one and half year many courses might have already been done. • The information sheet for the participants mentions 'patients' while the participants are not patients. • The information provided for answers like 'Why I have been chosen' etc. is very poorly written. • Such types of recourse and post course evaluations are good to study the impact of the training courses and improve the course. But the post course evaluation need to have good questions which will really evaluate the change. The some questions in the evaluation are too preliminary and include body temp of the human beings, respiratory rate, O2 flow rate for nasal canula. These are the basic things any nursing staff [or even nursing student] need to know. Unless the questionnaire is designed to assess higher level of clinical skills / knowledge and need to be based on the course content; there will not be assessment of the impact of the refresher course. • Though the title says government hospitals, the study is to include KGMU

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	nursing staff only. • Due to the lacunae in the questionnaire and study design, the information pamphlet, the proposal is not recommended. • The Hindi translation of the title is also clumsy. • Type of Study-give study design • There is a conflict of interest is there as PI is Principal of Nursing staff • There should be participant information sheet/nor patient information sheet. • Clarify Why the participant has to be chosen. • Hindi translation in appropriate. • There is a dissociate between title and objective. • Post test questionnaire has to be validated for content & construct. **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM IIA/P1***
2.	Research proposal entitled ***"Maternal near miss review (MNM-R) and corrective measures at selected tertiary level Hospitals in India"*** sponsored by ICMR, New Delhi submitted by Prof. Uma Singh, Head, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no.197/HRRC/2021 dated 15th July, 2021. **EC Decision:** Approved ***Dr. Shally Awasthi did not take part in the discussion & making decision.*** ***Ref. code: 111th ECM IIA/P2***
3.	Research proposal entitled ***"Risk for disease severity of COVID-19 infection among pregnant women and their neonates during and beyond neonatal period: A prospective cohort study"*** sponsored by ICMR submitted by Prof. Uma Singh, Head, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no.198/HRRC/2021 dated 15th July, 2021. **EC Decision:** Approved ***Dr. Shally Awasthi did not take part in the discussion & making decision.*** ***Ref. code: 111th ECM IIA/P3***
4.	Research proposal entitled ***"Impact of COVID 19 pandemic on paediatric musculoskeletal trauma patients admitted in a tertiary care centre"*** submitted by Dr. Vikas Verma, Associate Professor, Department of Paediatric Orthopaedic, King George's Medical University, U.P., Lucknow vide letter no.993/Paed.Ortho/2021 dated 17th July, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: • Subject selection: Vulnerable subjects not checked • Privacy and confidentiality: Not checked • Does a consent form need to be filled? • Study design: It is not a cohort study? • Random selection: Needs to be elaborated **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM IIA/P4***
5.	Research proposal entitled "***Establishing relationship of depression asserssments with behavioral markers from digital phenotyping in Indian context***" submitted by Prof. Vivek Agarwal, Head, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.1083/Psy/2021 dated 27th July, 2021. **Recommendation of Primary reviewer:** • Risks and benefit: If risk is not reasonable, why do the study? • How will random allocation take place? • What is the need for randomization? • Why 100 patients? • No statistical plan • Data sharing/protocol • Privacy protocol **EC Comment:** • What is the privacy protocol of the application what is the privacy patient data is not shared with third party. **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM IIA/P5***
6.	Research proposal entitled "***Estimation of hearing deficits following critical illness in patients discharged from intensive care unit***" submitted by Dr. Sai Saran, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.219/2021 dated 27th July, 2021. **EC Comment:** • There is a serious risk of overestimation of hearing deficits in this study as small deficits may not be reported/observed/record in people outside hospital who have

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	take care of this? • Statistical analysis: Univariate and multivariable analysis should be included to identify risk factors. **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM IIA/P6***
7.	Research proposal entitled "***Study of adverse effect profile of healthcare professionals vaccinated against COVID-19 at a tertiary care center in Northern India***" submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1611/MED/2021 dated 31st July, 2021. **EC Decision:** Approved ***Ref. code: 111th ECM IIA/P7***
8.	Research proposal entitled "***Detection of biofilm forming microbes having effect on gastrointestinal tract (GIT) infections and their control using plant extract***" submitted by Prof. Prasant Gupta, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.624/2021 dated 2nd August, 2021. **EC Comment:** • Kindly provide CTRI registration, New Medical devices, Insurance. • In the proposal the methods for sample collections are mentioned as stool, rectal swab and gastric biopsy of the patients suffering from diarrhea suggestive of gastrointestinal infections. Included population contains children and elderly too. Will gastric biopsy be done solely for the study or there will be some clinical indication for gastric biopsy and samples will be taken simultaneously? **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM IIA/P8***
9.	Research proposal entitled "***A study to evaluate the clinical efficacy of indigenously designed and manufactured titanium dental implant system with hybrid threads and anti-rotational features***" submitted by Prof. Balendra Pratap Singh, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.468/2021 dated 5th August, 2021. **EC Comment:** • In the proposal, study design is given as parallel or split mouth design, case studies for initial testing of new technology followed by RCT with proper randomization, allocation concealment and follow up. There is no mention about

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	an implant which will be considered as standard or gold standard for comparison. **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM IIA/P9***
10.	Research proposal entitled "***Magnetic resonance imaging in rhino-orbital-cerebral mucormycosis- an imaging experience from tertiary care center in North India***" submitted by Dr. Amit Kumar Verma, Assistant Professor, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no.1235/RD/2021 dated 11th August, 2021. **EC Comment:** • Consent form is not up to mark, Hindi & English are not similar. • This is a retrospective study-needs clarification as how does ICD fit into this picture. On one hand investigators indicate that ICD 'was obtained' while on the other hand they state that "the patients will be informed about the risks of the contrast agent": Please clarify. • On one hand the investigators intend to follow the patients clinically but no account of clinical data collection is mentioned. How will it be possible to follow up the patients in a retrospective study-will retrospective clinical data be also collected? Please clarify. • It would be further nice if the review of literature focuses more upon the known MRI findings in ROCM and the data collection to mention more about anticipated MRI features along with their assessment. **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM IIA/P10***
11.	Research proposal entitled "***Baseline data generation of time period from admission to discharge, of the admitted patients of oral and maxillofacial surgery as one of the quality indicators for quality control purposes: An observational study***" submitted by Dr. Arunesh Kumar Tiwari, Associate Professor, Department of Oral and Maxillofacial Surgery, King George's Medical University, U.P., Lucknow vide letter no.392/OMFS/2021 dated 8th July, 2021. **EC Comment:** • The methodology states that a set-proforma will be given to the patient to fill in the details further supplemented by the doctor on duty in case if any confusion. • a) Kindly enclose that set-proforma

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• If the patient is supposed fill in the proforma primarily then-Many aspects such as retrieval of reports, familiarity of referencing system may not be possible for a less educated patient to understand and hence it may produce a bias. So the data collection is to be done primarily by the doctor supplemented by the patient's inputs and not visa versa under such circumstances. This needs clarification. **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM IIA/P11***
12.	Research proposal entitled ***"Assessment of impact of different factors as a risk for mucormycosis pathogenesis in COVID times: A case series analysis"*** submitted by Dr. Shefali Gautam, Associate Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/683/2021 dated 5th August, 2021. **Primary reviewer recommendation:** • Incomplete Performa. • Methodology details not provided • Sample size calculations not given • It is not clear if the study will be performed on patients or just medical records/data will be retrieved and analyzed. **EC Comment:** As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM IIA/P12***
13.	Research proposal entitled ***"The incidence of plate removal in maxillofacial trauma patients: A retrospective study"*** submitted by Dr. Arunesh Kumar Tiwari, Associate Professor, Department of Oral and Maxillofacial Surgery, King George's Medical University, U.P., Lucknow vide letter no.394/OMF/2021 dated 8th July, 2021. **Primary reviewer recommendation:** • Is this a project or a paper? • Materials & Methods/Results/Discussion/Conclusions are given. • No details provided about the study. • Materials and methods section is sketchy. **EC Comment:** As above **EC Decision:** Modify and re-submit (Tracking changes in word format)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 111th ECM IIA/P13
14.	Research proposal entitled **"*Missed injury associated with maxillofacial trauma: An observational study*"** submitted by Dr. Arunesh Kumar Tiwari, Associate Professor, Department of Oral and Maxillofacial Surgery, King George's Medical University, U.P., Lucknow vide letter no.393/OMF/2021 dated 8th July, 2021. **Primary reviewer recommendation:** • The protocol appears to be a part of manuscript prepared for publication. Kindly resend the proposal in proper format. • Apply as fresh proposal for waiver **EC Comment:** As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM IIA/P14***
15.	Research proposal entitled **"*Registry of STEMI management in COVID era-India (PRESCO-India)*"** submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.1697/Cardi/Res/2021 dated 24th July, 2021. **Primary reviewer recommendation:** Approved **EC Decision:** Approved ***Ref. code: 111th ECM IIA/P15***
16.	Research proposal entitled **"*Surgical outcome of acetabulum fracture with kocher-langenback approach: A retrospective study*"** submitted by Dr. Dharmendra Kumar, Associate Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no.1006/OS/2021 dated 27th August, 2021. **Primary reviewer recommendation:** • Provide outcome variables. Hindi and English version of ICF are different. **EC Comment:** As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM IIA/P16***
IIB	**New Ph.D Scholar**
1.	Research proposal entitled **"*Genetic screening of susceptible loci for type 2 diabetes and gestational diabetes in the North Indian population identified in "Genome-wide***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	association" study*"** sponsored by Council of Science & Technology U.P submitted by Ms. Zoya Shakir, Ph.D Scholar 2019, under the guidance Dr. Wahid Ali, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.3048/21 dated 11th August, 2021. **Recommendation of Primary reviewer:** • Risks have been mentioned as unreasonable in the IEC form • Pregnant women are vulnerable subjects. This has not been mentioned in the IEC form. • Where will the subjects for the control arm are recruited from? If they will be recruited from students/staff, this will have to be mentioned under special groups. **EC Comment:** As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM II B-Ph.D/P1
2.	Research proposal entitled ***"A study to assess the impact of "Group motivational enhancement therapy" on clinical outcome and quality of life among patients with opioid dependence undergoing maintenance treatment"*** submitted by Mrs. Sudha Mishra, Ph.D Scholar, under the guidance Prof. Vivek Agrawal, Head, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.1394/21 dated 17th August, 2021. **Recommendation of Primary reviewer:** • It is unclear if the patients being recruited are in-patients or OPD patients • IEC form mentions No vulnerable participants, but in the details 'Any other' has been ticked. Please clarify. • IEC form mentions that study will include 'institutionalized' subjects. Are these In-patients? Or OPD patients? • Number of Co-PIs is untenable. Please reduce the number of Co-PIs from the same department as their roles are overlapping. **EC Comment:** As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM II B-Ph.D/P2***
3.	Research proposal entitled ***"Effect of yogic intervention on inflammatory cytokines and***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	oxidative stress level in the breast cancer patients" submitted by Mr. Mayank Jain, Ph.D Scholar, under the guidance Prof. Shailendra Kumar, Head, Department of Thoracic Surgery, King George's Medical University, U.P., Lucknow vide letter no.72/TH/21 dated 24th August, 2021. **Recommendation of Primary reviewer:** • No yoga expert is part of the study. • Co-PIs from Departments of Thoracic surgery and Vascular surgery have no locus standi to be part of a study involving either Yoga or Breast cancer since neither is their domain, hence their involvements is highly questionable. • No Medical Oncologist/Surgical Oncologist/Radiation Oncologist/Biochemistry faculty/Immunology faculty has been included in a study which aims to assess Oxidative stress by means of serum levels of ROS/NOS/SOD. **EC Comment:** • Elaborate the natural of the study. • Define clinical end points • In what stage of management of breast cancer yoga will be introduced. • Study cannot be approved as presented. **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 111th ECM II B-Ph.D/P3***
IIB	**Young Scientist**
1.	Research proposal entitled ***"Circulating miRNAs as predictive biomarkers of coronary heart disease development in type 2 diabetes mellitus patients"*** sponsored by MHFW, New Delhi submitted by Mr. Mohd Wamique, under the guidance Dr. D.Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1493/MED/21 dated 15th July, 2021. **Recommendation of Primary reviewer:** • Risk is marked as not reasonable in the IEC form • Study is recruiting subject with CAD from Cardiology OPD, yet no Co-PI has been added from Cardiology. It would be prudent to have a Co-PI from Cardiology for the study. **EC Comment:** As above **EC Decision:** Modify and re-submit (Tracking changes in word format)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 111th ECM II B-YS/P1
IIC	**Review of New Drug Trial**
1.	Research Protocol no.209682 entitled ***"A phase 4, open-label, single arm, 24-week, phase 4 study to evaluate the safety and efficacy of mepolizumab 100 mg SC administered every 4 weeks in Indian participants aged≥18 years with severe eosinophilic asthma requiring oral corticosteroid treatment to maintain asthma control (PRISM)"*** sponsored by Glaxo Smith Kline Pharmaceuticals Ltd. submitted by Dr. Ajay Kumar Verma, Professor Junior Grade, Department of Respiratory Medicine King George's Medical University, U.P., Lucknow, vide letter no. 1929/2021 dated 16th July, 2021. **Primary reviewer recommendation:** Approved **EC Comment:** • Insurance has to be reviewed. Blood samples cannot be send from out of Country without approval of competent authority (that is ICMR). **EC Decision:** Defer for the next Meeting because quorum is incomplete. ***Ref. code: 111th ECMIIC/P1***
2.	Research Protocol no.5030801/GOPI Study entitled ***"Prospective, non-interventional, multi-centre, post marketing surveillance study to evaluate the safety and tolerability of gaviscon oral suspension for the management of symptoms of gastroesophageal reflux disease"*** sponsored by Reckitt United Kingdom submitted by Dr. Ajay Kumar Patwa, Department of Medicine, King George's Medical University, U.P., Lucknow, vide letter no. MED/135/2021 dated 4th August, 2021. **Primary reviewer recommendation:** Approved **EC Decision:** Defer for the next Meeting because quorum is incomplete. ***Ref. code: 111th ECMIIC/P2***
III	**Modification**
1.	Modification of Research protocol no.GS-US-419-3895 entitled ***"Combined Phase 3, double-blind, randomized, placebo-controlled studies evaluating the efficacy and safety of filgotinib in the Induction and maintenance of remission in subjects with moderately to severely active crohn's disease"*** M/s Klinera corporation submitted by Dr. Ajay Kumar, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.MED/CT/147/2021 dated 15th August, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Primary reviewer recommendation: Approved **EC Decision:** Defer for the next Meeting because quorum is incomplete. ***Ref.code:89th ECMIIC/P14a***
2.	Modification of Research protocol no.GS-US-419-3896 entitled ***"A long-term extension study to evaluate the safety of Filgotinib in subjects with Crhon's disease"*** M/s Klinera corporation submitted by Dr. Ajay Kumar, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.MED/CT/146/2021 dated 18th August, 2021. **Primary reviewer recommendation:** Approved **EC Decision:** Defer for the next Meeting because quorum is incomplete. ***Ref.code:89th ECMIIC/P14b***
.3.	Modification of Research proposal entitled ***"Multi-centric prospective cohort study of TB recurrence free cure among microbiologically confirmed new pulmonary tuberculosis patients treated under NTEP with 4 month moxifloxacin containing regimen"*** instead of ***"Assessment of effectiveness of the 4 month moxifloxacin containing daily regimen in the treatment of microbiologically confirmed new pulmonary tuberculosis patients"*** submitted by Prof. Rajiv Garg, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2150 dated 16th September, 2021. **EC Decision:** Approved. ***Ref. code 110th ECM IB/P4***
IV	**Brought to Ethics Committee after V-PGTSC held on 4th September, 2021**
.	Minutes of V-PG Thesis sub Committee" of "Institutional Ethics Committee" Meeting ***virtually*** held on 4th September, 2021 from 11.30 AM. ***The following PGTSC Members were present in its Meeting:*** 1. Prof. G.G.Agarwal -Member 2. Prof. A.A. Mahdi -Member 3. Dr. D.N. Upadhyaya -Member 4. Prof. Shally Awasthi -Convener ***The following PGTSC Members were not present in its Meeting:*** 1. Prof. Anita Rani -Member

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	2. Prof. Rajendra Nath -Member
IA	**Action taken**
1-	Clarification of research proposal entitled ***"Role of respiratory biofeedback in improving pulmonary function and quality of life in stable C.O.P.D. patients: A randomized controlled trial"*** submitted by Dr. Mohd. Rashid, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 896/2021 dated 27th July, 2021. **Previous PGTSC Comment:** • If it is a trial then CTRI registration will be needed. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Pending **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P2***
3.	Clarification of research proposal entitled ***"To study the profile of empyema thorasis at a tertiary care center"*** submitted by Dr. Amit Kumar, JR, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1945/21 dated 26th July, 2021. **Previous PGTSC Comment:** • Sample size calculation is not clear. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Member-Secretary, IEC.*** **Recommendation of Primary reviewer:** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: 107th ECM II B-Thesis/P52***
4.	Clarification of research proposal entitled ***"Mindfulness, experiential avoidance, attachment and neurocognition in obsessive compulsive disorder"*** submitted by Ms. Divya Kansal, II Year under the guidance Dr. Shweta Singh, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1232/Psy/21 dated 26th August, 2021. **Previous PGTSC Comment:** • Specify from where the controls will be selected? ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Primary reviewer. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: 107th ECM IIB M. Phil/P1***
5.	Clarification of research proposal entitled ***"Acceptance and commitment therapy as Psychosocial supportive care in patients with Head and Neck Cancer"*** submitted by Ms. Pooja Varshney, II Year under the guidance Dr. Pooja Mahour, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1231/Psy/21 dated 26th August, 2021. **Previous PGTSC Comment:** • Remove patient identifiers from case record form. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: 107th ECM IIB M. Phil/P4***
6.	Clarification of research proposal entitled ***"A study of psychosocial correlates of infertility in women at a tertiary care Hospital"*** submitted by Ms. Ginni Sharma, II Year under the guidance Dr. Pooja Mahour, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1229/Psy/21 dated 26th August, 2021. **Previous PGTSC Comment:** • Remove patient identifiers from case record form ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: 107th ECM IIB M. Phil/P5***
7.	Clarification of research proposal entitled ***"A study of Character strengths, psychological well-being, anger rumination and self-harm in BPD patients"*** submitted by Ms. Shruti Yadav, II Year under the guidance Dr. Pooja Mahour, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1230/Psy/21 dated 26th August, 2021. **Previous PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Remove patient identifiers from case record form ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: 107th ECM IIB M. Phil/P6***
8.	Clarification of research proposal entitled ***"To study genital tract infections with special focus on Chlamydia trachomatis and neisseria gonorrhoeae in women attending infertility clinic at tertiary care center, Lucknow"*** submitted by Dr. Diksha Shukla, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 683/2021 dated 12th August, 2021. **Previous PGTSC Comment:** • Objectives are not properly defined so as to generate proper "Statistical Hypotheses". Statistical considerations are not mentioned. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: II-PGTSC-IIA /P3***
9.	Clarification of research proposal entitled ***"Microbial profiling and IgA/IgG Anti-SARS-CoV-2 in donor human milk: A pilot study at a regional milk bank"*** submitted by Dr. Astha Yadav, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 672/21 dated 10th August, 2021. **Previous PGTSC Comment:** • Objectives are not well-defined so as to generate proper "Statistical Hypotheses". Sample size is not shown. The methodology is incomplete. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: II-PGTSC-IIA /P4***
10.	Clarification of research proposal entitled ***"A hospital based observational study on HIV-TB coinfection"*** submitted by Dr. Akansha Soni, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 714/21

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	dated 19th August, 2021. **Previous PGTSC Comment:** • Objectives not defined • Methodology section incomplete • Sample size calculation is not shown. Statistical considerations are to be mentioned. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: II-PGTSC-IIA /P21***
11.	Clarification of research proposal entitled ***"Study on association of inflammatory and oxidative stress paradox during plaque vulnerability across the spectrum of acute coronary syndrome: A prospective case control study"*** submitted by Dr. Ram Kumar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 2127/21 dated 28th July, 2021. **Previous PGTSC Comment:** • The title is inappropriate. The case control study is retrospective, not prospective. Research hypothesis is not defined (involving parameter, variable, outcome measure etc.) Sample size calculations are not done. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P3***
12.	Clarification of research proposal entitled ***"Association of central obesity with cardiac autonomic parameters"*** submitted by Dr. Arun Kumar Yadav, JRI, Department of Physiology,King George's Medical University, U.P., Lucknow vide letter no. 2553/PHY/21 dated 26th July, 2021. **Previous PGTSC Comment:** • Get new Guide & Co-guide allotted • Give definition of controls and their inclusion and exclusion and exclusion criteria.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer. **Recommendation of Primary reviewer:** Pending **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P19***
13.	Clarification of research proposal entitled ***"Impact of smart phone technology on outcome of management in congenital nasolacrimal duct obstruction (CNLDO)"*** submitted by Dr. Shaurya Verma, SR, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 474/OPH/21 dated 3rd August, 2021. **Previous PGTSC Comment:** • Kindly provide primary and secondary objectives of the study. Provide sample size with justification. Provide outcome parameters. Instead of allocating subjects for a year as control and next year with video guidance….alternate allocation will make the efforts more reliable. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** As above ***Ref. code: III PGTSC-IIA/P13***
14.	Clarification of research proposal entitled ***"Survival outcomes of patients with early oral squamous cell carcinoma (pT1-T2pN0) undergoing a curative-intent surgery"*** submitted by Dr. Mamidipalli S Siddhartha, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/428/21 dated 29th May, 2021. **Previous PGTSC Comment:** • Study design mentioned a Retrospective, descriptive case series study, but mentioned that Patients will be followed up for 18 months and ICF is submitted, the study design should be modified. • Sample size calculation has not done. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P25***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

15.	Clarification of research proposal entitled ***"Clinical outcomes of interval cytoreduction in patients with stage III epithelial ovarian cancer-A tertiary care centre experience"*** submitted by Dr. Rohit Kashyap, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/604/21 dated 7th August, 2021. **Previous PGTSC Comment:** • Sample size no. 60 (Treatment naïve Stage III epithelial ovaria cancer patients underwent interval cytoreduction surgery during the period Jan, 2015-2020 and will be followed up for 2 years) Not calculated. • Study design mentioned as Retrospective case series study, but Principal-Investigator mentioned that patients will be followed up for 2 years or till death whichever is earlier and ICF is submitted, So the study design should be modified. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P26***
16.	Clarification of research proposal entitled ***"To assess the nutritional status and determinants of underweight among pediatric tuberculosis patients"*** submitted by Dr. Ashvini Rana, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1829/Ped/21 dated 26th July, 2021. **Previous PGTSC Comment:** • Study design:- • Principal-Investigator mentioned study design as Prospective observational study, but in setting part of summary he has mentioned it as Randomized prospective double blind clinical trial. This is making confusion. Actually the study design is Prospective Observational case control study. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P30***
17.	Clarification of research proposal entitled ***"Effect of non-surgical periodontal therapy on salivary and gingival crevicular fluid concentration of visfatin in periodontal***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	health and disease" submitted by Dr. Hira Ismail, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1926/P/21 dated 19th August, 2021. **Previous PGTSC Comment:** • According to the PI role of Visfatin as an inflammatory marker in periodontal disease is already established. What is the need for this study? • Proforma says the study I NOT a clinical trial. However, the PI says the study will be registered with clinical trial Registry of India. This is conflicting. • Role of everyone participating in the study needs to be defined. Is it a trial? Research question needs to be defined. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P34***
18.	Clarification of research proposal entitled ***"Evaluation of periodontal health status in patients with lung cancer in north Indian population: A case-control study"*** submitted by Dr. Pooja Singh, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1899/P/21 dated 12th August, 2021. **Previous PGTSC Comment:** • Periodontontal health and HBD-2 have already been linked to cancers in previous studies. Please argue the need for another study on the same subject. • Besides the PI there are seven Co-PI. Please define the role of every Co-PI. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P37***
19.	Clarification of research proposal entitled ***"Effect of antioxidant therapy in periodontal disease: A clinical study"*** submitted by Dr. Sakeena Tariq, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1870/P/21 dated 31st July, 2021. **Previous PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Role of antioxidants in reducing oxidative damage in periodontal disease has already been established. What new aspect do the investigators want to research? ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P38***
20.	Clarification of research proposal entitled ***"Incidence, etiological profile and outcome of ventilator associated pneumonia (VAP) in pediatric intensive care unit (PICU)"*** submitted by Dr. Naresh Kumar, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1931/Ped/2021 dated 4th August, 2021. **Previous PGTSC Comment:** • The study is prospective. Observational However, the PI has filled the Risk and benefit section in the proforma. In and non-interventional study there is no risk for the patient except form the disease. • The 'Background and review of Literature' mentions KGMU as a Central Government hospital, which it is not. This should be corrected. **Previous PGTSC Decision:** Approved ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P40***
21.	Clarification of research proposal entitled ***"Analysis of efficacy of elastography in comparison to dynamic renal nuclear scintigraphy in diagnosis of unilateral pelvi-ureteric junction obstruction"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Nirpex Tyagi, SRII, through his Mentor Prof. Anand Pandey, Associate Professor, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 272/2021/Ped Surg dated 29th July, 2021. **Previous PGTSC Comment:** • Age of PIs included to be given? • Complications of Radionuclide to be described ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: Approved **PGTSC Decision:** Approved ***Ref. code: IIIPGTSC-II B IMR-R/P1***
22.	Clarification of research proposal entitled "***A randomized clinical trial on comparative evaluation of intranasal combinations of midazolam-ketamine, dexmedetomidine ketamine, midazolam-fentanyl and dexmedetomidine-fentanyl for procedural sedation and analgesiain paediatric dental patients***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Agarwal Abhilasha Kishanlal, JRII, through her Mentor Prof. Rakesh Kumar Chak, Head, Department of Paediatric and Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 591/21 dated 29th July, 2021. **Previous PGTSC Comment:** • The PI mentions that the risk is not reasonable compared to anticipated benefits. Please correct this is it is a mistake in the proforma. • Privacy & Confidentiality is not mentioned in the proforma. • The PI mentions that there is risk to the patient, but there are no plans for reporting of adverse events or provisions of compensation. This is probably a mistake in filling the proforma. Please have it checked and edited. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Member-Secretary, IEC.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IIIPGTSC-II B IMR-R/P3***
23.	Clarification of research proposal entitled ***"Non-invasive predictors of oesophageal varices in liver cirrhosis"*** submitted by Dr. R. Sushma Swaraj, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2612/PHY/21 dated 24th August, 2021. **Previous PGTSC Comment:** • Kindly provide in ICF clear, understandable description of study procedure in simple language instead of writing study design. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: IV PGTSC-IIA/P11
24.	Clarification of research proposal entitled ***"Association of stress and primary Hypothyroidism"*** submitted by Dr. Monika Singh, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2601/PHY/21 dated 17th August, 2021. **Previous PGTSC Comment:** • Kindly provide clear criteria for enrolling control subjects and the setting from where these controls will be selected. • Kindly provide in ICF clear, understandable description of study procedure in simple language instead of writing study design ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P18***
25.	Clarification of research proposal entitled ***"Effect of disturbed circadian rhythm on autono.mic function in young healthy adults"*** submitted by Dr. Aparna Yadav, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2615/PHY/21 dated 26th August, 2021. **Previous PGTSC Comment:** • Kindly provide clear criteria for enrolling control subjects and the setting from where these controls will be selected. • Define clearly, the k parameters for selecting healthy controls. • Kindly provide clear criteria for enrolling control subjects and the setting from where these controls will be selected. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P20***
26.	Clarification of research proposal entitled ***"Assessment of efficacy of coagulation factors in fresh frozen plasma prepared at different time intervals"*** submitted by Dr. Shubhi Yadav, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 305/21 dated 18th August, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous PGTSC Comment: • Incomplete performa, neither methodology, nor sample size mentioned. No reference/bibliography. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P21***
27.	Clarification of research proposal entitled ***"Immunohistochemical expression of IDH1, ATRX and P53 in gliomas and their correlation with clinicopathological parameters"*** submitted by Dr. Shipra Singh, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 3098/21 dated 26th August, 2021. **Previous PGTSC Comment:** • Calculation of sample size to be mentioned as it is not clear as to why 80 subjects will be recruited. Complications/risks associated with the study need to be mentioned in the consent forms. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: IV PGTSC-IIA/P29***
28.	Clarification of research proposal entitled ***"Histopathological study of liver diseases in unclaimed and claimed dead bodies: A case-control study"*** submitted by Dr. Krishna Nishad, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 404/FMT/21 dated 31st July, 2021. **PGTSC Comment:** Consent forms need to be corrected as a legally acceptable representative will be giving the consent and it is mentioned in point no. 2 that "my participation", similarly in the Investigator's statement "subject" is the dead body so it may be deleted. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** • Consent form still not clear as samples for dead body are to be collected and the legal representation is giving furnish for that permission. It shall be specified.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approval subject to modification ***Ref. code: IV PGTSC-IIA/P30***
29.	Clarification of research proposal entitled ***"Morphology and anatomical relations of the spinal accessory nerves: A cadaveric and surgical neck dissection study"*** submitted by Dr. Surabhi Sachan, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 247/ANAT/21 dated 24th August, 2021. **Previous PGTSC Comment:** • The course, length, and relations of the SAN are well known. What is the need of this study? • Number of patients mentioned is 51 at one place and 60 at another place (20 cadavers and 40 patients) • Please argue the need for this study • Discrepancy in numbers within the proforma • The section on Consent is incompletely filled in the proforma • The Yes and No are both ticked in 'Confidential Handling of Data'. Direct Identifiers and Completely Anonymized are both ticked. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P31***
30.	Clarification of research proposal entitled ***"Genetic analysis of RB1 gene in retinoblastoma patients"*** submitted by Dr. Honey Zahra, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 246/ANAT/21 dated 24th August, 2021. **Previous PGTSC Comment:** • The study is being conducted in Pediatric patients with retinoblastoma. • How is this appropriate topic for a thesis work of an Anatomy postgraduate? • No anatomical study is being done. • Will encourage reconsidering the project. • Tissue samples are being sent out of the campus while a department of Biochemistry and a CFAR are present in the University. This will be difficult to overlook. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P32***
31.	Clarification of research proposal entitled ***"A comparative morphometric study of lumbosacral spine in normal subjects and patients of spondylolisthesis: A clinic-anatomical perspective using 64-SLICE multidetectoe computed tomography"*** submitted by Dr. Sumbul, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 248/ANAT/21 dated 24th August, 2021. **Previous PGTSC Comment:** • Is the Morphometry of the adult lumbo-sacral spine not known that this study is being undertaken? What new knowledge do the investigators propose to seek from the study? • How will volunteers for the control group be recruited? • Will the two groups be age and sex matched? The vertebral morphology will vary according to age/sex/racial characteristics and other confounding factors like growth disorders. • Sufficient work has already been done on this subject. Why another study? • Risk is not reasonable has been ticked. If this is true study cannot be approved. • Not specified. Please correct this in Voluntary, Non-coercive Recruitment of Participants. • The subject number will go up if the groups are age-sex matched. • Some conditions in the control group may act as confounding factors for eg. Osteopenia? • Informed consent doesn't have any mention of the risk of radiation that the volunteers will be exposed to. • Boxes not ticked. Please correct this in ICF • Direct identifiers, indirect identifiers, and Anonymized are all ticked. Please correct this in Privacy & Confidentiality. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P35***
32.	Clarification of research proposal entitled ***"Effect of surya-namaskar on anthropometric parameters and serotonin level in apparently healthy subjects"*** submitted by Dr. Ajaya Deep Singh, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.2514/PHY/21 dated 26th August, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous PGTSC Comment: • Does the study also intend to show changes in anthropometric dimensions during the period of study? No such relevant literature has been cited. Why has one particular 'Asana' been chosen? Will it not be better to have a more generic title like 'Effect of exercise/Yoga on Anthropometry and serotonin levels'? • The time period of measurement of serotonin levels is different in Aims and Objectives section from the Methodology section. • No data regarding affect of 'Surya Namaskar' on anthropometric changes has been cited. Will they say changes also occur with any other exercise, such as running, or aerobics? • Is risk reasonable has been answered with 'No'. • No mention has been made in the form. Please correct this in Involvement of Vulnerable Participants. • Volunteers have not been ticked in the form. • Contents not ticked in the form. Please correct this in ICF • How will they monitor adherence? ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P37***
33.	Clarification of research proposal entitled "***Application of Milan system for salivary gland cytology and diagnostic utility of PLAG-1 and SOX-10 immunocytochemistry markers in diagnosing salivary gland neoplasms and it's cyto-histological correlation for it's risk stratification***" sponsored by Research Cell, King George's Medical University, U.P., Lucknow submitted by Dr. Pooja Dwivedi, JRII through her Mentor Dr. Madhu Kumar, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 3097/21 dated 26th August, 2021. **Previous PGTSC Comment:** • Elaborate Methodology ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: IVPGTSC-II B IMR-R/P2
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"Effect of anthropometric factors on conduction parameters of peripheral nerve"*** submitted by Dr. Shivali Gupta, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2472/PHY/21 dated 16th June, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P1***
2.	Research proposal entitled ***"Association of hearing loss in children with cerebral palsy"*** submitted by Dr. Vinay Prakash Agarwal, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2482/PHY/21 dated 21st June, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P2***
3.	Research proposal entitled ***"A comparative study of outcome between COVID-19 positive and negative traumatic brain injury patient"*** submitted by Dr. Tripurari Pandey, JRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/1686/21 dated 5th January, 2021. **Primary reviewer recommendation:** • Outcome (Event) should be explicitly defined in terms of the proper study variables. Sample size calculations are missing. Statistical analysis is not prescribed. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: V PGTSC-IIA/P3***
4.	Research proposal entitled ***"Comparison of meld lactate and aarc score to predict mortality in acute on chronic liver failure patients"*** submitted by Dr. Khushboo Yadav, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1282/MED/21 dated 14th June, 2021. **Primary reviewer recommendation:** • Aim & Primary objective don't match. Since study design is not defined. Since

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	study design and study hypothesis is not properly defined, sample size calculations are not justified. Statistical analysis is not mentioned. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & Re-submit (Tracking changes in word format) ***Ref. code: V PGTSC-IIA/P4***
5.	Research proposal entitled ***"Long term outcome of operated head injury patients following decompressive craniectomy/craniotomy: A KGMU Experience"*** submitted by Dr. Nitish Kumar Singh, JRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/1675/21 dated 4th January, 2021. **Primary reviewer recommendation:** • Study design is not properly defined. Methodology, sample size calculation and statistical analysis description is missing. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: V PGTSC-IIA/P5***
6.	Research proposal entitled ***"Assessment of cortisol level and its correlation with outcome in traumatic brain injury patients"*** submitted by Dr. Alok Srivastav, JRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/1674/21 dated 4th January, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** As above ***Ref. code: V PGTSC-IIA/P6***
7.	Research proposal entitled ***"Relationship between abdominal girth, symphysio-fundal height and body mass index with incidence of hypotension in caesarean section under spinal anaesthesia"*** submitted by Dr. Pravesh Kumari, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/496/21 dated 21st June, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: V PGTSC-IIA/P7
8.	Research proposal entitled ***"Prevalence and Predictors of cognitive impairment among elderly population in rural areas of Lucknow"*** submitted by Dr. Pratyaksha Pandit, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no.276/CM/21 dated 25th June, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved
	Ref. code: V PGTSC-IIA/P8
9.	Research proposal entitled ***"Assessment of self care practices among type 2 diabetes mellitus patients undergoing treatment in secondary and tertiary care Hospitals of Lucknow"*** submitted by Dr. Maviya Khan, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 278/CM/21 dated 25th June, 2021. **Primary reviewer recommendation:** • The outcome (dependent) variables for assessing self care practices should be explicitly specified. There is no list of secondary and tertiary care centers to be included in the study. Sample size calculations are not clear, since outcome variable is not defined. Statistical analysis details are missing. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & Re-submit (Tracking changes in word format)
	Ref. code: V PGTSC-IIA/P9
10.	Research proposal entitled ***"A study on treatment delay in cancer patients at a tertiary care center of Lucknow district"*** submitted by Dr. Hisamurrahman, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 277/CM/21 dated 25th June, 2021. **Primary reviewer recommendation:** • Study hypotheses are not defined. • Sample size calculation is not clear in the absence of proper study hypotheses. • Study design is retrospective (not cross sectional) since patients (One year back) are to be included. Statistical analysis details missing. **PGTSC Comment:** • As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Revise & Re-submit (Tracking changes in word format) ***Ref. code: V PGTSC-IIA/P10***
11.	Research proposal entitled ***"Association of neutrophils lymphocytes (N/L) ratio and CRP with spirometry in COPD patients in North India"*** submitted by Dr. Kaushalendra Kumar Maurya, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.2478/PHY/21 dated 18th June, 2021. **PGTSC Comment:** • Kindly explain the study procedure to the patient in simple language instead of writing study design. • Kindly follow the SOP provided by IEC, available on Website. Use simple day to day Hindi language. **PGTSC Decision:** Approval after justification ***Ref. code: V PGTSC-IIA/P11***
12.	Research proposal entitled ***"A comparative study between fentanyl-lignocaine and dexmedetomidine-lignocaine nebulisation in awake nasal fibreoptic intubation"*** submitted by Dr. Asmita Gupta, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/519/21 dated 25th June, 2021. **PGTSC Comment:** • Statistical analysis is to be done by using SPSS 15, kindly explain the reason for not using the latest (27) version of the same. • References are not updated, while literature is available for the year 2020 on the same topic. • Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website. Use simple day to day Hindi language. **PGTSC Decision:** Approval after justification ***Ref. code: V PGTSC-IIA/P12***
13.	Research proposal entitled ***"Adherence to Iron folic acid supplementation among pregnant women in rural Lucknow"*** submitted by Dr. Gunjan Bhargava, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no.292/CM/21 dated 29th June, 2021. **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P13***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

14.	Research proposal entitled ***"A comparative evaluation of the levels of inflammatory marker after metal ceramic, all ceramic and peek crown restoration-in vivo study"*** submitted by Dr. Mohan Mahajan, JRI, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 105/21 dated 30th June, 2021. **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P14***
15.	Research proposal entitled ***"Interim analysis of the patients on bedaquilline based optimized regimen for drug resistant pulmonary tuberculosis at nodal DRTB center"*** submitted by Dr. Amaan Latif, JRI, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no.1812/Res/21 dated 19th June, 2021. **PGTSC Comment:** • Kindly provide the outcome variables • Kindly explain the study procedure to the patient in simple language instead of writing study design. • Kindly follow the SOP provided by IEC, available on Website. Use simple day to day Hindi language **PGTSC Decision:** Approval after justification ***Ref. code: V PGTSC-IIA/P15***
16.	Research proposal entitled ***"Conservative versus tube thoracostomy in patients with selected blunt injury chest-A prospective observational study"*** submitted by Dr. Shreedhar Shandilya, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no.1192/Surg/21 dated 23rd June, 2021. **PGTSC Comment:** • Kindly provide complete methodology. • Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website. Use simple day to day Hindi language. **PGTSC Decision:** Approval after justification ***Ref. code: V PGTSC-IIA/P16***
17.	Research proposal entitled ***"Association of ABCB1 gene polymorphism in children with west syndrome and its effect on response to steroid therapy"*** submitted by Dr. Dhruv Agrawal, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.1520/Ped/21 dated 25th June, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approved ***Ref. code: V PGTSC-IIA/P17***
18.	Research proposal entitled ***"A comparative study to evaluate masticatory performance and satisfaction level of the patient with conventional and three appointment complete denture"*** submitted by Dr. Deep Shikha Tripathi, JRI, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.152/2021 dated 30th June, 2021. **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P18***
19.	Research proposal entitled ***"Effect of occlusal splint versus sleep hygiene measures and progressive muscle relaxation on sleep bruxism: A randomized controlled trial"*** submitted by Dr. Ayushi Tandon, JRI, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.154/2021 dated 30th June, 2021. **Primary reviewer recommendation:** • Group detail not provided • References not provided **PGTSC Comment:** • As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: V PGTSC-IIA/P19***
20.	Research proposal entitled ***"Clinicopathological correlation of programmed death Ligand-1 (PDL-1) and HER2/neu expression in in lung carcinomas"*** submitted by Dr. Mohammad Arif, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.117/PCCM/2021 dated 28th June, 2021. **Primary reviewer recommendation:** • Departmental affiliation of Dr. Esha Jafa shall be corrected in "Undertaking by Principal Investigator" • Details of techniques and their reference shall be provided in Methodology. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P20***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

21.	Research proposal entitled ***"Diagnostic yield of medical thoracoscopy in cases of exudative pleural effusion of undiagnosed etiology"*** submitted by Dr. Hemant Kumar, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.118/PCCM/2021 dated 28th June, 2021. **Primary reviewer recommendation:** • Informed consent form states some minor complications including bleeding during the procedure. It shall be ensured that this point is also mentioned in the consent being taken from the subject. • Explain from where is the bleeding likely to occur? • In the Methods section it is mentioned that Biochemical and cytological examination of pleural fluid will be carried out. However, no details or methodology is provided. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P21***
22.	Research proposal entitled ***"Estimation of microbiota and inflammatory biomarker in tears and conjunctival secretions of ocular defect patients after using ocular prosthesis"*** submitted by Dr. Rohit Bhandari, SR, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.157/2021 dated 30th June, 2021. **Primary reviewer recommendation:** • How will microbiota be analyzed? No details provided. • It is mentioned that "after placing ocular prosthesis with healthy eye"? Please explain? • Which inflammatory markers will be assessed? Methods? Reference? By whom? • In inclusion criteria point number 2 Healed socket? Of whom? • References not provided (Bibliography) **PGTSC Comment:** • As above **PGTSC Decision:** Revise & Re-submit (Tracking changes in word format) ***Ref. code: V PGTSC-IIA/P22***
23.	Research proposal entitled ***"Quality of life among elderly people living in Lucknow"***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	submitted by Dr. Manoj Soni, JR, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no.302/CM/2021 dated 1st July, 2021. **Primary reviewer recommendation:** • References not provided (Bibliography) **PGTSC Comment:** • As above **PGTSC Decision:** Revise & Re-submit (Tracking changes in word format) ***Ref. code: V PGTSC-IIA/P23***
24.	Research proposal entitled ***"A comparative study of intraperitoneal instillation of levobupivacaine with different adjuvants on post laparoscopic cholecystectomy pain"*** submitted by Dr. Meenakshi, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/480/21 dated 17th June, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P24***
25.	Research proposal entitled ***"To study the correlation of blood ammonia levels and presence of portosystemic collateral veins in patients of chronic liver disease"*** submitted by Dr. Divyam Kansal, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1278/Med/21 dated 12th June, 2021. **Primary reviewer recommendation:** • Methodology and reference for measurement of Blood ammonia levels not provided. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P25***
26.	Research proposal entitled ***"A study of post acute complications in COVID-19 patients"*** submitted by Dr. Vikas Chandra Vidyarthi, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1279/Med/21 dated 12th June, 2021. **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: V PGTSC-IIA/P26
27.	Research proposal entitled ***"Correlation of pseudo cholinesterase level with clinical and biochemical parameters with special emphasis on cardiac profile in patients of organo phosphorus poisoning and its outcome"*** submitted by Dr. Arvind Kumar, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1280/Med/21 dated 14th June, 2021. **Primary reviewer recommendation:** • Methodology and reference for measurement of Blood ammonia levels not provided. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & Re-submit (Tracking changes in word format)
	Ref. code: V PGTSC-IIA/P27
28.	Research proposal entitled ***"Transfusion support in COVID-19 suspects"*** submitted by Dr. Anurag Singh, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no.148/21 dated 17th June, 2021. **Primary reviewer recommendation:** • Department Review Committee has only 3 members. • There are 3 Co-PIs from the same department which seems superfluous. Please decrease the number of Co-supervisors or define their roles. • IEC form doesn't mention – a. Type of study (Clinical/Epidemiological) b. Advertised or not? c. Contact person details in Consent Form d. Study involves blood sample collection which is not mentioned in the IEC form. • The topic doesn't reflect the Objectives, please reconsider. • IEC needs to be modified and resubmitted. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit (Tracking changes in word format)
	Ref. code: V PGTSC-IIA/P28
29.	Research proposal entitled ***"A mycological study on COVID associated rhino-orbito-cerebral mucormycosis"*** submitted by Dr. Mohd Saqib Hasan, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.416/21

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	dated 18th June, 2021. **Recommendation of Primary reviewer:** • 1 Supervisor and 2 co-supervisors from the same department. Please define their roles or decrease their number. • IEC forms lack in the following sections – a. Privacy and Confidentiality b. Use of biologic material not mentioned c. Consent details not ticked d. Risk is mentioned as not reasonable e. Adverse events are ticked. • Contact person details not present in Informed Consent **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P29***
30.	Research proposal entitled ***"Clinicopathological study of non haematological paediatric tumors"*** submitted by Dr. Rohit Singh, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.2819/21 dated 17th June, 2021. **Recommendation of Primary reviewer:** • 1 supervisor and 4 co-supervisors are from the same department. Please reduce the number or mention each one's unique contribution. • Following sections in IEC form are incorrect/unfilled/erroneous – a. Privacy and confidentiality b. Use of biological material c. details of Consent d. Risks and Benefits. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P30***
31.	Research proposal entitled ***"A fluoroscopic comparison between video laryngoscope***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	and macintosh laryngoscope for assessment of cervical spine mobility during tracheal intubation in patients with cervical spine injury" submitted by Dr. Muthunagarathinam. M, JR-I, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/489/21 dated 18th June, 2021. **Recommendation of Primary reviewer:** • 1 Supervisor and 3 co-supervisors from the same department. Please decrease the number or mention their unique roles. • Sponsor information incorrect • Vulnerable/Special groups not ticked in IEC form. • Privacy/Confidentiality section filled incorrectly. • Use of biological material not filled. • Details of Consent not filled in IEC form. • Risk is mentioned as not reasonable. • Benefits of Video laryngoscopy are already known. Why this study? • Conventional laryngoscopy in patients with cervical spine injury increases the risk of further trauma. Having Video laryngoscopy which is less risky and still doing laryngoscopy with a technique which is risky, will be UNETHICAL. Suggest this study be conducted in patients who may not be at risk of spinal trauma. • Informed consent doesn't mention details of complications due to spine movement and due to fluoroscopy usage. **PGTSC Comment:** • As above **PGTSC Decision:** Not approved ***Ref. code: V PGTSC-IIA/P31***
32.	Research proposal entitled ***"Outcome of patients with blunt trauma chest and possible risk factors affecting mortality in critical care unit"*** submitted by Dr. Neetu Pal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/500/21 dated 21st June, 2021. **Recommendation of Primary reviewer:** • 1 supervisor and 2 co-supervisors are from the same department. Please define their unique roles or decrease their number.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Sponsor information incorrectly filled. • Please modify and resubmit. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P32***
33.	Research proposal entitled ***"Accuracy of wilson's score and intubation prediction score for prediction of difficult intubation: gender-wise comparative, observational study"*** submitted by Dr. Vinay Bhadouria, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/499/21 dated 21st June, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P33***
34.	Research proposal entitled ***"To compare the effect of immediately loaded and delayed loaded implant on bone loss and inflammatory biomarkers"*** submitted by Dr. Akanksha Gautam, JRI, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.103/21 dated 2nd July, 2021. **Recommendation of Primary reviewer:** • DRC has only 4 members. • 3 Co-PIs are from the same department. They have overlapping roles. Please decrease the number of co-PIs. • PI has filled the 'Clinical Trials' section of the IEC forms. If this is not a Trial this mistake may be corrected. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & Re-submit (Tracking changes in word format) ***Ref. code: V PGTSC-IIA/P34***
35.	Research proposal entitled ***"Assessment of salivary and serum interleukin 1β levels in precancerous and healthy individuals using enzyme linked immunosorbent assay: an observational study"*** submitted by Dr. Thamarai Salvan. T, JRI, Department of Oral Medicine and Radiology, Faculty of Dental Sciences, King George's Medical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	University, U.P., Lucknow vide letter no.550/OMS/21 dated 21st December, 2020. **Recommendation of Primary reviewer:** • 1 Supervisor and 4 supervisors from same department is superfluous. Please decrease the number or define their unique roles. • It is unclear from the IEC form who will bear the financial burned of the ELISA test? If the patient is being asked to bear this burden, is it a test which would be done routinely in all patients or is it being done only for the purposes of this project? In case the latter is true, the financial burden must lie with the investigator and not the patient. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P35***
36.	Research proposal entitled ***"Effect of epidural dexmedetomidine and fentanyl infusion for postoperative analgesia in patients undergoingupper abdominal surgeries: A randomized double blind study"*** submitted by Dr. Jaideep. P, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 550/OMS/21 dated 21st June, 2021. **Recommendation of Primary reviewer:** • 1 supervisor and 3 co-supervisors. Please decrease the number of co-PIs or define their unique roles in the study, there are several overlapping roles. • Inclusion criteria is age 18-65 years but IEC form mentions Vulnerable population of Children as part of the study. Please clarify and correct. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P36***
37.	Research proposal entitled ***"Study of relationship between olfactory dysfunction and cognitive impairment in elderly patients with diabetes mellitus: A cross-sectional study"*** submitted by Dr. Porimita Chutia, JRI, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no.1055/DGMH/21 dated 2nd July, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: V PGTSC-IIA/P37
38.	Research proposal entitled ***"A randomized trial to compare decompressive hemicraniectomy versus adjuvant basal cisternostomy in traumatic brain injury cases in a tertiary care center in India"*** submitted by Dr. Sarita Kumari, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.332/21 dated 2nd July, 2021. **Recommendation of Primary reviewer:** • Please substitute the work 'Trial' with 'Study' in your topic. • There are 7 co-PIs from the same department. This is unacceptable. Please decrease the number of co-PIs and define their individual, UNIQUE roles. Their present roles are overlapping. • The study includes seriously ill patients which are a type of Vulnerable subjects. Please make appropriate changes in the IEC form. • If basal cisternostomy has been shown to have a beneficial effect on decompressing the ICP, not offering TBI patients this option to save their lives will be UNETHICAL. Thus, the PI is condemning the patients without basal cisternostomy to a poorer result than those who have had it. This is against human rights to be offered a treatment which is known to have inferior results. **PGTSC Comment:** • As above **PGTSC Decision:** Not approved
	Ref. code: V PGTSC-IIA/P38
39.	Research proposal entitled ***"Assessment of improved outcome of vascular intervention (Angioplasty with catheter guided thrombolysis) in infrapopliteal atherosclerotic occlusion in chronic limb ischemia"*** submitted by Dr. Juhi Rajpoot, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1253/21 dated 1st July, 2021. **Recommendation of Primary reviewer:** Provisionally Approved **PGTSC Decision:** Approved
	Ref. code: V PGTSC-IIA/P39
40.	Research proposal entitled ***"Comparison of I-Gel and laryngeal mask airway block buster in the management of difficult airway in post burns contracture patients: A ramdomized controlled trail"*** submitted by Dr. Manish Kumar Tripathi, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	letter no. Anaes/527/21 dated 28th June, 2021. **Recommendation of Primary reviewer:** The Title should be corrected as study is Randomized controlled Study not R C Trial. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P40***
41.	Research proposal entitled ***"Evaluation of serum tumor necrosis factor-α and vascular endothelial growth factor in primary open angle glaucoma"*** submitted by Dr. Priya Sharma, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no.210/OPH/21 dated 31st May, 2021. **Recommendation of Primary reviewer:** Provisionally Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P41***
42.	Research proposal entitled ***"The effect of root end cavity preparation by laser, ultrasonic and conventional bur under microscope on microleakage of different cements-an in vitro study"*** submitted by Dr. Vasanth M.N, JRII, Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.84/21 dated 16th June, 2021. **Recommendation of Primary reviewer:** Detailed study design not mentioned **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P42***
43.	Research proposal entitled ***"Platelet parameters and coagulation profile in primary open angle glaucoma patients"*** submitted by Dr. Shweta Singh, JRII, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 209/OPH/21 dated 31st May, 2021. **Recommendation of Primary reviewer:** Provisionally Approved **PGTSC Decision:** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: V PGTSC-IIA/P43
44.	Research proposal entitled ***"Comparative evaluation of antimicrobial activity of amniotic membrane and platelet rich fibrin on endodontic microflora"*** submitted by Dr. Lalruatfeli, JRII, Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 126/21 dated 8th July, 2021. **Recommendation of Primary reviewer:** Provisionally Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P44***
45.	Research proposal entitled ***"Effect of deferasirox on shunt fraction during thoracic surgery using one lung ventilation: A randomized control study"*** submitted by Dr. Parvathy S Nair, JRII, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/572/21 dated 12th July, 2021. **Recommendation of Primary reviewer:** Provisionally Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P45***
46.	Research proposal entitled ***"In vitro antimicrobial activity of propolis mixed with nanoparticles against enterococcus faecalis"*** submitted by Dr. Divya Pal, JRII, Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.124/21 dated 8th July, 2021. **Recommendation of Primary reviewer:** • Who will analyze the antimicrobial load before and after giving proposals mixed with Nanoparticles of E. fecalis? Co-guide from Microbiology is needed. • Work distribution of Dr. Suaib Luqman, Principal-Scientist (CSIR-CIMAP) not mentioned. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P46***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

47.	Research proposal entitled ***"Assessment of sealing ability of biodentin as endodontic sealer compared with conventional resin based sealer and bioceramic sealer using confocal laser scanning microscopy: An in vitro study"*** submitted by Dr. Manisha Lal, JRII, Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.125/21 dated 8th July, 2021. **Recommendation of Primary reviewer:** • Methodology, Total sample size and grouping not explained well **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P47***
48.	Research proposal entitled ***"Comparative study of blunt trauma chest patients (Multiple Rib Fracture/Flail Chest) managed by surgical fixation vs conservative management"*** submitted by Dr. Aditya Kumar Singh, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no.1307/21 dated 9th July, 2021. **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P48***
49.	Research proposal entitled ***"Comparison of efficacy of dexmedetomidine and clonidine on postoperative nausea and vomiting in paediatric patients undergoing abdominal surgeries"*** submitted by Dr. Khooshaboo Gupta, JRI, Department of Anaesthesiolgy, King George's Medical University, U.P., Lucknow vide letter no. Anaes/498/21 dated 21st June, 2021. **Recommendation of Primary reviewer:** • ICF-Assent form missing. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: V PGTSC-IIA/P49***
50.	Research proposal entitled ***"Universal newborn hearing screening: epidemiology of hearing impairment"*** submitted by Dr. Arti Rajpoot, JRI, Department of OTO-Rhino-Laryngolohy & Head & Neck Surgery, King George's Medical University, U.P.,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Lucknow vide letter no.161/ENT/21 dated 7th July, 2021. **PGTSC Comment:** • Petros picture data- can be used without case/Identifiers and waiver grant. • For prospective data to be informed consent taken **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P50***
	IMR-Resident
1.	Research proposal entitled "***A comparative evaluation of two piece and single piece implants immediately loaded in fresh extraction sockets***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Rohini R, JRII through her Mentor Dr. Lakshya Kumar, Department of Prosthodintics and Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.156/21 dated 30th June, 2021. **Primary reviewer recommendation:** • Study hypotheses are not defined. Study design and methodology are not specified. Sample size calculation is not clear in the absence of proper study hypotheses. Statistical analysis details missing. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & Re-submit (Tracking changes in word format) ***Ref. code: VPGTSC-II B IMR-R/P1***
2.	Research proposal entitled "***Educational intervention to create awareness about cervical and breast cancer in College going girls of Lucknow District***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Sarrah Maimoon Usmani, JRIII, through her Mentor Prof. Monika Agarwal, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no.505/21 dated 7th August, 2021. **Primary reviewer Recommendation:** • Several sections of the IEC form have been left unfilled. Please fill them properly. **PGTSC Comment:** • As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approval subject to modification ***Ref. code: VPGTSC-II B IMR-R/P2***
3.	Research proposal entitled ***"Comparison of Diagnostic accuracy of International ovarian tumor analysis and the risk of malignancy Index (RMI) to discriminate between benign and malignant adenexal masses"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Yamini Sharma, JR through her Mentor Prof. Uma Singh, Head, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no.OG/1310/2021 dated 10th August, 2021. **Primary reviewer Recommendation:** • Add consent form for Biopsy **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VPGTSC-II B IMR-R/P3***
III-A	**Additional Documents**
1-	Research proposal entitled ***"Clinical profile of SARS-CoV-2 infected patients admitted to a tertiary care centre of Northern India"*** submitted by Dr. Saurabh Pandey, SR, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1612/MED/21 dated 31st July, 2021. **PGTSC Decision:** Approved ***Ref. code: II ECMCOVID-19 IB/P1***
IV	**Modification**
1.	Modification research proposal entitled ***"Clinical trend analysis of orbital cellulitis in a tertiary care institute in northern India: A 15 years' experience"*** submitted by Dr. Ashutosh Maharana, JR, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no.507/OPH/21 dated 10th August, 2021. **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P12***

The next Meeting will be held on 23rd October, 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 112th ECM held on 23rd October, 2021

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the Institutional Ethics Committee Meeting virtually held on **23rd October, 2021** from 10.30 A.M.

The following members were present in its Meeting:

1. Prof. Alok Dhawan -Chairman
2. Prof. G.G. Agarwal -Member
3. Prof. Shubha R Phadke -Member
4. Mrs. Vasundhara Kumar- -Member
5. Mr. Ujjawal Krishna -Member
6. Dr. K.K. Yadav -Member
7. Prof. A.A. Mahdi -Member
8. Prof. Rajendra Nath -Member
9. Prof. Anupam Mishra -Member
10. Prof. Anita Rani Singh -Member
11. Dr. D.N. Upadhyaya -Member
12. Prof. Shally Awasthi -Member-Secretary, IEC

The following Member could not attend the Meeting:

1. Dr. Akash Agarwal- sent his written comment

	The following items carry on the last 111th IEC Meeting was postponed because quorum was incomplete
IA	**Clarifications**
1.	Clarification of research Protocol no.PreQuest-01 entitled "***Prospective, multi-centric, single arm post marketing surveillance of PRISTINE, everolimus eluting cobalt chromium coronary stent system to assess its continued safety and efficacy***" sponsored by Relisys Medicine Devices Ltd. submitted by Prof. Pravesh Vishwakarma, Department of Cardiology, King George's Medical University, U.P., Lucknow vide

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

letter no. 1778/Cardio/Res/2021 dated 1st September 2021.

Previous EC Comment:

- Sample size not given in protocol separately and not calculated
- Synopsis summary not given

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer: Approved

Action taken: Provisionally approved

The following documents were reviewed in its Meeting:-

Sr. No	Document	Version	Date
1	Protocol	4.1	15 Sept 2020
2	CRF	NA	NA
3	ICD Hindi	1.1	23 June 2020
4	ICD Hindi Back translated	1.1	11 Feb 2021
5	Translation Certificate	NA	NA
6	ICD English	1.1	23 June 2020
7	IB	1.1	25 Feb 2020
8	Investigator Undertaking	1.1	NA
9	CV GCP MRC of PI and Study Team	NA	NA
10	CTRI registration certificate	NA	NA
11	Draft CTA	NA	NA

EC Decision: Approved subject to fulfillment and administrative formalities

Ref. code: 110th ECMIIC/P1

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

phase 3 study to evaluate the efficacy and safety of fitusiran in patients with hemophilia A or B, without inhibitory antibodies to factor VIII or IX" submitted by Dr. S.P. Verma, Associate Professor, Department of Clinical Hematology, King George's Medical University U.P., Lucknow vide letter no.693/CH/21 dated 25th August, 2021.

Previous EC Comment:

- Is the study continuing?
- In what doses is the drug being given?
- Kindly provide updated information from KGMU site

The following documents were reviewed in its Meeting:-

Sr. No.	Document/Language	Document Details/Versions
1-	Investigators Brochure	Investigator's brochure Edition 07 Amendment 2 dated 25November2020 (Controlled Copy No: PPD/ALN-AT3SC-004/ Investigator's Brochure/Edition 07/Dated 25November2020/010-014) Clean Copy
2-	Investigators Brochure	Investigator's brochure Edition 07 Amendment 2 dated 25November2020 (Controlled Copy No: PPD/ALN-AT3SC-004/ Investigator's Brochure/Edition 07/Dated 25November2020/010-014) Track change version
3-	Investigators Brochure	Investigator's brochure Edition 07 dated Amendment 2 25November2020 (Controlled Copy No: PPD/ALN-AT3SC-004/ Investigator's Brochure/Edition 07/Dated 25November2020/010-014) Summary of Changes
4-	Investigators Brochure	Investigator's brochure Edition 07 Amendment 1 dated 08 September 2020 (Controlled Copy No: PPD/ALN-AT3SC-004/ Investigator's Brochure/Edition 07/Dated 25November2020/010-014) Clean Copy
5-	Investigators Brochure	Investigator's brochure Edition 07 Amendment 1 dated 08 September 2020 (Controlled Copy No: PPD/ALN-AT3SC-004/

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

letter no. 1778/Cardio/Res/2021 dated 1st September 2021.

Previous EC Comment:

- Sample size not given in protocol separately and not calculated
- Synopsis summary not given

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer: Approved

Action taken: Provisionally approved

The following documents were reviewed in its Meeting:-

Sr. No	Document	Version	Date
1	Protocol	4.1	15 Sept 2020
2	CRF	NA	NA
3	ICD Hindi	1.1	23 June 2020
4	ICD Hindi Back translated	1.1	11 Feb 2021
5	Translation Certificate	NA	NA
6	ICD English	1.1	23 June 2020
7	IB	1.1	25 Feb 2020
8	Investigator Undertaking	1.1	NA
9	CV GCP MRC of PI and Study Team	NA	NA
10	CTRI registration certificate	NA	NA
11	Draft CTA	NA	NA

EC Decision: Approved subject to fulfillment and administrative formalities

Ref. code: 110th ECMIIC/P1

2. Clarification of the modification of Research protocol no. ATLAS-A/B entitled *"A*

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	15-	DCGI Approval and Submission Acknowledgment for Main ICF v6.1.0_02Feb2021	Cover Letter Dated 24th Feb 2021 E-Mail Acknowledgement dated 24th Feb 2021

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer: As I understand the study is complete and closes on 31st August, 2021. That's ok.

Action taken: Provisionally approved

EC Decision: Approved subject to fulfillment and administrative formalities

Ref.code:90th ECMIIC/P2

IB — **Review of New Drug Trial**

1. Research Protocol no.209682 entitled "***A phase 4, open-label, single arm, 24-week, phase 4 study to evaluate the safety and efficacy of mepolizumab 100 mg SC administered every 4 weeks in Indian participants aged≥18 years with severe eosinophilic asthma requiring oral corticosteroid treatment to maintain asthma control (PRISM)***" sponsored by Glaxo Smith Kline Pharmaceuticals Ltd. submitted by Dr. Ajay Kumar Verma, Professor Junior Grade, Department of Respiratory Medicine King George's Medical University, U.P., Lucknow, vide letter no. 1929/2021 dated 16th July, 2021.

The following documents were reviewed in its Meeting:-

S. No	Document Details
1	**Study Protocol:** 1.1 Clinical Trial Protocol version 1.0 date 11-Sep-2020 1.2 Protocol Sign Page dated 17-May- 2021.
2	**Prescribing Information sheet with Summary of product characteristics** 2.1 Prescribing Information sheet with Summary of Product Characteristics V 2.0 dated 30 Jan 2019.
3	**Participant Information Sheet & Informed consent forms (ICFs) in English & Hindi:** 3.1 English ICF_Core Study ICD Version No. 2.0, dated 26-Mar-2021. 3.2 Hindi ICF_Core Study ICD Version No. 2.0, dated 26-Mar-2021 Translated from English to Hindi Version 1.0 dated 08-Apr-2021.
4	**Back Translations of Informed consent forms (ICFs):** 4.1 Core Study ICD Version No. 2.0, dated 26-Mar-2021 Translated from English to Hindi Version 1.0 dated 08-Apr-2021 Back Translated from Hindi to English Version 1.0 dated 09-Apr-2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

5	**Translation & Back Translation Certificates of ICF:** 5.1 ICD - Translation and Back-Translation Certificates for Hindi dated 29-Jun-2021.
6	**CV, MRC and GCP of Principal Investigator:** 6.1 Curriculum Vitae of Investigator dated 03-Mar-2021. 6.2 MRC – Reg.No.49103. 6.3 GCP certificate valid till 12-Jan-2024
7	**Insurance Policy with Certificate:** 7.1 Insurance certificate and complete Policy dated 21-Dec-2020.
8	**Clinical Trial Agreements:** 8.1 Draft clinical trial agreement.
9	**Undertaking by the Investigator:** 9.1 Signed Undertaking by the Investigator dated 17-May-2021.
10	**DCG(I) Submission and Approval Letters:** 10.1DCG(I) Submission Letter dated 27-Oct-2020. 10.2DCG(I) approval letter dated 05-Mar-2021.
11	**Case Report Form (CRF):** 11.1 Case Report Form version 1.0 dated 27-Apr-2021.
12	**Patient Diary in English & Hindi** 12.1 English Patient Diary Version 2.0 dated 29-Apr-2021. 12.2Hindi Patient Diary Translated from English to Hindi Version 2.0 dated 15-May-2021.
13	**Back translations of Patient Diary** 13.1Translated from Hindi to English_Version 02 dated 17-May-2021.
14	**Translation & Back Translation Certificates for Patient Diary** 14.1Translation Certificate for English to Hindi & Back Translation Certificate for Hindi to English dated 29-Jun-2021.

Primary reviewer recommendation: Approved

EC Comment:

- Insurance has to be reviewed. Blood samples cannot be send out of Country without approval of competent authority (that is ICMR).

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

EC Decision: Approval subject to modification

Ref. code: 111th ECMIIC/P1

2. Research Protocol no.5030801/GOPI Study entitled "***Prospective, non-interventional, multi-centre, post marketing surveillance study to evaluate the safety and tolerability of gaviscon oral suspension for the management of symptoms of gastroesophageal reflux disease***" sponsored by Reckitt United Kingdom submitted by Dr. Ajay Kumar Patwa, Department of Medicine, King George's Medical University, U.P., Lucknow, vide letter no. MED/135/2021 dated 4th August, 2021.

The following documents were reviewed in its Meeting:

S. No	Document Details
1	**Study Protocol:** 1.1 Clinical Trial Protocol version 1.0 date 11-Sep-2020 1.2 Protocol Sign Page dated 17-May- 2021.
2	**Prescribing Information sheet with Summary of product characteristics** 2.1 Prescribing Information sheet with Summary of Product Characteristics V 2.0 dated 30 Jan 2019.
3	**Participant Information Sheet & Informed consent forms (ICFs) in English & Hindi:** 3.1 English ICF_Core Study ICD Version No. 2.0, dated 26-Mar-2021. 3.2 Hindi ICF_Core Study ICD Version No. 2.0, dated 26-Mar-2021 Translated from English to Hindi Version 1.0 dated 08-Apr-2021.
4	**Back Translations of Informed consent forms (ICFs):** 4.1 Core Study ICD Version No. 2.0, dated 26-Mar-2021 Translated from English to Hindi Version 1.0 dated 08-Apr-2021 Back Translated from Hindi to English Version 1.0 dated 09-Apr-2021.
5	**Translation & Back Translation Certificates of ICF:** 5.1 ICD - Translation and Back-Translation Certificates for Hindi dated 29-Jun-2021.
6	**CV, MRC and GCP of Principal Investigator:** 6.1 Curriculum Vitae of Investigator dated 03-Mar-2021. 6.2 MRC – Reg.No.49103. 6.3 GCP certificate valid till 12-Jan-2024
7	**Insurance Policy with Certificate:** 7.1 Insurance certificate and complete Policy dated 21-Dec-2020.
8	**Clinical Trial Agreements:** 8.1 Draft clinical trial agreement.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	9	**Undertaking by the Investigator:** 9.1 Signed Undertaking by the Investigator dated 17-May-2021.
	10	**DCG(I) Submission and Approval Letters:** 10.1DCG(I) Submission Letter dated 27-Oct-2020. 10.2DCG(I) approval letter dated 05-Mar-2021.
	11	**Case Report Form (CRF):** 11.1 Case Report Form version 1.0 dated 27-Apr-2021.
	12	**Patient Diary in English & Hindi** 12.1 English Patient Diary Version 2.0 dated 29-Apr-2021. 12.2Hindi Patient Diary Translated from English to Hindi Version 2.0 dated 15-May-2021.
	13	**Back translations of Patient Diary** 13.1Translated from Hindi to English_Version 02 dated 17-May-2021.
	14	**Translation & Back Translation Certificates for Patient Diary** 14.1Translation Certificate for English to Hindi & Back Translation Certificate for Hindi to English dated 29-Jun-2021.

Primary reviewer recommendation: Approved

EC Decision: Approved subject to fulfillment and administrative formalities

Ref. code: 111th ECMIIC/P2

IC	Modification
1.	Modification of Research protocol no.GS-US-419-3895 entitled ***"Combined Phase 3, double-blind, randomized, placebo-controlled studies evaluating the efficacy and safety of filgotinib in the Induction and maintenance of remission in subjects with moderately to severely active crohn's disease"*** M/s Klinera corporation submitted by Dr. Ajay Kumar, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.MED/CT/147/2021 dated 18th August, 2021. ***The following documents were reviewed in its Meeting:*** 1. Study GS-US-419-3895, Protocol Amendment No. 8 dated 01 May 2020 2. Study GS-US-419-3895, Summary of changes dated 01 May 2020 for Protocol Amendment No. 8 3. Subject Information and Informed consent Form –Dr. Ajay Kumar English,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Version 9.1.1 dated 07 Jul 2020 4. Subject Information and Informed consent Form – Dr. Ajay Kumar English to Hindi, Version 9.1.1 dated 07 Jul 2020 5. Subject Information and Informed consent Form – Dr. Ajay Kumar Hindi to English, Version 9.1.1 dated 07 Jul 2020 6. Translation Certificates of Subject Information and Informed Consent form English to Hindi dated 07 Jul 2020 7. Back Translation Certificates of Subject Information and Informed Consent form English to Hindi dated 07 Jul 2020. **Primary reviewer recommendation:** Approved **EC Decision:** Approved ***Ref.code:89th ECMIIC/P14a***
2.	Modification of Research protocol no.GS-US-419-3896 entitled ***"A long-term extension study to evaluate the safety of Filgotinib in subjects with Crhon's disease"*** M/s Klinera corporation submitted by Dr. Ajay Kumar, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.MED/CT/146/2021 dated 18th August, 2021. ***The following documents were reviewed in its Meeting:*** 1 Study GS-US-419-3896, Protocol Amendment No.7 dated 23-Mar-2020 2 Study GS-US-419-3896, Summary of changes dated 23-Mar-2020 for Protocol Amendment No. 7 3 Subject Information and Informed Consent Form –Dr. Ajay Kumar English, Version: 8.1.1, dated 21-Apr-2020 4 Subject Information and Informed Consent Form –Dr. Ajay Kumar (Translation & Back translation with Certificates). · English to Hindi: Version 8.1.1, dated 08-May-2020 · Hindi to English: Version 8.1.1, dated 09-May-2020 **Primary reviewer recommendation:** Approved **EC Decision:** Approved ***Ref.code:89th ECMIIC/P14b***
	Current Agenda-112th IEC Meeting dated 23rd October, 2021
IA	**Action taken**
1.	Clarification of research proposal entitled ***"Formulation, optimization and evaluation of apigenin and cardamom essential oil based emulgel for mitigation of oral submucous fibrosis"*** sponsored by ICMR submitted by Ms. Sarita Pal, Ph.D Scholar 2019, under the guidance Dr. N.P. Yadav & Co-PI U.S. Pal, Department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	U.P., Lucknow vide letter no. 594/OMFS/2021 dated 8th October, 2021. **Previous EC Comment:** • 1-Section 5: This project is an in-vitro study: what is the need for subjects? • 2. Section 5: Many vulnerable subjects have been ticked: why? • Section 6: Privacy statement: not checked • Section 7: Organs and body fluids are being used: wrongly checked. • Section 8: All studies involving patient recruitment need a patient information sheet. • Section 8: Who administers the consent? • Section 10: Give details of interim data analysis points. • Biopsy is an invasive procedure: can have complications, can't be risk free. • Consent form and patient information sheet should be separate. • Why will oral cancer cell lines be used? The study is of OSMF, not cancer. • Objectives: Procurement of buccal mucosa cannot be an objective, at least for this study. • Please provide the Ayurvedic Text which tells about areca nut causing OSF. • Please provide itemized budget. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Pending ***Ref. code: 107th ECM II B-Ph.D/P1***
2.	Clarification of research proposal entitled "***Biosurveillance for spillover of henipaviruses and filoviruses in rural communities in India***" sponsored by Eco Health Alliance, United States submitted by Prof. Amita Jain, Head, Department of Microbiology, King George's Medical University U.P., Lucknow vide letter nos.427/2021 dated 22nd June, 2021, 792/2021 dated 1st September, 2021 and 854/2021 dated 11th September, 2021. **Action taken:** Provisionally approved **EC Comment:** Provisionally approved (ICMR – HMSC approval awaited) ***Ref. code: 108th ECM IIA/P2***
3.	Clarification of research proposal entitled "***To evaluate the role of RBP 4 as pediatric acute liver failure prognostic biomarker***" sponsored by CSIR submitted by Dr. Sanjeev Kumar Verma, Associate Professor, Department of Pediatrics, King George's Medical University U.P., Lucknow vide letter no.2146/Ped/2021 dated 11th October, 2021. **Previous EC Comment:** • The aim is to study the biomarker as a prognostic tool. However, nowhere in the proposal, any reference to the prognosis of ALF has been made. • Why include a control group in this study?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• No statistical plan has been given. • Flowchart is incomplete • Inclusion criteria: How will the fact that 'PT-INR >2 is of hepatic origin' will be ascertained? • Sec 5: Why include "institutionalized" subjects? • Sec 6: Why use direct identifiers? • Sec 7 is left blank, needs to be completed. • Sec10: If risk is not reasonable to anticipated benefit, why do the study? • Blank fields in benefit section need to be filled. ***Recommendation of Primary reviewer:*** Pending ***Ref. code: 109th ECM IIA/P2***
4-	Clarification of research proposal entitled "***An ambispective study of hemophagocytic lymphohistiocytosis in COVID-19***" submitted by Dr. Geeta Yadav, Associate Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.3192/21 dated 15th September, 2021. **Previous EC Comment:** • Consent waiver for retrospective patients has been mentioned but no consent waiver form is attached for consideration. • Few points in annexure are incomplete: need completion • Informed consent document should be more patient friendly such as in sections of purpose. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code: 110th ECM IIA/P1***
5.	Clarification of research proposal entitled "***A cross-sectional study of Mental Health of Women in North India***" sponsored by National Commission for Women; Government of India. submitted by Prof. Vivek Agarwal, Head, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.1488/Psy/2021 dated 7th October, 2021. **Previous EC Comment:** • Scientific review Committee has only three members. • There are five (5) Co-PI Role of PI are the same as in the proforma. Please justify. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Primary reviewer. ***Recommendation of Primary reviewer:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 110th ECM IIA/P8***
6.	Clarification of research proposal entitled "***Profile of orbital involvement in COVID associated mucormycosis: A tertiary health care center experience***" submitted by Prof. Apjit Kaur Chhabra, Head, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no.669/OPH/21 dated 13th September, 2021. **Previous EC Comment:** • Profile of orbital involvement in covid associated mucormycosis: a tertiary health care centre experience' • The researchers intend to study the profile of orbital involvement in patients with covid associated mucor mycosis in KGMU. • Is it a Prospective study? Will they include cases admitted earlier also (retrospective)? Will the closed cases [died or cured] include? • As per the proposal the researchers will be enrolling only new cases. This should be confirmed. • The evaluation and management will be done as per the institute protocol and hence, there are no ethics related issues. • Is purpose same as objective of the study? • APPROVED with the confirmation about enrolment limited to only new cases. • Scientific review to be done in the Department. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 110th ECM IIA/P11***
7.	Clarification of research proposal entitled "***Outcome of transcutaneous retrobulbar amphotericin B (TRAMB) in COVID-19 associated rhino-orbito-cerebral (ROCM) mucormycosis***" submitted by Prof. Apjit Kaur, Head, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no.677/OPH/21 dated 13th September, 2021. **Previous EC Decision:** • This project has a great overlap with the previous project by the same PI.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The PI need to clarify what is different from the previous project on the same area and the similar aspect of the disease in concern. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** With following comments:- • The response that the project is an important subset of the other study does not justify separate existence of this study. • Also the following answer in the reply is intriguing and makes one wonder about the necessity of the study. Both the sentences are contradictory to each other. • What the reply say, 'The current study has taken into consideration the application and outcome of the specific modality of treatment [TRAMB] which has proven effective in the scientific literature'. ***The above comment forwarded to the P.I., Reply has not given by P.I.*** **EC Decision:** Approved ***Ref. code: 110th ECM IIA/P12***
8.	Clarification of research proposal entitled "***Serum ferritin as a biochemical marker of severity for orbital disease in COVID associated mucormycosis***" submitted by Prof. Apjit Kaur, Head, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 710/OPH/21 dated 22nd September, 2021. **Previous EC Comment:** • Residents can't be co-investigators. • Innumerable deficiencies in Ethics form: a few are pointed below:- What is the meaning of "self" in budget: is patients paying of himself/herself Section 5: Incomplete Section 6: all have been ticked Section 7: Isn't blood a body fluid? • There is no methodology section ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Pending ***Ref. code: 110th ECM IIA/P13***
9.	Clarification of research proposal entitled "***Substance abuse and mental health issue among the LGBT community in India: A study of inter-relationship between mental health disorders and stress, coping, perceived social support, occupation and religiosity***" sponsored by National Human Right's Commission, New Delhi submitted by Prof. Vivek Agarwal, Head, Department of Psychiatry, King George's Medical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	University, U.P., Lucknow vide letter no. 1374/Psy/21 dated 20th September, 2021. **Previous EC Decision:** • This seems to be an interesting and very ambitious study as they are trying to cover whole country. • In this particular study, study design and sampling methods are very important. • There is no mention of type of study design used. • Theoretical population (population for generalization), study population (accessible population) and sampling frame are to be properly defined. • What are the variables and parameters? • Which sampling method is to be used (Simple random sampling, stratified random sampling, cluster sampling etc.)? • For stratified sampling, different non-overlapping groups are to be defined. • There is mention of purposive sampling. This is nonprobabilty sampling. The nonprobability samples cannot depend upon the rationale of probability theory. There will be problem in using the statistical theory (e.g. finding confidence intervals, testing of hypotheses etc.). • If it is a multi-centric study, all the prerequisite have to be followed. • The sample size calculation is not clear. Since variables and parameters are not defined. • Are the instruments used are gold-standard? ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code: 110th ECM IIA/P17***
10.	Clarification of research proposal entitled "***Assess job satisfaction in nurses and its correlation with experience of working in the COVID-19 Hospital***" submitted by Dr. Suchana Roy Bhowmik, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no. 1691/Y.PF/21 dated 21st September, 2021. **Previous EC Decision:** • There is mention of objectives, research question and hypotheses? It should be replaced by objectives and associated research hypotheses? There should be a main objective and the rest can be secondary objectives. • The sampling method is purposive. This is nonprobability sampling. • The nonprobability sample nay not depend upon the rationale of probability

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	theory. There will be problem in using the statistical theory (e.g. finding confidence intervals, testing of hypotheses etc.). • There will be problem in generalization (external validity) also. A threat to external validity is an explanation of how you might be wrong in making a generalization. For instance, you conclude that the results of your study (which was done in a specific place, with certain types of people, and at a specific time) can be generalized to another context (for instance, another place, with slightly different people, at a slightly later time). • The sample size calculations and statistical analysis methods are not clear, since the variables and parameters used in the study are not exclusively defined. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 110th ECM IIA/P18***
11.	Clarification of research Protocol entitled "***Impact of COVID-19 on heart failure hospitalization and outcome in India-A Cardiological society of India study (CSI-HF in COVID-19 times study-"The COVID C-HF study)***" sponsored by Cardiological Society of India submitted Dr. Sharad Chandra, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.1786/Cardio/Res/2021 dated 9th September, 2021. **Previous EC Comment:** • Few entries on page 6 of annexure are incomplete • As per the annexure only oral consent will be obtained (instead of written consent): what is the role of attached informed consent document? Will it be electronically mailed to the participant for signature or will just act as a guide for clarification? • Study timelines dating before March 2021 may be revised ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved ***Ref. code: 110th ECMIIA/P20***
12.	Clarification of research proposal entitled "***Effect of dietary modification and physical activity on blood glucose level of pregnant women with gestational diabetes mellitus: an interventional study***" sponsored by ICMR submitted by Dr. Mallicka, Ph.D Scholar 2019 under the guidance Prof. Jamal Masood, Head, Department of Community Medicine, King George's Medical University, U.P., Lucknow vide letter no.706/CM/21

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	dated 5th October, 2021. **Previous EC Decision:** • Sample size calculations – not important for Ethics committee • There will be two groups. Group II will get diet plan according to sample meal plan as given in guidelines prescribed by Government of India. Group I cannot be deprived of this management protocol which is approved by government operational guidelines. Also the counseling has to be provided to all women with gestational diabetes as it is an important part of management. • As diet and physical activity are important parts of approved management such two groups with one group deprived of approved management cannot be done. • THE STUDY NOT APPROVE IN THIS FORM. • In addition there are many limitations in the scientific part of the study about documenting and verifying the compliance for the dietary and exercise advices, etc. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code: 110th ECM II B-Ph.D/P2***
13.	Clarification of research proposal entitled "***Metagenomics approach in forensic science for human identification among North Indians***" submitted by Mr. Sangram Sandhu, Ph.D Scholar 2019 under the guidance Prof. Pooran Chand, Head, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.387/21 dated 18th September, 2021. **Previous EC Comment:** • It is a multicentric study. Subjects will be recruited at KGMU and DNA extraction and other laboratory work will be done at Birbal Sahni Institute but in the proposal it has been mentioned as a single centre study. • The role of the Ph.D. scholar is not defined in the proposal. His name is neither in PI nor Co-PI list. • Mr. Sangram Sandhu's biodata and role in work has to be defined. • Ethical approval from B.S.I has to be taken. • How will the dental guides give scientific inputs for this work which is on metagenomics? ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code: 110th ECM II B-Ph.D/P4***
14.	Clarification of research proposal entitled "***Efficacy of dietary intervention of flax seeds (Linum usitatissimum) on signs and symptoms associated with perimenopausal***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	syndrome*"** submitted by Ms. Rashmi Shrivastava, Ph.D Scholar, under the guidance Prof. Sunita Tiwari, Head, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.2655/PHY/21 dated 7th October, 2021. **Previous EC Comment:** • What is the budget and who is the sponsor • Is it alright to test herbal remedies by Allopathic Physicians • Section 5: Subject participation, type of subjects needs correction • Section 8: Elements need to check. If not ticked, mention reason CRF not included. • CRF not included **Methodology:** • There are no references. Has any such study ever been done? If not, how can you do a RCT as the first study? • It's a RCT: Mention all the elements of RCT • Inclusion criteria: Who have not used Vitamin from when to when? • Questionnaire: Where has the questionnaire been validated, in which language? • Sample size calculation: What is the effect size? ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer. **Recommendation of Primary reviewer:** Pending ***Ref. code: 110th ECM II B-Ph.D/P5***
15.	Clarification of research proposal entitled **"*Estimation of hearing deficits following critical illness in patients discharged from intensive care unit*"** submitted by Dr. Sai Saran, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.389/2021 dated 12th October, 2021. **Previous EC Comment:** • There is a serious risk of overestimation of hearing deficits in this study as small deficits may not be reported/observed/record in people outside hospital who have not had an audiometry on a pervious occasion. How do the investigators plan to take care of this? • Statistical analysis: Univariate and multivariable analysis should be included to identify risk factors. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Pending ***Ref. code: 111th ECM IIA/P6***
16.	Clarification of research proposal entitled **"*Detection of biofilm forming microbes having effect on gastrointestinal tract (GIT) infections and their control using plant extract*"** submitted by Prof. Prashant Gupta, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1070/21 dated 4th October, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous EC Comment: • Kindly provide CTRI registration, New Medical devices, Insurance. • In the proposal the methods for sample collections are mentioned as stool, rectal swab and gastric biopsy of the patients suffering from diarrhea suggestive of gastrointestinal infections. Included population contains children and elderly too. Will gastric biopsy be done solely for the study or there will be some clinical indication for gastric biopsy and samples will be taken simultaneously? ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code: 111th ECM IIA/P8***
17.	Clarification of research proposal entitled "***Baseline data generation of time period from admission to discharge, of the admitted patients of oral and maxillofacial surgery as one of the quality indicators for quality control purposes: An observational study***" submitted by Dr. Arunesh Kumar Tiwari, Associate Professor, Department of Oral and Maxillofacial Surgery, King George's Medical University, U.P., Lucknow vide letter no.591/OMFS/21 dated 7th October, 2021. **Previous EC Comment:** • The methodology states that a set-proforma will be given to the patient to fill in the details further supplemented by the doctor on duty in case if any confusion. • a) Kindly enclose that set-proforma • If the patient is supposed fill in the proforma primarily then-Many aspects such as retrieval of reports, familiarity of referencing system may not be possible for a less educated patient to understand and hence it may produce a bias. So the data collection is to be done primarily by the doctor supplemented by the patient's inputs and not visa versa under such circumstances. This needs clarification. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **Action taken:** Provisionally approved **EC Decision:** Approved ***Ref. code: 111th ECM IIA/P11***
18.	Clarification of proposal entitled "***Assessment of impact of different factors as a risk for mucormycosis pathogenesis in COVID times: A case series analysis***" submitted by Dr. Shefali Gautam, Associate Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/854/21 dated 9th October, 2021. **Previous EC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Incomplete Performa. • Methodology details not provided • Sample size calculations not given • It is not clear if the study will be performed on patients or just medical records/data will be retrieved and analyzed. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code: 111th ECM IIA/P12***
	The following Members were present in its Meeting: 1. Dr. Alok Dhawan -Chairman 2. Dr. Rajendra Nath -Member 3. Dr. D.N. Upadhyaya -Member 4. Mrs. Akansha Dubey -Member 5. Mrs. Vasundhara Kumar -Member 6. Mr. Ujjawal Krishna -Member 7. Dr. Shally Awasthi -Member-Secretary, Ex-Officio
A	**The following items were taken up on the last ADR-Sub Committee Meeting, which was postponed because the quorum was incomplete.**
	Minutes of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting ***virtually*** held on 18th September, 2021 from 10.00 AM. **(DCGI)** ***The following Members were present in its Meeting:*** 1. Dr. Alok Dhawan -Chairman 2. Dr. Rajendra Nath -Member 3. Dr. D.N. Upadhyaya -Member 4. Mrs. Akansha Dubey -Member 5. Mrs. Vasundhara Kumar -Member

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	6. Mr. Ujjawal Krishna	-Member
	7. Dr. Shally Awasthi	-Member-Secretary, Ex-Officio
	DCGI	
I-	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1692/Cardio/Res/2021 dated 19th July, 2021, 1791/Cardio/Res dated 16th September, 2021, 1792/Cardio/Res/2021 dated 16th September, 2021.
a	**Death** **Subject ID no. 010-0003** **Subject Initial:** S-T **Gender:** F **Age:** 41 years **Patient enrolled date:** 12th July, 2017 **Patient follow up under study:** 1st Month, 6th Month, 12th Month and every 6th Month till 5 year **Weight:** 58 KG **Height:** 155 CM **Subject History:** On 19th July, 2021 the P.I. informed to the Ethics Committee that 2nd scheduled follow-up call was made on 12th July, 2021 around 12:30 P.M. Subject's (Patient) LAR revealed that she passed away on 24th February, 2021 around 3:00 P.M. in the hospital emergency KGMU. She did her morning activity and then felt syncope, breathlessness and chest pain for which she was taken to the hospital but could not admitted and expired in the hospital premises, hence no documents are available. No autopsy was done. **Primary reviewer recommendation:** SAE (Death) seems to be due to disease outcome (RHD with severe MS/severe MR with mild AR) as patient was enrolled in INVECTUS Registry treatment arm (given intervention in the form of rivaroxaban) and completed all scheduled visits except last three visits from July 2021. As told by LAR to PI that Pts felt syncope, breathlessness and chest pain and taken to local hospital where she died in hospital premises on 24th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

b	February, 2021 prior to admission. **ADR sub Committee Decision:** • Causal relationship cannot be established as death occurred at hospital premises, prior to admission, therefore no documents are available and no autopsy was done. **Subject ID no. 010-0032** **Subject Initial:** V-L **Gender:** F **Age:** 55 years **Patient enrolled date:** 25th January, 2018 **Patient follow up under study:** 1st Month, 6th Month, 12th Month and every 6th Month till 5 year **Weight:** 50 KG **Height:** 160 CM **Subject History:** According to the P.I. many times tried to contact the patient but her phone was not reachable. On 16th Aug, 2021 the call was received by her LAR, who revealed that patient passed away on 13th April, 2021 around 4.00 PM at home. She developed breathlessness, fever and chest pain for that a local practitioner called at home and confirmed about death. She was not hospitalized anywhere, hence no documents are available. No autopsy was done. **Primary reviewer recommendation:** SAE (Death) seems to be due to disease outcome (RHD, severe MS /AS with CVR) and not due to intervention as patient was enrolled almost 3 ½ years back in invasive (VKA) arm. Patient developed breathlessness, fever and chest pain and for which local practitioner was called at home who declared her dead on 13-04-2021. Causal relationship cannot be established as she was declared dead by local practitioner at her home and was not hospitalized anywhere therefore no hospital records/ documents are available and no autopsy was done. (Documents shows that patient had completed up to 36th month visits (i.e. at 1st month,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	6th m, 12th m, 18th m, 24th m, 30th month and 36th month visit and planning for 42nd month visit after randomization) **ADR sub Committee Decision:** Causal relationship cannot be established as she was declared dead by local practitioner and was not hospitalized anywhere therefore no hospital records/ documents are available and no autopsy was done. ***Ref. code: 83rd ECM IIC/P6***
B	Minutes of **"ADR Sub Committee"** Meeting of **"Institutional Ethics Committee"**, ***virtually*** held on 23rd October, 2021 from 10.00 AM. **(DCGI)**
	DCGI
I-	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1787/Cardio/Res/2021 dated 7th September, 2021, 1792/Cardio/Res/2021 dated 16th September, 2021. **Death** **Subject ID no. 010-0098** **Subject Initial:** D-N-Y **Gender:** M **Age:** 59 years **Patient enrolled date:** 1st August, 2019 **Patient follow up under study:** 1st Month, 6th Month, 12th Month and every 6th Month till 5 year **Weight:** 58 KG **Height:** 167 CM **Subject History:** On 7th September, 2021, it was reported by the P.I. that after many follow-up calls ultimately on 31st August, 2021 at around 3:00 PM the LAR answered to the call. Subjects LAR informed that the Subject passed away on 19th July, 2021. He developed breathlessness, fever, cough and chest pain for that subject was taken to the local

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	practitioner and he referred subject to KGMU. On the way to the hospital, he expired and could not be hospitalized anywhere, hence no documents are available. No autopsy was done. ***Recommendation of Primary reviewer:*** SAE (Death) seems to be due to disease outcome (Rheumatic Heart Disease, severe MR/Mod. MS, PAH and AF) and not due to intervention as patient was enrolled more than 2 years back in invasive (VKA-Warfarin) arm. Patient developed breathlessness, fever and chest pain and for which he was taken to some local practitioner and he referred the subject to KGMU. On the way to the hospital he expired and could not be hospitalized anywhere and died. Causal relationship cannot be established as he died on the way to the hospital and could not be hospitalized anywhere, therefore no hospital records / documents are available and no autopsy was done. (Documents shows that patient had completed up to 18th month visits i.e. at 1st month, 6th m , 12th m , 18th m and planning for 24th m visit after randomization.) **ADR sub Committee Decision:** Causal relationship cannot be established as he died on the way to the hospital. He was not hospitalized anywhere therefore no hospital records/ documents are available and no autopsy was done. ***Ref. code: 83rd ECM IIC/P6***
II	**Other Matter**
1-	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow With reference to the above trial it was noticed by ADR Sub Committee that 32 deaths have occurred out of 102 subjects recruited at KGMU. A concern was raised by the IEC members on the numbers of deaths reported in this trial. It was recommended that an opinion of a competent Cardiologist in RML/SGPIMS be taken by the Ethics Committee -Member Secretary.
I-B	**Expedited review**
	Expedited review of research proposal entitled ***"Comparison of the seventh and eighth***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	editions of AJCC staging system in oral cancer patients*"** submitted by Dr. Sudhir Singh, Professor Jr. Grade, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no.560/RT/21 dated 23rd July, 2021 & 8th September, 2021. **Recommendation of both Primary reviewers:** • It is stated that 2 staging system proposed by AJCC will be compared on the data available in the records of the department of oral cancer patients. But the aims and objectives and title itself is not able to clearly state the purpose of study. • The study is involving data related to Humans. It has to be stated in the proforma that no patient will be contacted for any question stated in the proforma and that no patient will be contacted for any end point acertainment. Because it has not been stated anywhere even in inclusion criteria that patient record for which end point information is in record only those will be study participants. • No justification for sample size is given. • Proforma is not able to explain violation of human rights. • Proforma not justified for waiver • The ethical committee review may be waived for this study as the study is a retrospective study involving data collected for another purpose. **EC Decision:** Approved for waiver of informed consent with the above caveats ***Ref. code: 112th ECM IB/P1
II-A	**New Proposal**
1.	Research proposal entitled ***"Pan India epidemiological, virological and genomic surveillance for Human influenza and COVID-19 through DHR-ICMR VRDL network"*** sponsored by DHR-ICMR submitted by Dr. Suruchi Shukla, Assistant Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.708/2021 dated 18th August, 2021. **EC Comment:** • Risk and benefits: • There **is** physical risk/discomfort • It is more than minimal risk • There is **no** benefit to the subject • What is the definition of "self collected specimens" • What is the definition of "sentinel sites" • Sample size: Will diagnosed SARS CoV-2 patients be enrolled also (this is with reference to statement: in addition to ILI definition……) • Broadened case definition: Tuberculosis can present with more than 2 criteria. Body ache, headache, feverishness are common symptoms of patients of various

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	diseases: Malaria, Dengue, etc. Needs to be modified. • Children (2m-5yrs): is this the definition of ILI/SARI- please clarify • Oseltamivir: • Is it required to do a susceptibility test for osetamivir in patients with Influenza A before prescribing to patients? • Statistical plan and sample size justification is not given. • Patient information document: • 6. Will the sample be taken from only one of the sites or both. Consent form says 'or' but research protocol mentions 'and'. • Which report will be sent to the physician, when and for what purpose. How will it affect treatment protocol? • 17. Which test results will be communicated? • Hindi version of the patient information sheet doesn't have a description of what will be done. • Many fields are missing, which are present in the English version. **EC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: 112th ECM IIA/P1***
2.	Research proposal entitled "***To evaluate effects of antenatal maternal antibiotics exposure on neonatal outcomes-A prospective observational study***" sponsored by Nurturing Children's Development Program Scholarship submitted by Dr. Arpita Bhriguvanshi, Associate Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2010/Ped/2021 dated 16th August, 2021. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code: 112th ECM IIA/P2***
3.	Research proposal entitled "***Calcium & Vitamin-D deficiency in children: Design & Validation of questionnaire to assess knowledge, attitude & practices of parents***" submitted by Dr. Suresh Chand, Assistant Professor, Department of Paediatric Oethopadics, King George's Medical University, U.P., Lucknow vide letter no.1106/Ped Ortho/2021 dated 9th September, 2021. ***Recommendation of Primary reviewer:-*** • 1 PI and 4 Co-PIs from the same department are unacceptable for a research proposal which involves only questionnaire administration to 30 volunteers. • Please decrease the same for approval. **EC Comment:** As above **EC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: 112th ECM IIA/P3***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

4.	Research proposal entitled "***Dynamic assessment of fall risk among prosthesis using lower limb amputee***" sponsored by CST.U.P., submitted by Dr. Sudhir R. Mishra, Associate Professor, Department of PMR, King George's Medical University, U.P., Lucknow vide letter no.DPMR/3972/2021 dated 1st September, 2021. ***Recommendation of Primary reviewer:-*** • Study has 1 PI and 3 Co-PIs with overlapping roles. Please decrease the number of Co-PIs or define their UNIQUE roles. • One Co-PI (Dr. Ganesh Yadav) has not signed the proforma. **EC Comment:** As above **EC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: 112th ECM IIA/P4***
5.	Research proposal entitled "***Trauma patterns in patients coming to orthopedic surgery department of a North Indian tertiary care Hospital: An epidemiological, regional and comparative study of lockdown and non-lockdown phases***" submitted by Dr. Arpit Singh, Associate Professor, Department of Orthopedics Surgery, King George's Medical University, U.P., Lucknow vide letter no.1089/OS/2021 dated 14th September, 2021. ***Recommendation of Primary reviewer:*** Approved for waiver **EC Decision:** Approved & Waiver granted ***Ref. code: 112th ECM IIA/P5***
6.	Research proposal entitled "***The stress, depression and anxiety levels of first year medical students: their inter-relation and correlation with sleep quality***" submitted by Prof. Archna Ghildiyal, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.2574/PHY/2021 dated 4th August, 2021. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code: 112th ECM IIA/P6***
7.	Research proposal entitled "***Identification and characterization of extra-cellular proteins under antibiotic stress conditions in E.Coli strains from patients with UTI***" sponsored by Govt.Agency submitted by Dr. Sheetal Verma, Associate Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1048/2021 dated 1st October, 2021. **Recommendation of Primary reviewer:** • Objectives not properly enumerated, objective No. 5 is not clear. • Methodology details not provided. • Sample size not mentioned. **EC Comment:** As above **EC Decision:** Modify and re-submit (Tracking changes in word format). Also

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	submit a point wise response to the comments of EC in a tabular form. ***Ref. code: 112th ECM IIA/P7***
8.	Research proposal entitled "***Intraoperative precursor events correctable and non-correctable associated with postoperative major and minor adverse events in vascular surgeries***" submitted by Dr. Amit Chaudhary, Assistant Professor, Department of Vascular Surgery, King George's Medical University, U.P., Lucknow vide letter no.65/VS/2021 dated 24th September, 2021. **Recommendation of Primary reviewer:** • Aim and objectives are not explicitly defined, to be converted into proper research hypotheses. The research hypothesis should be in term of the parameters involved in the study. • In the absence of proper research hypothesis, other components of a well-planned study are meaningless; including study subjects, sample size calculation etc. • The sample size calculations are not clear. In sample size calculation, the number is shown to be 160, whereas in material and methods, it is mentioned "approximately 200 subjects" • The study design is not mentioned. • The methodology section is incomplete. • The statistical analysis section is missing. **EC Comment:** As above **EC Decision:** Modify and re-submit (Tracking changes in word format), Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: 112th ECM IIA/P8***
9.	Research proposal entitled "***Testing efficacy of hybrid planning approach for solitary brain metastasis using conformal arc techniques***" submitted by Dr. Navin Singh, Additional Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no.787/RT/21 dated 5th October, 2021. **EC Decision:** Approved ***Ref. code: 112th ECM IIA/P9***
IIC	**Review of New Drug Trial**
1.	Research Protocol no.CT-CE-CS-2020 entitled "***An open label, single arm, multi centre, phase IV clinical study to evaluate efficacy and safety of tropicamide 0.2mg/ml, phenylephrine HCl 3.1mg/ml, lidocaine HCl 10mg/ml intracameral injection in patients undergoing cataract surgery***" sponsored by Sunways India Pvt. Ltd. submitted by Dr. Pramod Kumar, Associate Professor, Department of Ophthalmology, King George's Medical University, U.P., Lucknow, vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

1OPH/241/2021 dated 20th September, 2021.

The following documents were reviewed in its Meeting:

Sl.No.	Study documents	Version No.	Dated
1-	Study Protocol	2.0	17-May-2021
2-	Informed Consent Documents (Patient Information Sheet)_English	2.0	17-May-2021
3-	Informed Consent Documents (Patient Information Sheet)_English to Hindi Translation	2.0	04-Aug-2021
4-	Informed Consent Documents (Patient Information Sheet)_ Hindi to English Backtranslation	2.0	04-Aug-2021
5-	Informed Consent Documents (Patient Information Sheet)_ Translation and Back translation Certificate (English to Hindi, Hindi to English)	NA	04-Aug-2021
6-	Subject reported VAS (Visual Analogue Scale) for Pain Assessment Annexure-II_English	2.0	17-May-2021
7-	Subject reported VAS (Visual Analogue Scale) for Pain Assessment Annexure-II_English to Hindi-Translation.	2.0	04-Aug-2021
8-	Subject reported VAS (Visual Analogue Scale) for Pain Assessment Annexure-II_ Hindi to English –Back Translation	2.0	04-Aug-2021
9-	Subject reported VAS (Visual Analogue Scale) for Pain Assessment Annexure-II_	NA	04-Aug-2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Translation and back translation certificate (English to Hindi, Hindi to English)		
10-	CRF	2.0	17-May-2021
11-	Draft CTA	NA	NA
12-	DCGI NOC	NA	23-Apr-2021
13-	Investigator Undertaking_Dr. Pramod Kumar	NA	24-May-2021
14-	CV of Principal Investigator_ Dr. Pramod Kumar	NA	24-May-2021
15-	MRC of Principal Investigator_ Dr. Pramod Kumar	NA	24-May-2021
16-	Protocol Signature page_Dr. Pramod Kumar	2.0	24-May-2021

Recommendation of Primary reviewer:

- Item [5 vi] – Vulnerable subjects - NOT MENTIONED
- Item [5vii] – Special groups – Mentioned yes. Which special groups - clarify.
- Item [10 i] – Is the risk reasonable compared to the anticipated benefit? Answer is NO. Clarify.
- Item [3 iv] – Is it an investigational new drug? Answer is YES. Which is the new drug?
- Page 7 – What is FDC? [Fixed drug combination] – NOT GIVEN IN ABBREVATIONS
- Nowhere in the protocol the dose is used. Only the formulation of the FDC is given.
- PATIENT INFORMATION DOCUMENT
- In general the information document is big and cluttered. I need to be made more simple.
- Use of the word 'Intracameral' should be avoided. Information should be simple.
- What does phase IV trial means should be clarified. The previous data should be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	given in simple form. What is the other option has not been given. What is the use of this drug in the surgery has not been given. • The information regarding research, study design and study procedure can be combined in two –three paragraphs. Results of previous studies done should be given. It should be clarified that the drug is marketed and it is a postmarketing survey as I understand by phase IV trial. • Some other expert need to see the part related to financial compensation. • Hindi translation should be simplified and easy speaking hindi need to be used. • With these modifications the trial can be approved. • CTRA registration is pending; **EC Decision:** Modify and re-submit (Tracking changes in word format), Also tabular format. Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: 112th ECMIIC/P1***
2.	Research Protocol no.MC/BAN/21-001,Version/Date: Version 1.0 Dated 22 March, 2021 entitled ***"A prospective, randomized, parallel group, double blind, multicentric, active controlled, School based study to evaluate the efficacy and safety of albendazole 400 mg & Ivermectin 3 mg/6 mg/12 mg combination vs albendazole 400 mg in reduction of soil-transmitted helminth infections in children"*** sponsored by Pvt. Ltd. submitted by Prof. Shally Awasthi, Head, Department of Pediatrics, King George's Medical University, U.P., Lucknow, vide letter no. 6602/2021 dated 25th September, 2021. ***The following documents were reviewed in its Meeting:***

Sl.No.	Documents
1-	Scientific Review Report
2-	Clinical trial protocol
3-	Summary of the project
4-	Protocol Signature page
5-	Informed Consent form document (ICD) in English
6-	Informed Consent form document (ICD) in Hindi
7-	Back translated Informed Consent documents
8-	Back translated assent form with Certificate
9-	Assent form in English with Certificate

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	10-	Assent form in Hindi with Certificate
	11-	Case record form
	12-	Insurance policy
	13-	Investigator's Undertaking
	14-	PI's CV, MRC and GCP
	15-	Pack Insert Bandy Plus
	16-	Budget
	17-	Draft CTA

Recommendation of Primary reviewer: Approved

EC Decision: Approval subject to fulfillment and administrative formalities

Dr. Shally Awasthi did not participate in discussion and discussion making.

Ref. code: 112th ECMIIC/P2

III — **Modification**

1. Modification of Research protocol entitled ***"Evaluate the effectiveness, safety and tolerability of various doses of linezolid in combination with bedaquiline and pretomanid in adults with extensively drug-resistant (XDR),MDR with additional resistance to fluroquinolones or second line injectables, intolerant/non-responsive multidrug-resistant (MDR) pulmonary tuberculosis in India"*** submitted by Prof. Surya Kant, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no.1897/Res/2021 dated 31st August, 2021.

Recommendation of Primary reviewer:
Revision (Amendment) have been done in version-3.0 to version 3.1 for better safety of patients and also updated the pt. information sheet. **Noted.**

EC Decision: Approved

Ref.code:109th ECM IB/P7

2. Modification of Research protocol entitled ***"Pediatric asthma presentations and risk factors in India"*** sponsored by M/s Cipla Foundation submitted by Dr. Sarika Gupta, Professor Jr. Grade, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no.1880/Ped/2021 dated 31st July, 2021.

Recommendation of Primary reviewer:

- Questionnaire submitted is only in English version, therefore Hindi version is

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	also required. • ICF-English and Hindi version is not similar and Assent form for children not submitted (if submitted previously then ignore) **EC Comment:** As above **EC Decision:** Re-submit. Also submit a point wise response to the comments of EC in a tabular form. ***Ref.code:97th ECM II A/P2***
3.	Modification of Research protocol entitled ***"Relationship and difference between central aortic and peripheral blood pressure measurement performed with the same device(CABP Study)"*** sponsored by M/s Eris Life sciences Ltd. submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.1783/Cardio/Res/2021 dated 8th September, 2021. ***The following documents were reviewed in its Meeting:*** 1. Protocol Version 01 dt 6th July 2020. 2. ICF English Version 00 dt 01/07/2020. 3. ICF Hindi Version 00 dt 01/07/2020. 4. CRF Version 01 dt 06/07/2020. 5. Clinical study agreement. 6. CTRI Draft 7. EC Approval letter of Batra Hospital Delhi ***Recommendation of Primary reviewer:*** Noted **EC Decision:** Approved ***Ref.code:104th ECM II C/P2***
IV	**Extension**
1-	Extension of the research proposal entitled ***"Role of Wnt/β catenin signaling in stroma- mediated chemoresistance of acute myeloid leukemia"*** submitted by Dr. A.K. Tripathi, Professor & Head, Department of Clinical Hematology King George's Medical University, U.P., Lucknow vide letter no.817/CH/21 dated 24th September, 2021. ***Note: The above proposal already approved by 87th IEC Meeting held on 3rd November, 2017.*** **Recommendation of Primary reviewer:** Approved **EC Decision:** As above ***Ref. code: 87th ECM II A/P7***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

V	**Brought to Ethics Committee after V-PGTSC held on 4th September, 2021**
	Minutes of VI PG Thesis sub Committee" of "Institutional Ethics Committee" Meeting held on 8th October, 2021 from 12.00 Noon. ***The following Members were present in its Meeting:*** 1. Prof. G.G. Agarwal -Member 2. Prof. A.A. Mahdi -Member 3. Prof. Rajendra Nath -Member 4. Prof. Anita Rani Singh -Member 5. Dr. D.N. Upadhyaya -Member 6. Prof. Shally Awasthi -Convener
I-A	**Action taken**
1-	Clarification of the research proposal entitled ***"Childhood trauma experiences, mentalized affectivity, empathy and experiential avoidance in adults with dissociative disorders"*** submitted by Dr. Gunjan Joshi, II year under the guidance of Dr. Shweta Singh, Additional Professor, Department of Psychiatry, King George's Medical University U.P., Lucknow vide letter no.1319/Psy dated 10th September, 2021. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Previous PGTSC Comment:** • Remove patient identifiers from case record form **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: 107th ECM IIB M.Phil/P7***
2-	Clarification of the research proposal entitled ***"To study the correlation of MTR (A919G) and MTHFR (C677T) gene with endometriosis in women of reproductive age group"*** submitted by Dr. Suman, JRI, Department of Obstetrics & Gynaecology King George's Medical University U.P., Lucknow vide letter no. OG/1330/2021 dated 12th August, 2021. **Previous PGTSC Comment:** • Introduction is a poor cut-paste job. Argument for the need of the study needs to be made. • Need for a control group needs to be argued. • Is it a case-control study or an observational study? Is any intervention being done? These need to be looked into and amended. • In Privacy/Confidentiality section of Thesis Proforma the researcher has ticked both 'Direct Identifiers' as well as 'Completely Anonymized'. This needs correction

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: II-PGTSC-IIA /P13***
3-	Clarification of the research proposal entitled ***"Comparison of clinic-radiological characteristics of spontaneous intracerebral hemorrhage in patients with and without hypertension and their clinical outcomes"*** submitted by Dr. Vikas Vittal Prabhu, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 251/NEURO/21 dated 7th September, 2021. **Previous PGTSC Comment:** • Research hypothesis is not properly defined. It is a comparative study involving two groups. Accordingly, study design should be defined. There are no sample size calculations. Statistical Analysis section is very general and is not in line with the objective of the study. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P7***
4-	Clarification of the research proposal entitled ***"Clinical predictors of neuroimaging findings in patients with subacute sclerosing panencephalitis- ZA prospective evaluation"*** submitted by Dr. Keerthiraj D.B, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 250/NEURO/21 dated 7th September, 2021. **Previous PGTSC Comment:** • Kindly provide justification for not calculating or providing sample size. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P16***
5.	Clarification of the research proposal entitled ***"Evaluation of changes in ultrasonographic optic nerve sheath diameter as a useful point of care tool to supplement invasive intracranial pressure measurement in Paediatric patients with hydrocephalus undergoing neurosurgical intervention"*** submitted by Dr. Malika Dhawal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/440/21 dated 20th September, 2021. **Previous PGTSC Comment:** • **Suggest changing the title:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ultrasonographic evaluation of changes in optic nerve sheath diameter as a useful point of care tool to supplement invasive intracranial pressure measurement in pediatric patents with hydrocephalus undergoing neurosurgical intervention" • Subject selection, Privacy and Confidentiality and Consent Sections of Proforma incompletely filled. • No co-supervisor/Co-PI from Radiology Department is there. Who will do the ultrasound? Does the person doing the ultrasound? Does the person doing the ultrasound have PCPNDT registration? • According to the PI, ONSD is already an established method of detecting raised intracranial pressure. What is the rationale behind this study then?? What is the research question? Also, please mention role of each member of the team of researchers. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P33***
6.	Clarification of the research proposal entitled ***"Clinical and radiographic assessment of the efficacy of three different materials used as pulpotomy medicaments in primary teeth: A randomized control trial"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Gunna Madhuri, JRII, through his Mentor Prof. Afro Alam Ansari, Department of Paediatric and Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/689/21 dated 18th September, 2021. **Previous PGTSC Comment:** • The Principal-Investigator mentions that there is risk to the patients, but there are no plans for reporting of adverse events or provision of compensation. This is probably a mistake in filling the proforma. Please have it checked and edited. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IIIPGTSC-II B IMR-R/P2***
7-	Clarification of the research proposal entitled ***"Proliferative and anti-apoptotic indices of ameloblastoma and odontogenic keratocyst"*** submitted by Dr. Eram Khan, JRI, Department of Oral Pathology and Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 193/OP/21 dated 3rd September, 2021. **Previous PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The study design sample size calculation, methodology etc. need to be specified ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P5***
8-	Clarification of the research proposal entitled ***"Expression pattern of muc1 and muc4 in (OPMD) oral premalignant disorders and oral squamous cell carcinoma (OSCC) and normal oral mucosa in an attempt to analyze its role played in oral carcinogenesis"*** submitted by Dr. Sharon John, JRI, Department of Oral Pathology and Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 192/OP/21 dated 3rd September, 2021. **Primary reviewer recommendation:** • Study design, sample size calculation are not mentioned, the aims & objectives do not match with Material and methods. In material & method, the three groups are selected. This is not obvious from aims & objectives. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P7***
9-	Clarification of the research proposal entitled ***"Overexpression of epstein barr virus encoded latent membrane protein-1 in oral squamous cell carcinoma and oral premalignant disorders"*** submitted by Dr. S. Ramya, JRI, Department of Oral Pathology and Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 194/OP/21 dated 3rd September, 2021. **Previous PGTSC Decision:** • Study design, sample size calculation are not mentioned, the aims & objectives do not match with Material and methods. In material & method, the three groups are selected. This is not obvious from aims & objectives. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P8***
10-	Clarification of the research proposal entitled ***"Predisposing factors for hypotension during prone positioning in patients under general anaesthesia: A prospective observational study"*** submitted by Dr. Anupam Kumar Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/727/21 dated 26th August, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous PGTSC Decision: • Kindly provide in ICF clear, understandable description of study procedure in simple language instead of writing study design. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P15***
11.	Clarification of research proposal entitled ***"A randomized controlled study comparing videolaryngoscopy to conventional laryngoscopy for intubation in adult patients in intensive care unit"*** submitted by Dr. Ravi Shankar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anas/753/21 dated 6th September, 2021. **Previous PGTSC Comment:** • The answer to 'Risk is reasonable' has been give as 'No'. Please check if this is correct. If the risk is not reasonable the study cannot be approved. • Not specified in proforma • Boxes not checked. Please complete in ICF • Direct identifiers and Completely Anonymized are both ticked. Please correct in privacy & confidentiality. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P34***
12.	Clarification of research proposal entitled ***"Morphometric analysis of coracoids process, acromion process and glenoid fossa: A computed tomography study"*** submitted by Dr. Akriti Anand, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no.276/ANAT/21 dated 28th August, 2021. **Previous PGTSC Comment:** • PI has answered 'No' to the point 'Is the risk reasonable?' • Number of subjects not mentioned in the Form filled by the PI. • Besides written consent, Oral explanation of the consent also must be done. Not ticked. Consent must also be taken after explaining additional radiation dose • No mention of extra radiation dose that the patient will be subjected to. • Direct identifiers, indirect identifiers, and Anonymized are all ticked. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: IV PGTSC-IIA/P36
13.	Clarification of research proposal entitled ***"Effectiveness of intravenous extension tubing in reducing peripheral intravenous catheter failure in children: an open label randomized controlled trial"*** submitted by Dr. Jaya Gupta, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.2226/Ped/21 dated 11th September, 2021. **Previous PGTSC Comment:** • **In ICF**-Guardian consent and is assent form are not attached ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified
	Ref. code: IV PGTSC-IIA/P41
14.	Clarification of research proposal entitled ***"Clinico-anatomical study of posterior tibial artery and its perforators"*** submitted by Dr. Saba Anjum, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 285/ANAT/21 dated 1st September, 2021. **Previous PGTSC Comment:** • Study design not mentioned in brief synopsis (given in ICF as Observational cross - sectional study) • Do we need ICF in donated bodies or required Waiver form, should be discussed in meeting ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified
	Ref. code: IV PGTSC-IIA/P43
15.	Clarification of research proposal entitled ***"Quality of life among elderly people living in Lucknow"*** submitted by Dr. Manoj Soni, JR, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no.677/CM/2021 dated 24th September, 2021. **Previous PGTSC Comment:** • References not provided (Bibliography) ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Primary reviewer recommendation:** Approved **PGTSC Decision:** Approval ratified
	Ref. code: V PGTSC-IIA/P23
16.	Clarification of research proposal entitled ***"The effect of root end cavity preparation by laser, ultrasonic and conventional bur under microscope on microleakage of***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	different cements-an in vitro study" submitted by Dr. Vasanth M.N, JRII, Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.210/2021 dated 27th September, 2021. **Previous PGTSC Comment:** • Detailed study design not mentioned ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P42***
17.	Clarification of research proposal entitled ***"In vitro antimicrobial activity of propolis mixed with nanoparticles against enterococcus faecalis"*** submitted by Dr. Divya Pal, JRII, Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.09/21 dated 27th September, 2021. **Previous PGTSC Comment:** • Who will analyze the antimicrobial load before and after giving proposals mixed with Nanoparticles of E. fecalis? Co-guide from Microbiology is needed. • Work distribution of Dr. Suaib Luqman, Principal-Scientist (CSIR-CIMAP) not mentioned. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P46***
18.	Clarification of research proposal entitled ***"Assessment of salivary and serum interleukin 1β levels in precancerous and healthy individuals using enzyme linked immunosorbent assay: an observational study"*** submitted by Dr. Thamarai Salvan. T, JRI, Department of Oral Medicine and Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.544/OMS/21 dated 1st October, 2021. **Previous PGTSC Comment:** • 1 Supervisor and 4 supervisors from same department is superfluous. Please decrease the number or define their unique roles. • It is unclear from the IEC form who will bear the financial burned of the ELISA test? If the patient is being asked to bear this burden, is it a test which would be done routinely in all patients or is it being done only for the purposes of this project? In case the latter is true, the financial burden must lie with the investigator and not the patient.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P35***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"Effect of pre-operative oral carbohydrate supplement on maternal and neonatal outcomes for cesarean section under spinal anaesthesia"*** submitted by Dr. Anee Akhtar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/533/21 dated 30th June, 2021. **Recommendation of primary reviewer:** • This is Double blinded RCT. It should be mentioned in the title. • The fundamentals of performing RCT are not completely Specified: • Clinical Trial Registry • control and treated groups are not explicitly defined • outcome events and method of measuring it • repeated measurements are being taken, • The Statistical analysis section is very general. Appropriate Statistical and methodological issues are to be addressed. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P1***
2.	Research proposal entitled ***"Association of umbilical cord artery blood pH with neurological status (Hammersmith Neonatal Neurological Score) of term neonates at discharge"*** submitted by Dr. Priyanshi Dudeja, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.1037/Ped/21 dated 4th May 2021. **Recommendation of primary reviewer:** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P2***
3.	Research proposal entitled ***"Awareness on cervical cancer and acceptance of screening among peripheral Health workers and rural Women: An educational intervention"*** submitted by Dr. Rizwana, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no.357/CM/21 dated 12th July 2021. **Recommendation of primary reviewer:** Approved **PGTSC Decision:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: VI PGTSC-IIA/P3
4.	Research proposal entitled ***"Correlation of corneal hysteresis and ocular blood flow in retinal vein occlusion"*** submitted by Dr. Mohd. Shadab, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 373/OPH/21 dated 13th July, 2021. **Recommendation of primary reviewer:** • Aims, Objectives & corresponding research hypotheses are not properly defined. • Sample size formula is not correct. It uses prevalence, whereas it is a correlation-based study. • Study design mentioned is cross-sectional. So it is not clear why are they choosing three groups? DO they want to make comparison. Then it should be mentioned in aims, objectives etc. • Statistical section is very general. It is not specific to the problem being investigated. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P4***
5.	Research proposal entitled ***"Comparison of infraclavicular brachial plexus block and combination of infraclavicular brachial plexus block with suprascapular nerve block for shoulder surgeries: A randomized control trial"*** submitted by Dr. Parul Saxena, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/577/21 dated 13th July 2021. **Recommendation of primary reviewer:** The fundamentals of performing RCT are not completely Specified: (a) Clinical Trial Registry (b) Is blinding needed? (c) Research hypothesis is not properly defined: whether it is (i) inferior, (ii) superior or (iii) equivalence trial? (d) The sample size will depend on the research hypothesis. Statistical Analysis section should be more specific. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P5***
6.	Research proposal entitled ***"The evaluation of clinical efficacy of four different pit and fissure sealant modalities in young permanent molars: A randomized controlled trial"*** submitted by Dr. Jyoti Solanki, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.524/21 dated 6th July, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of primary reviewer: The fundamentals of performing RCT are not completely Specified: (a) Clinical Trial Registry (b) Research hypothesis is not properly defined. Here four groups are being compared. (c)The hypothesis should be defined in terms of the parameters of these four groups. (d)The randomization procedure is to be explicitly written for sampling into four groups. (e)The sample size will depend on the proper hypothesis. At present, it is inappropriate. (f)Statistical Analysis section should be rewritten according to the proper research hypotheses being tested. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P6***
7.	Research proposal entitled ***"In vivo comparison of remineralization potential of three varnishes on with spot lesion-randomized clinical trial"*** submitted by Dr. Dipika Yadav, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.526/21 dated 6th July, 2021. **Recommendation of primary reviewer:** The fundamentals of performing RCT are not completely Specified: (a) Clinical Trial Registry (b) Research hypothesis is not properly defined. Here three groups are being compared. (c)The hypothesis should be defined in terms of the parameters of these three groups. (d)The randomization procedure is to be explicitly written for sampling into three groups. (e)The sample size will depend on the proper hypothesis. At present, it is inappropriate. (f)Statistical Analysis section should be rewritten according to the proper research hypotheses being tested. ANOVA as well as multiple comparison tests will be required. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P7***
8.	Research proposal entitled ***"A comparative evaluation of BRIX 3000, smart burs and conventional technique of caries excavation in Paediatric dental population: A randomized controlled Trial (An In-Vivo Study)"*** submitted by Dr. Jay Somkuwar, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no.523/21 dated 6th July, 2021. **Recommendation of primary reviewer:** The fundamentals of performing RCT are not completely Specified: (a) Clinical Trial Registry (b) Research hypothesis is not properly defined. Here three groups are being compared. (c)The hypothesis should be defined in terms of the parameters of these three groups. (d)The randomization procedure is to be explicitly written for sampling into three groups. (e)The sample size will depend on the proper hypothesis. At present, it is inappropriate. (f)Statistical Analysis section should be rewritten according to the proper research hypotheses being tested. ANOVA as well as multiple comparison tests will be required. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P7***
9.	Research proposal entitled ***"A comparative evaluation of efficacy of different Irrigants on smear layer in root canals of deciduous teeth with conventional Irrigation vs. Passive ultrasonic Irrigation: An in-vitro SEM study"*** submitted by Dr. Alisha S. Jadhav, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.522/21 dated 6th July, 2021. **Recommendation of primary reviewer:** The fundamentals of performing RCT are not completely Specified: (a) Clinical Trial Registry (b) Research hypothesis is not properly defined. There are three main groups and two subgroups within main groups. So basically, there are five groups for comparison purposes. (c)The hypothesis should be defined in terms of the parameters of these five groups. (d)The randomization procedure is to be explicitly written for sampling into five groups. (e)The sample size will depend on the proper hypothesis. At present, it is inappropriate. (f)Statistical Analysis section should be rewritten according to the proper research hypotheses being tested. ANOVA as well as multiple comparison tests will be required. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P9***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

10.	Research proposal entitled ***"A study to determine the quality of life (QOL) in geriatric type 2 diabetes mellitus patients using world Health organization (WHO) criteria"*** submitted by Dr. Mohd. Shakir Hussain, JRI, Department of Pharmacology and Therapeutics, King George's Medical University, U.P., Lucknow vide letter no.726/PH/21 dated 14th July, 2021. **Recommendation of primary reviewer:** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P10***
11.	Research proposal entitled ***"Comparing color match by conventional trial and error method with maxillofacial spectrophotometer method for the Indian skin: A subjective and objective assessment"*** submitted by Dr. A. Sunayana, JRI, Department of Prosthodntics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.196/21 dated 15th July, 2021. **Recommendation of Primary reviewer:** • Although references are cited, they are not listed. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P11***
12.	Research proposal entitled ***"Effect of "Planning Intervention" on parent supervised oral health related behaviours of their children: A randomized controlled trial"*** submitted by Dr. Priyambadha H. Subba, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.525/21 dated 6th July, 2021. **Recommendation of Primary reviewer:** • Although references are cited, they are not listed. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P12***
13.	Research proposal entitled ***"Comparative assessment of cleaning efficacy of prime PEDO™ and KEDO-SG BLUE™ PEDOrotary files with conventional H files in root canals of deciduous teeth using stereomicroscopy, CBCT and SEM: an in vitro study"*** submitted by Dr. Abhisek Bhattacharjee, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.521/21 dated 6th July, 2021. **Recommendation of Primary reviewer:** • Main guide has retired, so a change in guide is needed. Although references are cited, they are not listed. They have asked for a Human Subjects Waiver. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P13***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

14.	Research proposal entitled ***"Imaging characteristics in cases of non cpmpressive cervical myeloradiculopathy on conventional and advanced MRI"*** submitted by Dr. Vivek Mishra, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no.1132/RD/21 dated 7th July, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P14***
15.	Research proposal entitled ***"Short-term visual outcomes of endothelial keratoplasty in a teaching Hospital"*** submitted by Dr. Shilpi Arya, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no.389/OPH/21 dated 16th July, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P15***
16.	Research proposal entitled ***"Assessment of stress in operating surgeons during phacoemulsification under topical anaesthesia"*** submitted by Dr. Devanand Bharti, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no.390/OPH/21 dated 16th July, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P16***
17.	Research proposal entitled ***"Comparison of insulin like growth factor levels in children with iron deficiency anemia and non anemic children and the change in insulin like growth factor levels in iron deficiency anemia after iron therapy"*** submitted by Dr. Samridhi Nagpal, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.1654/Ped/21 dated 10th July, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P17***
18.	Research proposal entitled ***"An epidemiological study of substance abuse among youth in Lucknow district"*** submitted by Dr. Hariom Singh, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no.404/21 dated 20th July, 2021. **Recommendation of Primary reviewer:** • Approved, however, in the consent form it is mentioned that "The ***patient*** can withdraw". • Instead of "***patient*** "write "***subject"***. Investigators may be advised to make this minor correction in the consent form. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: VI PGTSC-IIA/P18
19.	Research proposal entitled ***"Radiological evaluation of spinal dysraphism with ultrasonography and its comparison with magnetic resonance imaging in children UPTO 1 year of age"*** submitted by Dr. Dhiraj Kumar Gupta, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no.1130/RD/21 dated 7th July, 2021. **Recommendation of Primary reviewer:** • In aims and objectives it is mentioned that biopsy will be performed but it is not mentioned in the consent form. • Subjects are minors and consent will be taken from parents/guardians, but in consent form "I" and "my" is mentioned. Make necessary language corrections. • Although the study will be performed on children less than one year of age, no co-supervisor has been taken from the Pediatrics Department, otherwise there are a lot many co-supervisors. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form.
	Ref. code: VI PGTSC-IIA/P19
20.	Research proposal entitled ***"Diagnostic yield of trans-vaginal ultrasound in post menopausal females and correlation with CA 125 levels"*** submitted by Dr. Vasav Tyagi, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no.1131/RD/21 dated 7th July, 2021. **Recommendation of Primary reviewer:** • How Ca 125 levels will be measured? Sample collection/Methodology/ References are not given. Who will do the test? **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form.
	Ref. code: VI PGTSC-IIA/P20
21.	Research proposal entitled ***"Randomized comparison of BASKA mask versus AMBU auragain for airway management of surgical patients"*** submitted by Dr. Surbhi Rampal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/520/21 dated 7th June, 2021. ***Recommendation of Primary reviewer:*** • Roles of both Co-PIs are overlapping **PGTSC Comment:** • As above **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: VI PGTSC-IIA/P21
22.	Research proposal entitled ***"Comparative study between shot blocker device versus vapocoolant spray for spinal needle pain relief during spinal block in elective caesarean section"*** submitted by Dr. Pratibha Mall, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/546/21 dated 3rd July, 2021. ***Recommendation of Primary reviewer:*** • Clinical trial section has been filled. If this is not a new device please change the details in the IEC form. If yes, please comment on CTRI registration. • Roles of all Supervisors are overlapping. • Co-Supervisor from General Surgery is part of the study (Why?) whereas no Co-Supervisor from Department of OBG has been taken from where the patients will be recruited. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form.
	Ref. code: VI PGTSC-IIA/P22
23.	Research proposal entitled ***"Retrospective analysis of geriatric traumatic brain injury at a tertiary care centre: A five-year experience"*** submitted by Dr. Abhishek Kumar, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/462/21 dated 26th July, 2021. ***Recommendation of Primary reviewer:*** • There is 1 Supervisor and 6 Co-Supervisors from Neurosurgery. This cannot be approved. Please decrease the number of Co-supervisors. • International Government and National Industry have been ticked as sponsors. • Clinical trial section has been filled. Is this a Trial? • Written consent has been ticked. How will consent be obtained in a retrospective study? • Risk is not reasonable has been ticked. Explain why? • Sample calculation not done. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form.
	Ref. code: VI PGTSC-IIA/P23
24.	Research proposal entitled ***"Effects of music intervention on anxiety and stress in patients undergoing total abdominal hysterectomy under spinal anaesthesia"*** submitted by Dr. Nishant Kaushik, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/623/21 dated 26th July, 2021. ***Recommendation of Primary reviewer:*** • No Co-PI from Department of OBG from where the patients will be recruited? • Risk is not reasonable has been ticked. • Section on Consent in the IEC form has been left blank.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Sample size calculation is 94 per group but PI has mentioned sample size as 70 in the IEC form. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P24***
25.	Research proposal entitled ***"3D assessment in TMJ ankylosis"*** submitted by Dr. Sharma Shivani Yogesh, JRI, Department of Oral and Maxillofacial Surgery, King George's Medical University, U.P., Lucknow vide letter no.318/MFS/21 dated 21st May, 2021. ***Recommendation of Primary reviewer:*** • Role of Supervisor and Co-Supervisors are overlapping. • Number of subjects is mentioned 30 at one place and 300 at another. • No sample calculation has been done. • There are tonnes of material describing deformity, treatment, and post-operative changes in TMJ ankylosis. What is the need for another study? • Methodology is incomplete. Are the patients being offered treatment? If so, what? What is the protocol for follow-up after that? **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P25***
26.	Research proposal entitled ***"Post ankylosis customized TMj replacement: A study"*** submitted by Dr. M. Haaris Khan, JRI, Department of Oral and Maxillofacial Surgery, King George's Medical University, U.P., Lucknow vide letter no.317/MFS/21 dated 21st May, 2021. ***Recommendation of Primary reviewer:*** • The study has 1 Supervisor and 4 Co-Supervisors. Please reduce their number or define their UNIQUE roles. • Clinical Trial section has been ticked. Please elaborate if this is a Clinical trial with a new drug or device. If yes, has CTRI registration been sought/will be sought? • Subject number is 10 at one place and 300 at another. • No sample calculation has been done. • Prosthetic TMJ replacement by titanium implants is a standard procedure. What, then. Is the purpose of this study? • For the patients taking part in the project, who will bear the cost of the customized 3D printed implant? **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P26***
27.	Research proposal entitled ***"Evaluation of expression of immunohistochemical markers Isocitrate dehydrogenase 1 (IDH1) and tumor protein 53 (p53) in high grade***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	glioma and its correlation with outcome-a prospective study" submitted by Dr. Vikas Kumar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.NS/482/21 dated 29th July, 2021. ***Recommendation of Primary reviewer:*** • Indian and International Private Agencies and National industry has been marked as sponsors of this study? Give supportive evidence if this is correct. • Section on Use of Biological Material has been filled incorrectly. • Section on Consent has been incompletely filled. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P27***
28.	Research proposal entitled ***"A prospective study of comparison between open cavity mastoid surgery versus posterior canal wall reconstruction technique using composite multi-fractured osteoperiosteal flap (CMOF)"*** submitted by Dr. G.C. Lalremruata, JRI, Department of OTO-Rhino-Laryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no.165/ENT/21 dated 12th July, 2021. ***Recommendation of Primary reviewer:*** • Project has 1 Supervisor and 5 Co-supervisors. Please decrease the number of Co-supervisors for approval. • National Industry is marked as sponsor and Budget as self. Please give supportive evidence if this is correct. • Sample size given as 25 in IEC form and 25 per group in sample calculation. • Section on Consent is incompletely filled. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P28***
29.	Research proposal entitled ***"Multi-Modal pre-emptive analgesia with pre-gabalin and naproxen in thoracotomy surgeries and its effect on COMT genotype"*** submitted by Dr. Prajjal Das, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/662/21 dated 3rd August, 2021. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P29***
30.	Research proposal entitled ***"Prospective observational study on hyponatremia in acute encephalitic syndrome in children: its occurrence and effect on the outcome"*** submitted by Dr. Nikita Diwan, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1932/Ped/21 dated 4th August, 2021. ***Recommendation of Primary reviewer:*** • Number of subjects is 200 or 215?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Vulnerable subjects have not been ticked even though it is a study on children. • Section on Consent is incomplete. • Answer to 'Risk is reasonable' is NO. 5. Assent form for children is not attached. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P30***
31.	Research proposal entitled ***"To see the effect of duration and size of perforation, its correlation with hearing loss in patients of chronic suppurative otitis media"*** submitted by Dr. Rahul Anand, JRI, Department of OTO-Rhino-Laryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 216/21 dated 2nd August, 2021. ***Recommendation of primary reviewer:*** • Thesis title should be modified to explain perforation of which part and it should be written as "perforation of tympanic membrane" • In Exclusion criteria the point no. 2 (Pts. with tubo tympanic membrane CSOM) should be deleted as it is the part of Inclusion criteria • Calculated sample size not given and discrepancy in sample size mentioned in SOP form (100 pts) and protocol synopsis (215) should be explained clearly that what is the actual sample size is. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P31***
32.	Research proposal entitled ***"Salivary and serum estrogen level assessment in oral lichen planus patients and its correlative analysis with oral lichen planus and stress"*** submitted by Dr. Heena Agrawal, JRI, Department of Oral Medicine and Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 430/OM/21 dated 2nd August, 2021. ***Recommendation of primary reviewer:*** • In Inclusion criteria specific age group not mentioned • Stress scale not attached **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P32***
33.	Research proposal entitled ***"Comparative evaluation of CBCT gray scale values with DXA values for diagnostic accuracy in osteoporosis"*** submitted by Dr. Deepak Kumar, JRI, Department of Oral Medicine and Radiology, Faculty of Dental Sciences,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	King George's Medical University, U.P., Lucknow vide letter no. 433/OM/21 dated 6th August, 2021. ***Recommendation of primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P33***
34.	Research proposal entitled ***"A comparative evaluation of circulatory and salivary miRNA signatures in oral leukoplakia and oral lichen planus: A perspective case control study"*** submitted by Dr. Anil Kumar, JRI, Department of Oral Medicine and Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 434/OM/21 dated 6th August, 2021. ***Recommendation of primary reviewer:*** • Age group not specified **PGTSC Decision:** Approval subject to modification ***Ref. code: VI PGTSC-IIA/P34***
35.	Research proposal entitled ***"Pharmacoeconomic evaluation of antidiabetic medication in geriatric type 2 diabetes-a brief study"*** submitted by Dr. Arun Jakhar, JRI, Department of Pharmacology and Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 829/21 dated 6th August, 2021. ***Recommendation of primary reviewer:*** • Sample size given according to WHO reference but calculation not done • Principal Investigator should be JR1 (but in this protocol Chief supervisor, Dr. Sanjay Khattri mentioned himself as PI and JR as Co-supervisor) • Work distribution of JR1 and Chief supervisor not mentioned • Detailed methodology for Pharmacoeconomic evaluation of Anti-diabetic drugs not mentioned **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P35***
36.	Research proposal entitled ***"Pharmacological analysis of therapeutic outcome of SGLT-2 inhibitors on heart failure in diabetes patients"*** submitted by Dr. Harshika Gupta, JRI, Department of Pharmacology and Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 727/Phar/21 dated 14th July, 2021. ***Recommendation of primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P36***
37.	Research proposal entitled ***"The tentorial notch anatomy and its variations in autopsy of head injury patients to correlate its impact over brainstem and its correlation with computed tomography scan of head findings"*** submitted by Dr. Anoop Kumar Singh, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/493/21 dated 3rd July, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of primary reviewer: • There are many Co-investigators ,8 in number (including 1 from Anatomy and 1 from Forensic Dept. + 6 from same dept.) and their roles given are almost same-Reduce Member or justify roles of each. • Sample size not mentioned at all. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P37***
38.	Research proposal entitled ***"To correlate the mammography density imaging findings with clinic pathological tumour characteristics in breast cancer patients"*** submitted by Dr. Upander Kumar, SR, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. 205/21 dated 17th July, 2021. ***Recommendation of primary reviewer:*** • Sample size not mentioned. **PGTSC Decision:** Approval subject to modification. ***Ref. code: VI PGTSC-IIA/P38***
39.	Research proposal entitled ***"Analysis of achievement of radiological parameters in uncemented total hip replacement-a retrospective cohort study"*** submitted by Dr. Md Ash Ar Reza, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2500/OS/21 dated 2nd July, 2021. ***Recommendation of primary reviewer:*** • 10 Co-investigators from same department with almost similar role in thesis. • Reduce or justify the need for these ID **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P39***
40.	Research proposal entitled ***"Association of cholinergic biomarkers with post operative delirium in elderly patients undrgoing spinal anaesthesia: A prospective cross-sectional study"*** submitted by Dr. Praveen Kumar Yadav, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/671/21 dated 4th August, 2021. ***Recommendation of primary reviewer:*** • Informed Consent Form -English and Hindi version not similar (Hindi version not complete) **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P40***
41.	Research proposal entitled ***"Evaluation of serum pro-brain natriuretic peptide as a biomolecular biomarker for severity of diabetic retinopathy"*** submitted by Dr. Prachi, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	vide letter no. 493/OPH/21 dated 4th August, 2021. ***Recommendation of primary reviewer:*** • Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P41***
42.	Research proposal entitled ***"The effectiveness of high flow nasal cannula as a weaning method compared to conventional weaning in mechanically ventilated patients in critical care unit: A randomized controlled trial"*** submitted by Dr. Gauri Arora, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/604/21 dated 20th July, 2021. ***Recommendation of primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P42***
43.	Research proposal entitled ***"A randomized clinical trial: comparison of pretreatment of magnesium with two different doses of rocuronium in rapid sequence intubation"*** submitted by Dr. Mudita Sharma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/535/21 dated 29th June, 2021. ***Recommendation of primary reviewer:*** • Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website. • Explain the risk properly to the patient in simple language. • Follow RCT protocol. • Get it registered with CTRI. **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P43***
44.	Research proposal entitled ***"To study the role of cerebrospinal fluid-c-reactive protein in the diagnosis of neonatal meningitis in NICU"*** submitted by Dr. Rajesh Kumar Singh, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1094/Ped/21 dated 8th May, 2021. ***Recommendation of primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P44***
45.	Research proposal entitled ***"Assessment of neuropsychiatric outcomein intensive care unit survivors-A prospective cohort study"*** submitted by Dr. Shivam Joshi, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	vide letter no. Anaes/670/21 dated 4th August, 2021. ***Recommendation of primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P45***
46.	Research proposal entitled ***"Effect of different head-and-neck positions on oropharyngeal leaking pressures of LMA-supreme™ and AuraGain™ in anaesthetized Paediatric patients: A randomized control trial"*** submitted by Dr. Neelam Chauhan, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/631/21 dated 27th July, 2021. ***Recommendation of primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P46***
47.	Research proposal entitled ***"Study on vaccine hesitancy against COVID-19 vaccines among patients with autoimmune rheumatic diseases"*** submitted by Dr. Chandwar Kunal Ashutosh, SRII, Department of Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/531/21 dated 11th August, 2021. ***Recommendation of primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P47***
48.	Research proposal entitled ***"Study on effect of COVID-19 on rheumatology trainee in India"*** submitted by Dr.Chandwar Kunal Ashutosh, SRII, Department of Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/532/21 dated 11th August, 2021. ***Recommendation of primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P48***
49.	Research proposal entitled ***"Intravenous bolus dose of phenylephrine and intravenous bolus dose of norepinephrine for treatment of maternal hypotension in spinal anasthesia during caesarean section-A comparative study"*** submitted by Dr. Danish Jamal Ansari, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/690/21 dated 10th August, 2021. ***Recommendation of primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VI PGTSC-IIA/P49***
50.	Research proposal entitled ***"The utility of thromboelastography for predicting the progression of intracranial hemorrhage in traumatic brain injury patients"*** submitted by Dr. Preshit Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/672/21 dated 4th August, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of primary reviewer: • Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website **PGTSC Decision:** Modify and re-submit (Tracking changes in word format). Also submit a point wise response to the comments of EC in a tabular form. ***Ref. code: VI PGTSC-IIA/P50***

Thanks

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 113th ECM held on 4th December, 2021

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the Institutional Ethics Committee Meeting *virtually* held on **4th December, 2021 from 10.30 AM.**

The following Members were present in the Meeting:-

1. Prof. Alok Dhawan -Chairman
2. Prof. G.G. Agarwal -Member
3. Prof. Shubha R Phadke -Member
4. Mrs. Vasundhara Kumar -Member
5. Mrs. Akansha Dubey -Member
6. Mr. Ujjawal Krishna -Member
7. Dr. Akash Agarwal -Member
8. Dr. K.K. Yadav -Member
9. Prof. A.A. Mahdi -Member
10. Prof. Rajendra Nath -Member
11. Prof. Anupam Mishra -Member
12. Prof. Shally Awasthi -Member-Secretary, IEC

The following Member could not attend the Meeting:

1. Prof. Anita Rani Singh - Sent her written comment
2. Dr. D.N. Upadhyaya - Sent his written comment

I-A	Action taken
1.	Clarification of research proposal entitled "***Molecular and metabolic profiling of obstructive sleep apnea in North Indian population***" submitted by Mr. Mohit, Ph.D Scholar 2018 under the guidance Prof. Pooran Chand, Head, Department of Prosthodontics, Faculty of Dental Sciences, K.G's Medical University, U.P., Lucknow letter no. 725/2021 dated 22nd October, 2021. ***The following comment forwarded to the P.I., Reply given by P.I. in tabular format was reviewed by the Primary reviewer.***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Sl.no.	EC Comment	EC Decision		
1-	Justify role of each guide		**Name and affiliation**	**Role justification**
		Guide	Prof. Pooran Chand, Head, Deptt. of Ptosthodontics, KGMU UP, Lucknow	Guidance, planning and execution. OPD clinical parameters. Sample collection & processing. Data analysis and interpretation. Review of progress of Ph.D. work.
		Co-Guide	Prof. Raghuwal Dayal Singh, Deptt. of Ptosthodontics, KGMU UP, Lucknow	Sample collection, Data analysis and interpretation. Review of progress of Ph.D. work.
		Co-Guide	Prof. Sumit Kumar Jurel, Deptt. of Ptosthodontics, KGMU UP, Lucknow	Sample collection, Data analysis and interpretation. Review of progress of Ph.D work.
		Co-Guide	Dr. Ashutosh Shrivastava, Associate Professor, Deptt. of CFAR, KGMU UP, Lucknow	As is a basic scientist and will help in the molecular biology experiments and metabolomics studies. Review of progress of PhD. work.
2	How will north Indian population be defined?	Any patients regardless of geographical location who shows up in the OPD-KGMU will be considered. This study no longer restricted to north Indian population, we have revised Ph.D. topic that now read as ***"Metabolomics and gene expression analysis to understand the severity of obstructive sleep apnea"***. Amendment letter signed by all the doctoral committee members is		

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			attached for your kind consideration.
	3	**Methodology** Needs to be elaborated with flow chart.	Flow chart attached
	4	**What are those "following criteria"** for subject collection?	The following criteria for subject collection are below: Patients visiting OPD of Prosthodintics and Crown & bridge and refer patients from other departments i.e., Respiratory, Pulmonary and ENT will be screened for OSA following questionnaire and Plysomnography. The patient will comprise of those who attend Dental O.P.D. An informed consent will be taken from the patients. The study is scheduled to begin only after obtaining Ethical Committee clearance. **Inclusion Criteria:** • Clinically confirmed and diagnosed OSA patients. • Willing to participate in the study. • Subjects who will be available on the day of examination. **Exclusion Criteria:** • Unwilling or unable to perform testing procedure. • Past or current smoking history • Medical condition (Uncontrolled and serious patients including cardiovascular disease, chronic pulmonary disease, diabetes, endocrinologic disease, chronic renal failure and psychiatric disease) • Systemic inflammatory conditions (system lupus erythematosus, rtheumatoid arthritis, sarcoidosis, Crohn's disease and ulcerative colitis)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		• Enrolled in other trials in the study period. • Other sleep disorders.
5	Need refinement and all criteria to be consolidated at one place.	**Inclusion Criteria:** • Clinically confirmed and diagnosed OSA patients. • Willing to participate in the study • Subjects who will be available on the day of examination.
6	**Control arm** Mention the source of controls?	Healthy volunteers with free of OSA based history and other medical conditions will be included.
7	What will be the consent procedure for controls and specially for obtaining the blood sample?	Taking part in this study is voluntary. All the samples from healthy volunteers will be collected after obtaining informed consent form as same as the case.
8	**ICF:** Study procedure section of informed consent document should be more understandable to the patients BUT study procedure section of informed consent document should be elaborated.	We appreciate the reviewer's comments. We have now elaborated the study procedure. To identify the molecular based biomarker in plasma samples of obstructive sleep apnea with the held of gas chromatography/mass spectromemetry and Real time-PCR technique.
9-	Include and Investigator form Respiratory from Respiratory Medicine.	Dr. R.A.S. Kushwaha, Professor, Department of Respiratory Medicine, KGMU is already in doctoral committee as an internal expert. (DC letter attached) and he is actively involved in subject's recruitments and selection.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	10-	Give budget & Source of funding.	The expected budget for the proposed study is around 2-3 lakhs. Mr. Mohit (Ph.D.Scholar) is recipient of a Senior Research Fellowship with contingency grant from the Indian Council of Medical Research, Government of India (Fellowship ID: 2020-3690)

Recommendation of primary reviewer: Provisionally Approved

EC Comment:

- Sample to be collected after the date of approval of protocol of EC

EC Decision: Approved

Ref. code: 107th ECM II B-Ph.D/P2

2. Clarification of research proposal entitled "***Pediatric thyroid nodules: A multi-institutional study from India***" submitted by Dr. Chanchal Rana, Associate Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 3315/2021 dated 18th October, 2021.

The following comment forwarded to the P.I., Reply given by P.I. in tabular format was reviewed by the Primary reviewer.

Previous EC Comment	Response
It is a retrospective cohort study, for patients undergoing fine needle aspiration cytological assessment. Incomplete Perform, sample size not mentioned.	This study is a retrospective descriptive/audit study, where the data will be collected from the departmental archives of the three institutes (KGMU, SGPGI and AIIMS) which will be analyzed under pediatric and adult category followed by statistical comparison between the two. No other procedure/staining/IHC etc will be performed. It is purely a descriptive study related to data collection followed by statistical analysis. The final sample size will depend upon the data collected, but we expect it to be around 4000-5000 cases of thyroid.

Recommendation of primary reviewer: Provisionally Approved

EC Decision: Approved

Ref. code: 110th ECM IIA/P3

3- Clarification of research proposal entitled "***Association of genetic variations of the TGF alpha and MTHFR genes with non syndromic cleft lip with or without cleft palate in***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	North Indian population*"** submitted by Dr. Juhi Yadav, Department of Dentistry Government allopathic Medical College, Banda, Through under the guidance Dr. Veerendra Prasad, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no.1109 dated 1st November, 2021. **Previous EC Comment:** • Sample size has not been calculated and given in protocol separately (Mentioned 100 pt. + 100 control in material method part). • Methodology details not given- study design not mentioned • English & Hindi Informed Consent Form are attached but Ascent form for children not attached. • Scientific review to be done in the Department. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer. **Primary reviewer recommendation:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 110th ECM IIA/P10***
4-	Clarification of research proposal entitled **"*Estimation of hearing deficits following critical illness in patients discharged from intensive care unit*"** submitted by Dr. Sai Saran, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.389/2021 dated 12th October, 2021. **Previous EC Comment:** • There is a serious risk of overestimation of hearing deficits in this study as small deficits may not be reported/observed/record in people outside hospital who have not had an audiometry on a pervious occasion. How do the investigators plan to take care of this? • Statistical analysis: Univariate and multivariable analysis should be included to identify risk factors. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** **Recommendation of Primary reviewer:** Provisionally Approved **EC Decision:** Approved ***Ref. code: 111th ECM IIA/P6***
5-	Clarification of research proposal entitled **"*A study to evaluate the clinical efficacy of indigenously designed and manufactured titanium dental implant system with hybrid threads and anti-rotational features*"** submitted by Prof. Balendra Pratap Singh, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.nil dated nil. ***The following comment forwarded to the P.I., Reply given by P.I. in tabular format was reviewed by the Primary reviewer.*** **Previous EC Comment** | **Response**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

In the proposal, study design is given as parallel or split mouth design, case studies for initial testing of new technology followed by RCT with proper randomization, allocation concealment and follow up. There is no mention about an implant which will be considered as standard or gold standard for comparison.	We will use Straumann (bone level, SLA modified) Implant as standard implant for comparison.

Primary reviewer recommendation: Provisionally Approved
EC Decision: Approved

Ref. code: 111th ECM IIA/P9

6- Clarification of research proposal entitled "***Magnetic resonance imaging in rhino-orbital-cerebral mucormycosis- an imaging experience from tertiary care center in North India***" submitted by Dr. Amit Kumar Verma, Assistant Professor, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no.40/RD/2021 dated 12th November, 2021.

The above comment forwarded to the P.I., Reply given by P.I. in tabular format was reviewed by the Primary reviewer.

Previous EC Comment	Response
Consent form is not up to mark, Hindi & English are not similar.	Consent forms have been updated in both Hindi and English.
This is a retrospective study-needs clarification as how does ICD fit into this picture. On one hand investigators indicate that ICD 'was obtained' while on the other hand they state that "the patients will be informed about the risks	This study is based on contrast enhanced MRI (CE-MRI) of the PNS, Orbits and Brain. Though this gadolinium based contrast agents helps in better detection f the disease/pathology, there may be some related risks as well. Therefore, as per SOP, all the patients who require a gadolinium based IV contrast are informed about the potential risks related to these agents and they must sign a mandatory informed consent before the study. This is irrespective of whether

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	of the contrast agent": Please clarify.	a patient is enrolled in a study or not. Contrast studies cannot be done for the patients who refused to sign the consent. That is why we have mentioned that all the patients were informed about the contrast related risk and an informed consent document was obtained before the study.
	On one hand the investigators intend to follow the patients clinically but no account of clinical data collection is mentioned. How will it be possible to follow up the patients in a retrospective study-will retrospective clinical data be also collected? Please clarify.	Primary aim of this research is to study the imaging spectrum and disease spread of the rhino-orbital-cerebra mucormycosis (ROCM) using contrast enhanced MRI, therefore the study is primary imaging based. However, a retrospective follow-up based on clinical data will be done for the duration of patients stay in the hospital, i.e. from presentation to discharge. Clinical data related to presenting symptoms, relevant risk factors and comorbidities and surgical procedures outcome will be collected for correlation with the imaging findings.
	It would be further nice if the review of literature focuses more upon the known MRI findings in ROCM and the data collection to mention more about anticipated MRI features along with their assessment.	In respect to the IEC response, review of literature has been updated.
	Primary reviewer recommendation: Provisionally Approved **EC Decision:** Approved ***Ref. code: 111th ECM IIA/P10***	
7-	Clarification of research proposal entitled "***Genetic screening of susceptible loci for type 2 diabetes and gestational diabetes in the North Indian population identified in "Genome-wide association" study***" sponsored by Council of Science & Technology U.P submitted by Ms. Zoya Shakir, Ph.D Scholar 2019 under the guidance Dr. Wahid Ali, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.3331/21 dated 20th October, 2021, K.G's Medical University, U.P., Lucknow. ***The above comment forwarded to the P.I., Reply given by P.I. in tabular format was reviewed by the Primary reviewer.***	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comment	Response
Risks have been mentioned as unreasonable in the IEC form.	Risk has been mentioned as unreasonable in the IEC form.
Pregnant women are vulnerable subjects. This has not been mentioned in the IEC form.	Yes, pregnant women as vulnerable subjects who is required be mentioned in the IEC form. It is not marked as due to typographical error. I will collect blood samples from pregnant women too for gestational diabetes screening and so it has to be mentioned under a vulnerable category.
Where will the subjects for the control arm are recruited from? If they will be recruited from students/staff, this will have to be mentioned under special groups.	Subject for the control arm will not be recruited from the students/staff. For T2DM screening, controls will be recruited from same OPD of medicine as from where its cases will be taken. Patients will be excluded as control who don't have diabetes and any other major illness like HIV, cancer. For GDM screening, controls will be recruited from same OPD of obstetrics and Gynecology as from where its cases will be taken. Pregnant ladies will be excluded as control that doesn't develop Gestational diabetes during their all three trimesters.

Recommendation of Primary reviewer: Provisionally Approved
EC Decision: Approved

Ref. code: 111th ECM II B-Ph.D/P1

8 Clarification of research proposal entitled "***A study to assess the impact of "Group motivational enhancement therapy" on clinical outcome and quality of life among patients with opioid dependence undergoing maintenance treatment***" submitted by Mrs. Sudha Mishra, Ph.D Scholar under the guidance Prof. Vivek Agrawal, Head, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.1611/21 dated 3rd November, 2021.

Previous EC Comment	Response
It is unclear if the patients being recruited are in-patients or OPD patients	Patients being recruited are OPD patients but they are registered in Opioid Substitution Therapy (OST)/ Drug treatment center (OST/DTC) at Department of Psychiatry, K.G's Medical University, Lucknow U.P.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

<table>
<tr><td></td><td></td><td>They are coming into the department on daily basis for taking Opioid Substitution Therapy. As this medicine is taken under the supervision of health care providers.</td></tr>
<tr><td></td><td>IEC form mentions No vulnerable participants, but in the details 'Any other' has been ticked. Please clarify.</td><td>Correction done, Performa attached</td></tr>
<tr><td></td><td>IEC form mentions that study will include 'institutionalized' subjects. Are these In-patients? Or OPD patients?</td><td>Subjects are OPD patients but they are registered in Opioid substitution therapy (OST)/Drug treatment center (OST/DTS) at the Department of Psychiatry, K.G's Medical University, Lucknow U.P. They are coming in the department on daily basis for taking Opioid Substitution Therapy. As this medicine is taken under the supervision of health care providers.</td></tr>
<tr><td></td><td>Number of Co-PIs is untenable. Please reduce the number of Co-PIs from the same department as their roles are overlapping.</td><td>One Co-PI reduced out of four Co-PIs and roles differs from each other.
<table>
<tr><th></th><th>Name, Designation & Qualifications</th><th>Role of Investigators</th></tr>
<tr><td>PI</td><td>Mrs. Sudha Mishra, Ph.D. Scholars</td><td>Designing the topic of the research and methodology Data collection, implementing the intervention, Data analysis, interpretation, thesis writing, manuscript preparation, publication.</td></tr>
<tr><td>Co-PI 1-</td><td>Chief-Guide:
Prof. Vivek Agrawal, Head, Deptt. of Psychiatry, KGMU</td><td>Overall Guidance in protocol preparation, helping in literature search, thesis writing.</td></tr>
<tr><td>2-</td><td>Co-guide:-
Prof. Anil Nischal, Deptt. of Psychiatry, KGMU</td><td>Guidance in methodology preparation, helping in the literature search</td></tr>
<tr><td>3-</td><td>Dr. Sujita Kumar Kar, Associate Professor, Deptt. of Psychiatry,</td><td>Guidance in designing the topic</td></tr>
</table></td></tr>
</table>

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	KGMU		of the research, data interpretation, manuscript editing.

Recommendation of Primary reviewer: Provisionally Approved
EC Decision: Approved

Ref. code: 111th ECM II B-Ph.D/P2

9. Clarification of research proposal entitled "***Circulating miRNAs as predictive biomarkers of coronary heart disease development in type 2 diabetes mellitus patients***" sponsored by MHFW, New Delhi submitted by Mr. Mohd Wamique under the guidance of Dr. D.Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.2092MED/21 dated 21st October, 2021.

The following comment forwarded to the P.I., Reply given by P.I. in tabular format was reviewed by the Primary reviewer.

Previous EC Comment	Response
Risk is marked as not reasonable in the IEC form	As per the above comment from IEC, risks to subjects are reasonable in relation to anticipated benefits to subjects/community/country. It is marker as not reasonable due to typographical error.
Study is recruiting subject with CAD from Cardiology OPD, yet no Co-PI has been added from Cardiology. It would be prudent to have a Co-PI from Cardiology for the study.	As per the suggestion of IEC we have added Co-PIs Dr. Sharad Chandra from Deptt. of Cardiology, KGMU, Dr. Roopali Khanna from Deptt. of Cardiology, SGPGI for sample collection of heart disease subjects and Dr. Wahid Ali from Deptt. of Pathology, KGMU for clinical tests and diagnosis of disease using laboratory testing of blood.

Recommendation of Primary reviewer: Provisionally Approved
EC Decision: Approved

Ref. code: 111th ECM II B-YS/P1

10. Clarification of the research proposal entitled "***Calcium & Vitamin-D deficiency in children: Design & Validation of questionnaire to assess knowledge, attitude & practices of parents***" submitted by Dr. Suresh Chand, Assistant Professor, Department of Paediatric Orthopadics, King George's Medical University, U.P., Lucknow vide letter no.1365/21 dated 17th November, 2021.

The following comment forwarded to the P.I., Reply given by P.I. in tabular format was reviewed by the Primary reviewer.

Previous EC Comment	Response

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	1 PI and 4 Co-PIs from the same department are unacceptable for a research proposal which involves only questionnaire administration to 30 volunteers.	I have decreased the Co-PIs.
	Please decrease the same for approval.	As per suggestion of EC, Co-PIs decreased from department.

Recommendation of Primary reviewer: Provisionally Approved
EC Decision: Approved

Ref. code: 112th ECM IIA/P3

11. Minutes of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting *virtually* held on 4th December, 2021 from 10.00 AM. **(DCGI)**

The following Members were present in it's Meeting:-

1. Dr. Alok Dhawan — Chairman
2. Dr. Rajendra Nath — Member
3. Mrs. Akansha Dubey — Member
4. Mrs. Vasundhara Kumari — Member
5. Mr. Ujjawal Krishna — Member
6. Dr. Shally Awasthi — Member-Secretary, IEC

DCGI

I- ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1869 /Cardio/Res/2021 dated 16th October, 2021.

Death
Subject ID no. 010-0036
Subject Initial: J

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Gender: M **Age:** 26 years **Patient enrolled date:** 31st January, 2018 **Patient follow up under study:** 1st Month, 6th Month, 12th Month and every 6th Month till 5 year **Weight:** 55 KG **Height:** 173 CM **Subject History:** PI's Narrative: Tried many times to contact with the patient but his phone was not reachable. So a letter had been sent at his place but it come back, not received and remarked that recipient passed away. Hence PI did not have any information about the cause of death, date and time of death and the course of event. ***Recommendation of Primary reviewer:*** SAE (Death) is most likely due to disease outcome (RHD/ Sev. MS/ MR, AF with FVR NYHA II) and not due to intervention (Rivaroxaban) as patient was taking VKA from almost 3 year 10 months and completed 36th Month visit without any complaint. Causal relationship can not be established as the letter sent back did not mentioned any history of hospitalization and autopsy, even the exact date of death is not known. ***ADR Sub Committee Decision:*** PI to send a copy of the letter which has not been delivered and returned with a remark that "recipient is dead". **EC Decision:** Noted ***Ref. code: 83rd ECM IIC/P6***
II	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1867 /Cardio/Res/2021 dated 16th October, 2021. **<u>Death</u>** **Subject ID no. 010-0070** **Subject Initial:** K-R **Gender:** M **Age:** 38 years **Patient enrolled date:** 25th September, 2018

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Patient follow up under study: 1st Month, 6th Month, 12th Month and every 6th Month till 5 year **Weight:** 46 KG **Height:** 162 CM **Subject History:** PI's Narrative: Tried several times to contact with the patient but his phone was not reachable. So a letter had been sent at his place but it come back, not received and remarked that recipient passed away. Hence PI did not have any information about the cause of death, date and time of death and the course of event. ***Recommendation of Primary reviewer:*** • PI has been unable to contact Subject on his family hence details of SAE are unknown. • Subject completed his 30th Month follow-up and missed the 36th month Follow-up. • Formal report submission to IEC date is 16th August, 2021 on agenda page and 18th October, 2021 on SAE Summary report. ***ADR Sub Committee Decision:*** PI to send a copy of the letter which has not been delivered and returned with a remark that "recipient is dead". **EC Decision:** Noted ***Ref. code: 83rd ECM IIC/P6***
III	Research Protocol no. 0063-17 entitled "***A global, multicenter, three arms, open- label randomized study to evaluate the efficacy and safety of nanosomal docetaxel lipid suspension compared to taxotere® (Docetaxel Injection Concentrate) in triple- negative breast cancer patients with locally advanced or metastatic breast cancer after failure to prior chemotherapy***" sponsored by M/s Lamda Therapeutic Research Pvt. Ltd. submitted by Dr. Sameer Gupta, Department of Surgical Oncology, K.G's Medical University, U.P., Lucknow vide letter no. SONC/027/2021 dated 15th November, 2021. **Death** **Subject ID no. 154-0063-17-09 (N-M)** **Subject Initial:** N-M **Gender:** F **Age:** 51 years **Patient follow up under study:** **Weight:** 153 KG **Height:** 43 CM **Subject History:** On 15th November, 2021 it was informed by the PI that Patient ID no. 154-0063-17-09 (N-M) was dosed on 22nd October, 2021. On 8th day i.e. 30th October, 2021 he was followed

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	up and blood investigations were also done, which were within normal limit. On 6th November, a normal follow-up call was made, which was not received. Again on 10th & 11th November follow-up calls were made. On 12th November again a follow-up call was made which was received by his care giver (Son of patient) and he informed that patient died on 4th November, 2021 around 4:30 AM. Cause of death could not be ascertained. ***Recommendation of Primary reviewer:*** SAE (death) of the patient seems to be due to disease outcome (triple negative breast cancer with metastasis, which generally does not respond to any conventional treatment) causing sudden cardiac arrest and not due to intervention (Nanosomal Docetaxel Lipid Suspension) as patient after receiving the drug was followed on day 8 visit done on 30th Oct., 2021, in which all the blood investigations done as per protocol, were found to be within normal limits and the patient had no complaints. Patient died suddenly at home during sleep on 04th November, 2021 (13 days after intervention) Causal relationship can not be established as death occurred suddenly at home during sleep and no hospitalization and autopsy could be done. ***ADR Sub Committee Decision:*** PI to send a copy of the letter which has not been delivered and returned with a remark that "recipient is dead". **EC Decision:** Noted ***Ref. code: 95th ECM IIC/P4***
II-A	**New Proposal**
1.	Research proposal entitled ***"Effect of COVID-19 pandemic on menstrual health of reproductive age group women"*** submitted by Prof. Nisha Singh, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no.OG/1766/2021 dated 4th October, 2021. **Recommendation of Primary reviewer:** Approved **EC Decision:** Approved ***Ref. code:113th ECM IIA/P1***
2.	Research proposal entitled ***"Integrative molecular profiling of prostate cancer: identification of molecular signature for risk stratification and advanced-stage disease management"*** submitted by Prof. Apul Goel, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no.357/Uro/2021 dated 6th September, 2021. **Recommendation of Primary reviewer:** • It is not clear whether the tumor samples will be taken from the part of biopsy or surgical sample collected as a part of diagnostic or therapeutic procedure or will it need separate surgical intervention? Clarify.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The language of the consent form can be made simple and easy to understand. (It is difficult to understand). **EC Comment:** • Kindly clarify that no separate surgical procedure will be done for collection of specimen. • Make consent form in simple language **EC Decision:** Approval subject to modification, with a table of changes done. ***Ref. code:113th ECM IIA/P2***
3.	Research proposal entitled "***Study of post operative complications and their risk factors in women undergoing caesarean section in a tertiary care setup-A retrospective study***" submitted by Prof. Nisha Singh, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no.OG/1750/2021 dated 30th September, 2021. **Recommendation of Primary reviewer:** • Retrospective data collection. Waiver of consent requested. • Sample size is 86, seems too small. Please justify **EC Comment:** • Clarify if there are controls also. • What is the basis of sample size **EC Decision:** Approval subject to modification ***Ref. code:113th ECM IIA/P3***
4.	Research proposal entitled "***Knowledge, attitude and practice of healthcare workers towards the use of contraception***" submitted by Prof. Nisha Singh, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no.OG/1751/2021 dated 30th September, 2021. **Recommendation of Primary reviewer:** Approved **EC Decision:** Approved ***Ref. code:113th ECM IIA/P4***
5.	Research proposal entitled "***Validation of online hearing assessment app (H3 HEARING TEST) for patients***" submitted by Dr. Anupam Mishra, Department of E.N.T Head Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no.283/AM/ENT/2021 dated 17th September, 2021. **Recommendation of Primary reviewer:** • It is sketchy. Although the rationale of the study is provided, neither objectives nor details about the project are given. It needs to be revised and resubmitted. **EC Comment:** As above **EC Decision:** Re-submit with a table of changes done. ***Ref. code:113th ECM IIA/P5***
6.	Research proposal entitled "***To estimate the prevalence of hepatotropic and non***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	hepatotropic viral infection by PCR in liver tissue in children with infantile cholestasis" sponsored by DBT & UPCST submitted by Dr. Sanjeev Kumar Gupta, Associate Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no.2090/Ped/2021 dated 13th October, 2021. **Recommendation of Primary reviewer:** Approved **EC Decision:** Approved ***Ref. code:113th ECM IIA/P6***
7.	Research proposal entitled "***Treatment adherence and spacer compliance in patient with asthma and COPD***" submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no.2204/2021 dated 6th October, 2021. ***Recommendation of Primary reviewer:*** • Study design is not mentioned • Sample size calculation not done **EC Comment:** As above **EC Decision:** Re-submit with a table of changes done. ***Ref. code:113th ECM IIA/P7***
8.	Research proposal entitled "***Elucidating the role of long non-coding RNA's (IncRNAs) in HIV-infected subjects on treatment***" submitted by Dr. D.Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.2047/MED/2021 dated 8th October, 2021. ***Recommendation of Primary reviewer:*** • PI should be from parent institute • Research proposal should not be sent by Co-PI (therefore, Dr. D Himanshu should act as PI and Dr. Ravi Tandon, Asstt. Professor, School of Biotechnology, JNU should be Co-PI). • Study design not mentioned • Sample size calculation not done **EC Comment:** As above **EC Decision:** Approval subject to modification, with a table of changes done. ***Ref. code:113th ECM IIA/P8***
9.	Research proposal entitled "***Development and Validation of artificial intelligence tool for screening/detection of pulmonary TB and other lung diseases using chest X-Rays***" submitted by Dr. Sarika Gupta, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.2308/Ped/2021 dated 20th September, 2021. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Exact study design not mentioned • Exact sample size and its calculation is not given for the subjects enrolled in our center **EC Comment:** As above **EC Decision:** Approval subject to modification, with a table of changes done. ***Ref. code:113th ECM IIA/P9***
10.	Research proposal entitled "***Development of a mobile application and IT based system for enhanced reporting of TB cases including self-reporting and contact tracing, follow-up, for initiation and compliance of treatment***" sponsored by ICMR submitted by Dr. Sarika Gupta, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.1881/Ped/2021 dated 31st July, 2021. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code:113th ECM IIA/P10***
11.	Research proposal entitled "***Assessing the knowledge, attitude and practices of health care professionals on antimicrobial stewardship in a university Hospital***" submitted by Dr. Sheetal Verma, Associate Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1141/2021 dated 8th October, 2021. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code:113th ECM IIA/P11***
12.	Research proposal entitled "***Clinical characteristics and outcomes of macrophage activation syndrome among patients attending a Rheumatology tertiary care centre in North India***" submitted by Dr. Kasturi Hazarika, Assistant Professor, Department of Clinical Immunology and Rheumatology, King George's Medical University, U.P., Lucknow vide letter no.Rh/703/2021 dated 26th October, 2021. ***Recommendation of Primary reviewer:*** • Sample size calculation has not been done. • Has consent been obtained from patients for use of their date for purposes other than treatment? • Data of children are being used. • Rental consent and assent of children is needed. • Vulnerable subjects section is marked as 'No' whereas data of children is being use. **EC Comment:** As above **EC Decision:** Re-submit for wavier of consent, with a point wise table of changes done. ***Ref. code:113th ECM IIA/P12***
13.	Research proposal entitled "***Clinical, laboratory, radiological parameters and risk factors in hospitalized COVID-19 patients during second wave-at tertiary care centre in Northern India***" submitted by Prof. Surya Kant, Head, Department of Respiratory

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 4th December, 2021.

	Medicine, King George's Medical University, U.P., Lucknow vide letter no.2027/2021 dated 17th August, 2021. ***Recommendation of Primary reviewer:*** • Is it a prospective study retrospective study? • Please mention this in the proforma. • The Methodology sections poorly written. • Sample size has not been calculated. • Vulnerable subjects has been ticked a 'No' • Kindly justify role of all investigators. **EC Comment:** As above **EC Decision:** Re-submit with a point wise table of changes done. ***Ref. code:113th ECM IIA/P13***
14.	Research proposal entitled ***"Knowledge of safe disposal of diabetic sharps among diabetic patients in Lucknow district, Uttar Pradesh"*** submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.2046/MED/2021 dated 8th October, 2021. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code:113th ECM IIA/P14***
15.	Research proposal entitled ***"Evaluating the effect of selective mTORC2 inhibition on breast cancer cell invasion and acquisition of stem cell-like phenotypean experimental modality against breast cancer metastasis"*** submitted by Prof. M.L.B. Bhatt, Ex. Vice Chancellor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no.834/RT/2021 dated 20th September, 2021. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code:113th ECM IIA/P15***
16.	Research proposal entitled ***"A comparative cross-sectional study of cyberchondria, subjective well-being & smartphone addiction in medical & non-medical students"*** submitted by Dr. Sujit Kumar Kar, Associate Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.1368/Psy/2021 dated 18th September, 2021. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code:113th ECM IIA/P16***
17.	Research proposal entitled ***"Study of LASER based cost-effective monitoring system for lung & breast cancer radiotherapy: Development of patient specific quality assurance technique"*** sponsored by Health Research, Ministry of Health and Family Welfare Government of India submitted by Dr. Teerthraj Verma, Additional Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	no.869/RT/2021 dated 30th September, 2021. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code:113th ECM IIA/P17***
18.	Research proposal entitled ***"Clinical testing of smartphone based upgradation of existing fluorescence spectroscopic device for early cervical cancer diagnosis"*** submitted by Dr. Smriti Agarwal, Additional Professor, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no.OG/1873/2021 dated 20th September, 2021. ***Recommendation of Primary reviewer:*** • Identify the study variables and population parameter and define the research hypothesis in terms of these variables and parameters. • Selection of control group is not clear. • Study design is not defined. • Sample size calculations are missing. • Statistical analysis section is very general. This is due to the lack of proper research hypothesis. • I am not clear: "How the smartphone will be used in the clinical testing?" • Is the clearance/permission required for the co-investigators as they are from outside the KGMU? **EC Comment:** As above **EC Decision:** Revise & Re-submit with a point wise table of changes done. ***Ref. code:113th ECM IIA/P18***
19.	Research proposal entitled ***"Skin flap necrosis after knife or electrocautery in patients undergoing inguinal lymph node dissection (SNAKE): a double blind randomized clinical trial"*** submitted by Dr. Shiv Rajan, Assistant Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no.SONC/937/2021 dated 25th September, 2021. ***Recommendation of Primary reviewer:*** • Research hypothesis should be properly defined in terms of the population parameter (proportion) and the direction of "treatment effect". If the direction of "effect" is known, it can be planned as a "Superior" trial. It will help in reducing the sample size. • The fundamentals of performing RCT are not completely specified: Clinical Trial Registry, Statistical and methodological issues in RCT. • Randomization section is not clear. Is it stratified random sampling? If it is, which kind of stratification will be done: proportional, optimal or else? • Sample size calculations are not clear. What formula is used for calculating sample size? **EC Comment:** As above **EC Decision:** Revise & Re-submit with a point wise table of changes done. ***Ref. code:113th ECM IIA/P19***
20.	Research proposal entitled ***"To evaluate feasibility of incorporating simulation based***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	training in the undergraduate teaching program of Obstetrics & Gynecology" submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no.GO/1946/2021 dated 25th October, 2021. ***Recommendation of Primary reviewer:*** • What is the sampling plan, including sample size? • What is the research hypothesis? It should be properly defined in terms of the population parameter after identifying the study variables? • The instrument (questionnaire) used is Google form. It is not attached. Is the validity and reliability of instrument done? • Define the parameters used for assessing the usefulness **EC Decision:** Approval subject to clarification. Also submit a point wise table of changes done. ***Ref. code:113th ECM IIA/P20***
21.	Research proposal entitled ***"Impact of 3D printed bolus on efficacy of Radiotherapy: moving from one-size-fits-all to patient specific approach"*** submitted by Dr. Teerthraj Verma, Additional Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no.899/RT/2021 dated 9th November, 2021. ***Recommendation of Primary reviewer:*** Pending **EC Comment:** **EC Decision:** ***Ref. code:113th ECM IIA/P21***
22.	Research proposal entitled ***"Skin and soft tissue necrotizing infections in the intensive care unit: a prospective multi-national cohort study: SKIN-ICU"*** submitted by Dr. Sai Saran, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.CCM/411/2021 dated 25th October, 2021. ***Recommendation of Primary reviewer:*** **EC Comment:** • Sec:5 Duration of subject participation is not mentioned vulnerable subjects? • Sec:6 Why use direct indentifies? • Confidential data handling? } Incomplete information. • Sec:7 Incomplete • Sec 8: Sponsor of study is not checked • Sec 10: Risks benefits: not filled • Sec 11: Details of DSMB not given • What A/Es are expected? • English consent point 12: Incomplete • Sponsor information is different in Consent form and protocol. • Is there a later version of the protocol? • Why a surgeon is not part of the study? **EC Decision:** Revise & Re-submit with a point wise table of changes done.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code:113th ECM IIA/P22
23.	Research proposal entitled ***"Multi centric community-based study of prevalence, KAP (Knowledge Attitude & Practice) for prevention first aid of burns, quality of life and out of pocket expoenditure of burn injury and evaluation of IEC interventions"*** sponsored by ICMR New Delhi submitted by Prof. Brijesh Mishra, Head, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no.1116/2021 dated 3rd November, 2021. ***Recommendation of Primary reviewer:*** • Budget amount and break up for KGMU PI • Sec 5: incomplete • Sec 6: Why direct identifiers? • What is the direct benefit to the subject? • If there is no plan for A/E reporting, what's the role of DSMB? • Details of pre-validated questionnaire? • Methodology: last sentence……..following details….. What are these? • Data collection tools are not given • Annexure 1: Not attached • IEC implementation: details? • KAP analysis post IEC: define population • Sample size calculation? • Statistical analysis? **EC Comment:** As above **EC Decision:** Re-submit with details and with a point wise table of changes done. ***Ref. code:113th ECM IIA/P23***
24.	Research proposal entitled ***"Epidemiological survey of Mucormycosis"*** submitted by Prof. Samir Misra, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no.TS/623/21 dated 22nd November, 2021. ***Recommendation of Primary reviewer:*** • Scientific Review Committee document not given • Work distribution of PI/Co-PI not mentioned • Sample size calculation not given **EC Comment:** As above **EC Decision:** Revise & Re-submit with a point wise table of changes done. ***Ref. code:113th ECM IIA/P24***
IIB	**New Ph.D Scholar**
1.	Research proposal entitled ***"Evaluation of factors leading to non-utilization of antenatal care services among pregnant women and assessment of their knowledge, attitude & perception towards government sponsored services during pregnancy and labour"***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	submitted by Ms. Namita Singh, Ph.D Scholar 2019, under the guidance Prof. Anjoo Agarwal, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no.OG/1638/21 dated 14th September, 2021. ***Recommendation of Primary reviewer:*** • Is sample size ok for the study 370 only? Simple questionnaire based study for Ph D program? No standard methods for income like Kuppuswamy scale, etc. **EC Comment:** • Kindly justify-Sample size • Is this a part of Ph.D. Project? • How was questionnaire developed? • How will it be validated? **EC Decision:** Submit clarifications with a point wise table of changes done. ***Ref. code:113th ECM II B-Ph.D/P1***
2.	Research proposal entitled ***"Assessment of auditory effects of noise exposures"*** submitted by Mr. Anupam Mehrotra, Ph.D Scholar, under the guidance Dr. S.K.Singh, Professor (Epidemiology), Upgraded & Dr. Manish Kumar Manar, Associate Professor, Department of Community Medicine and Public Health, King George's Medical University, U.P., Lucknow vide letter no. nil dated nil. ***Recommendation of Primary reviewer:*** • Research hypothesis is not properly defined. It should be in terms of the parameters involving some proper "measure" of Occupational noise. • The questionnaire is incomplete as this does not include the questions related to "aims and objectives": (i) evaluation of prevalence of NIHL, (ii) assessment of the auditory and non-auditory effects, (iii) remedial measures for mitigating effects of occupational noise, etc. • How the reliability and validity of the instrument shall be done? • Sample size calculations have to be in accordance with the research hypothesis, which is missing. **EC Comment:** • As above **EC Decision:** Approval subject to modification. Submit with a point wise table of changes done. ***Ref. code:113th ECM II B- Ph.D /P2***
3.	Research proposal entitled ***"Effect of vocational rehabilitation in myocardial infaraction patients and returning back to their work after myocardial infarction"*** submitted by Ms. Meenakshi Mishra, Ph.D Scholar 2019, under the guidance Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.1865/Cardio/Res/2021 dated 13th October, 2021. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Spelling and syntax errors in covering letter • Can PhD student by PI? • If this is a revised review, details of comments of first review? • Sec 5: Which employees (special Groups) will be included and why? • Sec 10: risk is not reasonable… why do the study? • How will the patient benefit? • Details of DSMB? • Phd Student should write a much better review of literature • Hypothesis: We….this kind…. Which kind?? Elaborate • When there is consensus that VR should be done, not providing VR to control are is unethical • App tracking activities is violation of patient privacy • Exclusion criteria: Define high risk patients • What type of randomization will take place? Please specify elements of RCT. • Sample size calculation is not for RCT • What is "appropriate statistical test"? • Are the questionnaire self designed or old? Have these been validated? How will the questionnaire be administered? Is there a validated Hindi translation? **EC Comment:** • Keep activity data as hard copy. • Use of a private app is not permitted **EC Decision:** Revise & Re-submit with a point wise table of changes done. ***Ref. code:113th ECM II B- Ph.D /P3***
4.	Research proposal entitled "***Expression and molecular mechanism of circadian genes and their association with sirt-1 and notch signaling pathway in the pathogenesis of chronic myeloid leukemia***" submitted by Ms. Nimra Habib, Ph.D Scholar 2019 under the guidance Dr. Ranjana Singh, Additional Professor, Department of Biochemistry, King George's Medical University, U.P.,Lucknow vide letter no.Bio/486/2021 dated 9th November, 2021. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Dr. A.A. Mahdi did not take part in the discussion and making decision.*** ***Ref. code:113th ECM II B- Ph.D /P4***
5.	Research proposal entitled "***Identification and the molecular mechanism of lethal giant disc in the pathogenesis of human T-Cell acute lymphoblastic leukemia and their association with notch signaling pathway***" submitted by Mr. Sandeep Pandey, Ph.D Scholar 2019, under the guidance Dr. Ranjana Singh, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no.Bio/487/2021 dated 9th November, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: Approved **EC Decision:** Approved ***Ref. code:113th ECM II B- Ph.D /P5***
6.	Research proposal entitled ***"A toxicogenomic study in lead-exposed occupational workers"*** submitted by Mr. Durgesh Kumar, Ph.D Scholar, under the guidance Prof. Abbas Ali Mahdi, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/494/2021 dated 11th November, 2021. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code:113th ECM II B- Ph.D /P6***
7.	Research proposal entitled ***"Effect of heavy metals on expression of MTHFR gene and bone alkaline phosphatase in cases of perthes disease and their correlation with its clinico radiological profiles: a parent-child triasd study"*** submitted by Mr. Praveen Kumar, Ph.D Scholar, under the guidance Prof. Ajai Singh, Head, Department of Paediatric Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 1167/Pardgtho/2021 dated 21st September, 2021. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code:113th ECM II B- Ph.D /P7***
8.	Research proposal entitled ***"Exploring therapeutic miRNA as a novel network in prostate cancer"*** submitted by Ms. Anveshika Manoj, Ph.D Scholar under the guidance Dr. Mohammad Kaleem Khan, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/2021/501 dated 13th November, 2021. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code:113th ECM II B- Ph.D /P8***
IIB	**Young Scientist**
1.	Research proposal entitled ***"Environmental exposure to toxins and their role in inducing hypothyroidism and infertility in women: A case control study"*** sponsored by DHR-HRD, New Delhi submitted by Dr. Saima Amjad under the guidance Prof. A.A Mahdi, Head, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no.448/Bio/21 dated 26th October, 2021. ***Recommendation of Primary reviewer:*** • The patient information sheet has to be customized. • Data analysis and statistical analysis should also brief the type of data / variables and anticipated statistical test used in analysis. **EC Comment:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Approval subject to modification. Submit with a point wise table of changes done. ***Ref. code: 113th ECM II B-YS/P1***
II C	**Review of New Drug Trial**
1.	Research Protocol no.D3250C00093 entitled ***"A postmarketing, phase 4, multicentre, prospective, single-arm study to assess the safety of fasenra® (Benralizumad) in adult patients of severe asthma with eosinophilic phenotype in India"*** sponsored by M/s Astra Zeneca Pharma India Ltd. submitted by Dr. Ajay Kumar Verma, Professor Junior Grade, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow, vide letter no.2203/2021 dated 5th October, 2021. ***The following documents were reviewed in it's Meeting:***

Sl.no.	Documents	Version and date
1.	Clinical Study Protocol	Version 1.0, Date: 09-Mar-2021
2.	Protocol Sign Page	Dated 21-Aug-2021
3.	Core Study ICD	Version No. 1.0, dated 12-Mar-2021
4.	Core Study ICD Version No. 1.0, dated12-Mar-2021 Translated from English to Hindi	Version 1.0 dated 26-Aug-2021
5.	Core Study ICD Version No. 1.0, dated 12-Mar-2021 Translated from English to Hindi Version 1.0 dated 26-Aug-2021 Back Translated from Hindi to English	Version 1.0 dated 27-Aug-2021
6.	ICD - Translation and Back-Translation Certificates for Hindi dated 06-Sep-2021	Dated 06-Sep-2021
7.	Investigator Brochure -Edition no- 19	Dated 17-Apr-2020
8.	Prescribing Information	NA
9.	Case Report Form	Version 1.0 dated 10 Aug 2021
10.	**10. Patient Diary** 10.1 Patient Diary	Version 1.0 dated 11-Mar-2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Translated from English to Hindi	2021
	10.3 Patient Diary V 1.0, 11-Mar-2021 Translated from English to Hindi version 1.0 dated 26-Aug-2021 Back Translated from Hindi to English version 1.0 dated 27-Aug-2021	Version 1.0 dated 27-Aug-2021
11.	Patient diary - Translation and Back-Translation Certificates for Hindi and English dated 06-Sep-2021	Dated 06-Sep-2021
12.	Thank You card	Version 1.0 dated 05-Aug-2021
13.	Thank You Card- Translated from English to Hindi	Version 1.0 dated 19-Aug-2021
14.	Thank You Card –Translation Certificates for Hindi	Dated 06-Sep-2021
15	**15. PI Documents**	
	15.1 Curriculum Vitae of Investigator	Signed on 21-Aug-2021
	15.2 MRC (1179)	NA
	15.3 GCP certificate	02-Sep-2021
	15.4 Signed Undertaking by the Investigator	Signed on 09-Sep-2021
	15.5 Declaration letter	Signed on 24-Aug-2021
	15.6 Consent Letter	Signed on 24-Aug-2021
16.	Insurance certificate and complete Policy	Dated 03-Sep-2021
17.	**17. DCGI Submission and Approval Letter**	
	17.1 Submission Letter (15-Mar-2021)	Submission Dated 15-Mar-2021
	17.2 DCGI Approval Letter (25-Jun-2021)	Approval Dated 25-Jun-2021
18.	Draft Clinical trial Agreement	
19.	CTRI Registration	14-Sep-2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Recommendation of Primary reviewer: Approved

EC Decision: Approval subject to fulfillment of administrative formalities

Ref. code:113th ECMIIC/P1

2. Research Protocol no.LIB003-004 entitled "***Randomized, double-blind, placebo-controlled, phase 3 study of evaluate the long-term efficacy and safety of LIB003 in heterozygous familial hypercholesterolemia patients on stable lipid-lowering therapy requiring additional low-density lipoprotein cholesterol reduction (LI Berate-HeFH)***" sponsored by M/s LIB Tharapestics, LLC submitted by Dr. Akshyaya Pradhan, Professor Junior Grade, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no.1787/Cardio/Res/2021 dated 9th September, 2021.

The following documents were reviewed in it's Meeting:

Sr.	Document	Version	Dated
1	Study Protocol	1.0	21 October 2020
2	Investigator Brochure (IB)	6.0	25 June 2021
3	Principal Investigator undertaking	N/A	18 June2021
4	Principal Investigator CV	N/A	N/A
5	Principal Investigator MRC	N/A	N/A
6	Principal Investigator GCP certificate valid till 20Mar2023	N/A	N/A
7	Principal Investigator PSP	1.0	21 October 2020
8	**Participant Information Sheet and Informed Consent Form in English**	Master :1.0 India: 1.0 Site-specific: 1.0	Master: 20 October 2020 India: 17 Jun 2021 Site-specific: 06 Aug 2021
9	Participant Information Sheet and Informed Consent Form in **Hindi** (translation dated 11Aug2021) with translation certificate	Master :1.0 India: 1.0 Site-specific: 1.0	Master: 20 October 2020 India: 17 Jun2 021 Site-specific: 06 Aug

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			2021
10	Participant Information Sheet and Informed Consent Form: Back translation from **Hindito English** (Back-translation dated 11Aug2021) with certificate	Master :1.0 India: 1.0 Site-specific: 1.0	Master: 20 October 2020 India: 17 Jun 2021 Site-specific: 06 Aug 2021
11	**Pregnant Partner Information And Informed Consent Form in English**	Master :1.0 India: 1.0 Site-specific: 1.0	Master: 09 April 2021 India: 17 Jun2021 Site-specific: 06 Aug 2021
12	Pregnant Partner Information And Informed Consent Form in **Hindi** (translation dated 11Aug2021) with translation certificate	Master :1.0 India: 1.0 Site-specific: 1.0	Master:09 April2021 India: 17Jun2021 Site-specific: 06Aug2021
13	Pregnant Partner Information And Informed Consent Form:Back translation from **Hindito English** (Back-translation dated 11Aug2021) with certificate	Master :1.0 India: 1.0 Site-specific: 1.0	Master:09 April2021 India: 17Jun2021 Site-specific: 06Aug2021
14	**Home nursing Informed Consent Form in English**	Master :1.0 India: 1.0 Site-specific: 1.0	Master:15September 2020 India: 17Jun2021 Site-specific: 06Aug2021
15	Home nursing Informed Consent Form in **Hindi** (translation dated 11Aug2021) with translation	Master :1.0 India: 1.0	Master:15September 2020

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	certificate	Site-specific: 1.0	India: 17Jun2021 Site-specific: 06Aug2021
16	Home nursing Informed Consent Form:Back translation from **Hindito English** (Back-translation dated 11Aug2021) with certificate	Master :1.0 India: 1.0 Site-specific: 1.0	Master:15September 2020 India: 17Jun2021 Site-specific: 06Aug2021
17	**Informed Consent Form For Audio-Video Recording of Informed Consent Process in English**	India: 1.0	India: 17Jun2021
18	Informed Consent Form For Audio-Video Recording of Informed Consent Process in **Hindi** (translation dated 11Aug2021) with translation certificate	India: 1.0	India: 17Jun2021
19	Informed Consent Form For Audio-Video Recording of Informed Consent Process : Back translation from **Hindito English** (Back-translation dated 11Aug2021) with certificate	India: 1.0	India: 17Jun2021
20	**Patient Emergency Card in English**	2.0	15March2021
21	Patient Emergency Card in**Hindi** (translation dated 29Jun2021) with translation certificate	2.0	15March2021
22	Patient Emergency Card : Back translation from **Hindito English** (Back-translation dated	2.0	15March2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Change (PGIC) of Severity		
6.	EORTC QLQ - NMIBC24	NA	Copyright dated
7.	Patient Global Impression of Severity	1.1	25-Sep-2017
8.	EORTC QLQ-C30	3.0	NA
9.	Biomarker Infographic One Sheet	1.0	04-Dec-2019
10.	Biomarker Infographic_Hindi	1.0	04-Dec-2019
11.	Study Drug Instruction Appointment Card	1.0	24-Sep-2019
12.	Study Drug Instruction Appointment Card_Hindi	1.0	24-Sep-2019
13.	Caregiver Support Guide	1.0	26-Mar-2020
14.	Caregiver Support Guide_Hindi	1.0	26-Mar-2020
15.	Thank You Card – Enrollment	1.0	26-Mar-2020
16.	Thank you card – Enrollment_Hindi	1.0	26-Mar-2020
17.	Thank You Card – Completion	1.0	26-Mar-2020
18.	Thank you card – Completion_Hindi	1.0	26-Mar-2020
19.	Visit Procedure Guide	1.0	26-Mar-2020
20.	Visit Procedure Guide_Hindi	1.0	26-Mar-2020
21.	Joint compound ad to be placed in 2020 GU ASCO Daily News	1.0	19-Dec-2019
22.	Bladder Cancer Joint Compound Ad	1.0	24-Nov-2020
23.	Patient recruitment Poster	1.0	26-Mar-2020
24.	Patient recruitment Poster_Hindi	1.0	26-Mar-2020
25.	Web Ad	1.0	26-Mar-2020
26.	Patient recruitment Brochure	1.0	26-Mar-2020
27.	Patient recruitment Brochure_Hindi	1.0	26-Mar-2020
28.	Patient Support Guide_English	1.0	26-Mar-2020
29.	Patient Support Guide_Hindi	1.0	26-Mar-2020
30.	ICF Flip Chart_English	2.0	26-Mar-2020
31.	ICF Flip Chart_Hindi	2.0	26-Mar-2020
32.	Translation certificate	NA	Signed on 24-Mar-21 & 27-Apr-21
33.	Wallet card	1.0	11-Feb-2021
34.	Wallet card (English to Hindi)	1.0	11-Feb-2021
35.	Wallet card (Hindi to English)	1.0	11-Feb-2021
36.	ICF Flip Chart_English	2.0	26-Mar-2020
37.	Front and Back Translation certificate	NA	Signed on 25-Feb-2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	29Jun2021) with certificate		
23	**Patient Instructions in English**	1.0	19October2020
24	Patient Instructionsin **Hindi** (translation dated 29Jun2021) with translation certificate	1.0	19October2020
25	Patient Instructions: Back translation from **Hindito English** (Back-translation dated 29Jun2021) with certificate	1.0	19October2020
26	**Draft CTA template**	1	N/A
27	**CRF specs**	2.0	29Mar2021

Recommendation of Primary reviewer:

- Compensation amount for visit etc. are not mentioned. Kindly justify why such information is not shared with EC?

EC Comment: As above

EC Decision: Approval subject to modification and fulfillment of administrative formalities.

Ref. code:113th ECMIIC/P2

3. Research Protocol no. 42756493BLC2003 entitled "***A randomized phase 2 study of erdafitinib versus investigator choice of intravesical chemotherapy in subjects who received bacillus calmette-guerin (BCG) and recurred with high risk non-muscle-invasive bladder cancer (NMIBC) and FGFR mutations or fusions***" sponsored by M/s Johnson & Johnson Pvt. Ltd. submitted by Prof. S.N.Sankhwar, Head, Department of Urology, King George's Medical University, U.P., Lucknow, vide letter no.414/URO/2021 dated 11th October, 2021.

The following documents were reviewed in it's Meeting:

S.No	Document	Version	Date
1.	Clinical Protocol	Amendment 3	26-Oct-2020
2.	Investigator's Brochure	Edition 9	28-May-2020
3.	Case report form Generated on 30-Jun-2020	2.03	22-Jun-2020
4.	Patient Diary	1.0	24-Sep-2019
5.	Patient's Global Impression of	NA	NA

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

38.	Consent for Audio Visual Recording of Informed Consent Process	1.1.0	21-Jul-2021
39.	Consent for Audio Visual Recording of Informed Consent Process (English to Hindi)	1.1.0	21-Jul-2021
40.	Consent for Audio Visual Recording of Informed Consent Process (Hindi to English)	1.1.0	21-Jul-2021
41.	Molecular Eligibility Testing Informed Consent Form Master ICF version date 17-Nov-2020; Version number 3.0	1.1.0	21-Jul-2021
42.	Molecular Eligibility Testing Informed Consent Form (English to Hindi) Master ICF version date 17-Nov-2020; Version number 3.0	1.1.0	21-Jul-2021
43.	Molecular Eligibility Testing Informed Consent Form (Hindi to English) Master ICF version date 17-Nov-2020; Version number 3.0	1.1.0	21-Jul-2021
44.	Front and Back Translation certificate	NA	Signed on 12-Aug-2021
45.	Pregnant Partner Informed Consent Form Master Pregnant Partner ICF Date 20-Nov-2019; Version number 1.0	1.1.0	21-Jul-2021
46.	Pregnant Partner Informed Consent Form (English to Hindi) Master Pregnant Partner ICF Date 20-Nov-2019; Version number 1.0	1.1.0	21-Jul-2021
47.	Pregnant Partner Informed Consent Form (Hindi to English) Master Pregnant Partner ICF Date 20-Nov-2019; Version number 1.0	1.1.0	21-Jul-2021
48.	Front and Back Translation certificate	NA	Signed on 12-Aug-2021
49.	Main Study Informed Consent Form Master ICF Version date: 20-Nov-2020; Version number 7.0	1.1.0	21-Jul-2021
50.	Main Study Informed Consent	1.1.0	21-Jul-2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Form (English to Hindi) Master ICF Version date: 20-Nov-2020; Version number 7.0		
51.	Main Study Informed Consent Form (Hindi to English) Master ICF Version date: 20-Nov-2020; Version number 7.0	1.1.0	21-Jul-2021
52.	Front and Back Translation certificate	NA	Signed on 12-Aug-2021
53.	Withdrawal of Consent Form Master Withdrawal ICF Version Date 20-Nov-2019; Version number 3.0	1.1.0	21-Jul-2021
54.	Withdrawal of Consent Form (English to Hindi) Master Withdrawal ICF Version Date 20-Nov-2019; Version number 3.0	1.1.0	21-Jul-2021
55.	Withdrawal of Consent Form (Hindi to English) Master Withdrawal ICF Version Date 20-Nov-2019; Version number 3.0	1.1.0	21-Jul-2021
56.	Front and Back Translation certificate	NA	Signed on 12-Aug-2021
57.	Urgent Safety Measure (USM) – modification of erdafitinib dose to 6 mg daily in NMIBC subjects	NA	02-Feb-2021
58.	Ophthalmologist Sheet	2.0	26-Oct-2020
59.	Colleague Networking Card	1.0	26-Mar-2020
60.	Colleague Referral Letter	1.0	26-Mar-2020
61.	DCGI approval letter: CT/21/000011	NA	Issued on 23-Jun-2021
62.	Insurance Certificate Certificate number: 4067/Johnson/230204 Policy number: 4067/127558828/04/000 Policy period: 01-Mar-2021 to 01-Mar-2022	NA	Issue date 09-Feb-2021
63.	CTRI temporary registration	NA	Generation date 11-Feb-2021
64.	Draft Clinical Trial Agreement template	Version 2.0	17-Jan-2019 Draft Dated 23-Feb-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			2021
65.	Principle Investigator's Curriculum Vitae	NA	Signed on 12-Jun-2021
66.	Principle Investigator's Medical Registration Certificate MRC number: 46238	NA	Signed on 12-Jun-2021
67.	Principle Investigator's GCP training certificate	NA	Completed on 26-Jul-2019 Signed on 12-Jun-2021
68.	Principle Investigator's Investigator Undertaking	NA	Signed on 12-Jun-2021
69.	Patient's Global Impression of Change (PGIC) of Severity- Hindi Translation along with translation certificate Patient's Global Impression of Change (PGIC) English version dated 16Feb21	NA	17 Mar 21
70.	EORTC QLQ - NMIBC24 - Hindi Translation	NA	NA
71.	Patient Global Impression of Severity - Hindi Translation along with translation certificate Patient Global Impression of Severity (PGIS) English version dated 16Feb21	Version 1.1	17 Mar 21
72.	EORTC QLQ-C30 - Hindi Translation along with translation certificate	Version 3.0	07 Apr 21
73.	EQ-5D-5L Tablet version - Hindi Translation	NA	NA
74.	Subject Reference Guide- Hindi Translation	3.0	08 Feb 21
75.	Patient's Global Impression of Change (PGIC) of Severity- Hindi Translation along with translation certificate	Version 1.0	10 Jun 21
76.	EORTC QLQ - NMIBC24 - Hindi Translation along with translation certificate	Version 1.0	07 Sep 21
77.	Patient Global Impression of Severity - Hindi Translation along with translation certificate	Version 1.0	10 Jun 21

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

78.	EORTC QLQ-C30 - Hindi Translation along with translation certificate	Version 1.0	17 Jun 21
79.	EQ-5D-5L - Hindi Translation along with translation certificate	Version 1.0	13 Jul 21
80.	Other Subject Facing Text - Hindi Translation along with translation certificate	Version 1.0	17 Jun 21
81.	Patient's Global Impression of Change (PGIC) of Severity-English	Version 1.0	24 Oct 19
82.	EORTC QLQ - NMIBC24 - English	Version 2.0	06 Nov 19
83.	Patient Global Impression of Severity - English	Version 1.0	17 Oct 19
84.	EORTC QLQ-C30 - English	Version 3.0	13 Nov 19
85.	EQ-5D-5L- English	Version 1.0	21 Oct 19
86.	Other Subject Facing Text-English	Version 3.0	18 Oct 19
87.	eCOA Subject Web Backup Quick Reference Guide -- English	Version 1.0	NA
88.	eCOA Subject Web Backup Quick Reference Guide -- Hindi Translation along with translation certificate	Version 1.0	16 Aug 21
89.	Notification of Urgent Safety Measure - Letter regarding Dose Change	NA	02 Feb 21
90.	Notification for authorization by competent authority: QP Declaration	NA	25 Mar 21
91.	eSugam Screenshot for EC reference	NA	14 Sep 21
92.	EQ5D5L Tablet Version: English	NA	NA
93.	Subject Reference Guide: English	3.0	08 Feb 2021
94.	Patient Accrual method: OPD and Referrals		
95.	EQ5D5L Tablet Version: English	NA	NA

Recommendation of Primary reviewer:

- The project can be approved as all formalities are complete and it is to be further noted that DCGI approval is till Oct 2022 while Insurance expires by end of February 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

EC Comment:
- Please get insurance extended.

EC Decision: Approval subject to fulfillment & Administrative formalities

Ref. code:113th ECMIIC/P3

4. Research Protocol no. EX9536-4773 entitled "***Effect of semaglutide 2.4 mg once-weekly on function and symptoms in subjects with obesityrelated heart failure with preserved ejection fraction, and type 2 diabetes***" sponsored by M/s Novo Nordisk India Pvt. Ltd. submitted by Dr. Pravesh Vishwakarma, Professor Junior Grade, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.1896/Cardio/Res/2021 dated 27th October, 2021.

The following documents were reviewed in it's Meeting:

Sr. No	Document
1.	Trial Protocol Clinical Trial Protocol. EX9536-4773, version 2.0 dated 22 Jan 2021_Status: Final EX9536-4773, Clinical trial protocol, Version 5.0, Dated 01 Oct 2021, Status: Final Protocol attachment 1- Global list of key staff and relevant departments and suppliers of clinical relevance. v 3.0, dated 22 March 2021, Status: Final Protocol attachment II: Country list of key staff and relevant departments Version 1.0 dated 06 Nov 2020_IN_Status: Final Agreement on Protocol version 2.0 dated 22 Jan 2021 signed by PI on 09/02/2021
2.	Investigator's Brochure of Semaglutide(s.c) edition 6 version 1.0 dated 03 Dec 2020_Status: Final
3.	SIIC EX9536-4773, Subject Information/Informed Consent with echo, Version 3.0_IN_EN, dated 19 Oct 2021, Status: Final EX9536-4773, Subject Information/Informed Consent without echo, Version 4.0_IN_English,dated 19 Oct 2021, Status: Final EX9536-4773, Subject Information/Informed Consent, Direct to Patient, Version 2.0_IN_English,dated 19 Oct 2021, Status: Final EX9536-4773, Subject Information/Informed Consent, Male partner of a female participant, Version 2.0_IN_English,dated 19 Oct 2021, Status: Final EX9536-4773, Subject Information/Informed Consent , Future research, Version 2.0_IN_English,dated 19 Oct 2021, Status: Final FORWARD TRANSI ATION Hindi EX9536-4773, Subject Information/Informed Consent with echo, Version 3.0_IN_Hindi, dated 20 Oct 2021,Status: Final EX9536-4773, Subject Information/Informed Consent without echo, Version 4.0_IN_Hindi,dated 20 Oct 2021, Status: Final EX9536-4773, Subject Information/Informed Consent-Future Research, Version 2.0_IN_HI, dated 20 Oct 2021, Status: Final EX9536-4773, Subject Information/Informed Consent-Male Partner of a Female Participant, Version 2.0_IN_HI dated 20 Oct 2021, Status: Final EX9536-4773, Subject Information/Informed Consent-Direct to Patient, Version

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		2.0_IN_HI dated 20 Oct 2021, Status: Final Translation certificate – Hindi (FT) Backward Translation: *Hindi:* EX9536-4773, Subject Information/Informed Consent-Direct to Patient, Version 2.0_IN_BT_HI dated 20 Oct 2021, Status: Final EX9536-4773, Subject Information/Informed Consent with echo, Version 3.0_IN_BT_HI dated 20 Oct 2021, Status: Final EX9536-4773, Subject Information/Informed Consent without echo, Version 4.0_IN_BT_HI dated 20 Oct 2021, Status: Final EX9536-4773, Subject Information/Informed Consent-Male Partner of a Female Participant, Version 2.0_IN_BT_HI dated 20 Oct 2021, Status: Final EX9536-4773, Subject Information/Informed Consent-Future Research, Version 2.0_IN_BT_HI,dated 20 Oct 2021, Status: Final Translation certificate- Hindi (BT)
	4.	Directions for use for DV3396 Pen-Injector, DFU_DV3396_v1.0_IN (EN) Directions for use for DV3396 Pen-Injector, DFU_DV3396_v1.0_IN (HI)
	5.	eCRF's:eCRF's , v1.0, Additional Pages Annotated Study Book for Study Design: EX9536-4773d, Version: 8.2, dated 16 Nov 2020
	6.	Global Insurance-DK00000831LI21A, Valid till April 30, 2022 Local Insurance: Policy no: 030P000302901000, valid till 31st Aug 2022 Clarification of typo error in the original copy of the insurance Policy no. 030P000302901000
	7.	**Principal Investigator documents** Curriculum Vitae, Medical Registration Certificate Good Clinical Practice document Investigator Undertaking
	8.	DCGI submission letter dated 09 Mar 2021 (File No. GCT/CT04/FF/2021/24350) DCGI approval for the trial, Protocol Number: EX9536-4773, Version 2.0 (Amendment 1) dated 22-JAN-2021; application no. CT/CT04/FF/2021/24350 (GCT/28/21) dated 10-MAR-2021 DCGI submission letter dated 10 Oct 2021 for Protocol Version 5.0 (Amendment 4.0) dated 01 Oct 2021 CTRI document, acknowledgement number- REF/2021/03/042332
	9.	Fully executed Clinical Trial Agreement date
	10.	Blood glucose meter manual, ART29756-502_rev-A.indd Laboratory Manual, version 1.0 dated 09 Feb 2021 Memo- Sample Retention and Destruction of Samples at ICON Laboratory Services Six-Minute Walk Test Instruction Manual, EX9536-4773 6MWT, Version 1.0, 09 Nov 2020
	11.	Visit Overview, Version 1.0, date 08-Dec-2020, GlobalMaster EN Injecting your study medicine, version 1.0, date 07-Nov-2020, EN Global Master Patient **Subject ID card:** EX9536-4773_Version 1.0_IN_EN_ 22-Sep-2021_Status: Final EX9536-4773, Version 1.0_IN_HI_27-Sep-2021_Status: Final Translation Certificate- Hindi, Version 1.0, 07-Nov-2020, Global MasterEN

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

12.	**Import license,** Licence Number: TL/CT/21/000248
13.	**Subject Diary:** EX9536-4773_Subject Diary_v.2.0_IN_EN_Dated 22/Sep/2021_Status: Final EX9536-4773_Subject Diary_v2.0_IN_HI_Dated 27/Sep/2021_Status: Final Translation Certificate - Hindi
14.	**Fear of injections:** Trial ID: EX9536-4773, version 1.0_IN_EN_date 22-Sep-2021_Status: Final **Translation:** EX9536-4773, version 1.0_IN_HI_date 20-Oct-2021_Status: Final Translation certificate- Hindi
15.	**Patient Flow chart:** EX9536-4773, Version 1.0_IN_EN_dated 22-Sep-2021_Status:Final **Translation:** EX9536-4773, Version 1.0_IN_HI_dated 20-Oct-2021 Status: Final Translation Certificate - Hindi
16.	**Covid 19 information:** Participation in HFpEF trials and COVID-19 vaccines_ Letter to vaccination center or site, dated 16 March 2021.
17.	**ePROs:** Patient Facing Screen Report: A-1383-0040/ EX9536-4773, version 1, dated 16 Feb **Hindi:** Patient Facing Screen Report: A-1383-0040/EX9536-4773, Hindi (India) hiIN, Version 1, dated 16-JUN-2021 Translation certificate- Hindi

Recommendation of Primary reviewer: Approved

EC Decision: Approval subject to fulfillment of administrative formalities

Ref. code:113th ECMIIC/P4

5. Research Protocol no.NV-05-1226-2021/BSV-ANTID-21-03 entitled "***A prospective, multi-centre, phase-IV study for post marketing safety evaluation of recombinant ANTI-RHO(D) immunoglobulin in the prevention of maternal rh-isoimmunization***" sponsored by M/s Bharat Serums and Vaccines Pvt. Ltd. submitted by Prof. Rekha Sachan, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no.OG/2043/21 dated 9th November, 2021.

The following documents were reviewed in it's Meeting:

S. No.	Documents	Version Number and Version Date
1	Study Protocol	Version 03 dated 26 Aug 2021
2	Prescribing Information Sheet	17 Mar 2021
3	DCGI Approval	30 Sep 2021
4	IMP Regulatory Status	Enclosed
5	Clinical trial protocol signaturepage for Version 03 dated 26 Aug 2021	Signed by the PI on 08 Oct 2021
6	Investigator Undertaking	Signed on 08 Oct 2021
	Investigator Curriculum Vitae,	CV signed on 28 Sep 2021;

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	7	Medical registration certificate andGCP certificate	MRC registration number: 039255 signed on 28 Sep 2021, GCP signed on 28 Sep 2021
	8	Patient Information sheet & Informed Consent Form	
	A	English	Site Specific Patient Information Sheet & InformedConsent Form_ Version 02 Dated: 26-Aug-21
	B	Translation ICFs	ICF_Hindi_Version 02_21 Sep 2021
	C	Back Translation ICFs	ICF_Hindi_Version 02_21 Sep 2021 ICF_Hindi to English_Version 02_dated 29Sep 2021
	D	Translation certificates	ICF_Hindi_Version 02_21 Sep 2021
	E	Back Translation certificates	ICF_Hindi_Version 02_21 Sep 2021 ICF_Hindi to English_Version 02_29 Sep 2021
	9	Insurance Certificate Policy Number: OG-22-1919-3306-00000003	Validity: 01-APR-21 To 31-MAR-22

Recommendation of Primary reviewer:

- Sample size calculation has not been done.
- ICF doesn't have contact details for PI.

EC Comment: As above

EC Decision: Approval subject to modification

Ref. code:113th ECMIIC/P5

6. Research Protocol no.ALK21-ASP1 entitled "***A multicentre, randomized, double-blind, double dummy, phase III study to compare safety and efficacy of fixed dose combination of Aspirin 150mg and Pantoprazole 20mg versus Aspitin 150mg alone for the prevention of gastroduodenal mucosal damage in patients taking Aspirin for secondary prevention of cardiovascular disease or cerebrovascular disease***" sponsored by M/s Alkem Laboratories Pvt. Ltd. submitted by Dr. Ayush Shukla, Assistant Professor, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no.1898/Cardio/Res/21 dated 27th September, 2021.

The following documents were reviewed in it's Meeting:

Sr. No.	Document	Version No. & Date
1.	Clinical Study Protocol	Version 1.0 Dated 03Dec2018
2.	Summary of Product Characteristic (SmPC) of Aspirin 75mg tablet	Dated 01-Mar-2021
3.	Summary of Product Characteristic(SmPC) of Pantoprazole 20mg	Dated 18-Nov-2020
4.	Patient Informed Consent Form - English	Version 1.0 Dated 26-Dec-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			2018
	5.	Patient Informed Consent Form - Hindi language along with translation certificate	Version 1.0 Dated 11/Sep/2021
	6.	Patient Informed Consent Form – Hindi to English (Back Translation) along with back translation certificate.	Version 1.0 Dated 14/Sep/2021
	7.	Patient Diary- English	Version 2.0 dated 03/Sep/2021
	8.	Patient Diary _ Hindi language along with translation certificate	Version 2.0 Dated 11/Sep/2021
	9.	Patient Diary _ Back translated Hindi to English language along with translation certificate	Version 2.0 Dated 14/Sep/2021
	10.	DCGI Approval	Dated 07/Oct/2019
	11.	Recommendation of SEC (Cardio & renal): FDC/MA/19/000025 Pantoprazole Sodium + Aspirin20mg/20mg + (81mg/150mg)Capsules	Dated: 07-09-2021 and 08-09-21
	12.	Declaration regarding Study Insurance	Dated 17/Sep/2021
	13.	Declaration regarding CTRI Registration	Dated 17/Sep/2021
	14.	Declaration regarding Clinical Trial Agreement	Dated 17/Sep/2021
	15.	Declaration regarding CRF	Dated 17/Sep/2021
	16.	Protocol Signature Page (Version 1.0, 03/Dec/2018)	Dated :22/Sep/2021
	17.	Signed Investigator's undertaking	Dated :22/Sep/2021
	18.	Signed CV & MRC of Principal Investigator	Dated :02/Jun/2021

Recommendation of Primary reviewer:

- Only CTA document is attached but without any name or signatures
- CTRI number is pending
- No Hindi version of informed consent is attached while English version of consent form neither mentions the name of investigator not his contact number. These need revision.
- Furthermore it is to be noted that the issue date of DCGI approval is 7th Oct 2019 and since its validity is usually 2 years the PI needs to ensure if it still stands valid (since the duration is not mentioned in the approval letter).

EC Comment: As above

EC Decision: Re-submit

Ref. code:113th ECMIIC/P6

7. Research Protocol no.AC-065B302 entitled "***A multicenter, randomized, double-blind, placebo-controlled, parallel-group, group-sequential, adaptive, phase 3 study with open-label extension period to assess the efficacy and safety of selexipag as an add-on to standard of care therapy in subjects with inoperable or persistent/recurrent after surgical and/or interventional treatment Chronic Thromboembolic Pulmonary Hypertension***" sponsored by M/s Actelion Pharmaceuticals, a Janseen Pharmaceutical Co. of Johnson and Johnson (CH-4123 Allschwil, Switzerland submitted by Prof. S.K.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no.1897/Cardio/Res/21 dated 27th October, 2021.

The following documents were reviewed in it's Meeting:

Sr. No	Document	Version	Date
1	Protocol	4	29 Sept 2020
2	Protocol Signature Page		27 May 2021
3	Investigator Brochure	Edition 15	27 Feb 2020
4	Investigator Brochure – Addendum 1	Edition 15	09 Jul 2020
5	IMPD dated 08 Aug 2018		
6	IMPD Addendum Jan 2020		
7	PI CV, GCP and MRC dated 27 May 2021		
8	Initial Investigator Undertaking dated 27 May 2021		
9	Annotated CRF dated 16 Oct 2020		
10	Insurance certificate, Policy No. – 4067/127558828/03/000		01 Mar 2021 to 28 Feb 2022
11	Draft CTA dated 27 Jul 2021		
12	Actigraph Site Manual, Version 6, dated 06 Feb 2020		
13	Actigraph Activity Monitoring Subject Guide, Version 1, dated 19 Sep 2018		
14	Universal Start Card for ERT eCOA Handheld for Bluebird SF550, dated 08 Jun 2017		
15	Central Laboratory Manual, Version 4 dated 05 Feb 2021		
16	Master ICF Version Date: 14 Oct 2020; Version Number: 6.0 Site ICF Version Date: 28 Jul 2021; Version Number: 1.1.0 Dr. S K Dwivedi, KGMU	Version 1.1.0	Personalised On 28 July 2021
16a	Master ICF Version Date: 14 Oct 2020; Version Number: 6.0 Site ICF Version Date: 28 Jul 2021; Version Number: 1.1.0 Dr. S K Dwivedi, KGMU Translated from English to Hindi on 12 Aug 2021		

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	16b	Master ICF Version Date: 14 Oct 2020; Version Number: 6.0 Site ICF Version Date: 28 Jul 2021; Version Number: 1.1.0 Dr. S K Dwivedi, KGMU Back Translated from Hindi to English on 12 Aug 2021		
	17	Master ICF Version Date: 14 Oct 2020; Version Number: 6.0 Site ICF Version Date: 28 Jul 2021; Version Number: 1.1.0 Dr. S K Dwivedi, KGMU	Version 1.1.0	Personalized On 28 July 2021
	17a	Master ICF Version Date: 14 Oct 2020; Version Number: 6.0 Site ICF Version Date: 28 Jul 2021; Version Number: 1.1.0 Dr. S K Dwivedi, KGMU Translated from English to Hindi on 12 Aug 2021		
	17b	Master ICF Version Date: 14 Oct 2020; Version Number: 6.0 Site ICF Version Date: 28 Jul 2021; Version Number: 1.1.0 Dr. S K Dwivedi, KGMU Back Translated from Hindi to English on 12 Aug 2021		
	17c	ICF Translation Certificates dated Aug 2021		
	18	Subject Wallet Card	Version 1.0	19 Feb 2021
	18a	Subject Wallet Card version 1.0 dated 19 Feb 2021 Translated on 01 Mar 2021 English to Hindi		
	18b	Subject Wallet Card version 1.0 dated 19 Feb 2021 Back Translated on 02 Mar 2021 Hindi to English		
	18c	Subject Wallet Card Front Translation Certificates dated 04 Mar 2021		
	18d	Subject Wallet Card Front Translation Certificates dated 04 Mar 2021		
	19	DCGI Approval Letter dated 17 Mar 2021		
	20	Patient Accrual method.		

Recommendation of Primary reviewer:

- The project can be approved as it fulfills all criteria but it is to be noted that DCGI approval is till Sept 2022 while Insurance expires by end of February 2022.

EC Comment:

- Insurance to be extended

EC Decision: Approval subject to fulfillment of Administrative formalities

Ref. code:113th ECMIIC/P7

8. Research Protocol no.21-09 entitled ***An active post-marketing surveillance study to evaluate the safety and immunogenicity of ZyVac TCV"*** sponsored by M/s Cadila Healthcare Limited in Healthy subjects submitted by Prof. Nishant Verma, Department of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Paediatrics, K.G's Medical University, U.P., Lucknow vide letter no.2739/Ped/2021 dated 15th November, 2021 submitted by Prof. Nishant Verma, Department of Paediatrics, K.G's Medical University, U.P., Lucknow vide letter no.2739/Ped/2021 dated 15th November, 2021.

Sr. No.	List of Documents Enclosed		
1.	Details of Investigator, Site and Sponsor		
2.	Protocol No. 21-09 (Version No. 00; Dated 20/08/2021) with Appendices:		
3.	Appendix 1	Protocol Synopsis	Version No. 00; Dated 20/08/2021
	Appendix 2	Case Report Form (CRF)	Version No. 00; Dated 20/08/2021
	Appendix 3	Unscheduled Visit Form	Version No. 00; Dated 20/08/2021
	Appendix 4	Subject Diary Card (For Subjects ≥ 2 Years of Age)	Version No. 00; Dated 20/08/2021
	Appendix 5	Subject Diary Card (For Subjects < 2 Years of Age)	Version No. 00; Dated 20/08/2021
	Appendix 6	Informed Consent Document (Including Subject Information Sheet and Informed Consent Form)	Version No. 00; Dated 20/08/2021
	Appendix 7	Assent Form	Version No. 00; Dated 20/08/2021
	Appendix 8	Serious Adverse Event (SAE) Reporting Form	Version No. 00; Dated 20/08/2021
4.	Undertaking by the Investigator		
5.	Curriculum Vitae (CV) and Medical Council Registration Certificate (MRC) of the Principal Investigator		
6.	Regulatory Authority's (DCGI's) Permission		
7.	Investigator's Brochure (Version No. 02; Dated 28/01/2019)		
8.	Prescribing Information of the Study Vaccine (ZyVac TCV)		
9.	Clinical Trial Insurance Policy (2021 – 2022)		
10.	Proposed methods for Subject Recruitment		
11.	CTRI Registration (CTRI/2021/11/03966)		
12.	Draft Clinical Trial Agreement		

Recommendation of Primary reviewer:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The insurance of this post marketing surveillance expires on 19th March 2022 and project can be approved. **EC Decision:** Approval subject to fulfillment of Administrative formalities. ***Ref. code:113th ECMIIC/P8***
III	**Modification**
1.	Modification of Research protocol entitled ***"Determination of in vitro susceptibility pattern of ceftriaxone/sulbactam/disodium edetate against Gram-negative bacilli/ comparison with meropenem and piperacillin Tazobactam"*** submitted by Dr. Sheetal Verma, Associate Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1147/2021 dated 18th October, 2021. ***Recommendation of Primary reviewer:*** • The word 'and' needs to be added in the title to make it more meaningful as in the title previously approved by ethics committee. • Sponsor is to make payment to PI that will be deposited in "KGMU Research Fund" the MOU attached needs attention since the name of Allahabad Bank is changed to Indian Bank and IFSC code altered accordingly. • While annexure III (payment schedule) indicates 100% of payment is to be made at 'start date of study', but the MOU (section 3.2: Milestones of payment) indicates part payment 50%/ 25%/ 25%. Kindly clarify? **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref.code:90th ECMIIA/P32***
IV	**Other Matter with the permission of Chair**
1-	Request for permission to change the laboratory M/s Park Diagnostic Centre, Rameshwaram, 6 Park Road, Lucknow Uttar Pradesh 226001 **in place of** M/s Central Laboratory CADMUS Clinical Laboratories CP-2, Sector F, Jankipuram, Lucknow, Uttar Pradesh 226021 under the Research Protocol no.MC/BAN/21-001,Version/Date: Version 1.0 Dated 22 March, 2021 entitled ***"A prospective, randomized, parallel group, double blind, multicentric, active controlled, School based study to evaluate the efficacy and safety of albendazole 400 mg & Ivermectin 3 mg/6 mg/12 mg combination vs albendazole 400 mg in reduction of soil-transmitted helminth infections in children"*** sponsored by Pvt. Ltd. submitted by Prof. Shally Awasthi, Head, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. BMGF-2/692/21 dated 25th November, 2021. **EC Comment:** • Give reason for the change of Laboratory.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Approved ***Dr. Shally Awasthi did not take part in the discussion and making decision.*** ***Ref.code:112th ECMIIC/P2***
2-	Reg. the enrollment target of 15 subjects then it was extended to 30th subjects, now again it is extended to 45 subjects, find attached EC notification and email communication from sponsor for further enrollment under the research protocol entitled ***"A randomized double-blind, placebo-controlled, multicentre trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease"*** submitted by Prof. S.K. Dwivedi, Head, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no.1943/Res/Cardio/2021 dated 2nd December, 2021. **EC Decision:** Give an explanation for increasing the size. ***Ref.code:101st ECMIIC/P5***
3-	Reg. A letter no. 1328/2021 dated 11th November, 2021 received from Prof. R.K. Singh, Dean Dental KGMU UP, Lucknow that during FODS faculty board meeting held on 8th November, 2021, many faculties raised the objection that the IEC has questioned the role of different Guides while evaluating the MDS thesis for approval & requesting therein to send the University/ Research Cell guidelines lines in this regard, based on which the above question have been raise by the IEC. **EC Decision:** To inform Hon'able Vice Chancellor about the same
V	**Brought to Ethics Committee after VI-PGTSC held on 27th November, 2021**
	Minutes of VII ***"PG Thesis sub Committee"*** of ***"Institutional Ethics Committee"*** Meeting ***virtually*** held on 27th November, 2021 from 11.30 AM. ***The following Members were present in its Meeting:*** 1. Prof. G.G. Agarwal — Member 2. Prof. Rajendra Nath — Member 3. Prof. Abbas Ali Mahdi — Member 4. Prof. Anita Rani Singh — Member 5. Prof. Shally Awasthi — Convener ***The following Member could not attend the Meeting:*** 1. Dr. D.N.Upadhyaya — Send his written Comment

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

I-A	Action Taken
1	Clarification of research proposal entitled ***"Impact of oil pulling on periodontitis in patients with and without type2 diabetes mellitus-A randomized controlled trial"*** submitted by Dr. Nehil Saran, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2018//P/21 dated 12th October, 2021. **Previous PGTSC Comment:** • Objectives of studying the efficacy of an Ayurvedic procedure in a modern medicine University by a person not trained in Ayurveda amounts to malpractice. • PI not trained in Ayurvedic sciences, thus cannot act as PI. • The PI and all exact one Co-PIs are not trained in Ayurveda • KGMU is a University imparting training in Modern Medicine. Research in subject pertaining to Ayurveda involving patients will be malpractice. • Patient has to be informed that they are being treated by an Ayurvedic method by a person not trained in Ayurveda. • Research on an Ayurvedic medication/Ayurvedic treatment/procedure cannot be conducted by a person not trained in Ayurvedic sciences and in a non-Ayurvedic University. This amounts to Malpractice. Suggest rethinking of the research topic on a subject from Modern Medicine. • Mention the compensation of oil to be used. • How will the oil be standardized? • Justify the role of Co-PIs. • Include a Doctor Ayush working in KGMU. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Approved** **PGTSC Decision:** Approved ***Ref. code: III PGTSC-IIA/P39***
2	Clarification of research proposal entitled ***"A randomized controlled trial to compare ligation of intersphincteric fistula (LIFT) v/s LIFT plus in complex anal fistula"*** submitted by Dr. Shristi Rathore, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1856/21 dated 7th October, 2021. **Previous PGTSC Comment:** • The fundamentals of performing RCT are not specified: Clinical Trial Registry, method of randomization, blinding, follow-up, outcome event, efficacy or effectiveness trial, statistical and methodology. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **PGTSC Decision:** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: IV PGTSC-IIA/P4
3	Clarification of research proposal entitled ***"To study soluble transferrin receptor level and serum visfatin level in beta thalassemia and iron Deficiency Anemia"*** submitted by Dr. Himadri Shukla, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter n. 2754/21 dated 7th June, 2021. **Previous PGTSC Comment:** • Define selection criteria for control subjects. • The study title does not address inclusion of patients of Iron deficiency anemia, but objectives of the study state comparison of various parameters between the two. The study topic is not appropriately addressing the objectives so either reconsider the study or modify. • Kindly provide in ICF clear, understandable description of study procedure in simple language instead of writing study design. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Comment:** After perusal of the documents and in consideration of the comments of the primary reviewer, the proposal is approved with the title as mentioned here. **PGTSC Decision:** Approved
	Ref. code: IV PGTSC-IIA/P12
4	Clarification of research proposal entitled ***"Histopathological study of liver diseases in unclaimed and claimed dead bodies: A case-control study"*** submitted by Dr. Krishna Nishad, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 446/FMT/21 dated 12th October, 2021. **Previous PGTSC Comment:** Consent forms need to be corrected as a legally acceptable representative will be giving the consent and it is mentioned in point no. 2 that "my participation", similarly in the Investigator's statement "subject" is the dead body so it may be deleted. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved
	Ref. code: IV PGTSC-IIA/P30
5	Clarification of research proposal entitled ***"A comparative study of outcome between COVID-19 positive and negative traumatic brain injury patient"*** submitted by Dr. Tripurari Pandey, JRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/958/21 dated 12th October, 2021. **Primary reviewer recommendation:** • Outcome (Event) should be explicitly defined in terms of the propoer study

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	variables. Sample size calculations are missing. Statistical analysis is not prescribed. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P3***
6	Clarification of research proposal entitled ***"Comparison of meld lactate and aarc score to predict mortality in acute on chronic liver failure patients"*** submitted by Dr. Khushboo Yadav, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.3179/MED dated 8th November, 2021. **Previous PGTSC Comment:** Aim & Primary objective don't match. Study design is not defined. Since study design is not defined. Since study design and study hypothesis is not properly defined, sample size calculations are not justified. Statistical analysis is not mentioned. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P4***
7	Clarification of research proposal entitled ***"Long term outcome of operated head injury patients following decompressive craniectomy/craniotomy: A KGMU Experience"*** submitted by Dr. Nitish Kumar Singh, JRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/892/21 dated 30th September, 2021. **Primary reviewer recommendation:** • Study design is not properly defined. Methodology, sample size calculation and statistical analysis description is missing. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P5***
8	Clarification of research proposal entitled ***"Assessment of self care practices among type 2 diabetes mellitus patients undergoing treatment in secondary and tertiary care Hospitals of Lucknow"*** submitted by Dr. Maviya Khan, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 722/CM/21 dated 6th October, 2021. **Previous PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The outcome (dependent) variables for assessing self care practices should be explicitly specified. There is no list of secondary and tertiary care centers to be included in the study. Sample size calculations are not clear, since outcome variable is not defined. Statistical analysis details are missing. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P9***
9	Clarification of research proposal entitled ***"A comparative study between fentanyl-lignocaine and dexmedetomidine-lignocaine nebulisation in awake nasal fibreoptic intubation"*** submitted by Dr. Asmita Gupta, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/912/21 dated 27th October, 2021. **PGTSC Comment:** • Statistical analysis is to be done by using SPSS 15, kindly explain the reason for not using the latest (27) version of the same. • References are not updated, while literature is available for the year 2020 on the same topic. • Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website. Use simple day to day Hindi language. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P12***
10	Clarification of research proposal entitled ***"Effect of occlusal splint versus sleep hygiene measures and progressive muscle relaxation on sleep bruxism: A randomized controlled trial"*** submitted by Dr. Ayushi Tandon, JRI, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.736/2021 dated 25th October, 2021. **Previous PGTSC Comment:** • Group detail not provided • References not provided ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P19***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

11	Clarification of research proposal entitled ***"Estimation of microbiota and inflammatory biomarker in tears and conjunctival secretions of ocular defect patients after using ocular prosthesis"*** submitted by Dr. Rohit Bhandari, SR, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.652/21 dated 8th October, 2021. **Previous PGTSC Comment:** • How will microbiota be analyzed? No details provided. • It is mentioned that "after placing ocular prosthesis with healthy eye"? Please explain? • Which inflammatory markers will be assessed? Methods? Reference? By whom? • In inclusion criteria point number 2 Healed socket? Of whom? • References not provided (Bibliography) ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P22***
12	Clarification of research proposal entitled ***"Correlation of pseudo cholinesterase level with clinical and biochemical parameters with special emphasis on cardiac profile in patients of organo phosphorus poisoning and its outcome"*** submitted by Dr. Arvind Kumar, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1998/Med/21 dated 30th October, 2021. **Previous PGTSC Comment:** • Methodology and reference for measurement of Blood ammonia levels not provided. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P27***
13.	Clarification of research proposal entitled ***"A mycological study on COVID associated rhino-orbito-cerebral mucormycosis"*** submitted by Dr. Mohd Saqib Hasan, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1337/21 dated 9th November, 2021. **Previous PGTSC Comment:** • 1 Supervisor and 2 co-supervisors from the same department. Please define their roles or decrease their number. • IEC forms lack in the following sections – a. Privacy and Confidentiality

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	b. Use of biologic material not mentioned c. Consent details not ticked d. Risk is mentioned as not reasonable e. Adverse events are ticked. • Contact person details not present in Informed Consent ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P29***
14	Clarification of research proposal entitled ***"Comparison of I-Gel and laryngeal mask airway block buster in the management of difficult airway in post burns contracture patients: A randomized controlled trail"*** submitted by Dr. Manish Kumar Tripathi, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/825/2021 dated 27th September, 2021. **Previous PGTSC Comment:** • The Title should be corrected as study is Randomized controlled Study not R C Trial. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P40***
15	Clarification of research proposal entitled ***"Assessment of sealing ability of biodentin as endodontic sealer compared with conventional resin based sealer and bioceramic sealer using confocal laser scanning microscopy: An in vitro study"*** submitted by Dr. Manisha Lal, JRII, Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.350/21 dated 12th October, 2021. **Previous PGTSC Comment:** • Methodology, Total sample size and grouping not explained well ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: V PGTSC-IIA/P47***
16	Clarification of research proposal entitled ***"Educational intervention to create awareness about cervical and breast cancer in College going girls of Lucknow District"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Sarrah Maimoon Usmani, JRIII, through her Mentor Prof. Monika Agarwal, Department of Community Medicine & Public

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Health, King George's Medical University, U.P., Lucknow vide letter no.812/21 dated 25th October, 2021. **Previous PGTSC Comment:** • Several sections of the IEC form have been left unfilled. Please fill them properly. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: VPGTSC-II B IMR-R/P2***
17	Clarification of research proposal entitled ***"Comparison of Diagnostic accuracy of International ovarian tumor analysis and the risk of malignancy Index (RMI) to discriminate between benign and malignant adenexal masses"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Yamini Sharma, JR through her Mentor Prof. Uma Singh, Head, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no.OG/1310/2021 dated 10th August, 2021. **Previous PGTSC Comment:** • Add consent form for Biopsy ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: VPGTSC-II B IMR-R/P3***
18	Clarification of research proposal entitled ***"Comparing color match by conventional trial and error method with maxillofacial spectrophotometer method for the Indian skin: A subjective and objective assessment"*** submitted by Dr. A. Sunayana, JRI, Department of Prosthodntics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.845/21 dated 20th November, 2021. **Previous PGTSC Comment:** • Although references are cited, they are not listed. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: VI PGTSC-IIA/P11***
19	Clarification of research proposal entitled ***"An epidemiological study of substance abuse among youth in Lucknow district"*** submitted by Dr. Hariom Singh, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no.921/21 dated 22nd November, 2021. **Previous PGTSC Comment:** • Approved, however, in the consent form it is mentioned that "The *patient* can

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	withdraw". • Instead of "*patient* "write "*subject*". Investigators may be advised to make this minor correction in the consent form. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: VI PGTSC-IIA/P18***
20	Clarification of research proposal entitled ***"A comparative evaluation of circulatory and salivary miRNA signatures in oral leukoplakia and oral lichen planus: A perspective case control study"*** submitted by Dr. Anil Kumar, JRI, Department of Oral Medicine and Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 434/OM/21 dated 6th August, 2021. **Previous PGTSC Comment:** • Age group not specified ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: VI PGTSC-IIA/P34***
21	Clarification of research proposal entitled ***"The tentorial notch anatomy and its variations in autopsy of head injury patients to correlate its impact over brainstem and its correlation with computed tomography scan of head findings"*** submitted by Dr. Anoop Kumar Singh, SR1, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/1074/21 dated 8th November, 2021. **Previous PGTSC Comment:** • There are many Co-investigators, 8 in number (including 1 from Anatomy and 1 from Forensic Deptt. + 6 from same dept.) and their roles given are almost same- Reduce Member or justify roles of each. • Sample size not mentioned at all. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: VI PGTSC-IIA/P37***
22	Clarification of research proposal entitled ***"To correlate the mammography density imaging findings with clinic pathological tumour characteristics in breast cancer patients"*** submitted by Dr. Upander Kumar, SR, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. 336/21 dated 15th November, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer. **Previous PGTSC Comment:** • Sample size not mentioned. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: VI PGTSC-IIA/P38***
23	Clarification of research proposal entitled ***"Retrospective analysis of geriatric traumatic brain injury at a tertiary care centre: A five-year experience"*** submitted by Dr. Abhishek Kumar, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/1111/21 dated 16th November, 2021. **Previous PGTSC Decision:** • There is 1 Supervisor and 6 Co-Supervisors from Neurosurgery. This cannot be approved. Please decrease the number of Co-supervisors. • International Government and National Industry have been ticked as sponsors. • Clinical trial section has been filled. Is this a Trial? • Written consent has been ticked. How will consent be obtained in a retrospective study? • Risk is not reasonable has been ticked. Explain why? • Sample calculation not done. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: VI PGTSC-IIA/P23***
24	Clarification of research proposal entitled ***"3D assessment in TMJ ankylosis"*** submitted by Dr. Sharma Shivani Yogesh, JRI, Department of Oral and Maxillofacial Surgery, King George's Medical University, U.P., Lucknow vide letter no.OMS/682 dated 15th November, 2021. **Previous PGTSC Comment:** • Role of Supervisor and Co-Supervisors are overlapping. • Number of subjects is mentioned 30 at one place and 300 at another. • No sample calculation has been done. • There are tonnes of material describing deformity, treatment, and post-operative changes in TMJ ankylosis. What is the need for another study? • Methodology is incomplete. Are the patients being offered treatment? If so, what? What is the protocol for follow-up after that? ***Recommendation of Primary reviewer:*** Approved ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: Approved **PGTSC Decision:** Approved ***Ref. code: VI PGTSC-IIA/P25***
25	Clarification of research proposal entitled ***"Evaluation of expression of immunohistochemical markers Isocitrate dehydrogenase 1 (IDH1) and tumor protein 53 (p53) in high grade glioma and its correlation with outcome-a prospective study"*** submitted by Dr. Vikas Kumar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.270/21 dated 20th November, 2021. **Previous PGTSC Decision:** • Indian and International Private Agencies and National industry has been marked as sponsors of this study? Give supportive evidence if this is correct. • Section on Use of Biological Material has been filled incorrectly. • Section on Consent has been incompletely filled. ***Recommendation of Primary reviewer:*** ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: VI PGTSC-IIA/P27***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"A prospective study of blood glucose profile during initial days in healthy at risk new born infants"*** submitted by Dr. Radhika Ranjan Biswas, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2072/Ped/21 dated 25th August, 2021. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Prospective study of complications after post traumatic decompressive craniectomy"*** submitted by Dr. Pritesh Bharatkumar Yadav, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/599/21 dated 16th August, 2021. ***Recommendation of Primary reviewer:*** • Research hypothesis is not defined. • Sample size calculation is missing. • There is no statistical analysis section. • There are three components for evaluation: (i) radiological, (ii) clinical and (iii) psychological. The analysis has to take into consideration all the three components. **PGTSC Comment:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Revise & re-submit, tabulating changes done at the time of revision. ***Ref. code: VII-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Prevalence and predictors of persistent pulmonary hypertension of neonates in hospitalised hypoxemic new born infants: A prospective hospital based study"*** submitted by Dr. Barnika Nath, JRI, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no.2094/Ped/21 dated 26th August, 2021. ***Recommendation of Primary reviewer:*** • This is an observational study primarily for finding prevalence of persistent pulmonary hypertension of neonates. • It should not be used for predicting the risk factors. • One use of a cross-sectional study is to determine the association between an outcome variable and some **explanatory variables**, for example to estimate the prevalence of a disease, perhaps as a function of some explanatory variables. An association between outcomes and explanatory variables may suggest causality, although a causal link usually cannot be established from a single cross-sectional survey because such studies give no information on the temporal ordering of possibly causal events. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, tabulating changes done at the time of revision. ***Ref. code: VII-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Cerebello-pontine angle tumors: A 10 years experience at a tertiary care center"*** submitted by Dr. Ravi Prakash Verma, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/601/21 dated 16th August, 2021. ***Recommendation of Primary reviewer:*** • Sample size and statistical analysis section are missing. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit, tabulating changes done at the time of revision. ***Ref. code: VII-PGTSC-IIA/P4***
5.	Research proposal entitled ***"Retrospective study of paediatric head injury: an institute experience from past 5 years"*** submitted by Dr. Vishal Kumar, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/600/21 dated 16th August, 2021. ***Recommendation of Primary reviewer:*** • Research hypothesis, sample size calculation and statistical analysis section are missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, tabulating changes done at the time of revision. ***Ref. code: VII-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Prospective randomized control trial for the management of***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	post traumatic cerebrospinal fluid rhinorrhea and otorrhea with acetazolamide" submitted by Dr. Shivam Madeshiya, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/598/21 dated 16th August, 2021 ***Recommendation of Primary reviewer:*** • There is no research hypothesis. • This is supposed to be a randomized controlled trial. • The fundamentals of performing RCT are not completely specified: Clinical Trial Registry, method of randomization, blinding, follow-up, outcome event, efficacy or effectiveness trial, Statistical and methodological issues in RCT. • They may also consider drug a prospective cohort study. **PGTSC Comment:** As above **PGTSC Decision:** Re-submit, tabulating changes done at the time of revision. ***Ref. code: VII-PGTSC-IIA/P6***
7.	Research proposal entitled ***"Analysis of outcome of severe head injury patients with surgically evacuable lesion"*** submitted by Dr. Aman Singh, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/597/21 dated 16th August, 2021. ***Recommendation of Primary reviewer:*** • Research hypothesis is not given • In the absence of proper research hypothesis, sample size calculation and statistical analysis section would be inappropriate. **PGTSC Comment:** As above **PGTSC Decision:** Re-submit, tabulating changes done at the time of revision. ***Ref. code: VII-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Evaluation of anxiety levels in patients undergoing interventional pain procedures"*** submitted by Dr. Puneet Kumar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/497/21 dated 21st June, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P8***
9.	Research proposal entitled ***"Prevalence of anatomical variations of nasal cavity & paranasal sinuses on computed tomography in people of Lucknow region"*** submitted by Dr. Rintu Biswas, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no.280/ANAT/21 dated 31st August, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P9***
10.	Research proposal entitled"***Ophthalmological manifestations in demyelinating disorders of central nervous system"*** submitted by Dr. Ankit Khetan, SRI, Department of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Neurology, King George's Medical University, U.P., Lucknow vide letter no.108/Neuro/21 dated 4th April, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Study on association of occurrence of oral mucormycosis with severity of COVID-19 infection, demographics and co-morbidities in COVID-19 patients"*** submitted by Dr. Nikhil Gupta, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.183/P/21 dated 31st August, 2021. **Recommendation of Primary reviewer:** • It is a retrospective observational study, however, in methodology it is given that participants will be screened and detailed history will be taken and clinical examination will be carried out. Thereafter biopsy samples will be taken. • From where patients will be recruited?? It's not clear. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit, tabulating changes done at the time of revision. ***Ref. code: VII-PGTSC-IIA/P11***
12.	Research proposal entitled ***"An observational study on prescription patterns of systemic antifungal medications in critically ill patients at tertiary care ICU"*** submitted by Dr. Surekha, JRI, Department of Pharmacology and Therapeutics, King George's Medical University, U.P., Lucknow vide letter no.848/Pha/21 dated 16th August, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Dr. Rajendra Nath did not take part in the discussion and making decision.*** ***Ref. code: VII-PGTSC-IIA/P12***
13.	Research proposal entitled ***"An observational study to find out rationality of polypharmacy in geriatric medicine OPD in tertiary care Hospital"*** submitted by Dr. Anand Pandey, JRI, Department of Pharmacology and Therapeutics, King George's Medical University, U.P., Lucknow vide letter no.893/Pha/21 dated 8th September, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P13***
14.	Research proposal entitled ***"Characteristics and factors affecting flares in spondyloarthritis patients and its impact on functional limitation"*** submitted by Dr. Abilash Krishnan V, JRI, Department of Rheumatology, King George's Medical University, U.P., Lucknow vide letter no.Rh/593/21 dated 9th September, 2021. **Recommendation of Primary reviewer:** • Start date of the project is given as July, 2021. Without IEC approval how was the project initiated? A clarification may be taken.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Kindly submit clarification ***Ref. code: VII-PGTSC-IIA/P14***
15.	Research proposal entitled ***"Effect of dexmedetomidine infusion on post operative cognitive dysfunction in elderly patients after oral cancer surgery and its correlation with ADRA2A genotype: A double blinded randomized controlled study"*** submitted by Dr. Swati Srivastava, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/737/21 dated 31st August, 2021. **PGTSC Comment:** • Kindly mention from which department oral cancer patient swill be enrolled. As the study subjects are patients undergoing surgery for oral cancers, kindly add a clinician who performs such surgeries or declare who among the investigator will perform such surgery. • If the patient is not being operated by the Co-guide, the surgeon must be informed about the inclusion of the patient in the study. **PGTSC Decision:** Kindly submit clarification ***Ref. code: VII-PGTSC-IIA/P15***
16.	Research proposal entitled ***"Clinical profile, treatment modalities and outcome of takayasu arteritis patients attending rheumatology tertiary care centre in Northern India"*** submitted by Dr. Dogga Prasanna Kumar, SRI, Department of Rheumatology, King George's Medical University, U.P., Lucknow vide letter no.Rh/594/21 dated 9th September, 2021. **PGTSC Comment:** • Submit for waiver of consent. Keep patient identifiers anonymous calculate power of the study on samples accrued in you department. **PGTSC Decision:** Re-submit ***Ref. code: VII-PGTSC-IIA/P16***
17.	Research proposal entitled ***"Study of endocrine dysfunction in patients with juvenile idiopathic arthritis"*** submitted by Dr. Sayan Mukherjee, SR, Department of Rheumatology, King George's Medical University, U.P., Lucknow vide letter no.Rh/606/21 dated 14th September, 2021. **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P17***
18.	Research proposal entitled ***"Infection profile of patients and utility of neutrophil CD64 expression, presepsin, procalcitonin, neutrophil to lymphocyte ratio and crp in differentiating infections from flares in systemic lupus erythematosus"*** submitted by Dr. Mukesh Kumar Maurya, SR, Department of Clinical Immunology and Rheumatology, King George's Medical University, U.P., Lucknow vide letter no.Rh/594/21 dated 14th September, 2021. **PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Kindly calculate power it your recruitments 100 patients. • Please state clearly that all the investigations are routine in nature and no additional cost will be borne by any participant and in case it is not so, kindly mention the same in the informed consent for. **PGTSC Decision:** Approval after subject to modification ***Ref. code: VII-PGTSC-IIA/P18***
19.	Research proposal entitled ***"Comparative study between quadratus lumborum versus transverse abdominis plane block in laparoscopic pyeloplasty for post-operative pain relief"*** submitted by Dr. Manoj Kumar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/774/21 dated 10th September, 2021. **PGTSC Comment:** • Kindly explain the study procedure to the patient in simple language instead of writing study design. • Kindly follow the SOP provide by IEC, available on Website. **PGTSC Decision:** Approval after subject to modification ***Ref. code: VII-PGTSC-IIA/P19***
20.	Research proposal entitled ***"Impact of disease perception education on health-related quality of life, mental health and disease activity in patients with rheumatoid arthritis"*** submitted by Dr. Ankush P.M, SR, Department of Rheumatology, King George's Medical University, U.P., Lucknow vide letter no.Rh/621/21 dated 17th September, 2021. **PGTSC Comment:** • Kindly justify the role of Child Psychologist for psycho education of subject>18 years. **PGTSC Decision:** Approval after subject to modification ***Ref. code: VII-PGTSC-IIA/P20***
21.	Research proposal entitled ***"3D assessment of ear morphology"*** submitted by Dr. Meleti Venkata Sowmya, JRI, Department of Oral and Maxillofacial Surgery, King George's Medical University, U.P., Lucknow vide letter no.316/OMFS/21 dated 21st September, 2021. **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P21***
22.	Research proposal entitled ***"Incidence of post operative low back pain with median and paramedian approach in obese women patients undergoing surgery in spinal anaesthesia"*** submitted by Dr. Robin Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/750/21 dated 4th September, 2021. **PGTSC Comment:** • Kindly tabulate the known advantages and disadvantages of 2 methods. • Who among the investigators will enroll the patients?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Who among the investigators will perform the procedure. **PGTSC Decision:** Approval after subject to modification ***Ref. code: VII-PGTSC-IIA/P22***
23.	Research proposal entitled ***"Role of GHR, IGF1R and IGF2R in craniofacial dimension variability-A genetic study"*** submitted by Dr. Gulnaz Husain, JRII, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.467/21 dated 17th September, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P23***
24.	Research proposal entitled ***"A comparative study of characteristics and outcomes in patients of interstitial pneumonia with autoimmune features(IPAF) and connective tissue disease associated interstitial lung disease (CTD-ILD) in a tertiary teaching center in northern India"*** submitted by Dr. Kamble Nishant Gautam, SR, Department of Rheumatogy, King George's Medical University, U.P., Lucknow vide letter no.Rh/641/21 dated 26th September, 2021. **Recommendation of Primary reviewer:** • Sample size calculation not done. • In subject Volunteers instead of patients has been ticked. • No option is selected in 'Vulnerable subject' section • Confidential handling of data has been ticked 'No' • Methods section in Proforma is inadequate/incomplete and has no details of data handling image acquisition/data usage/statistical methods applied etc. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit, tabulating changes done at the time of revision. ***Ref. code: VII-PGTSC-IIA/P24***
25.	Research proposal entitled ***"Correlation of serum endocan level in preterm labour"*** submitted by Dr. Anamika Shahi, JRII, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no.OG/1694/21 dated 21st September, 2021. **Recommendation of Primary reviewer:** • Use of blood/body fluids has not been ticked in Proforma • Inclusion criteria unclear. • No mention of statistical analysis/how data will be analyzed • Too many Co-PIs case management is not reason enough to be part of a research project; one has to actively participate in it. Justify. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit, tabulating changes done at the time of revision. ***Ref. code: VII-PGTSC-IIA/P25***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

26.	Research proposal entitled ***"Appraisal of skeletal maturity indicators with respect to non invasive biomarkers"*** submitted by Dr. Snigdha Kumar, JRII, Department of Orthodontics and Dentofacial Orthopaedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.481/21 dated 25th September, 2021. **Recommendation of Primary reviewer:** • Department Scientific Committee has the same people as those in the study. This cannot be accepted. Co-opt of Members from • IEC Proforma is incomplete use of body fluids is not mentioned, data monitoring section is not filled • Methodology is incomplete/unclear. **PGTSC Decision:** Revise & Re-submit, tabulating changes done at the time of revision. ***Ref. code: VII-PGTSC-IIA/P26***
27.	Research proposal entitled ***"Role of serum albumin, neutrophil-lymphocyte ratio, platelet lymphocyte ratio in guillain barre syndrome in Indian paediatric population presenting within 14 days of symptoms onset and evaluating their correlation with short term prognosis through medical research council sum score"*** submitted by Dr. Sakshi Tyagi, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.2129/Ped/21 dated 31st August, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P27***
28.	Research proposal entitled ***"A study on operation theatres of general surgery Department in a tertiary care Government Teaching Hospital"*** submitted by Dr. Kris Agarwal, JRI, Department of Hospital Administration,King George's Medical University, U.P., Lucknow vide letter no.HA/343/21 dated 11th October, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P28***
29.	Research proposal entitled ***"A study on cost incurred in sterilisation in the central sterile supply Department (CSSD) of a tertiary care Teaching Government Hospital"*** submitted by Dr. Anmol Jain, JRI, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no.HA/342/21 dated 11th October, 2021. **Recommendation of Primary reviewer:** Approved **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P29***
30.	Research proposal entitled ***"Retrospective study of demographic and clinical profile of patients of chronic rhinosinusitis with polyposis at tertiary care Centre"*** submitted by Dr. Neha Agarwal, JRI, Department of OTO-Rhino-Laryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no.308/ENT/21 dated 11th October, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • IEC form incompletely/incorrectly filled • Sample size calculation not done • Too many Co-PIs included in a project which requires only retrospective data handling. Please justify. **PGTSC Decision:** Revise & Re-submit, tabulating changes done at the time of revision. ***Ref. code: VII-PGTSC-IIA/P30***
31.	Research proposal entitled ***"Evaluation of red cell distribution width (RDW), mean platelet volume (MPV) and platelet count (PC) as a prognostic factor for maternal mortality in critically ill obstetric patients"*** submitted by Dr. Kirti Yadav, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no.OG/1806/21 dated 10th October, 2021. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P31***
32.	Research proposal entitled ***"Study the effect of melatonin on psychological and physical outcome in older adults with acute ischemic stroke"*** submitted by Dr. Prerak Kumar, SRI, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no.1248/DGMH/21 dated 13th October, 2021. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: VII-PGTSC-IIA/P32***
33.	Research proposal entitled ***"Comparative study of intraoperative parameters, postoperative voice change and laryngopharyngeal symptoms in patients undergoing thyroid surgery with supraglottic airway devices vs endotracheal intubation (Armoured vs non-armoured)"*** submitted by Dr. Rizhin Sooraj, SRI, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no.ENDO-SURG/257/21 dated 24th August, 2021. ***Recommendation of Primary reviewer:*** • Age specificity not mentioned in Inclusion criteria **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: VII-PGTSC-IIA/P33***
34.	Research proposal entitled ***"Intra-operative identification of parathyroid tissue using the ratio of aspartate transaminase to lactate dehydrogenase- a prospective observational study"*** submitted by Dr. Ganesh Bhat, SRI, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no.ENDO-SURG/256/21 dated 24th August, 2021. ***Recommendation of Primary reviewer:*** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approved ***Ref. code: VII-PGTSC-IIA/P34***
35.	Research proposal entitled ***"Correlation of body mass index and postoperative pain in patients undergoing abdominal hysterectomy under spinal anaesthesia"*** submitted by Dr. Bhagyesh Pratap Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/872/21 dated 12th October, 2021. ***Recommendation of Primary reviewer:*** • Age specification in Inclusion criteria not mentioned • VAS Score chart -not attached **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VII-PGTSC-IIA/P35***
36.	Research proposal entitled ***"Assessment of metal ions and it's correlation with therapeutic outcomes on cognitive and motor functions in the patients of parkinsonism coming to tertiary care Hospital"*** submitted by Dr. Aishwarya Mishra, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no.989/Pharma/21 dated 7th October, 2021. **Recommendation of Primary reviewer:** • Serum and urine samples are being collected but the section on Biological Material is not filled • The proposal has **SIX Co-PIs** out of which four are from one department, all with overlapping roles justify. • Risk is mentioned as not reasonable in the IEC form. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Dr. Rajendra Nath did not take part in discussion & making decision.*** ***Ref. code: VII-PGTSC-IIA/P36***
37.	Research proposal entitled ***"Comparative evaluation of dexmedetomidine and butorphanol on perioperative Hemodynamics, sedation and postoperative analgesia for patients undergoing lower abdominal surgery"*** submitted by Dr. Avinash Kumar Yadav, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/907/21 dated 26th October, 2021. ***Recommendation of Primary reviewer:*** • VAS Score chart for pain and Ramsay Sedation score (RSS) chart **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VII-PGTSC-IIA/P37***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

III	Other Matter
1	Request for permission change to the title ***"An epidemiological study of substance abuse among professional undergraduate students of Lucknow"*** in place of ***"An epidemiological study of substance abuse among youth in Lucknow district"*** submitted by Dr. Hariom Singh, JR-II. Department of Community Medicine & Public Health, K.G's Medical University, U.P., Lucknow. **PGTSC Comment:** Give details of sampling plan ***Ref. code: VI-PGTSC-IIA/P18***

Next IEC Meeting scheduled on 12th February, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 114th IEC virtually held on 10th February, 2022

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of 114th "Institutional Ethics Committee" Meeting ***virtually*** held on 10th February, 2022 from 3.00 P.M.

The following Members were present in the Meeting:-

1. Prof. Alok Dhawan -Chairman
2. Prof. G.G. Agarwal -Member
3. Prof. Shubha R Phadke -Member
4. Mrs. Vasundhara Kumar -Member
5. Mrs. Akansha Dubey -Member
6. Mr. Ujjawal Krishna -Member
7. Dr. Akash Agarwal -Member
8. Dr. K.K. Yadav -Member
9. Prof. A.A. Mahdi -Member
10. Prof. Rajendra Nath -Member
11. Prof. Anupam Mishra -Member
12. Prof. Anita Rani Singh - Member
13. Dr. D.N. Upadhyaya -Member
14. Prof. Shally Awasthi -Member-Secretary, IEC

I-A	Action Taken
1	Clarification of research proposal entitled ***"A randomized double-blind, placebo-controlled, multicentre trial assessing the impact of lipoprotein (a) lowering (a) lowering with TQJ230 on major cardiovascular events in patient with established cardiovascular disease"*** submitted by Prof. S.K. Dwivedi, Head, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1990/Cardio/Res/2021 dated 24th December, 2021. **Previous IEC Comment:** • Give an explanation for increasing the sample size. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Member-Secretary, IEC.*** ***Recommendation of Primary reviewer:*** **Decision:** Provisionally approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

EC Decision: Approved

Insurance expired on 31st December, 2021, kindly provide valid insurance

Ref. code: 101st ECMIIC/P18.

2- Clarification of research proposal entitled ***"Cellular fibroadenoma versus phyllodes tumors: A pre-operative diagnostic approach based on radiological and cytological features"*** submitted by Prof. Chanchal Rana, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 4081/21 dated 27th November, 2021.

Previous EC Comment	Response of PI
How will you get the patient consent?	Patient will be called and consent will be taken.
Discrepancy between mode of consent on IEC form.	Corrected EC form re-submitted with change highlighted in bold (Oral consent instead of written: corrected)
Sample size not mentioned	Mentioned in summary and highlighted in bold.
What radiological investigation will be included?	Mammography (Highlighted in bold in)
Will the histology and cytology slides of the patient re assessed or will previous documentation be used to extract data?	The histology and cytology slides will be reviewed and re assessed.
Recruitment of both the sexes been ticked in proforma.	Phyllodes neoplasm and fibroadenomas can be encountered in male patients as well, although rare. Hence if there will be any such cases encountered during retrospective analysis, those cases will be included.
Use of pre-existing/stored/left over samples has been ticked as No. Is this correct.	This study is based on morphological features which will be analyzed in slide review. Hence no stored or left over sample is required for any other analysis.
Use of biological material has been mentioned as NO.	Corrected proforma submitted

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer:

Decision: Provisionally approved

EC Decision: Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 109th ECMIIA/P8
3-	Clarification of research proposal entitled ***"Proteomics and promoter methylation approach for genetic signatures in early detection of lung cancer"*** submitted by Prof. Santosh Kumar, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no.2248/2021 dated 17th December, 2021. **Previous EC Comment:** • Dr. Santosh Kumar is the P.I; but role is more of investigator Dr. Seema who is listed in first position. Also Dr. Santosh is listed as co-investigator and his CV is submitted at the end. Hence, this needs rectification. • Patient information sheet is not attached but rather only guidelines are attached. Rectification is needed. • Informed consent document should be more patient friendly such as in sections of purpose of study and study procedure. • Study included healthy control subjects from which 6 ml blood samples need to be drawn BUT. a) No consent form for controls is attached. How will same geographical match be done (age/gender wise): Clarification needed? b) How will same geographical match be done (age/gender wise): Clarification needed? c) Inclusion criteria for controls need to be added. d) It would be nice to specify the sample size of controls as well. • Clarify if it is "Sponsored" or submitted

II-time opinion of Primary reviewer	**PI response**
The patient information sheet is not yet up to the expectation-Kindly revise	Revised patients information sheet is attached.
The consent form for patient and healthy controls need to be different for the lung reasons one of which is that the lung biopsy as specified for patient cannot be justified in healthy controls.	Consent form for healthy control is attached (in Hindi and English)

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:
Decision: Provisionally approved
EC Decision: Approved

Ref. code: 110th ECM IIA/P2

4-	Clarification of research proposal entitled ***"Effect of yoga on inflammatory cytokines***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

and oxidative stress level in the breast cancer patients" submitted by Mr. Mayank Jain, Ph.D. Scholar under the guidance of Prof. Shailendra Kumar, Head, Department of Thoracic Surgery, King George's Medical University, U.P., Lucknow vide letter no.119/TH/21 dated 23rd December, 2021.

Sl. No.	Recommendation of First PR-Dr. D.N. Upadhyaya	Response of PI
1	**111th EC Comment:** • No yoga expert is part of the study. • Co-PIs from Departments of Thoracic surgery and Vascular surgery have no locus standi to be part of a study involving either Yoga or Breast cancer since neither is their domain, hence their involvements is highly questionable. • No Medical Oncologist/Surgical Oncologist/Radiation Oncologist/Biochemistry faculty/Immunology faculty has been included in a study which aims to assess Oxidative stress by means of serum levels of ROS/NOS/SOD. • Elaborate the natural of the study. • Define clinical end points • In what stage of management of breast cancer yoga will be introduced. • Study cannot be approved as presented. **EC Decision:** Modify and re-submit (Tracking changes in word format)	Attached vide letter no. 93/TH/2021 dated 22nd October, 2021. **(Annexure-1)**
2-	**Second Opinion:** Photocopy attached vide letter dated 1st November, 2021**(Annexure-2)**	Attached vide letter no.105/TH/2021 dated 26th November, 2021**(Annexure-3)**
3	**Third Opinion:** Photocopy attached vide letter dated 16th December, 2021. **(Annexure-4)**	Attached vide letter no.119/TH/2021 dated 23rd December, 2021. **(Annexure-5)**
4	**Fourth Opinion:** Photocopy attached vide letter dated 30th December, 2021. **(Annexure-6)**	Response not given.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Secondary PR-Dr. Rajendra Nath.	Response of PI
1-	Provisional approval may be given (after putting before EC) subject to the assurance which should be given to all patients in the group of Yogic intervention by PI apart from Informed Consent Form ,that he can opt out of the study at any given point of time if he has any discomfort with Yogic exercises, but will be given proper Chemotherapy and Radiotherapy till needed.	Revised Consent forms Hindi & English are attached.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer:

Decision: Provisionally approved

EC Decision: Approved with partial modification of title- Change **"Yoga to Yogic"**

Ref. code: 111th ECM IIB-Ph.D./P3

5- Clarification of research proposal entitled ***"Integrative molecular profiling of prostate cancer: identification of molecular signature for risk stratification and advanced-stage disease management"*** submitted by Prof. Apul Goel, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no.29/Uro/22 dated 11th January, 2022.

Sl.No.	Previous EC Comment	Response of PI
1.	It is not clear whether the tumor samples will be taken from the part of biopsy or surgical sample collected as a part of diagnostic or therapeutic procedure or will it need separate surgical intervention? Clarify.	Annexure-1, Page no-3, Point no. 5: Subject selection: (i) Number of subjects- line 2-3 specifies that no separate surgical procedure /biopsy will be done for our study.
2.	The language of the consent form can be made simple and easy to understand. (It is difficult to understand).	Annexure-8 &9, Page no.-16-19. The language of the informed consent form has been made simple and easy to comprehend.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	3.	Kindly clarify that no separate surgical procedure will be done for collection of specimens.	Annexure-9, Informed consent form in English: Page no.- 3, Part 1: Point no.2- line2-3 specifies no separate biopsy/surgical procedure will be done for collection of specimens to be included in our study.
	4.	Make consent form in simple language.	Annexure-8 & 9, Page no.- 16-19. We have simplified the language in the Informed consent forms.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer:

Decision: Provisionally approved

EC Decision: Approved

Ref. code: 113th ECMIIA/P2

6- Clarification of research proposal entitled "***Treatment adherence and spacer compliance in patient with asthma and COPD***" submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no.2268/Res/21 dated 24th December, 2021.

Previous EC Comment	PI response
Study design is not mentioned	Multi centric, observational, prospective study
Sample size calculation not done.	Purposive sampling method is going to use to recruit participants Total sample size of study is 100 participants (50 Asthma and 50 COPD patients) 14 participants (7 Asthma and 7 COPD) are expected from each study site.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer:

Decision: Provisionally approved

EC Decision: Approved

Ref. code: 113th ECM IIA/P7

7- Clarification of research proposal entitled "***Elucidating the role of long non-coding RNA's (IncRNAs) in HIV-infected subjects on treatment***" submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.224/MED/22 dated 3rd February, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Sl.No.	Previous EC Comment	PI response
1-	PI should be from parent institute.	We have revised the proposal and made PI from parent Institute.
2-	Research proposal should not be sent by Co-PI (therefore, Dr. D Himanshu should act as PI and Dr. Ravi Tandon, Asstt. Professor, School of Biotechnology, JNU should be Co-PI).	We made the changes as suggested.
3-	Study design not mentioned.	Study design is mentioned in annexure I under section 2 and 3 with bold font.
4-	Sample size calculation not done.	The statement on sample size calculation has been added in the proposal in Annexure I under section 2 and 3 with bold font.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer:

Decision: Provisionally approved

EC Decision: Approved

Ref. code:113th ECM IIA/P8

8- Clarification of research proposal entitled "***Development and Validation of artificial intelligence tool for screening/detection of pulmonary TB and other lung diseases using chest X-Rays***" submitted by Dr. Sarika Gupta, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.33/Ped/22 dated 6th January, 2022.

Recommendation of Primary reviewer:

- Exact study design not mentioned
- Exact sample size and its calculation is not given for the subjects enrolled in our center

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer:

Decision: Provisionally approved

EC Decision: Approved

Ref. code:113th ECM IIA/P9

9- Clarification of research proposal entitled ***"Skin flap necrosis after knife or electrocautery in patients undergoing inguinal lymph node dissection (SNAKE): a double blind randomized clinical trial"*** submitted by Dr. Shiv Rajan, Assistant Professor, Department of Surgical Oncology, King George's Medical University, U.P.,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Lucknow vide letter no. SONC/133/22 dated 25th January, 2022.

Previous EC Comment	PI response
Comment 1: The research hypothesis should be properly defined in terms of the population parameter (proportion) and the direction of "treatment effect". If the direction of "effect" is known, it can be planned as a "Superior' trial. It will help in reducing the sample size.	In this study, we plan to compare the incidence (proportion) of skin necrosis using knife versus conventional electrocautery for elevating skin flaps during inguinal lymph node dissection. Our research hypothesis is that, in patients undergoing inguinal lymph node dissection, there will be a decrease in skin flap necrosis by using a knife compared to electrocautery for elevating skin flaps. Having said that, the **direction of effect is uncertain**. We think that a knife should be superior. However, there are no such studies done in the past, and evidence is lacking. Therefore, **a two-sided test** is chosen because it is unknown whether electrocautery or knife is superior.
Comment 2: The fundamentals	We have designed this RCT protocol in accordance with the CONSORT guidelines. We have tried to cover all the details. However, if there are any missing things, we will be delighted to

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	of performing RCT are not completely specified: Clinical Trial Registry, Statistical and methodological issues in RCT.	provide them. We will certainly plan to register this study with the clinical trial registry once we get the Institutional Ethics Committee approval, but before starting the trial. We have now elaborated on the statistical issues in the revised document.
	Comment 3: The randomization section is not clear. Is it stratified random sampling? If it is, which kind of stratification will be done: proportional, optimal or else?	Randomization will be stratified according to the site of primary cancer, where separate randomization lists will be generated for each primary cancer site. Blocked randomization will be used within each stratum (separate for each cancer site) to ensure that the random assignment is balanced over time using randomly selected block sizes of 4 and 6.
	Comment 4: Sample size calculations are not clear.	Sample size was calculated using PASS Software (PASS 2019 Power Analysis and Sample Size Software (2019). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass.) Here are the formulas from the documentation from PASS.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	What formula is used for calculating sample size?	**Z Test (or Chi-Square Test) with Continuity Correction (Pooled and Unpooled)** Frank Yates is credited with proposing a correction to the Pearson Chi-Square test for the lack of continuity in the binomial distribution. However, the correction was in common use when he proposed it in 1922. Although this test is often expressed directly as a Chi-Square statistic, it is expressed here as a *z* statistic so that it can be more easily used for one-sided hypothesis testing. Both *pooled* and *unpooled* versions of this test have been discussed in the statistical literature. The pooling refers to the way in which the standard error is estimated. In the pooled version, the two proportions are averaged, and only one proportion is used to estimate the standard error. In the unpooled version, the two proportions are used separately. The continuity corrected z-test is $$z = \frac{(\hat{p}_1 - \hat{p}_2) + \frac{F}{2}\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}{\hat{\sigma}_D}$$ where F is -1 for lower-tailed, 1 for upper-tailed, and both -1 and 1 for two-sided hypotheses. PASS Sample Size Software NCSS.com **Tests for Two Proportions** **Pooled Version** $$\hat{\sigma}_D = \sqrt{\hat{p}(1-\hat{p})\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}$$ $$\hat{p} = \frac{n_1\hat{p}_1 + n_2\hat{p}_2}{n_1 + n_2}$$ **Unpooled Version** $$\hat{\sigma}_D = \sqrt{\frac{\hat{p}_1(1-\hat{p}_1)}{n_1} + \frac{\hat{p}_2(1-\hat{p}_2)}{n_2}}$$ **Power** The power of this test is computed using the enumeration procedure described for the z-test above. For large samples, approximate results based on the normal approximation to the binomial are used.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the <u>Primary reviewer.</u>

Recommendation of Primary reviewer:

Decision: Provisionally approved

Comment: Since only patient is blinded but not the investigator, this can be a single blind trial only.

EC Decision: Approval after modification

Ref. code:113th ECM IIA/P19

10-	Clarification of research proposal entitled ***"Assessment of auditory effects of noise exposures"*** submitted by Mr. Anupam Mehrotra, Ph.D Scholar under the guidance Dr. S.K.Singh, Professor (Epidemiology), Upgraded & Dr. Manish Kumar Manar, Associate

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Professor, Department of Community Medicine and Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1051/22 dated 5th January, 2022.

Sl.No.	Previous EC Comment	PI response
1	Research hypothesis is not properly defined. It should be in terms of the parameters involving some proper measure of Occupational noise.	Research question has now been changed to: What is the effect of occupational noise on the truck drivers of Lucknow District?
2	The questionnaire is incomplete as this does not include the questions related to aims and objectives	
(i)	Evaluation of prevalence of NIHL	Pure tone audiometry is used to evaluate the prevalence of NIHL
(ii)	Assessment of the auditory and non – auditory effects	
	Auditory effect	Pure tone audiometry is used to assess the auditory effect
	Non – Auditory effect	Questions related to sleep, stress and Blood pressure have been included in the Questionnaire
(iii)	The remedial measures for mitigating effects of the occupational noise	Aims and Objectives (iii) has been modified as: To suggest if any, remedial measures for mitigating the effects of occupational noise.
3	How the reliability and validity of the instrument shall be done?	The instrument used for audiometry are pre-validated in the past and they are being used since long time in the Lucknow district and in the country as well.
4	Sample size calculation have to be in accordance with the research hypothesis, which is missing	Research question has now been changed to: What is the effect of occupational noise on the truck drivers of Lucknow District?

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

<table>
<tr><td></td><td><u>Primary reviewer.</u>
Recommendation of Primary reviewer:
Decision: Provisionally approved
EC Decision: Approved
Ref. code:113th ECM II B- Ph.D /P2</td></tr>
<tr><td>11-</td><td>Clarification of research proposal entitled "Environmental exposure to toxins and their role in inducing hypothyroidism and infertility in women: A case control study" sponsored by DHR-HRD, New Delhi submitted by Dr. Saima Amjad under the guidance Prof. A.A Mahdi, Head, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/666/22 dated 6th January, 2022.
<table>
<tr><th>Sl.No.</th><th>Previous EC Comment</th><th>PI response</th></tr>
<tr><td>1-</td><td>The patient information sheet has to be customized.</td><td>As per the comments/suggestions of the learned reviewer's Patient information sheet has been customized.</td></tr>
<tr><td>2-</td><td>Data analysis and statistical analysis should also brief the type of data / variables and anticipated statistical test used in analysis.</td><td>According to comments/suggestions of the learned reviewer's changes have been made.

Data analysis: Evaluation, data analysis and interpretation in correlation with variables between control and cases.

Statistical analysis: Experimental results will be calculated and represented on basis of mean ± SEM. Analysis of data will be carried out by SPSS 21 software for clinico-pathological correlation in different group of patients. Where, $p \leq 0.05$ will be considered significance.</td></tr>
</table>
The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the <u>Primary reviewer.</u>
Recommendation of Primary reviewer:
Decision: Provisionally approved
EC Decision: Approved with partial modification to Change the topic to "toxicants" instead of toxins
Dr. A.A. Mahdi did not take part in the discussion and making decision
Ref. code: 113th ECM II B-YS/P1</td></tr>
<tr><td>12-</td><td>Clarification of research Protocol no.NV-05-1226-2021/BSV-ANTID-21-03 entitled "A prospective, multi-centre, phase-IV study for post marketing safety evaluation of recombinant ANTI-RHO(D) immunoglobulin in the prevention of maternal rh-</td></tr>
</table>

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

***isoimmunization*"** sponsored by M/s Bharat Serums and Vaccines Pvt. Ltd. submitted by Prof. Rekha Sachan, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no.OG/CT/01/22 dated 7th January, 2022.

The following documents were reviewed it the Meeting:-

S. No.	Documents	Version Number and Version Date
1	Study Protocol	Version 03 dated 26 Aug 2021
2	Prescribing Information Sheet	17 Mar 2021
3	DCGI Approval	30 Sep 2021
4	IMP Regulatory Status	Enclosed
5	Clinical trial protocol signaturepage for Version 03 dated 26 Aug 2021	Signed by the PI on 08 Oct 2021
6	Investigator Undertaking	Signed on 08 Oct 2021
7	Investigator Curriculum Vitae, Medical registration certificate and GCP certificate	CV signed on 28 Sep 2021; MRC registration number: 039255 signed on 28 Sep 2021, GCP signed on 28 Sep 2021
8	Patient Information sheet & Informed Consent Form	
A	English	Site Specific Patient Information Sheet & Informed Consent Form_ Version 02 Dated: 26-Aug-21
B	Translation ICFs	ICF_Hindi_Version 02_21 Sep 2021
C	Back Translation ICFs	ICF_Hindi_Version 02_21 Sep 2021 ICF_Hindi to English_Version 02_dated 29Sep 2021
S. No.	Documents	Version Number and Version Date
D	Translation certificates	ICF_Hindi_Version 02_21 Sep 2021
E	Back Translation certificates	ICF_Hindi_Version 02_21 Sep 2021 ICF_Hindi to English_Version 02_29 Sep 2021
9	Insurance Certificate Policy Number: OG-22-1919-3306- 00000003	Validity: 01-APR-21 To 31-MAR-22
1	Study Protocol	Version 03 dated 26 Aug 2021

Sl.No.	Previous EC Comment	PI response
1-	The word 'and' needs to be added in the title to make it more meaningful as in the title previously approved by ethics committee.	**The word "and" has been added in the title as suggested.**
2-	Sponsor is to make payment to PI that will be deposited in 'KGMU Research Fund' MOU attached needs attention since the name of Allahabad bank is changed to Indian Bank and IFSC code altered	**In the new MOU already mentions the Indian bank and IFSC code.**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	accordingly.	
3-	While annexure III (payment schedule) indicates 100% of payment is to be made at 'start date of study', but the MOU (section 3.2: Milestones of payment) indicates part payment 50%/25%/ 25%. Kindly clarify.	**As per the new MOU the sponsor will provide 100% payment at the start.**

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Recommendation of Primary reviewer:

Decision: Provisionally approved
EC Decision: Approved

Ref. code: 113th ECM II C/P5

13- Clarification of Modification under the Research protocol entitled ***"Determination of in vitro susceptibility pattern of ceftriaxone/sulbactam/disodium edetate against Gram-negative bacilli/ comparison with meropenem and piperacillin Tazobactam"*** submitted by Dr. Sheetal Verma, Associate Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1749/22 dated 3rd January, 2022.

Sl. no.	Previous EC Comment	PI response
1	The word 'and' needs to be added in the title to make it more meaningful as in the title previously approved by ethics committee.	The word "and" has been added in the title as suggested.
2	Sponsor is to make payment to PI that will be deposited in 'KGMU Research Fund' MOU attached needs attention since the name of Allahabad bank is changed to Indian Bank and IFSC code altered accordingly.	In the new MOU already mentions the Indian bank and IFSC code.
3	While annexure III (payment schedule) indicates 100% of payment is to be made at 'start date of study', but the MOU (section 3.2: Milestones of payment) indicates part payment 50%/25%/ 25%. Kindly clarify.	As per the new MOU the sponsor will provide 100% payment at the start.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Primary reviewer. ***Recommendation of Primary reviewer:*** **Decision:** Provisionally approved **EC Decision:** Approved ***Ref.code:90th ECMIIA/P32***
14	**Minutes of ADR sub Committee (DCGI & Non DCGI)**
	Minutes of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting ***virtually*** held on 10th February, 2022 from 2:30 P.M. **(DCGI)** ***The following Members were present in the Meeting:*** 1. Prof. Alok Dhawan -Chairman 2. Mrs. Akansha Dubey -Member 3. Mrs. Vasundhara Kumari -Member 4. Mr. Ujjawal Krishna -Member 5. Prof. Rajendra Nath -Member 6. Dr. D.N. Upadhyaya -Member 7. Prof. Shally Awasthi -Member-Secretary, IEC
3.	Research Protocol no. 0063-17 entitled ***"A global, multicenter, three arms, open- label randomized study to evaluate the efficacy and safety of nanosomal docetaxel lipid suspension compared to taxotere® (Docetaxel Injection Concentrate) in triple-negative breast cancer patients with locally advanced or metastatic breast cancer after failure to prior chemotherapy"*** sponsored by M/s Lamda Therapeutic Research Pvt. Ltd. submitted by Dr. Sameer Gupta, Department of Surgical Oncology, K.G's Medical University, U.P., Lucknow vide letter no. SONC/027/2021 dated 15th November, 2021. **Death** **Subject ID no. 154-0063-17-09 (N-M)** **Subject Initial:** N-M **Gender:** F **Age:** 51 years **Patient follow up under study:** **Weight:** 153 KG **Height:** 43 CM **Subject History:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous ADR Sub Committee Decision: PI to send a copy of the letter which has not been delivered and returned with a remark that "recipient is dead". **Death Certificate received.** **ADR Sub Committee Decision:** Noted ***Ref. code: 95th ECM IIC/P4***
IB	**New SAEs**
I-	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 2012/Cardio/Res/22 dated 4th January, 2022. **Death** **Subject ID no. 010-0083** **Subject Initial:** J-R **Gender:** M **Age:** 45 years/01-01-1973 **Patient enrolled date:** 1st November, 2021 **Patient follow up under study:** 1st Month, 6th Month, 12th Month and every 6th Month till 5 year **Weight:** 42 KG **Height:** 159 CM **Subject History:** Many follow-up calls were made by the P.I. to the subject for scheduled follow up visit (36th Month 31-Sep-2021) but the calls were not answered. PI again tried to contact the subject on 27th December, 2021 and this time call was answered by Subject's LAR. LAR revealed that the subject passed away on 10th September, 2021 at around 11:00 AM. Subject had developed breathlessness and chest pain for which he was taken to a local practitioner who referred him to KGMU on the way to the hospital the subject expired and he was not hospitalized anywhere, the LAR does not have the exact records to ascertain the cause of death except the death certificate. No autopsy was done. Most likely the death is not related with the study drug. ***Recommendation of Primary reviewer:*** SAE (Death) is most likely due to disease outcome (RHD/ Sev. MS/ MVR/AF) and not due to intervention (Tab Rivaroxaban 20 mg OD) as patient was enrolled in Rivaroxaban

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	arm and successfully completed 30th month follow up visit (i.e. 2 years 10 months and 09 days after enrollment) Causal relationship cannot be established as subject passed away on the way to the hospital (KGMU) and no hospital records were found except death certificate and no autopsy were done. **ADR sub Committee Comment:** • Casual relationship cannot be established. **ADR sub Committee Decision:** • PI to submit a copy of death certificate which must have at least the district of residence, gender and age in years ***Ref. code: 83rd ECM IIC/P6***
II	ADR of research protocol no. EX9536-4388 SELECT: entitled ***"Semaglutide effects on cardiovascular outcomes in people with overweight or obesity"*** submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter nos. 1955/Cardio/Res/2021 dated 9th December, 2021, 1966/ Cardio/Res/2021 dated 15th December, 2021 & 2006/Cardio/Res/2021 dated 29th December, 2021. **<u>Death</u>** **Subject ID no. 2537-42** **Subject Initial:** D N D **Gender:** M **Age:** 63 years **Patient enrolled date:** 24th November, 2020 **Patient follow up under study:** Randomization visit 2, visit 3, visit 4, visit 5, visit 6, visit 7, visit 8, visit 9. **Weight:** 57.0 kg KG **Height:** 148.0 cm **Subject History:** Site staff made site follow-up calls to subject on 4th December, 2021 around 10:30 AM. Subject's family member informed PI that the subject passed away on 15th November, 2021 at 6:00 AM. Subject's family member informed that the subject woke up in morning of that day and did his normal routine activities however after about one hour of waking up he collapsed suddenly. They had not taken the subject to any hospital and he

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	died at home. Since there was no hospital visit or medical care given, there PI does not have any document related to his death and no autopsy was done. ***Recommendation of Primary reviewer:*** SAE (Death) is likely due to disease outcome [Acute MI (12/12/2019 F/W-Complete heart block –Temporary pacemaker implantation (TPI) – CART+STK- on 19-12-2019 + Heart failure (NYHA-II)] which lead to sudden cardiac death and is not due to intervention (Inj.Semaglutide 2.4 mg SC once a wk) as patient expired on 15th November ,2021. Causal relationship can not be established as subject passed away suddenly at home and there was no hospital visit or medical care given and therefore no hospital records are present and no autopsy was done.. **ADR sub Committee Comment:** • PI to submitted Follow up forms, only outdoor tickets of the visits are enclosed in documents • Casual relationship cannot be established. • **ADR sub Committee Decision:** PI to submit a copy of death certificate which must have at least the district of residence, gender and age in years ***Ref. code: 92nd ECM IIC/P1***
II	ADR of research protocol no. EX9536-4388 SELECT: entitled ***"Semaglutide effects on cardiovascular outcomes in people with overweight or obesity"*** submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter nos. 1955/Cardio/Res/2021 dated 9th December, 2021, 1966/ Cardio/Res/2021 dated 15th December, 2021 & 2006/Cardio/Res/2021 dated 29th December, 2021. **Death** **Subject ID no. 2537-42** **Subject Initial:** D N D **Gender:** M **Age:** 63 years **Patient enrolled date:** 24th November, 2020 **Patient follow up under study:** Randomization visit 2, visit 3, visit 4, visit 5, visit 6, visit 7, visit 8, visit 9. **Weight:** 57.0 kg KG **Height:** 148.0 cm **Subject History:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Site staff made site follow-up calls to subject on 4th December, 2021 around 10:30 AM. Subject's family member informed PI that the subject passed away on 15th November, 2021 at 6:00 AM. Subject's family member informed that the subject woke up in morning of that day and did his normal routine activities however after about one hour of waking up he collapsed suddenly. They had not taken the subject to any hospital and he died at home. Since there was no hospital visit or medical care given, there PI does not have any document related to his death and no autopsy was done.

Recommendation of Primary reviewer:
SAE (Death) is likely due to disease outcome [Acute MI (12/12/2019 F/W-Complete heart block –Temporary pacemaker implantation (TPI) – CART+STK- on 19-12-2019 + Heart failure (NYHA-II)] which lead to sudden cardiac death and is not due to intervention (Inj.Semaglutide 2.4 mg SC once a wk) as patient expired on 15th November ,2021. Causal relationship can not be established as subject passed away suddenly at home and there was no hospital visit or medical care given and therefore no hospital records are present and no autopsy was done..

ADR sub Committee Comment:

- PI to submitted Follow up forms, only outdoor tickets of the visits are enclosed in documents
- Casual relationship cannot be established.
- **ADR sub Committee Decision:** PI to submit a copy of death certificate which must have at least the district of residence, gender and age in years

Ref. code: 92nd ECM IIC/P1

Agenda of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting ***virtually*** will be held on 10th February, 2022 from 2:30 P.M. **(Non-DCGI)**

The following Members were present in the Meeting:

1. Prof. Alok Dhawan -Chairman
2. Mrs. Akansha Dubey -Member
3. Mrs. Vasundhara Kumari -Member
4. Mr. Ujjawal Krishna -Member
5. Prof. Rajendra Nath -Member

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	6. Dr. D.N. Upadhyaya -Member 7. Prof. Shally Awasthi -Member-Secretary, IEC
	Non-DCGI
I	Research Protocol entitled ***"A prospective, Randomized, open label, blinded endpoint (PROBE) study to evaluate DUAL antithrombotic therapy with dadigatran etexilate (110mg and 150 mgb.i.d.) plus clopidogel or ticagrelor vs. triple therapy strategy with warfarin (INR2.0-30) Plus Clopidogel or ticafrelor and asprin in patients with non valvular a trial fibrillation (NVAF) that have undergone a percutaneous coronary intervention (PCI) with stenting (RE-DUAL PCI)"*** submitted by Prof. Sharad Chandra, Department of Cardiology, K.G's Medical University, U.P. Lucknow vide letter no 1981/cardio/Res/21 dated 21st December, 2021. **Death** **Subject ID no. 110-40** **Subject Initial:** V-B **Gender:** M **Age:** 65 years- 13.10.2017 **Patient enrolled date:** 13th October, 2017 **Patient follow up under study:** Randomization visit, Month 1, Month 6, Month 12, Month 12, Month 24, every month 36. **Weight:** 63.0 KG **Height:** 158.0 cm **Subject History:** Site staff made a site follow-up call to subject on 14th December, 2021 around 03:15 PM. Subject's family member informed that the subject passed away on 19th November, 2020 at 08:00 PM. Subject's family member informed that the he was not feeling well from last 10 days. Subject had complaint of weakness, breathlessness for which he was taken to the hospital and expired there. He was not hospitalized hence no papers are available and autopsy was not done. ***Recommendation of Primary reviewer:*** SAE (Death) is most likely due to disease outcome (Old Acute Coronary Syndrome with Post Prandial Angina and Angina on Exertion –AOE-II CART) and not due to intervention (CART- dilation of a balloon over the retrograde wire and ante grade wiring & PTCA-S) which was without any complication and subject discharged in hemodynamically stable condition and completed 24 month follow-up successfully . On follow up call made on 14th December, 2021 ,subject's family member told that subject had complaint of weakness and breathlessness for which he was taken to hospital and

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	expired there on 19th November ,2020 (after more than 3 year of the intervention). Causal relationship cannot be established as subject passed away in hospital before hospitalization therefore no hospital records are available and no autopsy was done. **ADR Sub Committee Comment:** The documents is showing only up to 24th month visit. Then why call was made on 14th December, 2021 instead of December, 2020? Justification required by PI. Provide explanation for the same. **ADR Sub Committee Decision:** • Casual relationship cannot be established. ***Ref. code: 83rd ECM IIC/P5***
II a	ADR of research protocol no. ISCHEMIA: entitled ***"International study of comparative health effectiveness with Medical and Invasive approached"*** submitted by Prof. S.K. Dwivedi, Head, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1983/Cardio/Res/2021 dated 21st December, 2022, 2011/Cardio/Res/22 dated 1st January, 2022 respectively. **<u>Death</u>** **Subject ID no. 091019-149** **Subject Initial:** S-L **Gender:** M **Age:** 75 years- 10-01-1946 **Patient enrolled date:** 27th November, 2017 **Patient follow up under study:** Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic follow up till 5 year. **Weight:** 68.0 KG **Height:** 158.0 cm **Subject History:** Site person made a scheduled monthly follow-up call to subject 11th December, 2021 around 11:00, Subject's LAR informed us that subject passed away on 5th December, 2021 at 16:00 hrs, LAR told that on 4th December, 2021 subject developed hypoglycemia which was managed at home, then on 5th December, 2021 he developed uneasiness, sweating and foaming mouth for which he was taken to local hospital but could not reach

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

and died on the way to hospital. No documents are available and autopsy was not done.

Recommendation of Primary reviewer:

- The dates of randomization/enrolment mentioned in the documents are conflicting.
- The cover letter mentions that the patient was in 'Invasive arm' whereas the other documents record the patient to be in 'Conservative arm'.
- Length of follow up from registrations is mentioned as 5 years which should mean up to 2022, whereas it is mentioned that the remaining follow up was up till 2025.

ADR sub Committee Comment:

- As above

b **ADR sub Committee Decision:** Re-submit

Death

Subject ID no. 091019-139

Subject Initial: S-C-S

Gender: M

Age: 65 years- 03-12-1952
Patient enrolled date: 23rd October, 2017
Patient follow up under study: Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic follow up till 5 year.

Weight: 72.0 KG

Height: 162.0 cm
Subject History:

Site person made a scheduled monthly follow up call to subject 20th December, 2021 at 15:00 hrs, Subject's LAR informed that subject passed away on 25th August, 2021 at around 14:39 hrs, LAR said that subject was feeling down from last few days and on 25th August, 2021 morning he had complaint of chest pain and his BP was low. Subject was not taken anywhere and he died at home. They called local physician at home for the evaluation. No documents are available and autopsy was not done.

Recommendation of Primary reviewer:

- Monthly follow up call to the subject was made on 20th December, 2021 when it was discovered that the subject had passed away on 25th August, 2021. This means that no monthly follow up call were made in September/October/November of the year 2021. This required clarification/explanation.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Patient was enrolled in October 2017 with an intended follow up for 5 years which should be 2022. The follow up visits remaining mentioned in the report is till 2025 which may be corrected. **ADR sub Committee Comment:** • As above **ADR sub Committee Decision:** • Resubmit along with Death Certificate ***Ref. code: 60th ECM IIA/P13***
IA	**Action taken**
1-	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1869 /Cardio/Res/2021 dated 16th October, 2021. **Death** **Subject ID no. 010-0036** **Subject Initial:** J **Gender:** M **Age:** 26 years **Patient enrolled date:** 31st January, 2018 **Patient follow up under study:** 1st Month, 6th Month, 12th Month and every 6th Month till 5 year **Weight:** 55 KG **Height:** 173 CM ***Previous ADR Sub Committee Decision:*** PI to send a copy of the letter which has not been delivered and returned with a remark that "recipient is dead". **Death Certificate received.** **ADR Sub Committee Decision:** Noted ***Ref. code: 83rd ECM IIC/P6***
IB	**Expedited review**
1.	Expedited review of research proposal entitled ***"Mapping Neurosurgery practice in India: A survey-based cross-sectional study"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Ankur Bajai, Professor Junior Grade, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.1156/21

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	dated 26th November, 2021. ***Recommendation of Primary reviewer:*** **Decision:** Provisionally approved **EC Decision:** Approved ***Ref. Code 114th ECM IB/P1***
2.	Expedited review of research proposal entitled ***"Effect of guided probiotic colonization of dental implants on clinical outcomes, early healing dynamics and long-term success through immune-regulation: a randomized controlled trial"*** sponsored by Science and Engineering Research Board New Delhi submitted by Dr. Rameshwari Singhal, Additional Professor, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.2136/P/21 dated 10th December, 2021. ***Recommendation of Primary reviewer:*** **Decision:** Provisionally approved **EC Decision:** Approved ***Ref. Code 114th ECM IB/P2***
3.	Expedited review of research proposal entitled ***"Swallowing and speech rehabilitation of Head and Neck malignancy patients undergoing chemoradiotherapy (CRT)"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Manish Chandra, Assistant Professor, Department of Otorhinolaryngology & Head Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no.466/ENT/21 dated 2nd December, 2021 & 489/ENT/2021 dated 23rd December, 2021. **Recommendation of Primary reviewer:** **Decision:** Provisionally approved **EC Decision:** Approved ***Ref. Code 114th ECM IB/P3***
4.	Expedited review of research proposal entitled ***"Correlation between pure tone audiometry and brain stem evoked response audiometry in presbycusis patients"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Abhishek Bahadur Singh, Associate Professor, Department of ENT Head Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 425/ENT/21 dated 2nd December, 2021.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: **Decision:** Provisionally approved **EC Decision:** Approved ***Ref. Code 114th ECM IB/P4***
5.	Expedited review of research protocol no. 02-COV entitled "***An open-label, multicentre, randomized, adaptive platform trial of the safety and efficacy of several therapies, including antiviral therapies, versus control in mild cases of COVID-19***" sponsored by (DNDi) & ICMR India submitted by Prof. Avinash Agrawal, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/2022/0041 dated 13th January, 2021. ***Recommendation of Primary reviewer:*** **Decision:** Provisionally approved **EC Decision:** Approved ***Ref. code: 114thECMIB/P5***
6.	Expedited review of research proposal entitled "***To evaluate the bone mineral status in children with type 1 diabetes mellitus-a hospital based case-control study***" submitted by Dr. Arpita, Associate Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 350/Ped/22 dated 9th February, 2022. ***Recommendation of Primary reviewer:*** • Age of the children to be included in the study is mentioned as 5-20 years. Please explain why adolescents too are being included as subjects when the study is on children? ***The above comment communicates to the PI, reply given by PI.*** **EC Decision:** Approved ***Ref. code: 114thECMIB-IMR-F/P6***
II-A	**New Proposal**
1.	Research proposal entitled "***Assessing age of adults by measuring the pulp volume of biradicular teeth of lower arch with the help of cone beam computed tomography images. A pilot study***" submitted by Dr. Juhi Yadav under the guidance Prof. Shalini Gupta, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.nil dated nil. ***Recommendation of Primary reviewer:*** • This is a pilot study, so sample size calculation is not required. • But some sketch of possible statistical analysis should be given. • In Hindi translation of Consent form, some corrections are required, as it seems

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	literal translation from Google Form. **EC Comment:** • Who is paying for cone been CT? • Is CT being done for treatment of patient or just of the study? **EC Decision:** Resubmit. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM IIA/P1***
2.	Research proposal entitled ***"Evaluation of external validation of kocher's criteria to differentiate septic arthritis and transient synovitis in Children"*** sponsored by CST-UP submitted by Dr. Narendra Singh Kushwaha, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no.1442/OS/21 dated 3rd December, 2021. ***Recommendation of Primary reviewer:*** • Aim & objective is not clear. What do they mean by sensitivity and specificity of model and study variables? • Research hypothesis should be formulated properly in terms of population parameter (not variables). • Sample size calculation is not given. • Statistical analysis section is very general. It should be specific to the research hypothesis, which is absent here. **EC Comment:** As above **EC Decision:** Revise and re-submit with point wise table of modifications done along with the revised proposal. ***Ref. code: 114th ECM IIA/P2***
3.	Research proposal entitled ***"Management of ROCM: A clinico-radiological study- An institutional experience"*** submitted by Dr. Rajat Jain, Assistant Professor, Department of Otorhinolaryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no.432/ENT/RJ/21 dated 3rd December, 2021. ***Recommendation of Primary reviewer:*** • 1] The title has short form which is not explained. I do not know what is ROCM. • On the page 11 of 13, the fullform is mentioned..Rhino Oculo Cerbral Mucormycosis. • 2] 5-vi – No answer about vulnerable subjects. • 3] It is mentioned on point 8, that the written consent will be taken and patient information brochure is attached. But there is neither of them. • It is retrospective analysis of data. Please confirm if consent will be taken or not. If the answer is 'yes' provide appropriate document. • It is mentioned that the patient will be directly benefited. How? **EC Comment:** As above **EC Decision:** Resubmit. Give a tabular form of revisions done along with revised proposal.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 114th ECM IIA/P3
4.	Research proposal entitled "***A study to determine the outcome of patients with dysnatremia undergoing slow low efficiency dialysis (SLED) in ICU***" submitted by Dr. Sai Saran, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. CCM//2021/411 dated 4th December, 2021. ***Recommendation of Primary reviewer:*** • No significant ethical issues • No patient info brochure in Hindi • As it is a non funded project, it should be clearly mentioned that the testing done is a part of patient management. • The answer in the submission for 'Vulnerable subjects' is 'no'. But there will be elderly or seriously ill patients. So it should be 'Yes'. **EC Comment:** • Please give point wise response. **EC Decision:** Approval subject to modification. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM IIA/P4***
5.	Research proposal entitled "***Survey regarding the knowledge, attitude and practice of faculty at tertiary care medical institutions in India regarding equipment purchase and maintenance***" submitted by Dr. Sai Saran, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. CCM//2021/0410 dated 4th December, 2021. **EC Decision:** This is not in the preview of the Ethics Committee. ***Ref. code: 114th ECM IIA/P5***
6.	Research proposal entitled "***Antifungal sensitivity based management of COVID-19 associated Rhino-Orbital-cerebral mucormycosis (C-ROCM)- an outcome-based pilot analysis***" submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.3362/MED/21 dated 6th December, 2021. ***Recommendation of Primary reviewer:*** • Details of medical/surgical management protocol missing. • Details of follow-up missing. • Clinical end point of treatment/follow-up missing. **EC Comment:** • ICF does not details of consent person. **EC Decision:** Approval subject to modification. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM IIA/P6***
7.	Research proposal entitled "***International severe Asthma registry (ISAR)***" submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	University, U.P., Lucknow vide letter no.2291/21 dated 1st November, 2021. ***Recommendation of Primary reviewer:*** • It is a multi country, multicentre observational study with a sample size of just 20-25 subjects. Sample size calculation shall be mentioned. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM IIA/P7*** ***(Primary Reviewer: Dr. A.A. Mahdi)***
8.	Research proposal entitled ***"Global neurotrauma outcomes study: spine-an international, multi-centre, prospective, observational study on traumatic spine injury"*** sponsored by NIHR submitted by Dr. Ankur Bajaj, Associate Professor, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/1155/21 dated 26th November, 2021. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 114th ECM IIA/P8***
9.	Research proposal entitled ***"Correlates of the suicide crisis syndrome in major depression: A multicentric exploratory study"*** submitted by Dr. Sujita Kumar Kar, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1818/Psy/21 dated 11th December, 2021. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 114th ECM IIA/P9***
10.	Research proposal entitled ***"A study to assess the knowledge retained from various medical teaching methods and perception of medical students towards these methods"*** submitted by Dr. Sarvesh Singh, Professor Junior Grade, Department of Pharmacology, King George's Medical University, U.P., Lucknow vide letter no. 1215/Pharma/21 dated 21st December, 2021. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 114th ECM IIA/P10***
11.	Research proposal entitled ***"A survey-based study of the reasons behind regularity and irregularity in attendance of college-going Indian medical students: A post COVID-19 pandemic led lockdown scenario"*** submitted by Dr. Sarvesh Singh, Professor Junior Grade, Department of Pharmacology, King George's Medical University, U.P., Lucknow vide letter no. 1214/Pharma/21 dated 21st December, 2021. **EC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• A survey based study. • Modify the topic to irregularity in attendance of MBBS students of KGMU. A COVID pandemic lockdown. **EC Decision:** Approval subject to modification. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM IIA/P11***
12.	Research proposal entitled ***"3D printing technology: A novel approach of developing patient specific devices in radiotherapy treatment of various tumors"*** submitted by Dr. Shraddha Srivastava, Associate Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 829/RT/21 dated 16th October, 2021. ***Recommendation of Primary reviewer:*** **EC Comment:** • 3D painting is not a novel approach. Will the material allow? • Radiations to pass through? • Elaborate more on methodology cost of the devise should be passed to the patient. **EC Decision:** Resubmit. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM IIA/P12***
13.	Research proposal entitled ***"Evaluating clinically relevant molecular biomarkers to improve early detection and treatment of oral squamous cell carcinoma"*** submitted by Prof. Ranjit Kumar Patil, Department of Oral Medicine and Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. nil dated 20th December, 2021. ***Recommendation of Primary reviewer:*** • Patient Information sheet is not filled as per research context. • IFC: Patient has not been explained about the procedure properly. • Kindly explain the methodology appropriately in relation to transportation of tissue blocks. • As one of the co-investigator is currently employed at AIIMS New Delhi, Kindly justify her role in slide preparation. • Kindly also assure that PI has enough experience to perform biopsy. • Kindly justify, ZERO funding for research. **EC Comment:** • IHC is a common technique. • Bio markers are not specified. • The work must be done in India. • Sample size inadequate. **EC Decision:** Justify the need for conducting the study. Give a tabular form of revisions done along with revised proposal.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 114th ECM IIA/P13
14.	Research proposal entitled "***Factors and perceptions of medical undergraduate students influencing their choice of specialty and quality of life***" submitted by Dr. Rahul Kumar, Professor Junior Grade, Department of Pharmacology, King George's Medical University, U.P., Lucknow vide letter no.1222/Pharma/21 dated 24th December, 2021. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 114th ECM IIA/P14***
15.	Research proposal entitled "***Capacity building and strengthening of hospital infection control to detect and prevent antimicrobial resistance in India***" submitted by Prof. Vimala Venkatesh, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1710/21 dated 28th December, 2021. ***Recommendation of Primary reviewer:*** • This is the second cycle of the project funded by CDC USA to AIIMS New Delhi wherein KGMU is a collaborating center. No EC approval of the first cycle is enclosed herewith. It has to be ensured that the first cycle had been approved. • The budget for KGMU needs to be indicated in INR and its split needs to be submitted • The PI has requested for consent waiver and since this is an epidemiologic sort of data collection, this request can be ethically considered. • However it would be appropriate if the PI can submit the short summary of work that will be undertaken at KGMU in the form of flow chart. • Being a project of national importance this can be otherwise approved ethically. **EC Comment:** • Submit a copy of EC of AIIMS for this cycle **EC Decision:** Approval subject to modification. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM IIA/P15***
16.	Research proposal entitled "***Comparison of percutaneous vs open hamstring lengthening in patients of spastic diplegic cerebral palsy***" submitted by Dr. Syed Faisal Afaque, Assistant Professor, Department of Paediatric Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no.1500/Paedortho/22 dated 7th January, 2022. ***Recommendation of Primary reviewer:*** • In executive summary the formula for sample size calculation is indicated but not the sample size. • In budget section Rs 10,000/- is indicated under 'Research Associate'- Is that just for one time or for every month considering the duration of project to be 1.5 years. In later case the yearly head would be 120000. Also check the salary for a

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	research associate. It must be at par with ICMR norms • Many points in annexure 1 need to be filled up. For example to mention any benefits arising from this study • The type of study seems to be more of outcome of surgical comparison than epidemiological as indicated. Hence clinical category would be more appropriate. • Type of patients should be patients instead of volunteers as indicated • The patient information sheet is not attached • The above rectifications need to be submitted for re-consideration for ethical approval. **EC Comment:** As above **EC Decision:** Revise and re-submit. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM IIA/P16***
17.	Research proposal entitled "***Validation of online hearing assessment app (H3 Hearing Test)***" sponsored by Arth.ai/4500 Great America Parkway, Santa Clara, CA,USA submitted by Prof. Anupam Mishra, Department of ENT, Head Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no.580/ENT/22 dated 4th January, 2022. ***Recommendation of Primary reviewer:*** • Is this a new proposal or revised proposal? • Sample size: for correlation coefficient is different. Statistics expert can comment. • Inclusion Criteria: Patients of what disease will be included? • Is the study relevant still? • What is the scalability of this app based assessment: Different earphones, earwax and ambient noise. How do the investigators plan to account for these variables, which, in my opinion, can lead to erroneous results? • The app was extended free for 2 months: from 21 July, 2021. Time limit has expired. **EC Comment:** As above **EC Decision:** Revised & Re-submit. Give a tabular form of revisions done along with revised proposal. ***Dr. Anupam Mishra did not participate in the discussion and making decision.*** ***Ref. code: 114th ECM IIA/P17***
18.	Research proposal entitled "***Evaluation of clinic-pathological characteristics, prognostic factors and treatment outcomes in patients with Ewing sarcoma in children and young adults***" submitted by Dr. Nishant Verma, Additional Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no.47/Ped/22 dated 8th January, 2022. ***Recommendation of Primary reviewer:*** • Can SR is co-PI? Make them student Investigator. • Vulnerable subjects: not checked

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• How and why will data be Completely anonymized/delinked • Why collaborating institute has no Co-PI? • Waiver form: Activity IS research! Consent this. • Exclusion criteria: First point needs clarity. What is the definition of definitive treatment? • Method: Why exclude patients who didn't complete 2 cycles? • EFS: What is disease abandonment? Explain • Categorical data in two groups: which 2 groups? • Continuous data in two groups: which 2 groups? • What are the 2 groups for Log-Rank test? • If data be Completely anonymized/delinked, why does data collection sheet have Hospital ID? **EC Comment:** • Give definitions and treatment protocol also. **EC Decision:** Revised & Re-submit. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM IIA/P18***
19.	Research proposal entitled "***Identification and characterization of novel molecular biomarkers with prospects of targeted drug therapy development in pediatric B-Cell acute lymphoblastic leukemia (ALL) with diverse genetic subgroups***" submitted by Dr. Nishant Verma, Additional Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no.46/Ped/2022 dated 8th January, 2022. ***Recommendation of Primary reviewer:*** • Summary mentions: no funding, however, patient information sheet mentions: funding will be applied from Govt. Org or NGO • Study setting: Other participating institutions… which are these? • Study design: multi-centric: which all? • Sample size: last sentence: to achieve statistical significance…. What and how, which test? • Outcome measures: Do you think that this sample size is good enough to identify subgroups within this mixed bag and also find actionable solutions, despite the fact that WHO has been unable to do so, with possibly much larger sample size, genetic data, etc? • Statistical analysis: • Transcritomic and genomic data analysis needs specialized tests. • Categorical data in two groups: which 2 groups? • Continuous data in two groups: which 2 groups? • Means between more than 2 groups: specify groups • Ethical considerations: delinked?? Really?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Flowchart: what s yellow painted testing? • Dr. Anurag Gupta: He appears to be a student. Can he be co-investigator? He can be student Investigator? • Who will fund the study? • Sponsor information: needed • Biobanking will be done: who holds the rights? Any agreements? Any mention in consent? **EC Decision:** Revised & Re-submit. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM IIA/P19***
IIB	**New Ph.D Scholar**
1.	Research proposal entitled ***"A study on transcriptional regulation of tumors of oral cavity through gene expression analysis of homeobox gene family members"*** sponsored by ICMR submitted by Mrs. Jaya Singhal, Ph.D Scholar 2019 under the guidance Prof. Divya Mehrotra, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. OMSD/RP/243/01/21 dated 16th December, 2021. ***Recommendation of Primary reviewer:*** • Approved **EC Comment:** • Include a faculty with expertise in molecular technology as Co-guide. **EC Decision:** Approved ***Ref. code: 114th ECM II B-Ph.D/P1***
2.	Research proposal entitled ***"Decoding central nervous system microenvironment following JEV infection: a Neuroinflammation perspective"*** sponsored by DBT New Delhi submitted by Ms. Anjali Singh, Ph.D Scholar 2019 under the guidance Dr. Himanshu Dandu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 3460/MED/21 dated 22nd December, 2021. ***Recommendation of Primary reviewer:*** • The proposal is incomplete. • There is no research hypothesis, no sample size calculation, no methodology section, no statistical analysis section etc. **EC Decision:** Revised & Re-submit. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM II B-Ph.D/P2***
II-B	**IMR-Faculty**
1.	Research proposal entitled ***"Correlation of serum angiopoietin-1&2 & endothelin-1 with severity of pulmonary hypertension (PH) in patients of chronic obstructive***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	pulmonary disease (COPD)" sponsored by Research Cell KGMU Lucknow submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 02/Res/22 dated 3rd January, 2022. ***Recommendation of Primary reviewer:*** • This is a correlation study. The sample size formula is inaccurate as it is for prevalence study. • The study variables (variables for finding correlations) are not properly identified. • Sample size can be calculated after identifying variables only. • Statistical analysis section is vague. It is not specific to the study under investigation. **EC Decision:** Revised & Re-submit. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM II B-IMR-F/P1***
IIB	**Fellowship**
1.	Research proposal entitled ***"Evaluation of salivary melatonin as diagnostic and prognostic marker for oral squamous cell carcinoma"*** sponsored by ICMR submitted by Ms. Divya Tandon under the guidance Dr. Vikram Khanna, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.699/OM&R/21 dated 14th December, 2021. ***Recommendation of Primary reviewer:*** • The Ethics submission form mentions 'No' to vulnerable subjects. • Need to confirm that old or terminally ill patients willnot be included. The patient information brochure should mention that 8 hours fasting will be required for sample collection. • Is there any need for information brochure and consent form for controls? There is none. **EC Decision:** Revised & Re-submit. Give a tabular form of revisions done along with revised proposal. ***Ref. code: 114th ECM II B-FS/P1***
IIC	**Review of New Drug Trial**
1.	Research protocol no.Vedolizumab-4020 entitled ***"A multicentre, single-arm, open-label, phase 4 study to evaluate the safety and efficacy of vedolizumab in Indian patients with ulcerative colitis and crohn's disease"*** sponsored by M/s Takeda Pharmaceutical India Pvt. Ltd. submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow, vide letter no.3230/MED/2021 dated 10th November, 2021. ***Recommendation of Primary reviewer:*** • Scientific review Committee approval from department is not submitted. • IEC form with study details not submitted. • DCGI approval and CTRI registration papers do not have mentioned of KGMU

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	site. • Insurance policy does not mention KGMU site. **Legal opinion** • In clause 20 of CTA the exclusive jurisdiction may be of Lucknow • In clause 26 the seat of Arbitration may be Lucknow. Moreover, it is highlighted that the MCIA rules are being referred for arbitration in this case. **EC Comment:** As above **EC Decision:** Revised & Re-submit. Give a tabular form of revisions done along with revised protocol. ***Ref. code: 114th ECMIIC/P1***
2.	Research protocol no. EA-CT-18-015 entitled "***A prospective, randomized, open label, multi-Centre, parallel arm, comparative study with blinded assessment to test the non-inferiority of liraglutide biosimilar with victoza® in patients with type 2 diabetes mellitus***" sponsored by M/s Ecron Acunova (Navitaz-CRO) submitted by Dr. Harish Gupta, Associate Professor, Department of Medicine, King George's Medical University, U.P., Lucknow, vide letter no.3229/MED/2021 dated 16th November, 2021. ***Recommendation of Primary reviewer:*** • Departmental Scientific Research Committee recommendation not attached. • IEC proforma not filled/attached • DCGI letter does mention KGMU in the list of approved sited. • Insurance certificate does not mention list of approve sites. • Informed consent does not have details of PI. • Patient information sheet not present. **Legal opinion** • There is no specific provision relating to force majeure in this agreement. This may be included to cover unforeseen situations in the future. • In Clause 14 of the Agreement the seat of Arbitration is Bangalore. This may be changed to Lucknow for convenience. **EC Comment:** As above **EC Decision:** Revised & Re-submit. Give a tabular form of revisions done along with revised protocol. ***Ref. code: 114th ECMIIC/P2***
3.	Research protocol no. CLNA043A12202 entitled "***A 5-year, randomized, doule-blind, placebo-controlled, multi-center study assessing the efficacy, safety, and tolerability of intra-articular regimens of LNA043 versus placebo in patients with symptomatic knee osteoarthritis (ONWARDS)***" sponsored by M/s Novartis Healthcare Pvt. Ltd submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow, vide letter no.1410/OS/2021 dated 24th November, 2021. ***Recommendation of Primary reviewer:*** • No specific ethical issues. • No information about genetic testing has been provided in the consent [optional

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	genetic testing] and none in the protocol. Specify which…….. • Informed consent brochure / form in the submission part A and attached to the application by KGMU PI appear to be different. **Legal opinion** • There is no provision relating to Force Majeure in this agreement. This may be added to cover any unforeseen situation in the future. • There is no Dispute Resolution clause in the agreement. This may be added to ensure that arbitration is the primary mode of dispute resolution. • In Clause 26 of the Agreement the exclusive jurisdiction of Mumbai is referred to while this may be changed to Lucknow. **EC Comment:** As above **EC Decision:** Revised & Re-submit. Give a tabular form of revisions done along with revised protocol. ***Ref. code: 114th ECMIIC/P3***
4.	Research protocol no.CKJX839B12302 entitled ***"A randomized, double-blind, placebo-controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT)"*** sponsored by M/s Novartis Healthcare Pvt. Ltd submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no.1963/Cardio/Res/21 dated 15th December, 2021. ***Recommendation of Primary reviewer:*** • The drug had been tried in multiple trials since 2017 in more than 3500 patients. The mortality rates in drug and placebo are controlled. No major SUSAR. • Did the drug showed efficacy? • The drug has been approved in EU in 2020 and in USA in December 2021. • Does it mean it is a postmarketing survey? What is the need of this study? • The study protocol mentions 2020. Is it a new proposal or resubmission? • Healthy volunteers - ?DCGI –YES • The insurance certificate is available but has expired on dec 2021.INR – 73638000 per tested person. • Information brochure and consent form are ok • 15000 participants – how much from this centre -30 to 40 • Sample sent abroad for uniformity • CTRI –Pending • 27 centers in India- IEC – submitted, all under review. • Someone with experience in evaluating drug trials should look at it. • There is consent for DNA testing. But the protocol does not mention which genetic testing will be done? Will some specific pharmacogenetic variants will be studied or whole exam or whole genome sequencing will be done? Each has different implications. Protocol and consent should be clear for this issue. Page 72 of the protocol mentions – 12.5.3- provides very limited information.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Legal opinion • There is no specific provision relating to Insurance in this agreement. This may be included to ensure that insurance liabilities are recognized. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give a tabular form of revisions done along with revised protocol. ***Ref. code: 114th ECMIIC/P5***
6.	Research protocol no. MLTSP/04/2019 Version/Date: 2.0 Dated 21 September, 2020 entitled "***An open label, multicentric, phase III, prospective study to evaluate the efficacy, safety and tolerability of triple fixed dose combination of Timolol 0.5% + Brimonidine 0.2% + Brinzolamide 1% eye drops in patients with open angle glaucoma/ocular hypertension not responding to dual drug therapy***" sponsored by M/s Micro Labs Limited submitted by Prof. S.K. Bhasker, Department of Ophthalmology, King George's Medical University, U.P., Lucknow, vide letter no.336/OPH/21 dated 24th December, 2021. ***Recommendation of Primary reviewer:*** • Insurance policy should be revised as it is ending on 03-02-2022. **Legal opinion** • 1-There is no provision relating to Force Majeure in this agreement. This may be added to cover any unforeseen situation in the future. • There is no Dispute Resolution clause in the agreement. This may be added to ensure that arbitration is the primary mode of dispute resolution. • In Clause 26 of the Agreement the exclusive jurisdiction of Mumbai is referred to while this may be changed to Lucknow. **EC Comment:** As above **EC Decision:** Approval subject to modification(Give a tabular form of revisions done along with revised protocol ***Ref. code: 114th ECMIIC/P6***
7.	Research protocol no. MLBTL/05/2021 Version/Date: Version 2.0 Dated 05 Aug, 2021 entitled "***A randomized, double blind, parallel group, multicentric, phase-III clinical study to compare the efficacy, safety and tolerability of FDC of telmisartan 40mg + Review and approval tablets in the treatment of stage 1 and stage 2 Hypertension***" sponsored by M/s Micro Labs. Limited submitted by Dr. S.K. Sonkar, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 186/MED/21 dated 22nd December, 2021. ***The following documents were reviewed in the Meeting:***

Sl. No.	Documents	Version and Date
1.	Covering Letter	NA
2.	Annexure :1-RV-1/2029	SOP-IEC –KGMU
3.	Scientific Review Committee Approval letter	21-12-2021
4.	Team Member Responsibility	NA
5.	Clinical Trial Protocol	Version 2.0 Dated 05 Aug 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

6.	Investigator's Brochure	Version 2.0 Dated 05 Aug 2021
7.	Informed Consent Document (ICD)- English	Version 2.0 Dated 05 Aug 2021
8.	Informed Consent Document (ICD)(Site Specific)-English	Version 2.0 Dated 05 Aug 2021
9.	Translated Informed Consent Document in English to Hindi along with Translation certificate	Version 2.0 Dated 05 Aug 2021
10.	Translated Informed Consent Document (Site Specific) in English to Hindi(Translated on- 03 Jan 2022) along with Translation certificate	Version 2.0 Dated 05 Aug 2021
11.	Back Translated Informed Consent Document in Hindi to English Along with Back Translation certificate	ICF Version 2.0 Dated 05Aug 2021
12.	Case Report Form	Version 2.0 Dated 05 Aug 2021
13.	DCGI Approval Letter	Dated 21 Sept 2021
14.	Draft Clinical Trial Agreement	NA
15.	Clinical Trials Insurance Policy Period from 23-11-2021 to 22-11-2022	NA
16.	Investigator's undertaking	
17.	CV, MRC and GCP of Principal Investigator	

Recommendation of Primary reviewer:

- Approved

Legal opinion:

- There are no legal observations and hence this CTA may be processed.

EC Decision: Approval subject to fulfillment and administrative formalities

Ref. code: 114th ECMIIC/P7

III **Modification**

1. Modification of research protocol no.GS-US-417-0304 entitled "***A multicenter, open-label, long-term extension study to assess the safety and efficacy of filgotinib in subjects with rheumatoid arthritis***" submitted by Dr. Puneet Kumar, Department of Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/55/21 dated 30th November, 2021.

The following documents were reviewed:

Sr. No.	Study Documents	Version No.	Date
1	Study Protocol	Amendment- 6	11-Jun-2021
2	Summary of Changes for study protocol amendment 6	NA	NA
3	Certificate of Insurance	NA	24-Jun-2021
4	Subject Emergency Card Translation and Back Translation	Version - 3.0	Eng: 01-Jun-2021 Eng to Hin: 27-Aug-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			2021 Hin to Eng: 28-Aug-2021
5	Subject Emergency Card Translation and Back Translation certificates	Version - 3.0	Eng to Hin: 27-Aug-2021 Hin to Eng: 28-Aug-2021
6	Main ICF- Subject Information and Informed Consent Form India (Dr. Puneet Kumar) Translation and Back Translation	Version- 10.1.1	Eng to Hin: 24-Aug2021 Hin to Eng: 25-Aug-2021
7	Main ICF- Subject Information and Informed Consent Form India (Dr. Puneet Kumar) Translation and Back Translation Certificates	Version- 10.1.1	Eng to Hin: 24-Aug2021 Hin to Eng: 25-Aug-2021
8	Summary of Changes of Informed Consent Form From Version 9.1.0 To Version 10.1.0	NA	NA
9	Partner pregnancy follow up consent formIndia (Dr. Puneet Kumar) Translation and Back Translation	Version- 3.1.1	Eng: 16-Aug-2021 Eng to Hin: 24-Aug2021 Hin to Eng: 25-Aug-2021
10	Partner pregnancy follow up consent formIndia (Dr. Puneet Kumar) Translation and Back Translation Certificates	Version- 3.1.1	Eng to Hin: 24-Aug2021 Hin to Eng: 25-Aug-2021
11	Participants pregnancy follow up consent formIndia (Dr. Puneet Kumar) Translation and Back Translation	Version- 3.1.1	Eng: 16-Aug-2021 Eng to Hin: 24-Aug2021 Hin to Eng: 25-Aug-2021
12	Participants pregnancy follow up	Version- 3.1.1	Eng to Hin: 24-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		consent formIndia (Dr. Puneet Kumar) Translation and Back Translation Certificates		Aug2021 Hin to Eng: 25-Aug-2021
	13	Assignment of CTA with Galapagos	NA	16 Sep 2021
	14	DCGI Approval Letter PA-6 Snapshot	NA	15 Nov 2021
	15	Main ICF- Subject Information and Informed Consent Form India (Dr. Puneet Kumar)	Version- 11.1.1	Eng: 03-Nov-2021
	16	Main ICF- Subject Information and Informed Consent Form India (Dr. Puneet Kumar) Translation and Back Translation	Version- 11.1.1	Eng to Hin: 22-Nov-2021 Hin to Eng: 23-Nov-2021
	17	Main ICF- Subject Information and Informed Consent Form India (Dr. Puneet Kumar) Translation and Back Translation Certificates	Version- 11.1.1	Eng to Hin: 22-Nov-2021 Hin to Eng: 23-Nov-2021
	18	Summary of Changes of Informed Consent Form From Version 10.1.0 To Version 11.1.0	NA	NA

Recommendation of Primary reviewer:

- Approved and noted

EC Decision: Approved and noted

Ref.code:86th ECMIIE/P1

2. Modification of research protocol no. LTE15174 entitled ***"An open label long term safety and efficacy study of fitusiran in patients with Hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX"*** sponsored by M/s Bajaj Allianz Generali Insurance Co Ltd. Ltd. submitted by Dr. S.P. Verma, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. CH/03/21 dated 30th December, 2021.

The following documents were reviewed:

1-	Protocol No: LTE15174 (Clean copy)	Protocol LTE15174, Amendment Version 4.0 Dated 30 Sep 2021(Controlled Copy

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		No: PPD/GSK LTE15174/Protocol version 4.0 Dated 30 Sep 2021/001 – 004)
2-	Protocol No: LTE15174 (Track change copy)	Protocol LTE15174, Amendment Version 4.0 Dated 30 Sep 2021
3-	Protocol No: LTE15174 (Summary of changes)	Protocol LTE15174, Amendment Version 4.0 Dated 30 Sep 2021
4-	Protocol No: LTE15174 (Supportive rationale)	Supportive scientific rationale for the proposed protocol amendment_Sep2021
5-	DCGI Acknowledgment for Submission Screenshot_ Protocol LTE15174, Amendment Version 4.0 Dated 30 Sep 2021	Cover Letter dated 28 Oct 2021 & Email acknowledgement dated 28 Oct 2021
6-	Investigators Brochure	Investigator's brochure Edition 09 dated 29 Sep 2021 (Controlled Copy No: PPD/LTE15174/ Investigator's Brochure/Edition 09/Dated 29 Sep 2021/ 001-004) Clean Copy
7-	Investigators Brochure (Track change copy)	Investigator's brochure Edition 09 dated 29 Sep 2021
8-	Investigators Brochure (Summary of changes)	Investigator's brochure Edition 09 dated 29 Sep 2021
9-	DCGI Acknowledgment for Submission_ IB Ed 09 dtd 29 Sep 2021and ICF v 4.1_dtd 18 Oct 2021	Cover Letter Dated 17 Nov 2021 E-Mail Acknowledgement dated 18 Nov 2021
10-	English Patient Dosing Diary_PFP	Version 1.0, Dated 04 May 2021
11-	Hindi_Patient Dosing Diary_PFP along with COT	Version 1.0, Dated 04 May 2021
12-	Hindi_BT_Patient Dosing Diary_PFP along with COT	Version 1.0, Dated 04 May 2021
13-	English Patient Dosing Diary_Vial&Syringe	Version 3.0, Dated 15 Sep 2021
14-	Hindi_Patient Dosing Diary_Vial&Syringe along with COT	Version 3.0, Dated 15 Sep 2021
15-	Hindi_BT_Patient Dosing Diary_Vial&Syringe along with COT	Version 3.0, Dated 15 Sep 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

16-	English_Patient_Material_Vial IFU	Version 3.0, Dated 06 Oct 2021
17-	Hindi_Patient_Material _Vial IFU along with COT	Version 3.0, Dated 06 Oct 2021
18-	Hindi BT_Patient_Material_Vial IFU along with COT	Version 3.0, Dated 06 Oct 2021
19-	English_Patient_Material_50mg_PFP IFU	Version 2.0, Dated 29 Sep 2021
20-	Hindi_Patient_Material_50mg_PFP IFU along with COT	Version 2.0, Dated 29 Sep 2021
21-	Hindi BT_Patient_Material_50mg_PFP IFU along with COT	Version 2.0, Dated 29 Sep 2021
22-	English Participant/ Parental ICF (Clean copy):	India English Main ICF v4.1_24Nov2021_Site #: 3560005_Dr Shailendra Prasad Verma
23-	Hindi Participant/ Parental ICF along with COT	India Hindi Main ICF v4.1_24Nov2021_ Site #: 3560005_Dr Shailendra Prasad Verma
24-	Hindi to English Participant/ Parental ICF along with COT	India English Back Translated from Hindi Main ICF v4.1_24Nov2021_ Site #: 3560005_Dr Shailendra Prasad Verma
25-	English Assent ICF (Clean Copy)	ATLAS-OLE (LTE15174) ASSENT STATEMENT FOR CHILDREN 12 - 17 YEARS OF AGE India_V 4.1dated 24 Nov 2021_Site #: 3560005_Dr Shailendra Prasad Verma
26-	Hindi Assent ICF along with COT	ATLAS-OLE (LTE15174) ASSENT STATEMENT FOR CHILDREN 12 - 17 YEARS OF AGE India Hindi_V 4.1 dated 24 Nov 2021_ Site #: 3560005_Dr Shailendra Prasad Verma
27-	Hindi to English Assent ICF along with COT	ATLAS-OLE (LTE15174)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		ASSENT STATEMENT FOR CHILDREN 12 - 17 YEARS OF AGE India English Back Translated from Hindi_V 4.1dated 24 Nov 2021_ Site #: 3560005_Dr Shailendra Prasad Verma
Sr. No.	**Document/Language**	**Document Details/Versions**
1-	DCGI Acknowledgment for Submission_ IB Ed 08 dtd 25 Feb 2021and ICF v 3.1_dtd 29 Apr 2021	Cover Letter Dated 12 May 2021 E-Mail Acknowledgement dated 12 May 2021
2-	DCGI Approval screenshot for IB Ed 08 dtd 25 Feb 2021and ICF v 3.1_dtd 29 Apr 2021	Cover Letter Dated 12 May 2021 E-Mail Acknowledgement dated 12 May 2021
3-	DCGI Notification Acknowledgment for External communication on ERT Cyberattack dated 16 Apr 2021	Cover Letter Dated 1st Jun 2021
4-	Investigators Brochure	Investigator's brochure Edition 08 dated 25 Feb 2021 (Controlled Copy No: PPD/LTE15174/ Investigator's Brochure/Edition 08/Dated 25 Feb 2021/ 034-038) Clean Copy
5-	Investigators Brochure	Investigator's brochure Edition 08 dated 25 Feb 2021 (Controlled Copy No: PPD/LTE15174/ Investigator's Brochure/Edition 08/Dated 25 Feb 2021/ 034-038) Track change version
6-	Investigators Brochure	Investigator's brochure Edition 08 dated 25 Feb 2021 (Controlled Copy No: PPD/LTE15174/ Investigator's Brochure/Edition 08/Dated 25 Feb 2021/ 034-038) Summary

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Of Changes
7-	English Participant/ Parental ICF:	India English Main ICF v3.1_22Jun2021_ Site #: 3560005_Dr Shailendra Verma
8-	Hindi Participant/ Parental ICF	India Hindi Main ICF v3.1_22Jun2021_ Site #: 3560005_Dr Shailendra Verma 8.1_Translation Certificate dated 16 Aug 2021
9-	Hindi to English Participant/ Parental ICF	India English Back Translated from Hindi Main ICF v3.1_22Jun2021_ Site #: 3560005_Dr Shailendra Verma 9.1_ Translation Certificate dated 16 Aug 2021
10-	English Assent ICF	ATLAS-OLE (LTE15174) ASSENT STATEMENT FOR CHILDREN 12 - 17 YEARS OF AGE India_V 3.1dated 22 Jun 2021_Site #: 3560005_Dr Shailendra Verma
11-	Hindi Assent ICF	ATLAS-OLE (LTE15174) ASSENT STATEMENT FOR CHILDREN 12 - 17 YEARS OF AGE India Hindi_V 3.1dated 22 Jun 2021_ Site #: 3560005_Dr Shailendra Verma 11.1_ Translation Certificate dated 16 Aug 2021
12-	Hindi to English Assent ICF	ATLAS-OLE (LTE15174) ASSENT STATEMENT FOR CHILDREN 12 - 17 YEARS OF AGE India English Back Translated from Hindi_V 3.1dated 22 Jun 2021_ Site #: 3560005_Dr Shailendra Verma 12.1_ Translation Certificate dated 16 Aug 2021
13-	External communication on ERT Cyberattack	External communication on ERT Cyberattack dated 16 Apr 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • This is supposedly an ongoing project submitted for clearance of its modification this time. The submitted documents include investigator's brochure, ICF with its translation certification and other documents except: • CTRI registration • Clinical trial agreement including budget details • Insurance • Formal approval of DCGI on appropriate letter head (although email communication is submitted) • Despite my personal talk with the PI regarding clarification of the above lacunae, no papers have yet been submitted by him to me so far – hence if the above documents as evaluated during the previous ethics clearance do not stand appropriate for as of now, the PI needs to submit the above papers for reconsideration. **EC Decision:** Approved and noted ***Ref.code:90th ECMIIC/P2***
IV	**Additional Documents**
1-	Additional document of research protocol ***"Association of genetic variations of the TGF alpha and MTHFR genes with non syndromic cleft lip with or without cleft palate in North Indian population"*** submitted by Dr. Juhi Yadav, Department of Dentistry Government allopathic Medical College, Banda through under the guidance Dr. Veerendra Prasad, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no.26/22 dated 7th January, 2022. ***Recommendation of Primary reviewer:*** **Two Co-PIs have been added as follows:** • Dr. Divya Narain Upadhyaya (Addl. Prof. Plastic Surgery of KGMU) • Dr. Raj Kumar Mishra (Prof. & HOD, Plastic Surgery SIPS, Lucknow) • Can we add Co-PIs from Private Hospitals (Dr. R.K. Mishra) in our Research Projects? • To be discussed in EC Meeting before giving approval. **EC Decision:** Approved ***Ref. code: 110th ECM IIA/ P10***
V	**Extension**
1-	Extension of research proposal entitled ***"Nanostring nCounter based screening for molecular typing and target based therapeutics of TNBC in the Indian population"*** sponsored by C.S.I.R., New Delhi submitted by Dr. Neetu Singh, Associate Professor, Department of Molecular Biology Unit, Center for Advance Research, K.G's Medical University, U.P., Lucknow vide letter no. SONC/1148/2 dated 13th December, 2021. ***Recommendation of Primary reviewer:*** • Whether Prof. Vijay Kumar, Surgical Oncology, KGMU UP, Lucknow was the part of original Research Protocol? • In absence of PI (Dr. Neetu Singh) the approval of change or addition of PI & Co-PIs will have to be taken first from sponsoring authority (CSIR, New Delhi)?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Approval for extension can only be given after it has been approved by sponsoring authority and also submitting the Original protocol with sponsor documents. **EC Comment:** As above ***Ref. code: 93rd ECM II A/P5***
VI	**Brought to Ethics Committee after VIII-PGTSC held on 29th January, 2022**
	Minutes of VIII PG Thesis sub Committee" of "Institutional Ethics Committee" Meeting ***virtually*** held on 29th January, 2022 from 11.30 AM. ***The following Members were present in the Meeting:*** 1. Prof. G.G. Agarwal -Member 2. Prof. Abbas Ali Mahdi -Member 3. Prof. Rajendra Nath -Member 4. Prof. Anita Rani Singh -Member 5. Prof. Shally Awasthi -Convener
I-A	**Action Taken**
1-	Clarification of research proposal entitled ***"Demographic profile & different treatment outcome of urothelial carcinoma at a tertiary care centre in northern India : A retrospective & prospective study"*** submitted by Dr. Ravi Prakash Mishra, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 549/URO/2021 dated 30th December, 2021. **Previous EC Comment:** • Methodology has not been discussed in detail only summary given • Inclusion / Exclusion criteria- not mentioned • Sample size (Only number is given) calculation not done. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: 103rd ECM II B-Thesis/P7***
2-	Clarification of research proposal entitled ***"Study of pattern and outcome of acute poisoning cases at tertiary care Hospital in North India"*** submitted by Dr. Naman Aggarwal, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 3272/MED/2021 dated 23rd November, 2021. **Previous PGTSC Comment:** • Patient record form needed (Structured Proforma) • Sample size not given. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approval ratified ***Ref. code: III PGTSC-IIA/P32***
3-	Clarification of research proposal entitled ***"Randomization controlled trial for comparing conventional vs wide angle viewing system for sclera buckling surgery"*** submitted by Dr. Ruchi Agarwal, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 74/OPH/2021 dated 27th October, 2021. **Previous PGTSC Comment:** • Kindly explain the procedure for randomization • Kindly provide in ICF clear understandable description of study procedure in simple language instead of writing study design. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P16***
4-	Clarification of research proposal entitled ***"Comparison of laryngeal mask airway proseal and laryngeal mask airway protector in laparoscopic surgery"*** submitted by Dr. Deshraj Verma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1154/21 dated 23rd December, 2021. **Previous PGTSC Comment:** • In the proforma 'Subject Selection' section it is not mentioned whether the subjects whether the subjects will be patients or volunteers. • Proforma says risk is not reasonable compared to benefits. Please correct this • Not mentioned in proforma • Confliciting numbers of subjects given – 60 at one place and 120 at another. Please correct • Appropriate boxes not ticked in the proforma • Direct identifiers, Indirect Indentifiers and Anonymized are all ticked. Please correct this. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P33***
5-	Clarification of research proposal entitled ***"Effect of dexmedetomidine on elevated blood pressure inside operation theatre: A randomized controlled trial"*** submitted by Dr. Rahul Kumar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/12/2022 dated 4th January, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: • Is it a trial? How will blinding be done? What are two groups? What will be compared between the two groups? • The title labels the study as a 'Trial', but no permission has been sought from DCGI/CTRI. • Dexmedetomidine has already been studied, and its effects proven. Why this study? • Reasonable risk question is answered as 'No' • Both the arms of the study are getting the drug under study? Is the role of drug being assessed or is its dose being studied? • Consent section in the form mentions 'Healthy Volunteers'. Please check • Direct identifiers and completely anonymized are both ticked. Please check ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P40***
6-	Clarification of research proposal entitled ***"Correlation of plasma D-DIMER level with severity of liver cirrhosis: an observational study"*** submitted by Dr. Rituraj Singh, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1878/Med/21 dated 18th December, 2021. **Previous PGTSC Comment:** • Cross sectional observational study • All pts of liver cirrhosis of any etiology admitted in Medicine • Case Record Form not submitted ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P44***
7-	Clarification of research proposal entitled ***"Satisfaction levels in patients after rhinoplasty using outcome evaluation questionnaire"*** submitted by Dr. Devisha Agarwal, JR-I through her Mentor Dr. Manish Chandra, Associate Professor, Department of Otorhinolaryngology & Head, Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 367/ENT/2021 dated 1st November, 2021. **Previous PGTSC Comment:** • Justify 6 guides from ENT Department, KGMU as no cases are being recruited from ENT. • What are potential sources of bias? • Will patients operated in 2015 have same response as those operated later? Please Specify the research question/s • Confirm the study design prospective/retrospective.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Ethical clearance is required from SGPGIMS ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIB IMR-R/P1***
8-	Clarification of research proposal entitled ***"A study on treatment delay in cancer patients at a tertiary care center of Lucknow district"*** submitted by Dr. Hisamurrahman, JR-I, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 806/2021 dated 22nd October, 2021. **Previous PGTSC Comment:** • Study hypotheses are not defined. • Sample size calculation is not clear in the absence of proper study hypotheses. • Study design is retrospective (not cross sectional) since patients (One year back) are to be included. Statistical analysis details missing. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P10***
9-	Clarification of research proposal entitled ***"Association of neutrophils lymphocytes (N/L) ratio and CRP with spirometry in COPD patients in North India"*** submitted by Dr. Kaushalendra Kumar Maurya, JR-I, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2652/PHY/2021 dated 4th October, 2021. **Previous PGTSC Comment:** • Kindly explain the study procedure to the patient in simple language instead of writing study design. • Kindly follow the SOP provided by IEC, available on Website. Use simple day to day Hindi language. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P11***
10-	Clarification of research proposal entitled ***"Interim analysis of the patients on bedaquilline based optimized regimen for drug resistant pulmonary tuberculosis at nodal DRTB center"*** submitted by Dr. Amaan Latif, JR-I, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2301/2021 dated 3rd November, 2021. **Previous PGTSC Comment:** • Kindly provide the outcome variables

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Kindly explain the study procedure to the patient in simple language instead of writing study design. • Kindly follow the SOP provided by IEC, available on Website. Use simple day to day Hindi language ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P15***
11-	Clarification of research proposal entitled ***"To study the correlation of blood ammonia levels and presence of portosystemic collateral veins in patients of chronic liver disease"*** submitted by Dr. Divyam Kansal, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.3168/Med/21 dated 3rd November, 2021. **Previous PGTSC Comment:** • Methodology and reference for measurement of Blood ammonia levels not provided. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P25***
12-	Clarification of research proposal entitled ***"To compare the effect of immediately loaded and delayed loaded implant on bone loss and inflammatory biomarkers"*** submitted by Dr. Akanksha Gautam, JR-I, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 863/2021 dated 26th November, 2021. **Previous PGTSC Comment:** • DRC has only 4 members. • 3 Co-PIs are from the same department. They have overlapping roles. Please decrease the number of co-PIs. • PI has filled the 'Clinical Trials' section of the IEC forms. If this is not a Trial this mistake may be corrected. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P34)***
13-	Clarification of research proposal entitled ***"Effect of epidural dexmedetomidine and fentanyl infusion for postoperative analgesia in patients undergoingupper abdominal surgeries: A randomized double blind study"*** submitted by Dr. Jaideep. P, JRI,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/973/2021 dated 22nd November, 2021. **Previous PGTSC Comment:** • 1 supervisor and 3 co-supervisors. Please decrease the number of co-PIs or define their unique roles in the study, there are several overlapping roles. • Inclusion criteria are age 18-65 years but IEC form mentions Vulnerable population of Children as part of the study. Please clarify and correct. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P36***
14-	Clarification of research proposal entitled ***"A randomized trial to evaluate the role of adjuvant basal cisternostomy in traumatic brain injury patients planned for decompressive chaniectomy in a tertiary care center in India"*** submitted by Dr. Sarita Kumari, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/1213/2021 dated 6th December, 2021. **Previous PGTSC Comment:** • Please substitute the work 'Trial' with 'Study' in your topic. • There are 7 co-PIs from the same department. This is unacceptable. Please decrease the number of co-PIs and define their individual, UNIQUE roles. Their present roles are overlapping. • The study includes seriously ill patients which are a type of vulnerable subjects. Please make appropriate changes in the IEC form. • If basal cisternostomy has been shown to have a beneficial effect on decompressing the ICP, not offering TBI patients this option to save their lives will be UNETHICAL. Thus, the PI is condemning the patients without basal cisternostomy to a poorer result than those who have had it. This is against human rights to be offered a treatment which is known to have inferior results. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P38***
15-	Clarification of research proposal entitled ***"Comparison of efficacy of desmedetomidine and clonidine on postoperative nausea and vomiting in paediatric patients undergoing abdominal surgeries"*** submitted by Dr. Khooshaboo Gupta, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1166/21 dated 31st December, 2021. **Previous PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• ICF-Assent form missing ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P49***
16-	Clarification of research proposal entitled ***"Effect of pre-operative oral carbohydrate supplement on maternal and neonatal outcomes for cesarean section under spinal anesthesia"*** submitted by Dr. Anee Akhtar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1158/21 dated 27th December, 2021.

Previous PGTSC Comment	PI response
This is double blinded RCT. It should be mentioned in the title	Effect of pre-operative oral carbohydrate supplement on maternal and neonatal outcomes for caesarean section under spinal anaesthesia : A Double blinded Randomized control trial
The fundamentals of performing RCT are not completely specified: Clinical Trial Registry Control and treated groups are not explicitly defined Outcome events and method of measuring it Repeated measurements are being taken,	Yes, After Ethical clearance applied. Groups are defined methodology attached separately Attached separately
The statistical analysis section is very general. Appropriate statistical and methodological issues are to be addressed.	Attached separately

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Decision: Approved **PGTSC Decision:** Approval ratified ***Ref. code: VI PGTSC-IIA/P1***
17-	Clarification of research proposal entitled ***"Correlation of corneal hysteresis and ocular blood flow in retinal vein occlusion"*** submitted by Dr. Mohd. Shadab, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 274/OPH/21 dated 14th December, 2021. **Previous PGTSC Comment:** • Aims, Objectives & corresponding research hypotheses are not properly defined. • Sample size formula is not correct. It uses prevalence, whereas it is a correlation-based study. • Study design mentioned is cross-sectional. So it is not clear why are they choosing three groups? DO they want to make comparison? Then it should be mentioned in aims, objectives etc. • Statistical section is very general. It is not specific to the problem being investigated. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: VI PGTSC-IIA/P4***
18-	Clarification of research proposal entitled ***"The evaluation of clinical efficacy of four different pit and fissure sealant modalities in young permanent molars: A randomized controlled trial"*** submitted by Dr. Jyoti Solanki, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.829/2021 dated 2nd December, 2021.

Previous PGTSC Comment	PI response
Clinical Trial Registry	CTRI acknowledgement number is mentioned in page 11 on 5th line highlighted in yellow
Research hypothesis is not properly defined. Here four groups are being compared.	Research hypothesis is mentioned on page 6 on 25th line highlighted in yellow
The hypothesis should be defined in terms of the parameters of these four groups.	It is mentioned in page 6 on 28th line and page 9 on 25th highlighted in yellow
The randomization procedure is to be explicitly written for	Randomization procedure is explained and mentioned in page 8 on 29th line highlighted

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

sampling into four groups	in yellow
The sample size will depend on the proper hypothesis. At present, it is inappropriate.	Sample size according to hypothesis is mentioned is mentioned in page 8 on 16th line highlighted in yellow
Statistical Analysis section should be rewritten according to the proper research hypothesis being tested.	Statistical analysis is modified and mentioned in page 11 on 7th line highlighted in yellow.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/P6

19- Clarification of research proposal entitled ***"In vivo comparison of remineralization potential of three varnishes on with spot lesion-randomized clinical trial"*** submitted by Dr. Dipika Yadav, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.823/2021 dated 1st December, 2021.

Previous PGTSC Comment	PI response
Clinical Trial Registry	CTRI acknowledgement number is mentioned in page 10 on 23rd line using red colour font
Research hypothesis is not properly defined. Here three groups are being compared.	Research hypothesis is mentioned in page 6 on 8th line using red colour font
The hypothesis should be defined in terms of the parameters of these three groups.	It is mentioned in page 9 on 7th line using red colour font
The randomization procedure is to be explicitly written for sampling into three groups	Randomization procedure is explained and mentioned in page 6 on 32 line using red colour font
The sample size will depend	Sample size according to hypothesis is mentioned

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	on the proper hypothesis. At present, it is inappropriate.	in page 5 on 13th line using red colour font
	Statistical Analysis section should be rewritten according to the proper research hypotheses being tested. ANOVA as well as multiple comparison test will be required.	Statistical analysis is modified and mentioned in page 7 on 10th line using red colour font

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/7

20- Clarification of research proposal entitled ***"A comparative evaluation of BRIX 3000, smart burs and conventional technique of caries excavation in Paediatric dental population: A randomized controlled Trial (An In-Vivo Study)"*** submitted by Dr. Jay Somkuwar, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.821/2021 dated 30th November, 2021.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Previous PGTSC Comment	PI response
Clinical Trial Registry	CTRI acknowledgement number is mentioned in page 10 on 12th line using red colour font
Research hypothesis is not properly defined. Here three groups are being compared.	Research hypothesis is mentioned in page 7 on 15th line using red colour font
The hypothesis should be defined in terms of the parameters of these three groups.	It is mentioned in page 9 on 17th line using red colour font
The randomization procedure is to be	Randomization procedure is explained and mentioned in page 9 on 6th line using red colour font

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	explicitly written for sampling into three groups	Sample size according to hypothesis is mentioned in page 8 on 27th line using red colour font
	The sample size will depend on the proper hypothesis. At present, it is inappropriate.	Statistical analysis is modified and mentioned in page 10 on 3rd line using red colour font
	Statistical Analysis section should be rewritten according to the proper research hypotheses being tested. ANOVA as well as multiple comparison test will be required.	Statistical analysis is modified and mentioned in page 10 on 3rd line using red colour font

Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/8

21- Clarification of research proposal entitled ***"A comparative evaluation of efficacy of different Irrigants on smear layer in root canals of deciduous teeth with conventional Irrigation vs. Passive ultrasonic Irrigation: An in-vitro SEM study"*** submitted by Dr. Alisha S. Jadhav, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.830/21 dated 2nd December, 2021.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Previous PGTSC Comment	PI response
1. Clinical Trial Registry	With due respect, I, hereby, would like to bring to your kind attention that the study is an in-vitro study.
2. Research hypothesis is not properly defined.There are three main groups and two sub-groups within main	NULL HYPOTHESIS: There will be no difference in smear layer removal efficacy in deciduous teeth for all three irrigants observed - sodium hypochlorite and EDTA, Q-Mix , Morinda citrifolia and EDTA with variation in activation protocol within the groups.(changes have been made in null

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	groups.So basically ,there are five groups for comparison purposes.	hypothesis)
	3. The hypothesis should be defined in terms of the parameter of these parameters of these five groups.	NULL HYPOTHESIS: There will be no difference in smear layer removal efficacy in deciduous teeth for all three irrigants observed - sodium hypochlorite and EDTA, Q-Mix , Morinda citrifolia and EDTA with variation in activation protocol within the groups.(changes have been made in null hypothesis)
	4. The randomization procedure is to be explicitly written for sampling into five groups.	It is an in-vitro study.The teeth enrolled for the study will be randomly allocated in one of the three groups which later would be sub-divided into two sub-groups by **permuted block randomization method via computer generated sequence**.
	5. The sample size will depend on proper hypothesis at present, it is inappropriate	Sample size is calculated on the basis of variation in smear score in one of the study group using the formula , $n = k\frac{\left(z_\alpha + z_\beta\right)^2 \sigma^2}{d^2}$ Where σ = 0.71, The SD of smear score in QMix group (one of the study groups), d = 0.5 times mean (=1.367), the minimum mean difference consider to be clinically significant, k = 1.25, the design effect for adding subgroups, **(Ref. Dajana et. al.)** type I error α = 5% corresponding to 95% confidence level, type II error β = 10% for detecting results with 90% power of study, So the required sample size would be ***n* = 18 each group and n=9 in each sub-group.**
	6. Statistical analysis	Data will be analysed and expressed in mean (SD) for

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	section should be rewritten according to proper research hypotheses being tested.ANOVA as well as multiple comparison tests will be required.	proportion or percentages for qualitative data. Categorical variables will be compared by using Kruskal-Wallis among the groups. The continuous variables will be compared by using one way analysis of variance (ANOVA) test among the groups. Other appropriate tests will be used for the statistical analysis. 'p' value < 0.05 will be considered significant.

Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/P9

22- Clarification of research proposal entitled ***"Effect of "Planning Intervention" on parent supervised oral health related behaviours of their children: A randomized controlled trial"*** submitted by Dr. Priyambadha H. Subba, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.828/21 dated 1st December, 2021.
The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Previous PGTSC Comment	PI Response
Although references are cited, they are not listed.	It has now been mentioned in page no. 23 highlighted in yellow.

Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/P12

23- Clarification of research proposal entitled ***"Comparative assessment of cleaning efficacy of prime PEDO™ and KEDO-SG BLUE™ PEDOrotary files with conventional H files in root canals of deciduous teeth using stereomicroscopy, CBCT and SEM: an in vitro study"*** submitted by Dr. Abhisek Bhattacharjee, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.826/21 dated 1st December, 2021.
The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.

Previous PGTSC Comment	PI response
Main guide has retired, so a	Since Prof. (Dr.) Rakesh Kumar Chak has

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	change in guide is needed.	retired, Prof. (Dr.) Rajeev Kumar Singh, Prof. and Head, Department of Paediatric and Preventive Dentistry, King George's Medical University, Lucknow has replaced him as the Chief Guide for the project.
	Although references are cited, they are not listed.	Reference has now been listed and highlighted in page 8
	They have asked for a Human Subjects Waiver.	Human Subjects Waiver has been requested since this is an **in-vitro study**, done on human deciduous teeth which were **extracted for having very poor prognosis clinically and radiographically** due to various reasons. No direct intervention on any human subject shall be performed for this study.

PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/P13

24- Clarification of research proposal entitled ***"Randomized comparison of BASKA mask versus AMBU auragain for airway management of surgical patients"*** submitted by Dr. Surbhi Rampal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/113421 dated 17th December, 2021.

Previous PGTSC Comment	PI response
Roles of both CI-PIs are overlapping.	Role of co-investigators are overlapping as the patients will be recruited from different operations theaters which are located in different physical locations in King Georg's Medical University, Lucknow.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/P21

26- Clarification of research proposal entitled ***"Effects of music intervention on anxiety and stress in patients undergoing total abdominal hysterectomy under spinal anaesthesia"*** submitted by Dr. Nishant Kaushik, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1002/21 dated 30th November, 2021.

Previous PGTSC Comment	PI response
No Co-PI form department of OBG from where the patients will be recruited?	Dr. Manju Lata Verma, Associate Professor, Obstetrics & Gynaecology,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	KGMU, Lucknow added in CO-PI.
Risk is not reasonable has been ticked.	Attached separately
Section on consent in the IEC from has been left blank.	Attached separately
Sample size calculation is 94 per group but PI has mentioned sample size in 70 in the IEC form.	My Sample size is 94 per group but typing mistake 70 mentioned.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/P24

27- Clarification of research proposal entitled ***"Post ankylosis customized TMj replacement: A study"*** submitted by Dr. M. Haaris Khan, JRI, Department of Oral and Maxillofacial Surgery, King George's Medical University, U.P., Lucknow vide letter no.OMSD/731/21 dated 10th December, 2021.

Previous PGTSC Comment:

- The study has 1 Supervisor and 4 Co-Supervisors. Please reduce their number or define their UNIQUE roles.
- Clinical Trial section has been ticked. Please elaborate if this is a Clinical trial with a new drug or device. If yes, has CTRI registration been sought/will be sought?
- Subject number is 10 at one place and 300 at another.
- No sample calculation has been done.
- Prosthetic TMJ replacement by titanium implants is a standard procedure. What, then. Is the purpose of this study?
- For the patients taking part in the project, who will bear the cost of the customized 3D printed implant?

II-time-Reviewer opinion	PI response
The PI has refused to reduce the number of Co-PIs or define their unique roles. Assisting the surgery can't be a role of a Co-PI.	• The supervisor's (Prof. Shadab Mohammad) unique role is performing the said TMJ replacement surgery. • The co supervisor (Prof. Divya Mehrotra) unique role is helping in designing the artificial prosthesis on software and also perform the surgery. • The co supervisor(Prof RK Singh) unique role is to

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		check the clinical parameters which are being used for evaluation in this study. • The co supervisor (Prof Vibha Singh) unique role is to quality check and evaluate the design of the artificial prosthesis to avoid any bias. • The co supervisor(Dr Arunesh Kr. Tiwari) unique role is to screen and refer the TMJ ankylosis patients who report to trauma centre to OPD and also helps in diagnosing the type of TMJ ankylosis.
	Customised Titanium implants are a well accepted modality of care. The PI has not been able to define the Research question.	Customised Ti implants are a well accepted modality of care in developed countries. However in India, which is a developing country this particular modality of treatment has not been done and evaluated on the Indian population(especially north indian) due to lack of advanced infrastructure it requires. So we are evaluating its use in Indian population comparing it to the data in the literature.
	The cost of the 3D printed Customised implant for the purpose of the research project cannot be borne by the patient.	It is an observational study just to evaluate the assessment of functionality of replaced joint as compared to the available data in the literature. We have no control on allocation of the treatment modality offered to the patient. So no financial implication was imposed on the patient by the PI. As far as allocation of treatment modality for a patient is concerned, the patient has full control to opt for a particular treatment choices (one of which is customised TMJ replacement) amongst all the feasible choices provided to him/her routinely. The PI has just observed the clinical parameters of the patients who opted for the TMJ customised implant reconstruction choice.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/P26

28- Clarification of research proposal entitled ***"A prospective study of comparison between open cavity mastoid surgery versus posterior canal wall reconstruction technique using composite multi-fractured osteoperiosteal flap (CMOF)"*** submitted by Dr. G.C. Lalremruata, JRI, Department of OTO-Rhino-Laryngology & Head & Neck Surgery,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow vide letter no.403/ENT/21 dated 20th November, 2021.

Previous PGTSC Comment:

- Aims, Objectives & corresponding research hypotheses are not properly defined.
- Sample size formula is not correct. It uses prevalence, whereas it is a correlation-based study.
- Study design mentioned is cross-sectional. So it is not clear why are they choosing three groups? DO they want to make comparison? Then it should be mentioned in aims, objectives etc.
- Statistical section is very general. It is not specific to the problem being investigated.

II-time-Reviewer opinion	PI response
Project has 1 Supervisor and 5 co-supervisors. Please decrease the number of Co-supervisors for approval.	1 Supervisor (Dr. H.P. Singh) and 3 cosupervisors (Prof. Anupam Mishra, Prof. Veerendra Verma and Prof. Anit Parihar)
National Industry is marked as sponsor and Budget as self. Please give supportive evidence if this is correct.	Budget is self
Sample size given as 25 in IEC form and 25 per group in sample calculation	25 per group
Section on consent is incompletely filled.	Attached separately consent form

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/P28

29- Clarification of research proposal entitled ***"To see the effect of duration and size of perforation, its correlation with hearing loss in patients of chronic suppurative otitis media"*** submitted by Dr. Rahul Anand, JRI, Department of OTO-Rhino-Laryngology &

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 418/21 dated 26th November, 2021.

Previous PGTSC Comment:

- Thesis title should be modified to explain perforation of which part and it should be written as "perforation of tympanic membrane"
- In Exclusion criteria the point no. 2 (Pts. with tubo tympanic membrane CSOM) should be deleted as it is the part of Inclusion criteria
- Calculated sample size not given and discrepancy in sample size mentioned in SOP form (100 pts) and protocol synopsis (215) should be explained clearly that what is the actual sample size is.

II time –Reviewer opinion	PI response
Project has 1 Supervisor and 5 co-supervisors. Please decrease the number of Co-supervisors for approval.	1 Supervisor (Dr. H.P. Singh) and 3 co-supervisors (Prof. Anupam Mishra, Prof. Veerendra Verma and Prof. Anit Parihar)
National Industry is marked as sponsor and Budget as self. Please give supportive evidence if this is correct.	Budget is self
Sample size given as 25 in IEC form and 25 per group in sample calculation	25 per group
Section on consent is incompletely filled.	Attached separately consent form

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/P31

30- Clarification of research proposal entitled ***"Pharmacoeconomic evaluation of antidiabetic medication in geriatric type 2 diabetes-a brief study"*** submitted by Dr. Arun Jakhar, JRI, Department of Pharmacology and Therapeutics, King George's

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Medical University, U.P., Lucknow vide letter no. 1153/Pharma/2021 dated 4th December, 2021.

Previous PGTSC Comments	PI response
Sample size given according to WHO reference but calculation not done.	Sample Size Calculation: (page no. 15,16 of the ethical clearance document) The following formula is used for sample size calculation $n= Z^2 \times p \times q/d^2$[1] n- Sample size required p=Prevalence q=1-p d=Difference to be detected- usually (margin of error) 5% Z=Statistic corresponding to level of confidence In a study (Tripathy et al., 2017), the prevalence of uncontrolled diabetes is 65%, assuming 80% power, 5% significance level with 95% confidence interval and margin error of 5%, the sample calculated will be 349.58 [2]. Z = 1.96, P= 0.65, q=0.35, d=0.05 So estimated sample size will be 350. But we are using the WHO document "How to investigate drug use in health facilities", according to which at least 600 encounters should be included in a cross-sectional survey, with a greater number if possible [3]. So we will take 600 patients of T2DM
Principal Investigator should be JR 1 (but in this protocol Chief Supervisor, Dr. Sanjay Khattri mentioned himself as PI and JR as Co-supervisor)	JR-1 is now assigned as the Principal Investigator and Prof. Sanjay Khattri as the Chief supervisor (page no. 3 of ethical clearance document).
Work distribution of JR 1 and Chief supervisor not mentioned.	Work distribution:(page no. 4 of ethical clearance document) 1. Dr. Arun Jakhar (JR 1): Data collection, data analysis and interpretation, thesis preparation. 2. Prof. Sanjay Khattri (Chief supervisor): Researchideaconception, Developmentdesignofmethodology, Dataanalysisinterpretation, final approval.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		3. Prof.AmodKumar Sachan(Co-supervisor): Criticalrevisionofthesis and final approval 4. Prof.Kauser Usman(Co-supervisor):Supervision of clinical part ofthesis, dataacquisition, dataanalysis& interpretation, finalapproval. 5. Prof. K.K. Sawlani(Co-supervisor): Supervision of clinical part ofthesis, dataacquisition, dataanalysis& interpretation, finalapproval.
	Detailed methodology for Pharmacoeconomic evaluation of Anti-diabetic drugs not mentioned.	Detailed methodology: (page no. 16 of ethical clearance document) 1. The difference in the maximum and minimum price of the same drug manufactured by different pharmaceutical companies will be calculated. 2. Percentage cost variation will be found out by using the following formula: • Percentage cost variation = [(cost of highest price brand – cost of lowest price brand)/cost of lowest price brand] X 100 3. Prices of drugs will be calculated between following groups- controlled vs uncontrolled diabetes, with and without comorbidity, and stratification based on barthel index. 4. Following Predictors for cost will be evaluated: age, gender, BMI, HbA1C, FBG, comorbidity, barthel index in regression analysis.
	The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer. ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: VI PGTSC-IIA/P35***	
31-	Clarification of research proposal entitled ***"Analysis of achievement of radiological parameters in uncemented total hip replacement-a retrospective cohort study"*** submitted by Dr. Md Ash Ar Reza, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1395/OR/21 dated 15th December, 2021. **Previous PGTSC Comment:**	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• 10 Co-investigators from same department with almost similar role in thesis. • Reduce or justify the need for these ID ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: VI PGTSC-IIA/P39***
32-	Clarification of research proposal entitled ***"Association of cholinergic biomarkers with post operative delirium in elderly patients undergoing spinal anaesthesia: A prospective cross-sectional study"*** submitted by Dr. Praveen Kumar Yadav, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/13/2022 dated 4th January, 2022. **Previous PGTSC Comment:** Informed Consent Form -English and Hindi version not similar (Hindi version not complete) ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: VI PGTSC-IIA/P40***
33-	Clarification of research proposal entitled ***"Evaluation of serum pro-brain natriuretic peptide as a biomolecular biomarker for severity of diabetic retinopathy"*** submitted by Dr. Prachi, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 1252/OPH/21 dated 9th December, 2021. **Previous PGTSC Comment:** Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: VI PGTSC-IIA/P41***
34-	Clarification of research proposal entitled ***"A randomized clinical trial: comparison of pretreatment of magnesium with two different doses of rocuronium in rapid sequence intubation"*** submitted by Dr. Mudita Sharma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1096/21 dated 10th November, 2021. **Previous PGTSC Comment:** • Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Website. • Explain the risk properly to the patient in simple language. • Follow RCT protocol. • Get it registered with CTRI. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: VI PGTSC-IIA/P43***
35-	Clarification of research proposal entitled ***"The utility of thromboelastography for predicting the progression of intracranial hemorrhage in traumatic brain injury patients"*** submitted by Dr. Preshit Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1153/21 dated 23rd December, 2021. **Previous PGTSC Comment:** • Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: VI PGTSC-IIA/P50***
36-	Clarification of research proposal entitled ***"Prospective randomized control trial for the management of post traumatic cerebrospinal fluid rhinorrhea and otorrhea with acetazolamide"*** submitted by Dr. Shivam Madeshiya, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/03/22 dated 11th January, 2022.

Previous PGTSC Comments	PI response
There is no research hypothesis	Hypothesis: Decrease in CSF production by drug acetazolamide, it may stop or decrease CSF leakage in form of CSF rhinorrhea /otorrhea .
This is supposed to be a randomized control trial	RCT will not be done.
The fundamentals of performing RCT are not completely specified :clinical trial registry ,method of	RCT will not be done.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

randomization, blinding, follow up, outcome event, efficacy or effectiveness trial , statistical and methodological issues in RCT	
They may also consider drug a prospective cohort study	We will be doing a prospective study. Role of acetazolamide in the treatment of CSF rhinorrhea/ otorrhea is not clear. This study will help in standardizing the role of acetazolamide in CSF leaks. In this prospective study the drug acetazolamide will be used in patients as per his/her consent to participate in study.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P6

37- Clarification of research proposal entitled ***"Analysis of outcome of severe head injury patients with surgically evacuable lesion"*** submitted by Dr. Aman Singh, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/1360/22 dated 10th January, 2022.

Previous PGTSC Comments	PI Response
There is no research hypothesis	Despite guideline protocols for the surgical management of Traumatic Brain injury patients, various studies have shown major practice variations in the surgical management of severe traumatic brain injury at different centers. Since, the mortality rates in severe traumatic brain injury are quite high, hence various studies have been done aimed at reducing the mortality and morbidity of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		such patients. In this study, we will be aiming at the determinants of mortality in patients with surgically evacuable lesion in severe traumatic brain injury including demography, clinical status (GCS score), radiological features and other associated co-morbid conditions. Moreover, we will be comparing the group of the patients of adverse outcomes (expired) with the survival group with similar clinical status (GCS score) and will focus on the impact of other relevant factors on the outcome of patients undergoing surgery. We will also evaluate the functional outcome of these patients at regular intervals using the GOS(E) score and study the progression of improvement or deterioration in such cases.
	In the absence of proper research hypothesis, sample size calculation and statistical analysis section would be in appropriate.	A flowchart representation of the study is being attached with this letter. The determinants of mortality will be tabulated and compared statistically using logistic regression analysis and their significance will be noted.
	The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer. ***Recommendation of Primary reviewer:*** **Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: VII-PGTSC-IIA/P7***	
38-	Clarification of research proposal entitled ***"Appraisal of skeletal maturity indicators with respect to non invasive biomarkers"*** submitted by Dr. Snigdha Kumar, JRII, Department of Orthodontics and Dentofacial Orthopaedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.580/Ortho/22 dated 5th January, 2022. **Previous PGTSC Comment:**	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Department Scientific Committee has the same people as those in the study. This cannot be accepted. Co-opt of Members from
- IEC Proforma is incomplete use of body fluids is not mentioned, data monitoring section is not filled
- Methodology is incomplete/unclear.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P26

39- Clarification of research proposal entitled ***"Comparative study of intraoperative parameters, postoperative voice change and laryngopharyngeal symptoms in patients undergoing thyroid surgery with supraglottic airway devices vs endotracheal intubation (Armoured vs non-armoured)"*** submitted by Dr. Rizhin Sooraj, SRI, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no.ENDO-SURG/390/21 dated 27th December, 2021.

Previous PGTSC Comment:	PI response
Age specificity not mentioned in Inclusion criteria	Age of the patients > 18 years will be used as inclusion criteria for all the patients in my study.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P33

40- Clarification of research proposal entitled ***"Assessment of metal ions and it's correlation with therapeutic outcomes on cognitive and motor functions in the patients of parkinsonism coming to tertiary care Hospital"*** submitted by Dr. Aishwarya Mishra, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no.27/Pharma/22 dated 14th January, 2022.

Previous PGTSC Comment:	PI response
Serum and urine samples are being collected but the section on Biological Material is not filled.	Copy attached separately with necessary corrections done.
The proposal has **SIX Co-PIs** out of which four are from one	Number of Co-PIs has been reduced to 4 now Roles mentioned separately.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	department, all with overlapping roles justify.	
	Risk is mentioned as not reasonable in the IEC form.	Copy attached separately with necessary corrections done.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.
Recommendation of Primary reviewer:
Decision: Approved
PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P36

II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"Three dimensional evaluation of palatal plane in different vertical facial patterns-a CBCT study"*** submitted by Dr. Sharon K Sabu, JRII, Department of Orthodontics and Dentofacial Orthopaedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 509/21 dated 18th November, 2021. ***Recommendation of Primary reviewer:*** • Research hypothesis is not defined. • Study design and sampling method are not mentioned. • Study variables and parameters are not given. • Sample Size calculation is not given. • Statistical Analysis section is vague. **PGTSC Comment:** As above **PGTSC Decision:** Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Ref. code: VIII-PGTSC-IIA/P1***
2.	Research proposal entitled ***"A study on treatment regimen outcome and ADR monitoring in adult patients with tubercular meningitis at tertiary care Centre"*** submitted by Dr. Ajit Kumar Mishra, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 988/Pharma/21 dated 7th October, 2021. ***Recommendation of Primary reviewer:*** • There are eight Co-PIs including one from RML Institute-Justify their roles. • Study variables and population parameters are to be properly chosen. • Research hypothesis is to be defined in term of population parameters. • Methodology section is poorly written. • Sample size calculation is inaccurate. Sample size formula picked arbitrarily.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Statistical Analysis section is not specific to the study. It is written arbitrarily. **PGTSC Comment:** As above **PGTSC Decision:** Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Dr. Rajendra Nath did not take part in discussion and making decision.*** ***Ref. code: VIII-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Evaluation of correlation between the sedation-agitation scale and the bispectral index in ventilated patients in the intensive care unit"*** submitted by Dr. Pralobh Kumar Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/954/21 dated 12th November, 2021. ***Recommendation of Primary reviewer:*** • Research hypothesis and objective are not in conformity. Research hypothesis mentions it as a "comparative study", whereas the objective mentions it as an "correlation study". • Sample size calculation is not clear. There is no or poor justification for selecting the values in the formula. • Statistical Analysis section is very general and not specific to the study. **PGTSC Comment:** As above **PGTSC Decision:** Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Ref. code: VIII-PGTSC-IIA/P3***
4.	Research proposal entitled ***"To study the association of early biomarkers of acute kidney injury in hepatitis B induced chronic liver disease on tenofovir treatment"*** submitted by Dr. Shivani Rani, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 3347/MED/21 dated 3rd December, 2021. ***Recommendation of Primary reviewer:*** • Research hypothesis is not defined. It should be defined after properly identifying the study variables and population parameters of the study. • Sample size calculation is out of context. It is not specific to the study. • Statistical Analysis section is missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Ref. code: VIII-PGTSC-IIA/P4***
5.	Research proposal entitled ***"A comparison of internal jugular vein cannulation by anatomical landmark and ultra sound guided technique in operation theater and Intensive care unit (ICU)"*** submitted by Dr. KRL Chetan, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Anaes/1084/21 dated 9th December, 2021. ***Recommendation of Primary reviewer:*** • Sample size calculation is not given. Sample size of 100 picked arbitrarily. • Sampling method is not mentioned. • Statistical Analysis section is not specific to the study. **PGTSC Comment:** As above **PGTSC Decision:** Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Ref. code: VIII-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Predictor of outcome in children with tuberculous meningitis and effect of leukotriene A4 hydrolase gene polymorphism on outcome of tuberculous meningitis in children: A prospective observational study"*** submitted by Dr. Dhruvi Rai, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2854/Ped/21 dated 2nd December, 2021. ***Recommendation of Primary reviewer:*** • Since the objective of the study is to find predictors of short-term outcome, outcome has not been defined. • Research hypothesis is not given. • Sample size formula is arbitrarily chosen and not specific to the study. • Statistical Analysis section is missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Ref. code: VIII-PGTSC-IIA/P6***
7.	Research proposal entitled ***"Bronchopulmonary dysplasia in preterm neonates in NICU- risk factors and outcome"*** submitted by Dr. Pragya Mishra, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2853/Ped/21 dated 2nd December, 2021. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VIII-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Study of correlation of clinic-pathological features of extremity squamous cell carcinoma developing over scar (Marjolin ulcer) with lymph node metastasis"*** submitted by Dr. Deepak Kumar Gupta, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2273/21 dated 16th December, 2021. ***Recommendation of Primary reviewer:*** • Patient Information Sheet Not attached, Sample Size: kindly confirm 50/60, ICF: Kindly explain the study procedure to the patient in simple language instead of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	writing study design. Kindly follow the SOP provided by IEC, available on Website. **PGTSC Comment:** As above **PGTSC Decision:** Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Ref. code: VIII-PGTSC-IIA/P8***
9.	Research proposal entitled ***"A prospective study of perioperative and quality of life outcomes after endoscopic groin hernia repair by extended totally extraperitoneal repair"*** submitted by Dr. Sheefali Chandra, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no.2283/21 dated 17th December, 2021. ***Recommendation of Primary reviewer:*** • Patient Information Sheet Not attached, Sample Size: kindly confirm 30/35, Duration of study: kindly confirm 1 year/2 years , ICF: Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website. **PGTSC Comment:** As above **PGTSC Decision:** Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Ref. code: VIII-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Comprehensive evaluation with prediction of morbiditty and mortality using different scoring systems in fournier's gangrene- A prospective observational study"*** submitted by Dr. Abhishek Singh, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no.2303/21 dated 28th December, 2021. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: VIII-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Role of micro RNA expression as biomarker in breast cancer"*** submitted by Dr. Nijarth Shahi, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no.2304/21 dated 28th December, 2021. ***Recommendation of Primary reviewer:*** • Sample size calculation is not clear. Justify the sample size of 60 patients. Methodology is not properly described.ICF: Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website. **PGTSC Comment:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Ref. code: VIII-PGTSC-IIA/P11***
12.	Research proposal entitled ***"Assessing health seeking behaviour among chronic obstructive pulmonary disease patients reaching at a tertiary care centre"*** submitted by Dr. Gaurav Srivastava, JRII, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2287/Resp/21 dated 28th December, 2021. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: VIII-PGTSC-IIA/P12***
13.	Research proposal entitled ***"Analysis of post cholecystectomy bile duct injury, risk factors, management and its outcome at tertiary care centre"*** submitted by Dr. Rambit Chandra Dwivedi, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 145/Surg/22 dated 2nd January, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: VIII-PGTSC-IIA/P13***
II-B	**IMR-Student**
1.	Research proposal entitled ***"Microbial contamination of surgical scrubs & mobile phones in the operating theatre- A pilot study"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Mr. Vaibhav Singh through his Mentor Dr. Sheetal Verma, Associate Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1596/21 dated 13th December, 2021. ***Recommendation of Primary reviewer:*** • Sample size calculation not done (it is a Pilot study) **PGTSC Decision:** Approved ***Ref. code: VIII-PGTSC-II B IMR-S/P1***
2.	Research proposal entitled ***"An observational prospective analysis of suspected poisoning cases admitted in Medicine and Pediatrics Departments of a North-Indian Teaching Medical University"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Ms. Yashita Khulbe & Mr. Yash Chandani, both are MBBS students through their Mentor Dr. Raja Rupani, Additional Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 533/FMT/21 dated 15th December, 2021. ***Recommendation of Primary reviewer:*** • As the patients will also be taken from Paediatric Deptt. –therefore Guardian and Child Assent form is needed apart from general ICF

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Cutting of written matter in SOP form is not required (Only ticks against the written matter in every point is permissible) **PGTSC Comment:** As above **PGTSC Decision:** Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Ref. code: VIII-PGTSC-II B IMR-S/P2***
3.	Research proposal entitled ***"CD44 expression in different histological grades of renal cell carcinoma and its clinicopatholgical correlation"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Ms. Varsha Singhal, MBBS 2019 through her Mentor Dr. Atin Singhai, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.4168/21 dated 21st December, 2021. ***Recommendation of Primary reviewer:*** • Justification for including HSRW Form along with ICF (E/H) • JRs cannot act as Co-PIs in Research Projects? **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VIII-PGTSC-II B IMR-S/P3***
4.	Research proposal entitled ***"Diphtheria: A prospective study of incidence of diphtheria in the emergency unit of the department of Pediatrics in a hospital of a medical University of Northern India"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Mr. Shubhajeet Roy & Ms. Aditi Singh both are MBBS students through their Mentor Dr. Sciddhartha Koonwar, Prof. Jr. Grade, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.64/Ped/2022 dated 10th January, 2022. ***Recommendation of Primary reviewer:*** • Exact sample size and its calculation not done • PI has made several cuts of contents in SOP Form –which is not required therefore Revised SOP Form should be submitted with only necessary Ticks • Title has been altered in Protocol and ICF by erasing the few words by whitener which is not permissible. Please give exact title. • Child Assent form not submitted along with ICF **PGTSC Comment:** As above **PGTSC Decision:** Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Ref. code: VIII-PGTSC-II B IMR-S/P4***
5.	Research proposal entitled ***"Study of single nucleotide polymorphism in MGMT gene promoter region and correlation with MGMT methylation status and prognosis in glioblastoma"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Krachi Agarwal, JR-I through her Mentor Dr.Shivanjali Raghuvanshi, Associate

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.17 dated 6th January, 2022. ***Recommendation of Primary reviewer:*** • Total 6 Co-PIs , 2 from Pathology and 2 from Neurosurgery with same role, please reduce the number of Co-PIs or justify the same and correct the name of Department of Prof. B K Ojha (HOD , Neurosurgery Deptt.). • Age specificity not mentioned in Inclusion criteria • Revise SOP form as not filled properly leaving parts of the question no.-5 ,8 & 10 unanswered. **PGTSC Comment:** As above **PGTSC Decision:** Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Ref. code: VIII-PGTSC-II B IMR-R/P5***
6.	Research proposal entitled ***"Analysis and relevance of single or combination mutations of BRAF, TERT and NRAS genes and their clinic-pathologic relationship in papillary thyroid carcinoma: A study using sanger sequencing"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Isha Makkar, JR-I through her Mentor Dr. Chanchal Rana, Associate Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.26 dated 10th January, 2022. ***Recommendation of Primary reviewer:*** • Justify Co-PI numbers and their roles or reduce the Co-PIs-Total 6 (2 from Pathology and 3 from Endocrine Surgery with almost same role) • Study design mentioned is different in Protocol and ICF (informed consent form) • No any sample has been mentioned in SOP Form. If it is retrospective cross sectional observational study with 2 year follow up then why PI mentioned that histopathological processing ,reporting and molecular analysis will be done by Sanger sequencing. • Details of Sanger sequencing with reference has not been mentioned in methodology. **PGTSC Comment:** As above **PGTSC Decision:** Revise and re-submit. (Give a tabular form of revisions done along with revised proposal. ***Ref. code: VIII-PGTSC-II B IMR-R/P6***
IIC	**Nursing students- KGMU Institute**
1.	Research proposal entitled ***"A study to assess compulsive drinking behavior, anger level and self-esteem among patients with alcohol dependence syndrome in tertiary care centre"*** submitted by Ms. Sarita Bhatt under the guidance Ms. Sudha Mishra, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1938/X.51/21 dated 30th October, 2021. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Approved **PGTSC Decision:** As above ***Ref. code: VIII-PGTSC-IIC/P1***
2.	Research proposal entitled ***"Impact of life style modification behaviour (LSMB) on physiological parameters, sleep pattern and quality of life among patients with poly cystic ovarian syndrome (PCOS) in tertiary care Hospital"*** submitted by Ms. Pratibha Singh under the guidance Dr. Suchana Roy Bhowmik, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1937/X.51/21 dated 30th October, 2021. ***Recommendation of Primary reviewer:*** • The proforma has not been signed by the Co-PI from Deptt. of Obst. & Gynaecology **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VIII-PGTSC-IIC/P2***
3.	Research proposal entitled ***"Effectiveness of education intervention on knowledge regarding perimenopausal problems and its management in selected slum area of Lucknow"*** submitted by Ms. Shubhi Prabhakar under the guidance Mr. Rohitash Kumar, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1990/X.51/21 dated 11th November, 2021. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VIII-PGTSC-IIC/P3***
4.	Research proposal entitled ***"Effectiveness of community-based education on knowledge regarding Hypertension and its preventive measures among adults residing in selected urban slum"*** submitted by Ms. Adarshika Sachan under the guidance Mr. Rohitash Kumar, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1987/X.51/21 dated 11th November, 2021. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VIII-PGTSC-IIC/P4***
5.	Research proposal entitled ***"Effectiveness of parenting education module on knowledge regarding development milestones and delay among mothers of infant at selected urban immunization centre, Lucknow"*** submitted by Ms. Anjali Sharma under the guidance Mr. Rohitash Kumar, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1988/X.51/21 dated 11th November, 2021. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: VIII-PGTSC-IIC/P5
6.	Research proposal entitled ***"Effectiveness of community based education on knowledge regarding prevention of diabetes mellitus among young adults of selected urban slums"*** submitted by Ms. Ankita Singh under the guidance Mr. Rohitash Kumar, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1989/X.51/21 dated 11th November, 2021. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above
	Ref. code: VIII-PGTSC-IIC/P6
7.	Research proposal entitled ***"Effect of infrared radiation on post-operative pain and wound healing of patient who underwent sternotomy in tertiary care Hospital"*** submitted by Ms. Sneha Angel Solomon under the guidance Mrs. Rashmi P. John, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2026/21 dated 8th November, 2021. ***Recommendation of Primary reviewer:*** • Will suggest changing 'Infrared Radiation' to 'Infrared Light' or 'Infrared therapy' to avoid misconceptions. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification
	Ref. code: VIII-PGTSC-IIC/P7
8.	Research proposal entitled ***"Effectiveness of educational package on knowledge regarding care of children receiving chemotherapy among caregivers of tertiary care Hospital"*** submitted by Ms. Nandita under the guidance Mr. Subin.S, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2024/21 dated 8th November, 2021. ***Recommendation of Primary reviewer:*** • Name and phone number of contact person not mentioned on consent form. • Consent and assent for children are both required. • Under vulnerable subjects 'Elderly' is ticked **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification
	Ref. code: VIII-PGTSC-IIC/P8
9.	Research proposal entitled ***"Effectiveness of the premature infant oral motor intervention on oral feeding among preterm infants in tertiary care Hospital"*** submitted by Ms. Divya Chakraverty under the guidance Mr. Subin.S, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2023/21 dated 8th November, 2021. ***Recommendation of Primary reviewer:*** • Hindi consent form shall be in simple language. • Annexure-I Need of the study shall be re-written in future tense as it seems the study has already been done.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• "My study" used everywhere needs to be corrected to in the "proposed study" **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VIII-PGTSC-IIC/P9***
10.	Research proposal entitled ***"Assess the awareness and attitude towards maternal rights among reproductive age women in tertiary care Hospital"*** submitted by Ms. Alka Bharti under the guidance Mrs. Sudha Mishra, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2021/21 dated 8th November, 2021. ***Recommendation of Primary reviewer:*** • Hindi consent form shall be in simple language. • "Client awareness" "ghrahak" needs to be changed **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VIII-PGTSC-IIC/P10***
11.	Research proposal entitled ***"Efficacy of hands-on-training on performance of use of incentive spirometry and oxygen saturation among hospitalized patients in respiratory ward at tertiary care Centre"*** submitted by Ms. Priya under the guidance Dr. Suchana Roy Bhowmik, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2027/21 dated 8th November, 2021. ***Recommendation of Primary reviewer:*** • Hindi consent form shall be in simple language **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VIII-PGTSC-IIC/P11***
12.	Research proposal entitled ***"Effectiveness of splint on peripheral intravenous therapy among hospitalized children in tertiary care Hospital"*** submitted by Ms. Chaudhari Amrita Singh under the guidance Mr. Subin. S, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2025/21 dated 8th November, 2021. ***Recommendation of Primary reviewer:*** • Very poorly written. • Hindi consent form shall be in simple language • Study group is mentioned as an experimental group and needs to be corrected. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VIII-PGTSC-IIC/P12***
13.	Research proposal entitled ***"A study to assess the work-family conflict and its association with psychological distress among working women"*** submitted by Ms. Shweta Ranjan under the guidance Mrs. Sudha Mishra, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	no.1936/X.51/21 dated 30th October, 2021. ***Recommendation of Primary reviewer:*** • Hindi consent form shall be in simple language **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VIII-PGTSC-IIC/P13***
14.	Research proposal entitled ***"Assess the quality of life and emotional distress among infertile women in tertiary care Centre"*** submitted by Mrs. Deeksha under the guidance Mrs. Sudha Mishra, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2021/X.51/21 dated 8th November, 2021. ***Recommendation of Primary reviewer:*** • Hindi consent form shall be in simple language **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VIII-PGTSC-IIC/P14***
15.	Research proposal entitled ***"Impact of Nurse led renal Rehabilitation information module (NLRRIM) on quality of life, activity of daily living and renal function among hemodialysis patients in tertiary care hospital"*** submitted by Mrs. Preeti Singh under the guidance Dr. Suchana Roy Bhowmik, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2029 dated 8th November, 2021. ***Recommendation of Primary reviewer:*** • Hindi consent form shall be in simple language **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VIII-PGTSC-IIC/P15***
16.	Research proposal entitled ***"Effect of education related to danger signs of pregnancy on knowledge among pregnant mothers in tertiary care hospital"*** submitted by Ms. Nidhi Schan under the guidance Dr. Suchana Roy Bhowmik, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2028 dated 8th November, 2021. ***Recommendation of Primary reviewer:*** • Hindi consent form shall be in simple language • In the questionnaire "Nuclear family' is translated to "Parmanu pariwar" needs to be corrected and Hindi translation needs to be improved. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: VIII-PGTSC-IIC/P16***

The next meeting will be scheduled on 2nd April, 2022 (Saturday)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 115th IEC Meeting virtually held on 2nd April, 2022

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of 115th "Institutional Ethics Committee" Meeting *virtually* held on 2nd April, 2022 from 10.30 AM.

The following Members were present in the Meeting:-

1. Prof. Alok Dhawan -Chairman
2. Prof. G.G. Agarwal -Member
3. Prof. Shubha R Phadke -Member
4. Mrs. Vasundhara Kumar -Member
5. Mrs. Akansha Dubey -Member
6. Mr. Ujjawal Krishna -Member
7. Dr. Akash Agarwal -Member
8. Dr. K.K. Yadav -Member
9. Prof. A.A. Mahdi -Member
10. Prof. Rajendra Nath -Member
11. Prof. Anupam Mishra -Member
12. Prof. Anita Rani Singh - Member
13. Dr. D.N. Upadhyaya -Member
14. Dr. Shally Awasthi -Member-Secretary, IEC

I-A	Action Taken
1-	Clarification of research proposal entitled "***Photobiostimulation (Low Level Iaser Therapy) as a non-invasive therapeutic adjunct for non-surgical management of periapical bone defects during COVID-19 pandemic***" sponsored by UPCST Lucknow submitted by Dr. Rhythm, Prof. Jr. Grade, Department of Conservative Dentistry & Endodontics, K.G's Medical University, U.P., Lucknow vide letter no.428/2020dated 29th December, 2020. **Previous EC Comment:** • Sponsor Information: UPCST is State, not Institutional • Budget is not mentioned-Needs itemized budget • Needs patient information sheet/brochure in English and Hindi • Needs Case Report Form. • Hypothesis: need to differentiate between a research hypothesis and null hypothesis.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Study design: What type of randomization and why? • Will RCT be done in all patients? If yes- mention it, if no: correct consent form. • What type of statistics will be used? Please mention detailed statistical plan. • What are the endpoints and how will they be assessed / measured? • Sample size: explain calculation, effect size and baseline efficacy. • Consent form: There is a risk of using non standard treatment, should be mentioned. ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by PR.*** ***Recommendation of Primary reviewer:-*** • Provisionally approved **EC Decision:** Approved ***Ref. code: 107th ECM IIA/P7***
2-	Clarification of research proposal entitled "***Formulation, optimization and evaluation of apigenin and cardamom essential oil based emulgel for mitigation of oral submucous fibrosis***" sponsored by ICMR submitted by Ms. Sarita Pal, Ph.D Scholar 2019, under the guidance Dr. N.P. Yadav & Co-PI U.S. Pal, Department of Oral and Maxillofacial Surgery, FODS, K.G's Medical University, U.P., Lucknow vide letter no. 594/OMFS/21 dated 8th October, 2021. **Previous EC Comment:** • 1-Section 5: This project is an in-vitro study: what is the need for subjects? • 2. Section 5: Many vulnerable subjects have been ticked: why? • Section 6: Privacy statement: not checked • Section 7: Organs and body fluids are being used: wrongly checked. • Section 8: All studies involving patient recruitment need a patient information sheet. • Section 8: Who administers the consent? • Section 10: Give details of interim data analysis points. • Biopsy is an invasive procedure: can have complications, can't be risk free. • Consent form and patient information sheet should be separate. • Why will oral cancer cell lines be used? The study is of OSMF, not cancer. • Objectives: Procurement of buccal mucosa cannot be an objective, at least for this study. • Please provide the Ayurvedic Text which tells about areca nut causing OSF. • Please provide itemized budget. ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***The <u>second Recommendation</u> of Primary reviewer:*** • Budget not mentioned • Risk is not reasonable, why do the study? • Biopsy is an invasive procedure with discomfort, risk of complications: need to

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	have a compensation policy. • KGMU should have its own PI answer researcher outside KGMU will not be interaction with patients. • Right to participation (Consent form): tissue sample is patient's property and rights can't be waived off. • Outcome measures are not in sync with aim/objectives. ***The above comment forwarded to the P.I., Reply received by PI on 31st March, 2022 was forwarded to PR vide this office letter no. 2382/Ethics/22 dated 31st March, 2022.*** **EC Comment:** • List of queries raised previously and their clarifications have not been attached. Please ask the researched to do the needful. ***Ref. code: 107th ECM II B-Ph.D/P1***
3-	Clarification of research proposal entitled "***To determine the role of RBP 4 and retinoic acid levels as pediatric acute liver failure prognostic biomarker***" sponsored by CSIR submitted by Dr. Sanjeev Kumar Verma, Associate Professor, Department of Pediatrics, King George's Medical University U.P., Lucknow vide letter no.1151/Ped/2021 dated 13th May, 2021. **Previous EC Comment:** • The aim is to study the biomarker as a prognostic tool. However, nowhere in the proposal, any reference to the prognosis of ALF has been made. • Why include a control group in this study? • No statistical plan has been given. • Flowchart is incomplete • Inclusion criteria: How will the fact that 'PT-INR >2 is of hepatic origin' will be ascertained? • Sec 5: Why include "institutionalized" subjects? • Sec 6: Why use direct identifiers? • Sec 7 is left blank, needs to be completed. • Sec10: If risk is not reasonable to anticipated benefit, why do the study? • Blank fields in benefit section need to be filled. ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***Second Recommendation of Primary reviewer:*** • If diagnosis of hepatic origin of deranged PT-INR cannot be made before admin 2 doses of Vit K, patient cannot be included in study before day 3. Day 1 sample becomes problematic. • Why control group? • Budget: Itemized budget is needed

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Statistical analysis:
- What results will be analysed I mean +/-SD
- Which groups will be compared?
- What is the role of predictive markers, what will they predict, how will the prediction be established and why do you want to study "PREDICTIVE markers" when the study title says "PROGNOSTIC markers"

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by PR. Recommendation of Primary reviewer:-

- Provisionally approved

EC Decision: Approved

Ref. code: 109th ECM IIA/P2

4. Clarification of research proposal entitled "***Inter-observer variation in assessing depth of invasion, pattern of invasion and extranodal extension as histological parameters in oral squamous cell carcinoma(OSCC)***" submitted by Dr. Sumaira Qayooom, Associate Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 369 dated 23rd March, 2022.

Sl. No.	Previous EC Comment	PI response
1.	This is a retrospective study. The resected specimen has already been collected.	In material and methods mentioned "already received "in the dept. of pathology.
2.	The variables and associated parameters have already been measured.	During routine reporting the mentioned variables have been measured by single pathologist. In this study more than one pathologist will review the same slides and remeasure the said parameters.
3.	The study proposes to assess the new variables. How shall this be done reliably and precisely? This is a real challenge.	This is not the problem as all these parameters can be assessed from already prepared slides and we do measure these variables routinely.
4.	The assessment is to be done by 5 pathologists. There will be 10 possible kappa coefficients. A	The number of observers has been reduced to 4. One-way

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		statistical test has to be performed on equality of these 10 coefficients. If the hypothesis is rejected, how these coefficients will be interpreted.	random effects ANOVA model will be fitted to test the equality of these 8 coefficients. Post -hoc analysis will also be done, if hypothesis is rejected. We can also go for Fleiss Kappa instead of Cohen Kappa.
	5.	The calculation of kappa coefficients shall depend on the type of data (categorical, ordinal or ratio). The sample size calculation and statistical analysis will depend on it .	In this study the outcome variable is continuous, ordinal and Nominal. Continuous data will be analyzed by ICC and ordinal/nominal data by Fleiss Kappa. Necessary Changes done in material/ methods section.
	6.	There are some paradoxes associated with Kappa associated with Kappa (i) prevalence effect (ii) bias effect. If these are present, then prevalence and bias adjusted kappa (PABAK) has to be calculated.	We don't expect bias effect in this study as all the observers will be blind to the clinical details, observation findings of other observers. However, the test analysis regrading prevalence effect and bias effect will also be done. If present, adjusted kappa (PABAK) will be calculated.
	7.	Involve statistician as co-investigator	Statistician added. Revised list of co- investigators attached.
	8.	Remove SR as co-investigator	SR removed. Revised list of co- investigators attached
	9.	The calculation of kappa coefficients shall depend on the type of data (categorical, ordinal or ratio).	In this study the outcome variable is continuous,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		The sample size calculation and statistical analysis will depend on it.	ordinal and Nominal. Continuous data will be analyzed by ICC and ordinal/nominal data by Fleiss Kappa. Necessary Changes done in material/ methods section.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by PR. Recommendation of Primary reviewer:-

- Provisionally approved

EC Decision: Approved

Ref. code: 110th ECM IIA/P19

5- Clarification of research proposal entitled "***Study of T regulatory cells, soluble cytotoxic T lymphocyte associated antigen-4 and transforming growth factor-β1 in patients of chronic myeloid leukemia on dasatinib therapy***" sponsored by ICMR submitted by Dr. Akanksha Singh, Ph.D Scholar 2019 under the guidance Prof. Rashmi Kushwaha, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.33/22 dated 11th January, 2022.

Previous EC Comment:

- The investigator plans to study biomarkers at the start of treatment and after 3 months in patients with CML on dasatinib.
- The consent does not mention how much amount of blood to be collected and how many times.
- The patient information in the consent [English] is not appropriate. Benefit should mention the direct or indirect benefits to the patient and then to the medical science.
- Hindi consent is a very poor quality translation, incorrect, complex and clumsy. It needs to be rewritten in simplified form by Hindi speaking person. Automatic translation by software is not appropriate.
- It need to be confirmed that the decision of giving a particular drug is not dependent on the trial and is independent and before considering the patient for the study.

The above comment forwarded to the P.I. was reviewed by Primary reviewer with her <u>Second opinion:-</u>

Second opinion	PI response
The consent still does not mention about the amount of blood collected in EDTA and plain vials. It does not mention that	2 ml blood will be collected in each EDTA and plain vial.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

only the patients on dasatinib therapy will be included.	Yes, only patients on dasatinib therapy will be included.
The Hindi consent is a very very poor translation, not meaningful and incorrect. Needs to be rewritten and not to be translate by online translated by online translation software's.	Attached separately

The above comment again forwarded to the P.I. was reviewed by Primary reviewer with her <u>third opinion:-</u>

Third opinion	PI response
The Hindi consent especially the objective has exactly opposite meaning as compared to the English version. To me it translates [means] that 'to do dasatinib therapy to measure T Cells' This is not correct.	Attached separately
The English and Hindi consents still do not clarify that only the patients who are on Dasatinib will be included.	Attached separately
The Methodology mentions all patients diagnosed a CML by blood and bone marrow test will be included in the study.	Only newly diagnosed CML patients on blood and bone marrow who will be later on given Dastinib Medicine by the Clinical Hematologist as part of their treatment regime will be included in the study and followed up for 3 months.
The automatic translation method should not be used but the person knowledgeable should make correct translation. It will be good if another person does back translation of Hindi consent to English and check.	Response not given by PI

The above comment again forwarded to the P.I. was reviewed by Primary reviewer with her <u>Third opinion:-</u>

- Kindly revise Hindi consent form in layman language

Reply has given by PI was forwarded to Dr. Shubha R Phadke vide this office letter no. 2363/Ethics/2022 dated 25th March, 2022.

EC Comment:

- Hindi translation of ICF needs correction so that it is meaningful.

EC Decision: Approval subject to modification

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 110th ECM II B-Ph.D/P1
6-	Clarification of research proposal entitled "***Efficacy of dietary intervention of flax seeds (Linum usitatissimum) on signs and symptoms associated with perimenopausal syndrome***" submitted by Ms. Rashmi Shrivastava, Ph.D Scholar, under the guidance Prof. Sunita Tiwari, Head, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.2491/PHY/21 dated 28th June, 2021. **Previous EC Comment:** • What is the budget and who is the sponsor • Is it alright to test herbal remedies by Allopathic Physicians • Section 5: Subject participation, type of subjects needs correction • Section 8: Elements need to check. If not ticked, mention reason CRF not included. • CRF not included **Methodology:** • There are no references. Has any such study ever been done? If not, how can you do a RCT as the first study? • It's a RCT: Mention all the elements of RCT • Inclusion criteria: Who have not used Vitamin from when to when? • Questionnaire: Where has the questionnaire been validated, in which language? • Sample size calculation: What is the effect size? ***The above comment again forwarded to the P.I. was reviewed by Primary reviewer with his <u>Second opinion:-</u>*** • Inclusion criteria: Define subject criteria according to Indian Menopause society. • Expected outcomes: shouldn't estrogen increase after intervention. • What are the expected outcome variables • What are the expected differences in outcomes • Validated Hindi translations of questionnaires are not provided • Why sample size has been calculated on basis of FSH and estrogen is being measured? ***The above comment again forwarded to the P.I. was reviewed by Primary reviewer with his <u>third opinion:-</u>*** The researcher has sent responses to the queries. However, the modified research proposal, with the clarifications incorporated within it has not been sent. The documents sent are incomplete and hence, cannot be reviewed. ***The above comment forwarded to the P.I., Reply has given by P.I. Recommendation of Primary reviewer:-*** • Provisionally approved **EC Decision:** Approved ***Ref. code: 110th ECM II B-Ph.D/P5***
7-	Clarification of research proposal entitled "***Impact of COVID 19 pandemic on paediatric musculoskeletal trauma patients admitted in a tertiary care centre***" submitted by Dr. Vikas Verma, Associate Professor, Department of Paediatric

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Orthopaedic, King George's Medical University, U.P., Lucknow vide letter no.1572/Paed.Ortho/2022 dated 8th February, 2022. **Previous EC Comment:** • Subject selection: Vulnerable subjects not checked • Privacy and confidentiality: Not checked • Does a consent form need to be filled? • Study design: It is not a cohort study? • Random selection: Needs to be elaborated ***The above comment forwarded to the P.I., Reply has given by P.I. Recommendation of Primary reviewer:-*** • Provisionally approved **EC Decision:** Approved ***Ref. code: 111th ECM IIA/P4***
8-	Clarification of research proposal entitled "***Establishing relationship of depression assessments with behavioral markers from digital phenotyping in Indian context***" submitted by Prof. Vivek Agarwal, Head, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1863/Psy/2022 dated 23rd December, 2021. **Previous EC Comment:** • Risks and benefit: If risk is not reasonable, why do the study? • How will random allocation take place? • What is the need for randomization? • Why 100 patients? • No statistical plan • Data sharing/protocol • Privacy protocol • What is the privacy protocol of the application what is the privacy patient data is not shared with third party. ***The above comment forwarded to the P.I. was reviewed by Primary reviewer with his second opinion:-***

Second opinion	PI response
The title of the study is not clear	Title is revised *"Assessment of Behavioral markers from digital Phenotyping in patients with Depression in Indian Context"*
Sponsor of the study is a private organization: Please attach MOU/Agreement documents.	It has been enclosed.
Details of industry are to be provided and	It has been corrected.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	can't be NA	
	If budget is NA, who pays for coupons and app subscription?	It has been corrected.
	All scales/Questionnaires are supposed to be self administered by patient: Attach validated translations in local language.	It has been attached
	Objectives 1: Can't be fulfilled by present research plan	It has been described.
	Objectives 2: What are the metrics of comparison in the 2 group-explain in methodology.	It has been described.

The above comment again forwarded to the P.I. was reviewed by Primary reviewer with his <u>third opinion:-</u>

- Please see the attached agreement. To me, as a layperson, it seems to be unusual, due to the following issues:
- There is no stamp of Institute/ University or letter Head.
- It seems unusual that a faculty is allowed to get into an agreement. I think that the University authorities are supposed to sign and stamp.
- The language is not of the legal kind as is used in agreements.
- Prof. Amita Jain's agreement which was attached had a different format.
- I would request you to kindly have a look into this.
- Please understand that I am not interested in stalling or discouraging research, but this does not look appropriate to me as this may cause you problem.

The above comment forwarded to the P.I., Reply has given by P.I. Recommendation of Primary reviewer:-

- Provisionally approved

EC Decision: Approved

Ref. code: 111th ECM IIA/P5

9- Clarification of research Protocol no.209682 entitled "***A phase 4, open-label, single arm, 24-week, phase 4 study to evaluate the safety and efficacy of mepolizumab 100 mg SC administered every 4 weeks in Indian participants aged≥18 years with severe eosinophilic asthma requiring oral corticosteroid treatment to maintain asthma control (PRISM)***" sponsored by Glaxo Smith Kline Pharmaceuticals Ltd. submitted by Dr. Ajay Kumar Verma, Professor Junior Grade, Department of Respiratory Medicine King George's Medical University, U.P., Lucknow, vide letter no. 2215/2021 dated 30th November, 2021.

Previous EC Comment:

- Insurance has to be reviewed. Blood samples cannot be send out of Country without approval of competent authority (that is ICMR).

The above comment forwarded to the P.I. was reviewed by the <u>Member-Secretary, IEC-</u>

- Provisionally approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

EC Decision: Approved

The following documents were reviewed it the Meeting:

Sr. No.	Document
1-	Study Protocol 1.1. Study Protocol Number 209682 [Amendment 03] dated 17 Mar 2021. 1.2. Sponsor Protocol signature Page [Amendment 03]. Investigator's Protocol Signature Page [Amendment 03].
2-	Study Reference Manual Study Reference Manual Version 1.0 dated 30 Nov 2020
3-	**Investigator Brochure** Mepolizumab (SB-240563) Version 19 dated 15-Dec-2020
4.	**Informed Consent Form:** 4.1. **English language** site specific ICF "India, Centre No. 244727 PI Name Dr. Ajay Kumar Verma ICF Version Number_02, Dated: 26 Mar 2021, based on Model ICF Version Number 04, Dated: 18 March 2021. 4.2. **Translated ICF:**Hindi language site specific ICF "India, Centre No. 244727 ICFTranslated from English to HindiVersion Number 02, Dated 09 Apr 2021." 4.3. **Back translated ICF:**Hindi to English translated ICF "India, Centre No. 244727 ICFTranslated from Hindi to EnglishVersion Number 02, Dated 10 Apr 2021. 4.4. Translation Certificate and Back Translation Certificate of ICF
5.	**Case Report Form** 5.1 CRF version 3.0 dated 30 Mar 2021.
6.	**Medical Problems/Medications taken Worksheets:** 1 **English language** Medical Problems/Medications taken Worksheets Version 1.0; dated 24 Mar 2021. 2 **Translated Medical Problems/Medications taken Worksheets:** Hindi

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		nguage Medical Problems/Medications taken Worksheets Translated from nglish to HindiVersion Number 01, Dated 27 Mar 2021. **3 Back translated Medical Problems/Medications taken Worksheets:** Hindi to English translated Medical Problems/Medications taken Worksheets Translated from Hindi to EnglishVersion Number 01, Dated 30 Mar 2021. **6.4** Translation and Back Translation Certificates of Medical Problems/Medications taken Worksheets.
	7.	**Work Productivity and Activity Impairment Questionnaire: General Health (WPAI-GH)** **7.1 English language** Work Productivity and Activity Impairment Questionnaire: General Health Version 2.0 **7.2 Hindi language** Work Productivity and Activity Impairment Questionnaire: General Health Version 2.0
	8.	**Asthma Control Questionnaire (ACQ-5)** **8.1English Language** ACQ-5 dated 30-Jan-2004. **8.2Hindi Language** ACQ-5 version of 01 Sep 2017 Linguistic Validation Certificate Asthma Control Questionnaire (ACQ) dated 13-Oct-2017
	9.	**Patient Card** **9.1English Language** Patient Card AM3+ Instruction for study GSK 209682 Version 1.0 dated 05 Nov 2019. **9.2Hindi Language** Patient Card AM3+ Instruction for study GSK 209682 Version 1.0 dated 04 Dec 2019. Translation Certificate of Patient Card Version 1.0 dated 04 Dec 2019.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

10.	**Vacation Card** 10.1 **English Language** Vacation card AM3 Version 4.0 dated 10-Sep-2012. 10.2 **Hindi Language** Vacation card AM3 Version 4.0 dated 25-Apr-2019. Translation Certificate of Vacation Card Version 4.0 dated 25 Apr 2019.
11.	**Instruction for use Peak flow Meter AM3 Option G+** **11.1 English Language** Instruction for use peak flow meter AM3 option G+ Version 3.0 dated 13 MAR 2017 for Firmware ≥9.40. **11.2 Hindi Language** Instruction for use peak flow meter AM3 option G+ Version 1.0 dated 28 Sep 2017 for Firmware ≥9.40. **11.3 Translation Certificate of** Instruction for use Peak flow Meter AM3 Option G+ Version 1.0 dated 28 Sep 2017.
12.	**Package Insert and Material Safety Data Sheet:** 12.1 Medication package insert Version NUC/PI/IN/2018/02 dated 17 July 2018 12.2 Material Safety Data Sheet Mepolizumab Version 8.0 dated 15 May 2018.
13.	**Laboratory Instruction Manual** 13.1 Laboratory Instruction Manual Version 1.0 dated 25 Jan 2021
14.	**Sponsor Clinical Trial Agreement** 14.1Sponsor Clinical Trial Agreement
15.	**Regulatory Documents** 15.1 DCGI Submission letter for protocol amendment 01 dated 14 Feb 2019. 15.2 DCGI Approval letter for protocol amendment 01 dated 15 Jan 2020 15.3 DCGI submission letter for protocol amendment 03 dated 24 Mar 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		CTRI Registration letter dated 12 Nov 2020.
	16.	**Certificate of Insurance** **16.1 Certificate of Insurance** – Policy Number P 0222200001/9999/100139 from 01-01-2022 to 31-12-2022
	17.	Site Specific Documents 17.1 Signed and dated PI's CV and 17.2 Signed and dated PI's Medical Registration Certificate 17.3 Investigator undertaking

Ref. code: 111th ECMIIC/P1

10-	Clarification of research proposal entitled **"*Pan India epidemiological, virological and genomic surveillance for Human influenza and COVID-19 through DHR-ICMR VRDL network*"** sponsored by DHR-ICMR submitted by Dr. Suruchi Shukla, Assistant Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1858/2022 dated 22nd January, 2022. **Previous EC Comment:** • Risk and benefits: • There **is** physical risk/discomfort • It is more than minimal risk • There is **no** benefit to the subject • What is the definition of "self collected specimens" • What is the definition of "sentinel sites" • Sample size: Will diagnosed SARS CoV-2 patients be enrolled also (this is with reference to statement: in addition to ILI definition……) • Broadened case definition: Tuberculosis can present with more than 2 criteria. Body ache, headache, feverishness are common symptoms of patients of various diseases: Malaria, Dengue, etc. Needs to be modified. • Children (2m-5yrs): is this the definition of ILI/SARI- please clarify • Oseltamivir: • Is it required to do a susceptibility test for osetamivir in patients with Influenza A before prescribing to patients? • Statistical plan and sample size justification is not given. • Patient information document: • 6. Will the sample be taken from only one of the sites or both. Consent form says 'or' but research protocol mentions 'and'. • Which report will be sent to the physician, when and for what purpose. How will it affect treatment protocol?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• 17. Which test results will be communicated? • Hindi version of the patient information sheet doesn't have a description of what will be done. • Many fields are missing, which are present in the English version. ***The above comment forwarded to the P.I., Reply has given by P.I. Recommendation of Primary reviewer:-*** • Provisionally approved **EC Decision:** Approved ***Ref. code: 112th ECM IIA/P1***
11-	Clarification of research proposal entitled "***Identification and characterization of extra-cellular proteins under antibiotic stress conditions in E.Coli strains from patients with UTI***" sponsored by Govt. Agency submitted by Dr. Sheetal Verma, Associate Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1430/21 dated 26th November, 2021. **Previous EC Comment:** • Objectives not properly enumerated, objective No. 5 is not clear. • Methodology details not provided. • Sample size not mentioned. ***The above comment forwarded to the P.I. was reviewed by Primary reviewer with his second opinion:-*** • Calculation/Justification not provided for his sample size. ***The above comment forwarded to the P.I. was reviewed by Member Secretary, IEC:*** • Provisionally approved **EC Decision:** Approved ***Ref. code: 112th ECM IIA/P7***
12-	Clarification of research Protocol no.CT-CE-CS-2020 entitled "***An open label, single arm, multi centre, phase IV clinical study to evaluate efficacy and safety of tropicamide 0.2mg/ml, phenylephrine HCI 3.1mg/ml, lidocaine HCI 10mg/ml intracameral injection in patients undergoing cataract surgery***" sponsored by Sunways India Pvt. Ltd. submitted by Dr. Pramod Kumar, Associate Professor, Department of Ophthalmology, King George's Medical University, U.P., Lucknow, vide letter no. OPH/241/2021 dated 20th September, 2021. **Previous EC Comment:** • Item [5 vi] – Vulnerable subjects - NOT MENTIONED • Item [5vii] – Special groups – Mentioned yes. Which special groups -clarify • Item [10 i] – Is the risk reasonable compared to the anticipated benefit? Answer is NO. Clarify. • Item [3 iv] – Is it an investigational new drug? Answer is YES. Which is the new drug?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Page 7 – What is FDC? [Fixed drug combination] – NOT GIVEN IN ABBREVATIONS
- Nowhere in the protocol the dose is used. Only the formulation of the FDC is given.
- PATIENT INFORMATION DOCUMENT
- In general, the information document is big and cluttered. It needs to be made simpler.
- Use of the word 'Intracameral' should be avoided. Information should be simple.
- What does phase IV trial means should be clarified. The previous data should be given in simple form. What is the other option has not been given. What is the use of this drug in the surgery has not been given.
- The information regarding research, study design and study procedure can be combined in two –three paragraphs. Results of previous studies done should be given. It should be clarified that the drug is marketed and it is a post-marketing survey as I understand by phase IV trial.
- Some other expert need to see the part related to financial compensation.
- Hindi translation should be simplified and easy speaking Hindi need to be used.
- With these modifications the trial can be approved.
- CTRI registration is pending;

The above comment forwarded to the P.I. was reviewed by Primary reviewer with her second opinion:-

- The investigator had written wrong answers to many questions INADVERTENTLY and now they have corrected. This is a matter of concern for FDC, there is no data as per the investigators. The drugs are approved. Does FDC need approval of DCGI?

The above comment again forwarded to the P.I. was reviewed by Primary reviewer with her third opinion:-

- Approve if Dr. Shally agrees with the definition of vulnerability.

The following documents were reviewed in the Meeting:

Sr. No.	Study Documents	Version No.	Dated
1.	Study Protocol	2.0	17-May-2021
2.	Informed Consent Document(Patient Information sheet)_English	2.0	17-May-2021
3.	Informed Consent Document(Patient Information sheet)_English to Hindi-Translation	2.0	04-Aug-2021
4.	Informed Consent Document(Patient Information sheet)_Hindi to English- Back translation	2.0	04-Aug-2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		5.	Informed Consent Document(Patient Information sheet)_Translation and Back translation Certificate (English to Hindi, Hindi to English)	NA	04-Aug-2021
		6.	Subject Reported VAS (Visual Analogue Scale) for Pain Assessment Annexure-II _English	2.0	17-May-2021
		7.	Subject Reported VAS (Visual Analogue Scale) for Pain Assessment Annexure-II _English to Hindi-Translation	2.0	04-Aug-2021
		8.	Subject Reported VAS (Visual Analogue Scale) for Pain Assessment Annexure-II _Hindi to English- Back translation	2.0	04-Aug-2021
		9.	Subject Reported VAS (Visual Analogue Scale) for Pain Assessment Annexure-II Translation and Back translation Certificate (English to Hindi, Hindi to English)	NA	04-Aug-2021
		10.	CRF	2.0	17-May-2021
		11.	Draft CTA	NA	NA
		12.	DCGI NOC	NA	23-Apr-2021
		13.	Investigator Undertaking_ Dr. Pramod Kumar	NA	24-May-2021
		14.	CV of Principal Investigator_Dr. Pramod Kumar	NA	24-May-2021
		15.	MRC of Principal Investigator_ Dr. Pramod Kumar	NA	24-May-2021
		16.	Protocol Signature Page_ Dr. Pramod Kumar	2.0	24-May-2021
	The Member-Secretary, IEC has Provisionally approved. **EC Decision:** Approved ***Ref. code: 112th ECMIIC/P1***				
13-	Clarification of research proposal entitled "***Study of post operative complications and their risk factors in women undergoing caesarean section in a tertiary care setup-A retrospective study***" submitted by Prof. Nisha Singh, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no.OG/2439/21 dated 1st January, 2022. **Previous EC Comment:** • Retrospective data collection. Waiver of consent requested. • Sample size is 86, seems too small. Please justify • Clarify if there are controls also. • What is the basis of sample size ***The above comment forwarded to the P.I. Reply was forwarded to Primary reviewer. Reply PR. :Provisionally approved.*** **ECDecision:** Approved				

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code:113th ECM IIA/P3

14- Clarification of research proposal entitled ***"To evaluate feasibility of incorporating simulation based training in the undergraduate teaching program of Obstetrics & Gynecology"*** submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no.GO/263/22 dated 4th February, 2022.

Previous EC Comment:	PI response
What is the sampling plan, including sample size?	**1. Sample Size Calculation** Sample size calculation for the study is done using the following formula for proportions: $n - \frac{z^2[p(1-p)]}{e^2}$ As reported by Iusia Alsuwaidi - The statistical analyses demonstrated that the rate of change among the group with simulation (23.46%) was significantly higher than the rate of change among the group without simulation Hence, for sample size calculation taking p=0.23, **e** is error allowance (at 5% allowance its value is 0.05), **z** is constant at a certain confidence level (its value at 95% confidence limit is 1.96). $n = 1.96^2 [(0.23*(1-0.23)/ (0.05)^2] = 272.13$ Accounting for missing observations or errors (10%) in reporting/collecting observations the sample size is rounded off to a total = 245 **students in the study.** **Reference** Alsuwaidi L, Kristensen J, Hk A, Al Heialy S. Use of simulation in teaching haematological aspects to undergraduate medical students improves student's knowledge related to the taught theoretical underpinnings. BMC Med Educ. 2021 May

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		12; 21 (1):271.
	What is the research hypothesis? It should be properly defined in terms of the population parameter after identifying the study variables?	Null hypothesis – Simulation based training has no advantage over traditional teaching for undergraduate students in Obst & Gyn.
	The instrument (questionnaire) used is Google form. It is not attached. Is the validity and reliability of instrument done?	The questionnaire is being attached. It has been validated by taking opinion from peers
	Define the parameters used for assessing the usefulness.	Parameters used for assessing usefulness are attached as feedback form.

The above comment forwarded to the P.I. was reviewed by Primary reviewer.

- Provisionally approved

EC Decision: Approved

Ref. code:113th ECM IIA/P20

15- Clarification of research proposal entitled ***"Impact of 3D printed bolus on efficacy of Radiotherapy: moving from one-size-fits-all to patient specific approach"*** submitted by Dr. Teerthraj Verma, Additional Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no.899/RT/2021 dated 9th November, 2021.

Previous EC Decision: Pending

The Primary reviewer has given his reply.

Primary reviewer recommendation:

- A departmental committee member is a Co-Investigator: potential conflict of interest.
- Subject participation: 20 months. Will all subjects be followed up for 20 months?
- Privacy and confidentiality: incomplete.
- Who will obtain consent: not filled.
- Section 10 i, ii, not filled
- Section 11: not filled
- Section 12: not filled
- Justification: Last sentence doesn't make much sense?
- What material will be used for 3D printing? How do you plan to evaluate its properties?
- Please elaborate how each 2D and 3D bolus will act as its own control?
- The title is not commensurate with the methodology. It appears that this is a dosimetric study, not an efficacy study.
- Outcome measures are vague and not clearly understandable.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- What statistical tests will be used? And what "other tools" will be used?
- Budget break up is not provided.

The above comment forwarded to the P.I. Response has given by PI. which is forwarded to the Primary reviewer:

EC Decision: Approved

Ref. code:113th ECM IIA/P2

16. Clarification of research proposal entitled ***"Skin and soft tissue necrotizing infections in the intensive care unit: a prospective multi-national cohort study: SKIN-ICU"*** submitted by Dr. Sai Saran, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/47/2022 dated 18th January, 2022.

Sl. No.	Previous EC Comment	PI Response
1.	Sec:5 Duration of subject participation is not mentioned vulnerable subjects?	6 months
2.	Sec 6: Why use direct identifiers? Confidential data handling : Incomplete information	By mistake, Direct identifiers were selected. It was changed to indirect identifiers.
3.	Sec 7: Incomplete	Completed
4.	Sec 8: Sponsor of the study is not checked	Checked
5.	Sec 10: Risk benefits : not filled	Filled
6.	Sec 11: Details of DMSB not given	There is no mention of DMSB, as it is observational study only no adverse effects are anticipated. If any such happens it will be reported to IEC
7.	What A/Es are expected?	As it is observational study only no adverse effects are anticipated. If any such happens it will be reported to IEC
8.	English consent point 12: Incomplete	Completed
9.	Sponsor information is different in Consent form and protocol	Revised
10.	Is there a later version of the protocol	The latest version is being attached as an enclosure . It is available on CTRI :

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		ClinicalTrials.gov Identifier: NCT05116956
11.	Why a surgeon is not part of the study?	Included as per your suggestions

The above comment forwarded to the P.I. Response has given by PI. was reviewed by PR.

***Recommendation of PR*:** Provisionally approved

EC Decision: Approved

Ref. code:113th ECM IIA/P22

17- Clarification of research proposal entitled ***"Multi centric community-based study of prevalence, KAP (Knowledge Attitude & Practice) for prevention first aid of burns, quality of life and out of pocket expenditure of burn injury and evaluation of IEC interventions"*** sponsored by ICMR New Delhi submitted by Prof. Brijesh Mishra, Head, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no.57/22 dated 17th January, 2022.

Sl. No.	Previous EC Comment	PI response
01	Budget amount and break up for KGMU PI	Rs. 7568440.00 Page number- 57 to 59
02	Sec.5 incomplete	Completed Page number- 16
03	Sec. 6 Why direct identify	Community based study of selected areas can be called indirect identifieRS
04	What is the direct benefit to the subject 2	Awareness
05	It there is no plan for A/E reporting what he role of DSMR?-	Its in epidemiological studies is form of survey. No chance of adverse events.
06	Detail of pre validated questioner?	Page number- 30 to 53
07	Methodology last sentence Following details what area these?	Page number- 23 to 25
08	Data Collection tools not given	Page number- 21 detailed Questionnaire.
09	Annexure 1 not attached	Corrected & attached
10	IEC implementation: Details	KAP analysis & report KAP

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			analysis at for 3 months
	11	KAP analysis Post IEC: Define	From General Page-17 all resident form same community
	12	Sample size calculation:	Page number- 16- 340x8
	13	Statistical analysis?	Data will be process at ABVIMS (RML New Delhi) Central PI wil decide

The above comment forwarded to the P.I. Response has given by PI. was reviewed by PR.

Recommendation of PR: Provisionally approved

EC Decision: Approved

Ref. code:113th ECM IIA/P23

18- Clarification of research proposal entitled ***"Epidemiological survey of Mucormycosis"*** submitted by Prof. Samir Misra, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no.TS/96/2022 dated 8th February, 2022.

Previous EC Comment:	**PI response**
Scientific Review Committee document not given	Scientific review Committee document is attached
Work distribution of PI/Co-PI not mentioned	Work distribution of PI/Co-PI is attached
Sample size calculation not given	Sample size calculation is attached

The above comment forwarded to the P.I. was reviewed by the Primary reviewer:

- Provisionally approved

EC Decision: Approved

Ref. code:113th ECM IIA/P24

19- Clarification of research Protocol no.LIB003-004 entitled ***"Randomized, double-blind, placebo-controlled, phase 3 study of evaluate the long-term efficacy and safety of LIB003 in heterozygous familial hypercholesterolemia patients on stable lipid-lowering therapy requiring additional low-density lipoprotein cholesterol reduction (LI Berate-HeFH)"*** sponsored by M/s LIB Tharapestics, LLC submitted by Dr. Akshyaya Pradhan, Professor Junior Grade, Department of Cardiology, King George's

Medical University, U.P., Lucknow, vide letter no.2063/Cardio/Res/22 dated 1st February, 2022.

Previous EC Comment:	PI response
Compensation amount for visit etc. are not mentioned. Kindly justify why such information is not shared with EC?	Please find attached updated main ICF with the prorated compensation amount information for reference.

The following documents were reviewed in the Meeting:-

Sr. No	Document	Version	Version Date
1	Study Protocol	1.0	21 October 2020
2	Investigator Brochure (IB)	6.0	25 June 2021
3	Principal Investigator undertaking	N/A	18 June2021
4	Principal Investigator CV	N/A	N/A
5	Principal Investigator MRC	N/A	N/A
6	Principal Investigator GCP certificate valid till 20Mar2023	N/A	N/A
7	Principal Investigator PSP	1.0	21 October 2020
9	Participant Information Sheet and Informed Consent Form in **Hindi** (translation dated 11Aug2021) with translation certificate	Master :1.0 India: 1.0 Site-specific: 1.0	Master:20 October 2020 India: 17Jun2021 Site-specific: 06Aug2021
10	Participant Information Sheet and Informed Consent Form: Back translation from **Hindito English** (Back-translation dated 11Aug2021) with certificate	Master :1.0 India: 1.0 Site-specific: 1.0	Master:20 October 2020 India: 17Jun2021 Site-specific: 06Aug2021
11	**Pregnant Partner Information And Informed Consent Form in English**	Master :1.0 India: 1.0 Site-specific: 1.0	Master:09 April2021 India: 17Jun2021 Site-specific: 06Aug2021
12	Pregnant Partner Information And Informed Consent Form in **Hindi** (translation dated 11Aug2021) with translation certificate	Master :1.0 India: 1.0 Site-specific:	Master:09 April2021 India: 17Jun2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			1.0	Site-specific: 06Aug2021
	13	Pregnant Partner Information And Informed Consent Form:Back translation from **Hindito English** (Back-translation dated 11Aug2021) with certificate	Master :1.0 India: 1.0 Site-specific: 1.0	Master:09 April2021 India: 17Jun2021 Site-specific: 06Aug2021
	14	**Home nursing Informed Consent Form in English**	Master :1.0 India: 1.0 Site-specific: 1.0	Master:15September 2020 India: 17Jun2021 Site-specific: 06Aug2021
	15	Home nursing Informed Consent Form in **Hindi** (translation dated 11Aug2021) with translation certificate	Master :1.0 India: 1.0 Site-specific: 1.0	Master:15September 2020 India: 17Jun2021 Site-specific: 06Aug2021
	16	Home nursing Informed Consent Form:Back translation from **Hindito English** (Back-translation dated 11Aug2021) with certificate	Master :1.0 India: 1.0 Site-specific: 1.0	Master:15September 2020 India: 17Jun2021 Site-specific: 06Aug2021
	17	**Informed Consent Form For Audio-Video Recording of Informed Consent Process in English**	India: 1.0	India: 17Jun2021
	18	Informed Consent Form For Audio-Video Recording of Informed Consent Process in **Hindi** (translation dated 11Aug2021) with translation certificate	India: 1.0	India: 17Jun2021
	19	Informed Consent Form For Audio-Video Recording of Informed Consent Process : Back translation from **Hindito English** (Back-translation dated 11Aug2021) with certificate	India: 1.0	India: 17Jun2021
	20	**Patient Emergency Card in English**	2.0	15March2021
	21	Patient Emergency Card in**Hindi** (translation dated 29Jun2021) with translation certificate	2.0	15March2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	22	Patient Emergency Card : Back translation from **Hindito English** (Back-translation dated 29Jun2021) with certificate	2.0	15March2021
	23	**Patient Instructions in English**	1.0	19October2020
	24	Patient Instructionsin **Hindi** (translation dated 29Jun2021) with translation certificate	1.0	19October2020
	25	Patient Instructions: Back translation from **Hindito English** (Back-translation dated 29Jun2021) with certificate	1.0	19October2020
	26	**Draft CTA template**	1	N/A
	27	**CRF specs**	2.0	29Mar2021
	28	**Insurance certificate_4067-LIB003-004_13 May 2021 to 31 March 2022**	N/A	17May2021

The above comment forwarded to the P.I. was reviewed by the Primary reviewer:

- Provisionally approved

EC Decision: Approved

Ref. code:113th ECMIIC/P2

20- Clarification of research Protocol no.ALK21-ASP1 entitled "***A multicentre, randomized, double-blind, double dummy, phase III study to compare safety and efficacy of fixed dose combination of Aspirin 150mg and Pantoprazole 20mg versus Aspitin 150mg alone for the prevention of gastroduodenal mucosal damage in patients taking Aspirin for secondary prevention of cardiovascular disease or cerebrovascular disease***" sponsored by M/s Alkem Laboratories Pvt. Ltd. submitted by Dr. Ayush Shukla, Assistant Professor, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.2036/Cardio/Res/22 dated 24th January, 2022.

Sl.No.	Previous EC Comment	PI response
1	Only CTA document is attached but without any names or signatures.	Partially executed CTA sent to your site on 05 Jan 2022. Updated signed copy of CTA re-sent on 13 Jan 2022.
2.	CTRI Number is pending	CTRI/2021/11/037831 (CTRI registration letter attached)
3.	No Hindi version of informed consent is attached while English version of consent form neither mentions the name of investigator not	Site specific ICFs have been shared with your site on 05 Jan 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	his contact number. These need revision.	
4.	It is noted that date of DCGI approval is 7th Oct 2019 and since its validity is usually 2 years the PI needs to ensure if it still stand valid (since the duration is not mentioned in the approval letter).	As per DCGI approval letter dated 07/Oct/2019, DCGI recommended the sponsor to present result of BE study before the committee before initiation of clinical trial. As per SEC meeting minutes (90th held on 07 Sep 2021 and 08 Nov 2021) at CDSCO HQ, New Delhi – "The firm (Alkem Laboratories) presented the results of Bioequivalence (BE) study report before the committee. After detailed deliberation, the committee recommended for initiation of the Phase-III Clinical trial for which permission has already been granted by CDSCO." on 07/Oct/2019.

The following documents were reviewed in the Meeting:-

Sr. No.	Document	Version No. & Date
1-	Clinical Study Protocol	Version 1.0 Dated 03Dec2018
2-	Summary of Product Characteristic (SmPC) of Aspirin 75mg tablet	Dated 01-Mar-2021
3-	Summary of Product Characteristic(SmPC) of Pantoprazole 20mg	Dated 18-Nov-2020
4-	Patient Informed Consent Form - English	Version 1.0 Dated 26-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Dec-2018
5-	Patient Informed Consent Form - Hindi language along with translation certificate	Version 1.0 Dated 11/Sep/2021
6-	Patient Informed Consent Form – Hindi to English (Back Translation) along with back translation certificate.	Version 1.0 Dated 14/Sep/2021
7-	Patient Diary- English	Version 2.0 dated 03/Sep/2021
8-	Patient Diary _ Hindi language along with translation certificate	Version 2.0 Dated 11/Sep/2021
9-	Patient Diary _ Back translated Hindi to English language along with translation certificate	Version 2.0 Dated 14/Sep/2021
10-	DCGI Approval	Dated 07/Oct/2019
11-	Recommendation of SEC (Cardio & renal): FDC/MA/19/000025 Pantoprazole Sodium + Aspirin20mg/20mg + (81mg/150mg)Capsules	Dated: 07-09-2021 and 08-09-21
12-	Declaration regarding Study Insurance	Dated 17/Sep/2021
13-	Declaration regarding CTRI Registration	Dated 17/Sep/2021
14-	Declaration regarding Clinical Trial Agreement	Dated 17/Sep/2021
15-	Declaration regarding CRF	Dated 17/Sep/2021
16-	Protocol Signature Page (Version 1.0, 03/Dec/2018)	Dated :22/Sep/2021
17-	Signed Investigator's undertaking	Dated :22/Sep/2021
18-	Signed CV & MRC of Principal Investigator	Dated :02/Jun/2021

The above comment forwarded to the P.I. was reviewed by the Primary reviewer:

- Provisionally approved

EC Decision: Approved

Ref. code:113th ECMIIC/P7

21- Clarification of research proposal ***"A study to determine the outcome of patients with dysnatremia undergoing slow low efficiency dialysis (SLED) in ICU"*** submitted by Dr. Sai Saran, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/2022/0147 dated 7th March, 2022.

Sl.No.	Previous EC Comment	PI response
1	No significant ethical issues	Thanks
2	No patient info brochure in Hindi	Attached (page 12-14)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	3	As it is a non-funded project it should be clearly mentioned that testing done is a part of patient management	Line added in the methodology
	4	The answer in the submission for "Vulnerable subjects" is "no", But there will be elderly and seriously ill patients, so it should be 'Yes'	Changed accordingly

The above comments forwarded to the P.R. vide this office letter no. 2312/Ethics/2022 dated 10th March, 2022.
The first reminder forwarded to the PR by email dated 21st March, 2022.

EC Decision: Approved

Ref. code:114th ECMIIA/P4

22- Clarification of research proposal entitled "***A survey-based study of the reasons behind regularity and irregularity in attendance of college-going Indian medical students: A post COVID-19 pandemic led lockdown scenario***" submitted by Dr. Sarvesh Singh, Professor Junior Grade, Department of Pharmacology, King George's Medical University, U.P., Lucknow vide letter no. 217Pharma/22 dated 8th March, 2022.

Previous EC Comment	PI response
Modify the topic	Irregularity in Attendance of MBBS students of KGMU:A COVID Pandemic Lockdown study.
Revise proposal	Attached

The above comment forwarded to the P.I. was reviewed by the Primary reviewer:

- Provisionally approved

EC Decision: Approved

Ref. code: 114th ECM IIA/P11

23- Clarification of research proposal entitled "***3D printing technology: A novel approach of developing patient specific devices in radiotherapy treatment of various tumors***" submitted by Dr. Shraddha Srivastava, Associate Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 829/RT/21 dated 16th October, 2021.

Sl. No.	Previous EC Comment	PI Response
1	3D painting is not a novel approach. Will the material allow to pass through?	• It is true that 3D printing is not a novel approach. However, its use in radiotherapy is very limited in India. Hardly any center in India is using this technique for patient treatment in radiotherapy department. Therefore, the application of 3D

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			printed devices in our department will be beneficial for patient. • Yes, the material used for preparation of patient-specific devices like bolus and surface mould in radiotherapy will allow the radiation to pass though.
	2-	Elaborate more on methodology cost of the devise should be passed to the patient.	• As suggested, the modifications in the methodology have been made and added in the revised proposal. • The cost of device will be around 500 INR per patient for acrylonitrile butadiene styrene (ABS) and polylactic acid (PLA) printing materials.

The above comments forwarded to the Primary reviewer vide this office letter no. 2349/Ethics/2022 dated 22nd March, 2022.

- Provisionally approved

EC Decision: Approved

Ref. code: 114thECM IIA/P12

24- Clarification of research proposal entitled "***Capacity building and strengthening of hospital infection control to detect and prevent antimicrobial resistance in India***" submitted by Prof. Vimala Venkatesh, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1710/21 dated 28th December, 2021.

Sl.No.	Previous EC Comment	PI response
1	This is second cycle of the project funded by CDC USA to AIIMS New Delhi where in KGMU is A collaborating center. No EC approval of the first cycle is enclosed herewith. It has to be ensured that the first cycle had been approved.	EC approval of 1st cycle is enclosed as appendix 1.
2.	The budget for KGMU needs to be indicated in INR and its spilt needs to be submitted	Budget for KGMU is enclosed as appendix 2.
3.	The PI has requested for consent waiver and since this is an epidemiologic sort of the data collection, this request can be ethically considered	Thank you for the comment
4.	However it would be appropriate if the PI can submit the short summary of work that will be	Short summary of work at KGMU is enclosed as

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	undertaken at KGMU in the form of flow chart	appendix 3
5.	Being a project of national importance this can be otherwise approved ethically	Thank you for the comment
6.	Submit a copy of EC of AIIMS for this Cycle	Copy of EC of AIIMS for this cycle is enclosed as appendix 4.

The above responses forwarded to the Dr. Anupam Mishra vide this office letter no. 2372/Ethics/2022 dated 28th March, 2022-

Recommendation of PR: Provisionally approved

- Provisionally approved

EC Decision: Approved

Ref. code: 114thECM IIA/P15

25- Clarification of research proposal entitled "***Decoding central nervous system microenvironment following JEV infection: a Neuroinflammation perspective***" sponsored by DBT New Delhi submitted by Ms. Anjali Singh, Ph.D Scholar 2019 under the guidance Dr. Himanshu Dandu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 589/MED/22 dated 23rd March, 2022.

Previous EC Comment	PI Response
Hypothesis	We hypothesize that Microglia/macrophages are the key players in the neuroinflammation and functional outcome following Japanese encephalitis viral infection. Understanding the key factors (genetic/metabolic) including microparticle mediated signaling pathways involved in microglia/macrophages activation can be beneficial for modulation of JE virus pathogenesis and functional outcome.
Sample size	Assuming 35% relative error (equivalent margin of error =9.72%) in Japanese Encephalitis of 27.7% prevalence , at minimum two-sided 95% confidence interval estimated sample size came out to be 82. Sample size was estimated using software Power analysis and sample size version -16 (PASS-16, NCSS, LLC, USA).

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Finally, in this study, we will target at least 85 Acute Encephalitis syndrome (AES) confirmed cases.
	Methodology	**Study subjects** The present study will be conducted on patients having JEV infection, acute encephalitis syndrome (AES) and other neurological diseases admitted in Department of Medicine, KGMU, Lucknow. **Inclusion and exclusion criteria:** **(A) Inclusion criteria:** Persons having Japanese Encephalitis will include in this study. **(B) Exclusion criteria** Persons having following problem will be excluded from this study • Severe malnourishment • Acute infectious disease • Ear infection • Tuberculosis • Heart, liver and kidney problems • Allergy • Person treated with any immunosuppressive therapy **Sample Collection:-** ➢ Blood samples (4 ml) will be collected in EDTA vials from JE-AES, Non-JE-AES, and other neurological diseases patients for genetic analysis and microparticle characterization. ➢ CSF samples (100µl) will be collected from the JE-AES, Non-JE AES and other neurological disease patients for metabolic profiling. All samples will be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		centrifuged at 4°C, 3000rpm for 10 minutes. Then protease inhibitors will be added in samples and will be stored at -80°C for further use. **Methods:** Patients of either sex of all age group will be selected for this study. **Specific methods for achieving objective-1: To determine the genetic changes involve in immune cell activation in JE-AES, Non-JE-AES and other neurological diseases patients.** **DNA extraction:** DNA will be extracted from Blood samples by Qiagen DNA extraction kit according to manufacturer's instruction and stored at −20 °C. DNA concentration and quality will be determined using the NanoDrop 2000 spectrophotometer (Thermo fisher). **Genetic analysis:** Genetic analysis such as PCR-RFLP/qPCR will be performed for inflammatory markers/neuronal cell death (such as HMGB1, TNFα, ubiquitin etc.) and Iron regulatory gene biomarkers such as Transferrin in the blood of (1) Japanese encephalitis; (2) Non-JE AES and (3) other neurological diseases patients. **PCR-RFLP:** Polymerase chain reaction -restriction fragment length polymorphism (PCR-RFLP) method will be used to investigate Gene polymorphism of inflammatory markers/neuronal cell death (such as HMGB1, TNFα, ubiquitin etc.) and Iron regulatory gene biomarkers such as Transferrin

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		in the blood. SNPs will be amplified by PCR using the designed PCR primers. Amplified PCR product will be visualized in agarose gel electrophoresis with ethidium bromide (EtBr) staining and digested with specific restriction enzyme (Fermentas, New England Biolabs) at optimum condition. The digested fragments of DNA will be visualized on 2% agarose gel and categorized in three genotypes: Wild type, Heterozygous and Homozygous. **Measurement of mRNA level of genes blood samples:** **RNA extraction:** Total RNA will be isolated by RNAiso Plus Kit (TaKaRa Biotechnology Co., Dalian, China.),from blood of patients. TriZol will be added in blood sample and phase separation will be done using chloroform by centrifugation at 12,000g for 15minute, 4 °C. Upper layer will be collected and mixed in equal volume of Isoproponol. Pellet recovered by centrifugation at 12,000g for 10minute, 4 °C. RNA concentration and quality will be determined using the NanoDrop 2000 spectrophotometer (Thermo fisher). **Real-time quantitative PCR:** RNA will be converted to cDNA using Verso cDNA RT kit (Thermo Scientific, Pittsburg, PA, USA); the protocols used will be according to the manufacturer's instructions. Real-time PCR will be performed using an ABI 7500 Sequence Detection System (Applied Biosystems) in the presence of SYBR Green. Standard PCR conditions will be used as prescribed in SYBR Green I core reagent protocol. PCR will be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		performed using nucleotide primers of inflammatory markers/neuronal cell death (such as HMGB1, TNFα, ubiquitin etc.) and Iron regulatory gene biomarkers such as Transferrin (Integrated DNA Technology, Coralville, IA, USA). Relative expression level will be normalized by GAPDH expression. Comparisons of gene expression will be calculated by 2−ΔCt comparative Ct method. **Specific methods for achieving objective –2: To study metabolic profile for inflammatory associated protein (such as, Glutamate) and lipid in JE-AES, Non-JE-AES and other neurological diseases patients.** Metabolites analysis such as LC/MS will be performed for inflammatory associated protein (such as, Glutamate) and lipid in the CSF of (1) Japanese encephalitis; (2) Non-JE AES and (3) other neurological diseases patients. **LC/MS:** Extraction and quantification of PLs will be performed by standard protocol of LC/MS. Briefly; the collected samples will be mixed and sonicated with a 10-fold volume of methanol and an internal standard. After centrifugation at 21,500 × g, the resulting supernatant will be recovered and will be processed for LC/MS analysis. 20 µL of methanol extract will be separate using columns and a gradient of solvent A (5 mM ammonium formate in water) and solvent B (5 mM ammonium formate in 95% [v/v] acetonitrile). Elution will be sequentially ionized and the parent ion and fragment ion will be monitored in the positive mode using a

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Quantum Ultra Triple Quadrupole Mass Spectrometer (Thermo Fisher Scientific). **Specific methods for achieving objective –3: To characterized blood microparticle in JE-AES, Non-JE-AES and other neurological diseases patients.** Blood microparticle will be isolated from (1) Japanese encephalitis; (2) Non-JE AES and (3) other neurological diseases by using differential centrifugation. **Blood microparticle Isolation:** Plasma will be isolated from blood and centrifuge at 1500×g for 5minutes, supernatant will be collected and again centrifuge at 15000×g for 30minutes. After that, Supernatant will be collected and ultracentrifuge at 100,000×g for 60minutes and pellet will be resuspended in PBS. Isolated microparticles characterized by using the technique like Nanoparticle tracking Analysis and electron microscope. **Nanoparticle tracking Analysis:** Size distribution and concentration of EVs will be visualized using Nanosight (NTA 3.2 Dev Build 3.2.16) equipped with sCMOS. Briefly, samples in PBS will be thawed to room temperature and after 30s vortex injected into sample chamber. Three replicates of analysis by 60s for each sample will be captured at 25 °C and processed using NTA software **Electron microscope:** Blood microparticle size and structure will be further analysed by using Scanning Electron Microscope (SEM).

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Statistical Analysis	Statistical software SPSS (version 20.0, Chicago, LA) and GraphPad Prism 5 will be used for statistical analysis. Hardy-Weinberg equilibrium (HWE) for genotypes, comparisons between the groups of study populations and clinical symptoms were analyzed by chi-squared test. All continuous variables will be expressed as mean ± standard deviation whereas; percentages will be used to express categorical variables.

The above comments forwarded to the PI were reviewed by Primary reviewer.
Recommendation of Primary reviewer:

- Provisionally approved

EC Decision: Approved

Ref. code: 114th ECM II B-Ph.D/P2

26 Clarification of research protocol no.Vedolizumab-4020 entitled "***A multicentre, single-arm, open-label, phase 4 study to evaluate the safety and efficacy of vedolizumab in Indian patients with ulcerative colitis and crohn's disease***" sponsored by M/s Takeda Pharmaceutical India Pvt. Ltd. submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow, vide letter no. 591/MED/22 dated 21st March, 2022.

Previous EC Comment	PI Responses
Comment 1: Scientific review committee approval from the department not submitted	Scientific review committee approval from the department has already been submitted with the Initial EC submission dossier (In both hard and soft copies format).
Comment 2: IEC form with study detail not submitted.	IEC form with study detail has already been submitted with the Initial EC submission dossier (In both hard and soft copies format).
Comment 3: DCGI approval and CTRI registration papers do not have mentioned of KGMU site.	DCGI site addition notification letter along with the CTRI registration letter with the site detail has been attached.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Comment 4: Insurance policy does not mention KGMU site.	Insurance policy with the site details has been attached.
Legal Opinion	
In clause 20 of CTA the executive jurisdiction may be of Lucknow In clause 26 the seat of Arbitration may be Lucknow. Moreover, it is highlighted that the MCIA rules are being referred for arbitration in this case.	As per the opinion from the Legal expert, changes in both the clause 20 and 26 of the CTA have been made and the copy of the changes made have been attached. And will be submitted in the corrected form in the final CTA for approval.

The above responses forwarded to the Primary reviewer was reviewed:
Recommendation of Primary reviewer: Provisionally approved
Legal opinion: Approved
The following documents were reviewed in the Meeting:-

Sr. No.	Document
1-	**Study Protocol** 1.3. Study Protocol Number 209682 [Amendment 03] dated 17 Mar 2021. 1.4. Sponsor Protocol signature Page [Amendment 03]. Investigator's Protocol Signature Page [Amendment 03].
2-	**Study Reference Manual** 2.1 Study Reference Manual Version 1.0 dated 30 Nov 2020
3-	**Investigator Brochure** 3.1 Mepolizumab (SB-240563) Version 19 dated 15-Dec-2020
4-	**Informed Consent Form:** 4.1. **English language** site specific ICF "India, Centre No. 244727 PI Name Dr. Ajay Kumar Verma ICF Version Number_02, Dated: 26 Mar 2021, based on Model ICF Version Number 04, Dated: 18 March 2021. 4.2. **Translated ICF:**Hindi language site specific ICF "India, Centre

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		No. 244727 ICFTranslated from English to HindiVersion Number 02, Dated 09 Apr 2021." 4.3. **Back translated ICF:**Hindi to English translated ICF "India, Centre No. 244727 ICFTranslated from Hindi to EnglishVersion Number 02, Dated 10 Apr 2021. 4.4. Translation Certificate and Back Translation Certificate of ICF
	5-	**Case Report Form** 5.1 CRF version 3.0 dated 30 Mar 2021.
	6-	**Medical Problems/Medications taken Worksheets:** **6.1 English language** Medical Problems/Medications taken Worksheets Version 1.0; dated 24 Mar 2021. **6.2 Translated Medical Problems/Medications taken Worksheets:** Hindi language Medical Problems/Medications taken Worksheets Translated from English to HindiVersion Number 01, Dated 27 Mar 2021. **6.3 Back translated Medical Problems/Medications taken Worksheets:** Hindi to English translated Medical Problems/Medications taken Worksheets Translated from Hindi to EnglishVersion Number 01, Dated 30 Mar 2021. **6.4** Translation and Back Translation Certificates ofMedical Problems/Medications taken Worksheets.
	7-	**Work Productivity and Activity Impairment Questionnaire:General Health (WPAI-GH)** **7.1 English language** Work Productivity and Activity Impairment Questionnaire: General Health Version 2.0 **7.2 Hindi language** Work Productivity and Activity Impairment Questionnaire: General Health Version 2.0
	8-	**Asthma Control Questionnaire (ACQ-5)** **8.1 English Language** ACQ-5 dated 30-Jan-2004. **8.2 Hindi Language** ACQ-5 version of 01 Sep 2017 **8.3** Linguistic Validation Certificate Asthma Control Questionnaire (ACQ) dated 13-Oct-2017
	9-	**Patient Card** **9.1 English Language** Patient Card AM3+ Instruction for study GSK 209682 Version 1.0 dated 05 Nov 2019. **9.2 Hindi Language** Patient Card AM3+ Instruction for study GSK

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		209682 Version 1.0 dated 04 Dec 2019. **9.3** Translation Certificate of Patient Card Version 1.0 dated 04 Dec 2019.
	10-	**Vacation Card** 10.3 **English Language** Vacation card AM3 Version 4.0 dated 10-Sep-2012. 10.4 **Hindi Language** Vacation card AM3 Version 4.0 dated 25-Apr-2019. Translation Certificate of Vacation Card Version 4.0 dated 25 Apr 2019.
	11-	**Instruction for use Peak flow Meter AM3 Option G+** **11.1 English Language** Instruction for use peak flow meter AM3 option G+ Version 3.0 dated 13 MAR 2017 for Firmware ≥9.40. **11.2 Hindi Language** Instruction for use peak flow meter AM3 option G+ Version 1.0 dated 28 Sep 2017 for Firmware ≥9.40. **11.3 Translation Certificate of** Instruction for use Peak flow Meter AM3 Option G+ Version 1.0 dated 28 Sep 2017.
	12-	**Package Insert and Material Safety Data Sheet:** 12.1 Medication package insert Version NUC/PI/IN/2018/02 dated 17 July 2018 12.2 Material Safety Data Sheet Mepolizumab Version 8.0 dated 15 May 2018.
	13-	**Laboratory Instruction Manual** 13.1 Laboratory Instruction Manual Version 1.0 dated 25 Jan 2021
	14-	**Sponsor Clinical Trial Agreement** 14.1 Sponsor Clinical Trial Agreement
	15-	**Regulatory Documents** 15.1 DCGI Submission letter for protocol amendment 01 dated 14 Feb 2019. 15.2 DCGI Approval letter for protocol amendment 01 dated 15 Jan 2020 15.3 DCGI submission letter for protocol amendment 03 dated 24 Mar 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		15.4 CTRI Registration letter dated 12 Nov 2020.
	16-	**Certificate of Insurance** **16.1 Certificate of Insurance** – Policy Number P 0222200001/9999/100139 from 01-01-2022 to 31-12-2022
	17-	Site Specific Documents 17.1 Signed and dated PI's CV and 17.2 Signed and dated PI's Medical Registration Certificate 17.3 Investigator undertaking

EC Decision: Approval subject to fulfillment and administrative formalities

Ref. code: 114th ECMIIC/P1

27- Clarification of research protocol no. CLNA043A12202 entitled "***A 5-year, randomized, double-blind, placebo-controlled, multi-center study assessing the efficacy, safety, and tolerability of intra-articular regimens of LNA043 versus placebo in patients with symptomatic knee osteoarthritis (ONWARDS)*** sponsored by M/s Novartis Healthcare Pvt. Ltd. submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow, vide letter no.1893/OS/22 dated 16th March, 2022.

Sl. No.	Previous EC Comment	PI response
1.	No information about genetic testing has been provided in the consent [optional genetic testing] and none in the protocol. Specify which.	*The details of genetic testing provided in section 2 of optional genetics and about volume of blood section 4 of the consent. The optional genetic is also mentioned in page 67 of the protocol (8.5.3 of the protocol).*

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			DNA sampling / Pharmacogenetics The study includes an optional genetic research component which requires a separate informed consent signature if the participant agrees to participate. As permitted by local governing regulations and by IRB/IEC, it is required as part of this protocol that the Investigator presents these options to the participant. The purpose of genetic research may be to better understand the safety and efficacy of LNA043, or to learn more about human diseases, or to help develop ways to detect, monitor and treat diseases. As technology changes over time, the most appropriate technology will be used at the time the exploratory genetic research is performed. This may include the study of the entire genome. Laboratory manuals will be provided with detailed information on sample collection, handling, and shipment. To maximize confidentiality, all samples and the information associated with the samples will be double-coded to prevent the exposure of the participant's information and identity. This double-coding process allows Novartis to go back and destroy the sample at the participant's request. In addition, sample information is stored in one secured database while genetic data is stored in an independent secured database.
	2.	Informed consent brochure / form in the submission part A and attached to the application by KGMU PI appear to be different.	*The ICF in the submission part A will be used for taking consent.*
	3.	There is no specific provision for force majeure in this agreement. This may be included to cover	*For Force Majeure, we can include the below clause in agreement as it is approved from our legal experts.* *"Neither party shall be held responsible for non-fulfilment of their respective obligation under this agreement to the extent that such failure is due to circumstances beyond its control which it could not have avoided by the exercise of reasonable diligence and due to the exigency of one or more of the force*

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		unforeseen situations in the future.	*majeure events such as but not limited to Acts of God, War, Flood, Earthquakes, Pandemics, provided on occurrence and cessation of such events, the party affected by these shall give a notice in writing to the other party within one month of such occurrence and cessation. If the majeure conditions continue beyond one month, the parties shall then mutually decide about the future course of action".*
	4.	In clause 14 of the agreement the seat of arbitration is Bangalore. This may be changed to Lucknow for convenience.	*The comment made by the EC doesn't align with what has been mentioned in the clause 14 of the agreement.*
	5.	There is no dispute resolution clause in the agreement, This may be added to ensure arbitration is the primary mode of dispute resolution	*Regarding arbitration, please note that it is not accepted by our legal experts.* *"Since arbitration is more expensive than litigation, and that courts are interfering with the arbitration proceedings u/s.9 of the Arbitration & Conciliation Act, 1996, leading to further delays and inefficiencies"*
	6.	In clause 26 of the agreement the exclusive jurisdiction of Mumbai is	*This will be changed in the CTA.*

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	referred to while this may be changed to Lucknow for convenience.	

The above responses forwarded to the Primary reviewer vide this office letter no. 2355/Ethics/2022 dated 23rd March, 2022.

Legal opinion: Approved

The following documents were reviewed in its Meeting:-

Sl.No.	Documents
1-	Clinical Trial Protocol (Version Number: 00; Dated: 23-Feb-2021)
2-	Investigator's Brochure (Edition 8; release date 16-Dec-2020)
3-	eCRF Template
4-	Patient Information and Informed Consent Form (Version 3.0, Dated 30 Apr 2021)
5-	Patient Information and Informed Consent Form (Version 3.0, Dated 30 Apr 2021) translated from English to Hindi on 27 May 2021
6-	Patient Information and Informed Consent Form (Version 3.0, Dated 30 Apr 2021) back translated from Hindi to English on 1 Jun 2021
7-	Translation and back translation certificate for Patient Information and Informed Consent Form (Version 3.0, Dated 30 Apr 2021): Hindi
8-	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 1 Mar 2021)
9-	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 1 Mar 2021) translated from English to Hindi on 09 Mar 2021
10-	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 1 Mar 2021)back translated from Hindi to English on 17 Mar 2021
11-	Translation and back translation certificates for Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 1 Mar 2021): Hindi

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	12-	Subject Information and Informed Consent – Consent for Exploratory Genetic Research (Version 1.0, Dated 1 Mar 2021)
	13-	Subject Information and Informed Consent – Consent for Exploratory Genetic Research (Version 1.0, Dated 1 Mar 2021) translated from English to Hindi on 09 Mar 2021
	14-	Subject Information and Informed Consent – Consent for Exploratory Genetic Research (Version 1.0, Dated 1 Mar 2021) back translated from Hindi to English on 17 Mar 2021
	15-	Translation and back translation certificates for Subject Information and Informed Consent – Consent for Exploratory Genetic Research (Version 1.0, Dated 1 Mar 2021): Hindi

EC Decision: Approval subject to fulfillment and administrative formalities

Ref. code: 114th ECMIIC/P3

28. Clarification of research proposal entitled "***Evaluation of factors leading to non-utilization of antenatal care services among pregnant women and assessment of their knowledge, attitude & perception towards government sponsored services during pregnancy and labour***" submitted by Ms. Namita Singh, Ph.D Scholar 2019, under the guidance Prof. Anjoo Agarwal, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no.OG/781/22 dated 29th March, 2022.

Previous EC Comment:	PI response
• Is sample size ok for the study 370 only? Kindly justify sample size?	The sample size calculation was based on the study of Upadhyay et al: Internet J community Med Public Health. 2017;4: 680-685. But as per your comments and discussion with the guide and co- guides, we will take 370 pregnant women from the slums of Lucknow city and 370 from the villages of district Lucknow. Total 740 subjects would be taken for the study.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

• Simple questionnaire based study for PhD?	The researcher is P.G. in sociology and Human Development & family studies, in both of these subjects, researches are based on questionnaire and researchers deal with sociological aspects of any problem. In such type of studies, the society plays the role of laboratory and questionnaire is the best tool to gather the information. In present research, the researcher wants to do medical social research in which during interview the researcher would not only collect the data but also counsel the study participants and will develop an IEC on the basis of results.
• No standard method for income	We have incorporated modified B.G.Prasad scale classification for per capita income 2021.
• Is this a part of Application project?	No, this study is not a part of any project.
• How was questionnaire developed?	After reviewing the literature, following studies and material were taken into account for developing the questionnaire: 1.Rivero-Fuentes ME, Rama Rao S, Estrada R, et al. Assessing Integration Methodology (AIM): a handbook for measuring and assessing the integration of family planning and other reproductive health services. FRONTIERS Manual, Population Council, Washington DC, 2008.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		2. Shashi Kiran Ganjeer. Santosh Devi Yadav. An Empirical Study to investigate factors affecting the Utilization of Antenatal Care in Indore Madhya Pradesh, 2020. Sodhganga: a reservoir of Indian theses @ INFLIBNET. 3.Jacob Islary. Antenatal Care Services Practices and utilization: A study among the bodos of Asam, 2018. Sodhganga: a reservoir of Indian theses @ INFLIBNET 4.MCP card has also been studied and considered to develop the questionnaire.
	• How will it be validated?	The face validation and content validation of the questionnaire has been sought from various experts. The names are: • Dr. Vinita Das (Retd. Dean Faculty of Medicine, HOD ob & gyn dept KGMU Lucknow), • Dr. Seema Tondon (Deputy Director, FRU/ RRTC- UPTSU), • Dr. Sukant Chowdhary (prof. Dept of sociology, university of Lucknow), • Dr. Shalini Agarwal (Asso prof.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Dept of human development & family studies, BBAU, Lucknow). Pre testing of the questionnaire has been done on 10% of study population and Cronbach's alpha of the KAP section is - 868 which shows the good reliability of the questions. This questionnaire is not a psychometric scale, the basic objective of the study is to check the utilization pattern of the ANC and knowledge & attitude of the pregnant women towards the Government sponsored services. Most of the questions are only descriptors of the problem. which have to be evaluated independently and does not form a gradation / scaler pattern. The basic purpose of the study is to carry out audit of the ANC utilization trends using a semi-structured but not a scaler inventory. After pre testing of the questionnaire some irrelevant and unnecessary questions have been removed and few questions have been adopted to get the proper and correct information, with the suggestions of the Guide and co- guides.
	The above responses forwarded to the Primary reviewer. ***Recommendation of Primary reviewer:*** • Provisionally approved **EC Decision:** Approved ***Ref. code:113th ECM II B-Ph.D/P1***	
29	Clarification of research protocol no. CKJX839B12302 entitled "*A randomized,*	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

double-blind, placebo-controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT)" sponsored by M/s Novartis Healthcare Pvt. Ltd submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no.2151/Cardio/Res/21 dated 28th March, 2022.

Sl.No.	Previous EC Comment:	PI response
1-	Kindly share approval of other Institute The drug had been tried in multiple trials since 2017 in more than 3500 patients. The mortality rates in drug and placebo are controlled. No major SUSAR	Does not need any clarification
2-	Did the drug showed efficacy?	Drug was effective and lowered LDL cholesterol significantly
3-	The drug has been approved in EU in 2020 and in USA in December 2021.	Yes, it has been approved
4-	Does it mean it is a post marketing survey? What is the need of this study?	No, it is not post marketing survey it has shown reduce LDL significantly but this is first study to show
5-	The study protocol mentions 2020. Is it a new proposal or resubmission?	It is a new protocol.
6-	Healthy volunteers - ?DCGI –YES	No
7-	The insurance certificate is available but has expired on dec 2021.INR – 73638000 per tested person.	Renewed Insurance certificate attached
8-	Information brochure and consent form are ok	Does not need any clarification

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

9-	15000 participants – how much from this centre -30 to 40	At least 30 to 40 may be increased because of comparative enrollment
10-	Sample sent abroad for uniformity	Yes
11-	CTRI –Pending	Attached
12-	27 centers in India- IEC – submitted, all under review.	Yes, some reviewed and some under review
13-	Someone with experience in evaluating drug trials should look at it.	Yes, PI, Co-PI & CRC
14-	There is consent for DNA testing. But the protocol does not mention which genetic testing will be done? Will some specific pharmacogenetic variants will be studied or whole exam or whole genome sequencing will be done? Each has different implications. Protocol and consent should be clear for this issue. Page 72 of the protocol mentions – 12.5.3- provides very limited information.	Participation in genetic sub-study is optional and is completely patient's decision. At this point of time, we have not entered into any agreement for analysis
15-	Kindly share approval of other Institute	EC approval attached for those sites who got approvals

The above responses forwarded to the Primary reviewer.
Recommendation of Primary reviewer:

- To the question 14- the answer is that the type of genetic testing to be done has not been decided yet. In that case the investigators can not collect the samples of patients for genetic testing without telling what type of genetic test will be done. In that case the consent for DNA testing can not be taken and staples can not be collected. This part may be deleted.

EC Comment: Reply pending by PI
EC Decision: Defer in the next Meeting

Ref. code: 114th ECMIIC/P4

30-	**Minutes of ADR Sub Committee Meeting virtually held on 02-04-2022**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Minutes of the **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting ***virtually*** held on 2nd April, 2022 from 10:00 A.M. **(DCGI)**

The following Members were present in the Meeting:

1. Prof. Alok Dhawan -Chairman
2. Mrs. Akansha Dubey -Member
3. Mrs. Vasundhara Kumari -Member
4. Mr. Ujjawal Krishna -Member
5. Prof. Rajendra Nath -Member
6. Dr. D.N. Upadhyaya -Member
7. Prof. Shally Awasthi -Member-Secretary, IEC

IA	Action taken
1	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc. submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow. **Death** **Subject ID no. 010-0070** **Subject Initial:** K-R **Gender:** M **Age:** 38 years **Patient enrolled date:** 25th September, 2018 **Patient follow up under study:** 1st Month, 6th Month, 12th Month and every 6th Month till 5 year **Weight:** 46 KG **Height:** 162 CM ***Previous ADR Sub Committee Decision:*** PI to send a copy of the letter which has not been delivered and returned with a remark that "recipient is dead". **ADR Sub Committee Comment:** • Prof. Rishi Sethi has sent his letter no. 2168/cardio/res/2022 dated 1st April, 2022 that ***"This is to confirm that despite of several calls subjects LAR yet not provided Death Certificate".*** **ADR Sub Committee Decision:** Noted-Submit to DCGI. ***Ref. code: 83rd ECM IIC/P6***
2	ADR of research protocol no. EX9536-4388 SELECT: entitled ***"Semaglutide effects on cardiovascular outcomes in people with***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		overweight or obesity" submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter nos. 1955/Cardio/Res/2021 dated 9th December, 2021, 2154/ Cardio/Res/2021 dated 28th March, 2022. **Death** **Subject ID no. 2537-42** **Subject Initial:** D N D ***Previous ADR Sub Committee Decision:*** PI to send a copy of the letter which has not been delivered and returned with a remark that "recipient is dead". **Death Certificate received.** **ADR Sub Committee Decision:** Death Certificate received. Submit to DCGI. ***Ref. code: 92nd ECM IIC/P1***
	IB	**New SAEs**
	1-	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc. submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 2050 /Cardio/Res/2022 dated 27th January, 2022. **Death** **Subject ID no. 010-0054** **Subject Initial:** B **Gender:** F **Age:** 54 years **Patient enrolled date:** 9th July , 2018 in VKA arm **Patient's follow up under study:** 1st Month, 6th Month, 12th Month and every 6th Month till 5 years. **Follow up visit completed :** 1st Month , 6th Month , 12th Month , 18th Month , 24th Month , 30th Month and 36th Month (last visit- 08 July- 2021.) **Date of detection of SAE:** 19th January 2022 **Start and Stop date of SAE :** 21st August- 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Weight: 65 KG **Height:** 152 CM **Patient History:** A letter was received in the office of the Ethics Committee on 28th January, 2022. The letter stated that for 42nd follow up visit many calls were made but the calls were not answered. On 19th January, 2022, the call was made again and the LAR received it. The LAR revealed that the patient passed away on 21st August, 2021 around 9:00 PM at home Local Practitioner was contacted and treatment was given but the patient did not improve and finally expired. The subject was not hospitalized anywhere. The PI does not have any records to confirm the cause of death except the death certificate. No Autopsy was done. Most likely it is not related with study drug. ***Recommendation of Primary reviewer:*** SAE (Death) is most likely due to disease outcome (RHD/ Sev. MS/ Mod MR/LAA clot with AF) and not due to intervention (Rivaroxaban) as patient was taking VKA from more than 3 years and completed 36th Month visit without any complaint. Causal relationship cannot be established as the subject was not hospitalized anywhere and there are no records to confirm the cause of death except the death certificate. Autopsy was also not done. **ADR Sub Committee Comment:** Confirm age of the patient from the PI and get documents with correct age resubmitted **ADR Sub Committee Decision:** Re-submit ***Ref. code: 83rd ECM IIC/P6***
IB	**Expedited review**	
1	Expedited review of the research proposal entitled ***"Risk factors and effect on inflammatory markers in fungal infections during Covid-19 pandemic: A pilot study"*** submitted by Dr. Atin Singhai, Additional Professor, Department of Pathology, K.G's Medical University, U.P., Lucknow vide letter 2792 dated 11th June, 2021. ***The above proposal was forwarded to 2 PRs.*** ***Recommendation of First reviewer*** -Approved ***Recommendation of Secondary reviewer with following points:*** • Background:	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	All studies, however novel, have some background information on which any research is built on. This study doesn't mention any background or rationale for testing the variables mentioned. It is necessary to provide this. • Objectives: Objective 2 is very vague. Please mention explicitly, what is planned. • Justification of Study: i) In the absence of data from patients of first wave, it will be extremely difficult to understand the difference in risk factors between the two waves. ii) How can you use the information gathered in your CRF to identify biomarkers that may allow early prediction of disease when you are recording biomarkers at onset of symptoms (of fungal infection) and at time of admission (which I presume, will be after onset of symptoms). Even if it is vice versa, this study cannot, in my understanding, fulfill this purpose? iii) Also, your justification doesn't match with the objectives of your study. • Inclusion criteria: i) Will the included patients be those who have had covid infection or any patient with any fungal infection? ii) If only covid positive patients will be taken, how many days/ weeks old covid positivity will be considered for inclusion or only currently covid positive patients will be included? iii) Will any other fungal infection, other than the 3 mentioned, be included? • Case Record Form: i) Socioeconomic status: What tool will be used? ii) Risk factors: What is the importance of a negative covid test? iii) How is a person defined as "vaccinated" for this study? iv) Patients with covid can be admitted sequentially in multiple hospitals: Which admission will be documented and analyzed? v) How do you plan to quantify oxygen therapy: Patients are on multiple doses and multiple modes/levels of O2 therapy at different points of times vi) Steroid therapy can be by different routes (oral, IV) different drugs. Similarly, dosage doesn't always remain the same during therapy. How do you plan to address this issue? vii) Define recent blood transfusions viii) Define controlled/uncontrolled diabetic ix) Will you consider, for example, an adult of say 60 yrs who had a malignancy at 20 yrs of age and is disease free till now as having a malignancy or not? x) Any use of antifungal drugs, for example Tinea infestation, any time in life, will be recorded? xi) Define recent dental or nasal surgery. xii) How will trauma and burns be defined? And how long ago incidents and what extent of injury will be recorded?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	xiii) How can you be certain that a whole set of investigations mentioned have been done on the day of onset of symptoms? And what symptoms are you looking for? xiv) What if some/ all of the investigations are missing/ not done? Will these patients be included? xv) Imaging: What does one understand by this? What type, time, site? • There are about 30 risk factors that will be analyzed, in a sample size of 60 patients. How do you plan to eliminate the role of chance in a factor showing statistical significance? ***The above comment forwarded to the P.I. Reply Pending by 25th February, 2022.*** ***A letter by forwarded to Dr. Atin Singhai by the Member-Secretary, IEC that kindly send your reply within seven days' or else your proposal will be taken as withdrawn.*** **EC Comment:** Response of PI is not received by Monday i.e. 4th April, 2022 **EC Decision:** Since you have not sent the revised proposal till date it is considered that you have withdrawn it from the Ethics Committee. ***Ref. Code: 115th ECM IB/P1***
2	Expedited review research proposal entitled "***Covidsurg-3: outcomes of surgery in COVID-19 infection***" submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/134/2022 dated 25th January, 2022. ***The above proposal was forwarded to First Primary reviewer & Secondary PR.*** ***Recommendation of First PR with following points:*** • No. patient information sheet is attached. Kindly format as per SOP and attach. • Sample size & its calculation are not indicated. Whether 2000 patients from every 400 centers are to be recruited/ analyzed? Kindly clarify. • What type of data & how will it be collected to define the predictors of morbidity. • Proposal summary needs to be rewritten in a more understandable manner rather than affixing the few protocol pages. The various sub heads of description need to be as per EC (IRB) SOP protocol. • The duration of project in more likely to include retrospective patients-then how is ICF possible in every patient? • Kindly attach a relevant document of sponsor revealing the name. • If this is an International project then summaries the international stake holders/partners. • If this is multicentric project then mention the names of other collaborating centers or give clarification otherwise. ***The above comment forwarded to PI, reply has given by PI was reviewed by Dr.***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Anupam Mishra:

- Provisionally approved

Recommendation of Secondary PR with following points:

- The research proposal seeks to collect data regarding the management and outcome of Covid patients from several hospitals across the world. This being data related to the pandemic could be sensitive information. Would it not be prudent to seek permission from the University or State/Central authorities for sharing of this data on an International level?
- The proposal has on PI and 18 Co-PI which seems rather far-fetched and unnecessary considering that the project involves only data collection and no intervention. Clarification may be sought on this and number of Co-PIs reduced accordingly.
- Most of the Covid patients undergoing surgery may have been seriously ill, however, the section on 'Vulnerable Subject' has not been filled by the PI.
- The study will be both prospective as well as retrospective. How will the consent be obtained from patient in the retrospective arm?

The above comment forwarded to PI was reviewed by Dr. DNU with his second opinion:-

Second opinion of Secondary PR	PI Response
The PI has not justified the sample size.	The recruitment will be from approximately 400 hospitals around the world with a mean of 5 patients per hospital, providing a sample size estimate of 2,000 patients. The primary outcome is 30-day mortality. The secondary outcomes are 30-day postoperative pulmonary complication and 30-day venous thromboembolism. Non-parametric data will be summarised with medians and interquartile ranges and differences between groups tested using the Mann-Whitney U test. The $\chi 2$ test was used for categorical data. Missing data will be included in flowcharts and summary tables, allowing denominators to remain consistent in calculations. Hierarchical multivariable, mixed-effects logistic regression will be used to identify risk predictors of 30-day

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		mortality and 30-day postoperative pulmonary complications summarised as odds ratios and 95% confidence intervals. Clinically plausible patient, disease, operation and location specific factors have been selected *a priori* for inclusion in adjusted analyses based on previous studies1-2: age sex, ASA grade, indication for surgery, urgency of surgery, grade of surgery, timing of SARS-CoV-2 diagnosis, in addition to vaccination and previous infection status.
	The permission for this International study of data related to the Covid Pandemic has been sought from ICMR-Health Ministry's Screening Committee but has not been granted yet.	Yes, as communicated in the previous reply that the all sites in India are waiting for approval from **ICMR-Health Ministry's screening committee, and the study will start only after the approval. We will be communicating to IEC as and when we get the approval.**
	The PI has sought IEC waiver in this sensitive International study using data from the Pandemic.	As per the previous IEC comments, IEC recommended to take consent waiver in regard to the study timeframe. The issue was brought in the notice of the Honorary Member Secretary who advised to get the consent waiver as a part of Ethics Committee waiver form (attached with the previous reply)

The PI has given his reply was reviewed by Secondary PR.
Third opinion given by Secondary PR:

- The project may be approved conditional to the obtaining of approval from ICMR-Health Ministry's screening committee.

EC Decision: Approved

Ref. code: 115th ECM IB/P2

3	Expedited review research proposal entitled "***Development of "Digital Dentistry" as module for undergraduate prosthodontics curriculum***" submitted by Dr. Shuchi Tripathi, Additional Professor, Department of Prosthodontics and Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1069/2022 dated 1st February, 2022. ***The above proposal forwarded to 2PRs.*** ***of First PR with following points:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Do you think that the reason for Expedited Review is justified-"educational Project with 8 month duration"?
- It's on a topic which is not dependent on any timeline (eg. Pandemic), nor are the participants going to change if it comes through the normal channel.
- Last, whatever the results of this study are, they will not bring about any rapid change in the training programme.
- **Please let me know your thoughts on this. I don't have any problem with reviewing it.**

Recommendation of Secondary PR:

- The project is interesting and nicely planned
- Provisionally approved

EC Decision: Approved

Ref. code: 115th ECM IB/P3

4 Expedited review research proposal entitled "***Smartphone-based COVID-19 cough detection with artificial intelligence***" submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/191/2022 dated 7th February, 2022.

The above proposal forwarded to 2 PRs.

Previous EC comment of First PR	PI response
Comment 1: There are 15 co-PIs. What is the need and rationale of 15 Co-PIs at a single center?	Firstly, the study involves adult patients from both surgical and nonsurgical departments and health volunteers this will ensure the comprehensive study sampling. And, to do that we involved multiple COPI. Secondly, this will allow enrolling the required patients in a reasonable time frame given the rapidly changing situation of COVID. Thirdly, the given departments have been collaborating with us in other international studies so we find it very convenient for data collection.
Comment 2: Scientific review committee of the department reviews the project. But not a single member from his own department (ie Surgical Oncology) is in the scientific review	Because all faculty members from the PI department (Surgical Oncology) are the Co-Investigators in this study, therefore we found it more essential to include members from another

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

committee of the department. There is one member from the department of radiotherapy and two members from the department of pathology.	department for constituting scientific review committee. However if the reviewer wants the committee members from the parent department we are happy to do so.
Comment 3: How will the researchers assure the participants' privacy while they are using a third party app while researchers are offering them to use it for the study.	Intellectual property rights for Indian data remain with Indian investigators. KGMU data property rights remain with KGMU and can be used for their own studies after information to the national coordinating investigator as well as sponsoring body.
Comment 4: Undertaking by PI {annexure 2-RV-1/2019 (SOP-IEC-KGMU)}: point number 3 is vacant while they have stated as multicentric study.	CTRI document has been attached with the participating sites details.
Comment 5: In exclusion criteria: Any conditions that would significantly affect interpretation of the study result will be excluded. Ideally these conditions should be predefined rather than spot exclusion depending on the recruiting person's will.	The reviewer is right. This has been amended. The newer version of the protocol has been attached where this issue has been resolved.
Comment 6: In exclusion criteria: It is mentioned that recruited subjects will have RT PCR testing prior to recruitment while on page number 39 under heading of facilities it has mentioned that samples for RT PCR will be processed at CMC Ludhiana. It seems there is some ambiguity and should be clear.	Apologies for this. RTPCR will be done at the site and not in CMC Ludhiana for KGMU. KGMU samples will be tested as per KGMU protocols and at KGMU. We do not envisage any change in practice at KGMU. Changes have been made in protocol.

The above comment forwarded to First PR-Reply pending

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comment of Secondary reviewers	PI response
Comment 1: 15 co-investigators with exactly similar roles (obtaining informed consent, including patients, data entry) may be curtailed if possible. Considering assessment of cough the entire list (comprising 10 out of 15 co investigators from surgical specialty), should be complemented with more investigators from medicine and at least one from pulmonary medicine (that deal with cough more often that surgical specialty) Accordingly the selection of co- investigators may be modified	All Co-PIs are the faculties in the institute and sees patients individually therefore the basic screening inclusion/exclusion consenting, responsibilities lies individually with these Co-PI therefore we believe it is essential that all those who are participating share the responsibilities equally. Yes the reviewer is right that cough as a symptom is more often seen in the OPD of Departments such as Medicine, ENT and Respiratory medicine. Having said that this study is not solely looking at the pathological cough therefore this was the reason for not including these specialities at first place. However if the committee thinks that more Co-PIs are illegible and can be added then we will be happy to include as many departments/Co-PIs as stated by the reviewer.
Comment 2: Kindly indicate the members for data and safety monitoring committee/ board.	**Data Protection Policies:** All data collected via the data collection mobile app will be sent securely to Virufy's infrastructure located in the US regions. It will be protected by various controls such as access controls, encryption at rest, etc. Only members of the Virufy engineering / clinical research team will be able to access collected data. Proper security controls, including multi-factor authentication and training

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			including information security and HIPAA awareness will be administered to all members with access to patient data on a need-to-know basis. Data will be accessed by Stanford faculty-advised AI development team for training and validating AI models to predict for COVID-19 and by Stanford faculty-advised clinical team which will analyze data for scientific publication and articles. Information input by patients into the web app will be encrypted in-transit and sent directly to Virufy's Amazon Web Services ("AWS") cloud infrastructure in the US for storage and processing. (ii) All data will be stored in an encrypted, password secured RDS Postgres database with daily automated backups. (iii) Access to AWS infrastructure is protected with multi-factor authentication and logging of all user activities with CloudWatch. Secure user authentication policies and procedures are enforced, and all members with access are required to undergo security training. (iv) In conjunction with data privacy lawyers, Virufy has developed and maintains a robust Data Protection Impact Assessment ("DPIA"). (v) Virufy's information security team includes experts who have worked at Google, Okta, HP, Cisco, and f5 Security. (vi) Virufy has implemented suggested best security practices from AWS and industry standard practices and continues to advance practices to

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			ensure the confidentiality, integrity and, availability of data. Information about security and privacy-related audits and certifications performed by AWS, including information on ISO 27001 certification and Service Organization Control (SOC) reports, is available from the AWS Security Website and the AWS Compliance Website. (vii) In addition, Virufy is only using AWS HIPAA Eligible Services. Participant data will be labeled with an auto-generated and anonymous unique ID. Stanford and collaborating nonprofit (Virufy) will receive no identifiable information through the study, except for speech data, and de-identification will not be possible. Participant names and other directly identifiable information will not be available to Stanford or the Virufy research team and thus will not appear on reports, publications, or disclosures of clinical study outcomes. Subject vocal recordings and textual survey results will only be accessible by Stanford and collaborating nonprofit's US and India-based clinical research and AI development teams. PCR test results will be accessible by local study staff and protected by existing patient confidentiality protocols in-place through their healthcare institutions. Collected participant health data will be labeled with an auto-generated and anonymous unique ID, during storage into the AWS Postgres database.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		All data will be encrypted in the Postgres database and only accessible to authorized users with AWS accounts protected by multi-factor authentication as described in further detail prior. The collaborating research group, Virufy may share anonymized participant personal information (for example, biometric information and health information stripped of information that could be used to identify participants) with third parties (including academic research institutions, public and private sector) for profit and non-profit purposes as a dataset for use globally to accelerate the development of technologies for the detection of COVID-19. This sharing of data is described thoroughly in Virufy's posted privacy policies (https://virufy.org/privacy_policy/) and will require singning and adherence to a strict Data Transfer Agreement (DTA) for external parties. All uploading and downloading of study data will take place using secure transmission protocols, e.g. through AWS S3 bucket data transfers. Data recipients will be required to create AWS accounts with similar security measures employed by Virufy members, such as multifactor authentication. Proper security controls, including multi-factor authentication and training including information security and HIPAA-equivalent awareness will be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 2nd April, 2022

	administered to all Virufy research team members with access to participant data. Local clinical research staff will have already received training focused on the importance of protecting privacy & rights of participants.
Comment 3: Regarding the policy for owning intellectual property rights, The KGMU should have the right to own its contribution and it is expected for international agencies to concur with the KGMU team for using its data for some other purpose in future.	Has been discussed with the sponsor and the same will be covered as a part of the CTA as per the KGMU policies.
Comment 4: attach CTRI document as indicated on page 3.	It has been attached
Comment 5: CTA documents need to be enclosed. Necessary paperwork from international sponsors (Stanford, Virufy) and other collaborators (CMC Ludhiana) also needs to be enclosed.	We are in the process of finalizing the CTA and India Hub Team is working on it in collaboration with the sponsor.
Comment 6: While in point no. 11 there is no plan for reporting adverse event , it is further indicated that CRCs at each site will be responsible for reporting AE/ SAEs to Virufy and respective IRBs - - Why this discrepancy?	This as per each individual IEC requirements. Some IECs in India mandate reporting all adverse events with patients even if it is not related to study in any manner. This study is low risk and no AE is expected.
Comment 7: the title suggests smartphone based covid-19 cough detection but other type of patients are also included and may be with phasing covid the title may not justify selection - this may be discussed with collaborators and if sponsors feel it to be correct then the title may go as such.	The response from the sponsor for this comment is as follows "this is an effort to triage covid patients and thus the title. Other patient frequencies are being used to ascertain differences (could be considered control). We would like to keep the title."
Comment 8: Inclusion criteria are includes patients who have undergone RTPCR for Covid. Later it is indicated that RTPCR samples will be processed	Apologies for this. RTPCR will be done at the site and not in CMC Ludhiana for KGMU. KGMU samples will be tested as

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

at CMC Ludhiana. Kindly resolve this confusion.	per KGMU protocols and at KGMU. We do not envisage any change in practice at KGMU. Changes have been made in protocol.
Comment 9: Kindly indicate any other data apart from HEALTH INFORMATION COLLECTION SHEET that will be sent to Verify.	No data apart from health information sheet data and cough frequencies will be sent
Comment 10: Kindly indicate the methodology of voice / speech recording, the hardware used and sensitivity/ quality of microphone to be used as this is important for a proper voice that will be scientifically analysed later. The aim is to record a good quality voice - Will the hardware/ microphone be provided by Verify or who will bear the cost?	The cough frequencies will be recorded on a good quality standard mobile with high quality microphone. The hardware and app software will be provided by Virufy and Virufy will bear the costs.
Comment 11: Regarding point number 5, voice recording with any mask will not be scientifically correct. The mask needs to be standardized (surgical/ cloth/ N95 etc) for the speech to be recorded with it or else the quality of mask will interfere with the result.	The reviewer is right. Only surgical (3ply or 2ply) and cloth masks will be used for recording cough frequencies. N95 will distort recording.
Comment 12: Kindly indicate the calculation of the sample size for 1547 participants	Sample Size Calculation: We estimated, using two-tailed inference proportion, the minimum sample size as 1547 participants considering the number of positive cases patients with an allocation ratio of 1 to achieve a minimum power of 85% with alpha = 0.05. While this sample size is expected to be sufficient to train and test a statistically powerful deep learning model (primary endpoint), we plan to recruit more participants across our various study sites to increase the generalizability of the model to a global population, and allow for further stratification for secondary

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 2nd April, 2022

		outcomes of the research. Overall sample size may be re-evaluated depending on weekly monitoring reports. For instance, if we find that there is a large effect size between COVID-19 positive and negative cough sounds, we will decrease the overall sample size needed for training of the machine learning model. In this case, subject data will be used for validation testing of the model in Phase Two of the study, as a larger testing sample will increase statistical power, generalizability, and relevance of the model. Sample should be representative of the global community to reflect region-specific phonological differences that may affect the algorithm's performance.
	Comment 19: Patient information sheet to be 3 attached as per the SOP of IEC/ IRB KGMU.	Patient Information sheet is attached as a part 1 of Informed consent form of the study.
	The above Comment forwarded to PI was reviewed by Secondary PR. ***The Recommendation of Secondary PR received on 31st March 2022*** • PI has cleared the objection raised & agreed to add Co-PIs from Medicine & Respiratory Medicine. • In response to comment 2 the PI has described the data safety procedures. • For comment 3 response of PI is acceptable • CTA documents yet awaited. • PI has given explanation & necessary rectification that need to be incorporated. • Patient information sheet should be as per SOP of IEC/IRB KGMU both in English & Hindi. **EC Comment:** As above **EC Decision:** Approval subject to modification of patient information sheet. ***Ref. code: 115th ECM IB/P4***	
5	Expedited review research proposal entitled "***Students and teachers' perceptions about factors that contribute to academic performance in undergraduate medical students***" submitted by Prof. Vimala Venkatesh, Department of Microbiology, King George's	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Medical University, U.P., Lucknow vide letter no. 1904/CA/2022 dated 31st January, 2022.

The above proposal forwarded to 2 PRs..

Sl. No.	Previous EC comment of First PR	PI response
1	The questionnaire has name and the marks of the student and hence the information brochure should mention that the data collected will have these details but the data will be anonymized later and will kept confidential.	The online consent form already contains the confidentiality clause, as does the information sheet at point 16.
2.	In such studies, can we call them healthy volunteers? I am not sure.	In the Ethical form (1-RV-1/2019), point 5, subject selection: subject selected is "Special group subjects, Students & Teachers. As there is no alternative in point 8 to the term healthy volunteer, this was chosen as the default option.
3.	The ethical proforma says, the information brochure for healthy volunteers is enclosed but the information sheet has the title as ' for patients'	This information format is not required in our study as an online form will be administered. However, the change has been effected in the information sheet to "Student & Teacher Information sheet"

The above responses forwarded to the First PR vide this office letter no. 2364/Ethics/2022 dated 25th March, 2022.

Recommendation of Secondary PR: Approved

EC Decision: Approved

Ref. code: 115th ECM IB/P5

Minutes of extraordinary Meeting virtually held on 04-03-2022

Extraordinary meeting of EC committee held on 4th March 2022 to streamline functioning of review of the proposals. it was attended by:-

1. Dr. Alok Dhawan - Chairman

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 2nd April, 2022

	2. Dr Akash Agarwal - Member 3. Dr DN Upadhyaya - Member 4. Dr Rajendra Nath - Member 5. Dr Anupam Mishra - Member 6. Dr Shally Awasthi - Member Secretary ***Recommendation of the Chairman & following EC Members:-*** 1. Dr A.A. Mahdi said that there are minor errors in the submission check list of the project. This may be done by the secretariat if it is strengthened with technical staff. 2. Dr Anupam Mishra pointed out that the scientific content of certain works needs strengthening. 3. Dr D.N. Upadhyaya pointed out that a lot of time is wasted by comments going back and forth between primary reviewer and PI. 4. Dr Rajendra Nath said that the SOPs be circulated again in the departments with a request to adhere to them. 5. Dr Shally Awasthi said that an excel sheet has been developed and that the projects sent for review to members will be maintained by date to tag turnaround time. 6. Dr Alok Dhawan said that if the Primary reviewer deems it necessary, the PI may be called to present the work in the EC meeting so that combined inputs of all members can be given for speedy redressal of issues. He said that the primary responsibility of EC is to examine the proposals from ethical perspective. Hence departmental RCs must ensure quality of scientific review. **Decisions:-** 1. Shally Awasthi to circulate SOP of EC to all the departments with a request to ensure adherence. 2. PIs to be called to present their work in the EC at the recommendation of primary reviewer. This will be in exceptional cases and not a norm. **EC Decision:** Noted
II-A	**New Proposal**
1.	Research proposal entitled ***"Predicting ear drum central perforation using AL protocol: a pilot study"*** submitted by Prof. Anupam Mishra, Head, Department of ENT, Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 591/ENT/2022 dated 12th January, 2022. **EC Comment:** • Kindly remove the names of foreign Investigators ***Dr. Anupam Mishra did not take part in the discussion and making decision.*** **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM IIA/P1***
2.	Research proposal entitled ***"Heavy metal level estimation in patient with complete heart block of unknown etiology: A pilot project"*** submitted by Dr. Ayush Shukla, Assistant Professor, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 2014/Cardio/2022 dated 10th January, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Approved ***Ref. code: 115th ECM IIA/P2***
3.	Research proposal entitled "***Matrix metalloproteinases in angiogenesis and tumor invasion: clinicopathological impact in urothelial bladder carcinoma patients***" submitted by Prof. Apul Goel, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 39/URO/2022 dated 14th January, 2022. **EC Comment:** • Patient information sheet (Part-I) has no information about sample collection. It has to be modified in both English & Hindi. **EC Decision:** Approval subject to ***Ref. code: 115th ECM IIA/P3***
4.	Research proposal entitled "***Investigation of the human papillomavirus (HPV) infection type in head and neck cancer and its association with patient outcomes***" submitted by Prof. Ranjit Kumar Patil, Department of Oral Medicine and Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 63/OM&R/2022 dated 31st January, 2022. **EC Comment:** • Patient information sheet (Part-I) has no information Kindly provide document of clearance to send samples abroad. • What are the criteria for giving compensation? Kindly provide document of clearance to send samples abroad. **EC Decision:** Re-write and include procedures for formalir fixation of samples. ***Ref. code: 115th ECM IIA/P4***
5.	Research proposal entitled "***Indian trial of tranexamic acid in spontaneous intracerebral haemorrhage (Intrinsic Trial)***" sponsored by ICMR, New Delhi submitted by Dr. Praveen Kumar Sharma, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 32/Neuro/2022 dated 19th January, 2022. **EC Comment:** • Clarify what compensation will be given? What are the criteria for giving compensation? **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P5***
6.	Research proposal entitled "***To assess sociodemographic, clinical and serological profile of allergic bronchopulmonary aspergillosis (ABPA) patients***" submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2291/2021 dated 30th December, 2021. **EC Comment:** • No case report from is there.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 2nd April, 2022

	• Patient information sheet has to give more details. **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P6***
7.	Research proposal entitled "***The HOLD study-stomach cancer elective surgery morbidity and mortality at 90-Day: A TUGS multinational audit***" sponsored by University of Sunderland, NHS Foundation Trust, England submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/143/2022 dated 28th January, 2022. **EC Comment:** • Complete the protocol check list of KGMU. **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P7***
8.	Research proposal entitled "***The outlive study-Oesophageal and Junctional cancer elective surgery morbidity and mortality at 90-Day: A TUGS multinational audit***" sponsored by University of Sunderland, NHS Foundation Trust, England submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/153/2022 dated 25th January, 2022. ***Recommendation of Primary reviewer:*** • Kindly attach patient information sheet as per SOP of EC KGMU. It is indicated in the annexure last page that patient information sheet is attached but no such enclosure is submitted. • Kindly enclose the protocol for data collection and explain the procedure in methodology. There is no indication of mortality parameters to be assessed as well as the anticipated factor as per second aim. • Kindly attach some document/ correspondence from the sponsor (University of Sutherland) • Kindly indicate the anticipated number of subjects to be recruited in study. • No case report form is enclosed as indicated on last page of annexure one. Kindly attach a copy. **EC Comment:** As above • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P8***
9.	Research proposal entitled "***A prospective, multicenter, observational study of bifurcation coronary stenting in India to determine clinical and angiographic outcomes (IBIS Registry)***" sponsored by Cardiovascular Research Society-Kerala submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 2052/Cardio/Res/2022 dated 27th January, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • Patient information sheet as per SOP EC KGMU to be attached • Signed copy of Clinical registry agreement need to be submitted before initiation of project • If budget is 250 INR per subject as indicated in budget then it should also be indicated in sponsor letter- why this discrepancy? • How will the budget be channelized in KGMU? a policy copy needs to be attached • While annexure indicates it is a natural and national industry the sponsor letter states that it is not industry - why discrepancy ?? • While annexure states that adverse events will not be reported, point number 11 indicates otherwise - why this discrepancy? • Kindly fill the following information in annexure a- Confidentiality of records b- Contact information c- Right to withdraw d- Consent form in English and Hindi e- Plan for interim analysis • In ICF the right to participation should include right to withdraw at any stage both in English and Hindi versions. **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P9***
10.	Research proposal entitled "***Anesthetic challenges and perioperative management of pheochromocytoma and paraganglioma***" submitted by Dr. Shefali Gautam, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/103/2022 dated 1st February, 2022. ***Recommendation of Primary reviewer:*** • Many entries in annexure need to be filled such as a- Vulnerable subjects b- Special group subjects c- Patient information sheet details d- Consent form details e- If risk is indicated as YES then indicate what is that risk d- What sort of physical/ social/ psychological / risk discomfort is feasible in this study. Kindly indicate. • How will you report adverse events in these four patients assessed retrospectively? • How will you do interim analysis in these four patients assessed retrospectively?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 2nd April, 2022

	• Copy of case report form/ protocol/ project questionnaire as indicated in annexure should be attached separately. • It has to be indicated as to how to obtain written informed consent retrospectively. Will the patients be called for assessment or the details be recorded through retrospective records. kindly clarify. • Kindly attach patient information sheet as per SOP EC KGMU separately if applicable in ICF "right of the participants" should include a statement indicating the right to withdraw from the study at any stage. **EC Comment:** As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM IIA/P10***
11.	Research proposal entitled ***"Assessment of trends and factors influencing smokeless tobacco use in Lucknow"*** submitted by Dr. Gaurav Mishra, Associate Professor, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 58/PHD/2022 dated 10th February, 2022. ***Recommendation of Primary reviewer:*** • Patient information sheet as per SOP EC KGMU to be attached • Annexure 1 needs to be complete. Many information are not available such as. a- Sponsor information (yes or no) b- In 'subject selection' kindly indicate types of special group subjects c- Give response regarding risk and benefit d- Give response regarding data monitoring e- Give response regarding "Is their compensation for injury" • Give a brief detail about statistical analysis **EC Comment:** • As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM IIA/P11***
12.	Research proposal entitled ***"Knowledge, attitudes, and practices of School Teachers toward Oral Health in Uttar Pradesh, India"*** submitted by Dr. Sumit Kumar, Associate Professor, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 66/PHD/2022 dated 4th February, 2022. ***Recommendation of Primary reviewer:*** • Kindly attach patient information sheet as per SOP EC KGMU (mentioned as attached in annexure) • Kindly complete following details of an excel in subject selection kindly

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	indicate which special group subjects in risk benefit kindly indicate is there social physical risk discomfort • Give a brief account of how sampling will be done how will the division or schools be selected whether age will be a criteria for randomly selected teachers. • Give a brief account of statistical analysis **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P12***
13.	Research proposal entitled **"*Lung oscillometry registry for patients with various Respiratory disorders and healthy subjects (LEAD Study)*"** submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 99/2022 dated 24th January, 2022. ***Recommendation of Primary reviewer:*** • The sponsor information indicates that private sponsor is both from India as well as international. The name is not indicated. There is no address indicated as well. Kindly indicate the name of sponsor and its correspondence with principal investigator officially. • A few responses in annexure are left blank such as use of existing/ leftover samples • The study procedure indicates that study is going on in "18 different centres of the world". The list of investigators attached show 18 centres in India - So what other centres of world are collaborating in this international sponsored private party research? Kindly indicate. • Kindly also mention the various centres where these 18 investigators are based in India. Who is the lead person? Will multi-centre data be combined for analysis? If yes then where exactly the analysis will be done? What will be the situation of intellectual property rights issue?? • Give a brief account on outcome parameters and statistical analysis • What is the speculated sample size overall and in KGMU (expected). • While undertaking by principal investigator indicates that it is a multicentric international study, the name and address of other medical institutes/ Hospital is missing. • In executive summary the methodology indicates "following locations in India as well as from international countries" - but neither any Indian nor foreign Centre is mentioned. • The methodology selection further states that data will be captured at clinics and hospitals while study Centre (in material and methods) indicates only

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 2nd April, 2022

	KGMU. Kindly resolve the discrepancy. • The only single investigator maybe overburdened with this non-funded study. Will it be feasible all alone by a single investigator? **EC Comment:** • As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM IIA/P13***
14.	Research proposal entitled "***Traumatic Anterior cruciate ligament injury: A study on the prognostic implications of Vitamin D and micronutrient supplementation***" sponsored by UPCST submitted by Dr. Kumar Shantanu, Additional Professor, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 1695/OS/2022 dated 4th February, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation missing • ICF of both English and Hindi version should be an exact replica • Patient information sheet in hindi need to be attached • In use of "biological hazardous material" it is indicated that collection for banking / future research is applicable - kindly indicate in detail about the material to be stored and incorporate the patient consent accordingly. The same is true for use of organ and body fluids • The " risk and benefit" in annexure need to be addressed properly • Where is the CV for non-KGMU investigators as per indicated in annexure. • Brief some outcome parameters and their relevant statistical analysis **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P14***
15.	Research proposal entitled "***A comparative prospective study of the various parameters of the wave like involuntary movements in scrotum in apparently normal individuals and patients of hydrocele, varicocele and primary idiopathic infertility***" submitted by Prof. D. Dalela, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 536/URO/2022 dated 28th December, 2021. ***Recommendation of Primary reviewer:-*** • This is a pilot study. It should be mentioned in the title. • The term "various parameters" is vague. Research hypothesis should be defined properly after identifying the parameters. • Sample size is not required, as it is a pilot study, but the data analysis section should be properly addressed. **EC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P15***
16.	Research proposal entitled "***Outcomes of surgically addressed impacted injury in the patients of acetabulum fracture***" sponsored by ICMR, New Delhi submitted by Dr. Dharmendra Kumar, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1699/OS/2022 dated 7th February, 2022. ***Recommendation of Primary reviewer:-*** • Title should be "Assessment of outcomes……." • The proposal is incomplete. There is no research hypothesis, no sample size calculation, no methodology, no statistical analysis section. **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P16***
17.	Research proposal entitled "***Study on patient satisfaction and psychological well-being of patients on oral anticoagulant therapy after atrial fibrillation (AF), arterial or venous thromboembolism (VTE)***" submitted by Dr. Sujita Kumar Kar, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 176/Psy/2022 dated 4th February, 2022. ***Recommendation of Primary reviewer:-*** • The primary objective and secondary objectives are being mixed. • The primary objective uses cross-sectional (observational) design, whereas the secondary objective uses prospective comparative study. • The focus should be on primary objective, as the sample size, methodology etc. will be different for two kind of designs. • Sample size calculation is not clear. What is the formula used? • Data analysis section is also vague. It just give the terms: Ftests- ANOVA: Repeated measures, within factors. This makes no sense. **EC Comment:** • As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM IIA/P17***
18.	Research proposal entitled "***Knowledge, attitude and practice of Paediatric trauma management among the health care workers providing trauma care in government run major Hospitals of Lucknow: A questionnaire based study***" submitted by Dr. Vikas Verma, Associate Professor, Department of Paediatric Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no.1600/PaedOrtho/2022 dated 17th February, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 2nd April, 2022

	Recommendation of Primary reviewer:- • The title should be "Development and validation of a questionnaire to assess Knowledge, attitude modify accordingly. • The methodology to develop, assess reliability and validity of the questionnaire should be given in detail. For example, what kind of "validity" is required for the present situation? **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P18***
19.	Research proposal entitled "***Assessment of Death certificates filled by medical professionals during the COVID pandemic***" submitted by Dr. Shiuli, Assistant Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 291/FMT/2022 dated 31st January, 2022. ***Recommendation of Primary reviewer:-*** • In evaluating the death certificates, the prevalence of "attributes of discrepancies" should be reported. These should be arranged in an increasing order. • This will give an idea of worst to best area of discrepancies. **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P19***
20.	Research proposal entitled "***COVID third wave: profile of patients at a L3 Centre***" submitted by Dr. Shrikant Srivastava, Additional Professor, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 1438/DGMH/2022 dated 3rd February, 2022. ***Recommendation of Primary reviewer:-*** • Approved **EC Decision:** As above ***Ref. code: 115th ECM IIA/P20***
21.	Research proposal entitled "***A naturalistic study of obsessive-compulsive disorder-A retrospective chart analysis***" submitted by Dr. Shrikant Srivastava, Additional Professor, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 1395/DGMH/2022 dated 11th January, 2022. ***Recommendation of Primary reviewer:-*** • Approved **EC Decision:** Approved ***Ref. code: 115th ECM IIA/P21***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

22.	Research proposal entitled "***To join Indian stroke clinical trial network phase II (INSTRuCT Network Phase II)***" submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 31/Neuro/2022 dated 19th January, 2022. ***Recommendation of Primary reviewer:-*** • Approved **EC Decision:** Approved ***Ref. code: 115th ECM IIA/P22***
23.	Research proposal entitled "***To explore the role of vitamin K1 in osteoporosis and correlate the synergistic interplay with Vitamin D: A randomized control study***" sponsored by ICMR, New Delhi submitted by Dr. Dharmendra Kumar, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1679/OS/2022 dated 1st February, 2022. **EC Comment:** • It is a randomized control study in which neither methodology; hypothesis or any references have been included. Where biochemical estimations will be carried out? • Consent form needs correction as going through it seems as if the study has already been completed. **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P23***
24.	Research proposal entitled "***To develop and validate the protocol for post-operative rehabilitation in acetabulum fracture cases: A prospective case control study***" sponsored by ICMR, New Delhi submitted by Dr. Dharmendra Kumar, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1681/OS/2022 dated 1st February, 2022. **EC Comment:** • Consent form needs correction as going through it seems as if the study has already been completed. • Methodology and references not provided • Correct the affiliation of Dr. Urmila. • Hypothesis and Methodology is missing • Justify whether the Investigations can be done in ESIC Hospital • There are no references. • **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM IIA/P24***
25.	Research proposal entitled "***A comparative study of patients from UP and Bihar for assessing surgical outcomes in obese and non-obese patients***" sponsored by ICMR, New Delhi submitted by Dr. Dharmendra Kumar, Additional Professor, Department of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1677/OS/2022 dated 1st February, 2022. **EC Comment:** • Consent form needs correction as going through it seems as if the study has already been completed. • Objectives/hypothesis not clear. • Methodology and references not provided • In metal ions why carbon monoxide has been included? • Where biochemical estimations will be carried out? • Entire proposal is sketchy. • Consent form in English and Hindi missing • There are no references **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM IIA/P25***
26.	Research proposal entitled "***An intervention in total knee arthroplasty through metal ions and RANKL mediate gene expression: A randomized control trial study***" sponsored by ICMR, New Delhi submitted by Dr. Dharmendra Kumar, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1680/OS/2022 dated 1st February, 2022. **EC Comment:** • Tile not clear, Centre proposal is sketchy • It seems that the study is completed, Why only fenalcs are selected? • Objectives/hypothesis not clear ("To investigate in vivo blood metal ion concentrations…" NOT CLEAR). • Methodology and references not provided • Consent form needs correction as going through it seems as if the study has already been completed. **EC Decision:** Pause -Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM IIA/P26***
27.	Research proposal entitled "***Correlation of epidemiological profile, management strategies and functional outcomes in acetabular fractures in North India: A multicentric study***" sponsored by ICMR, New Delhi submitted by Dr. Dharmendra Kumar, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1678/OS/2022 dated 1st February, 2022. **EC Comment:** • Methodology is sketchy there are no references **EC Decision:** Pause -Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM IIA/P27***
28.	Research proposal entitled "***Evaluation of long term complications, their spectrum***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	and magnitude in ICU survivor being followed in critical care follow up clinic" submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/158/2022 dated 17th February, 2022. ***Recommendation of Primary reviewer:*** • Kindly provide outcome parameters. Without knowing, what information is retrieved from the patient, waiver cannot be confirmed. Also, as the time frame has been fixed, it would be better to consider calculation of sample size. **EC Comment:** Same as above **EC Decision:** Pending ***Ref. code: 115th ECM IIA/P28***
29.	Research proposal entitled **"*Implementation of AMSP in various tertiary care centers across India*"** sponsored by ICMR, New Delhi submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/437/2022 dated 18th February, 2022. ***Recommendation of Primary reviewer:*** • Approved for Waiver **EC Decision:** Permission granted for waiver ***Ref. code: 115th ECM IIA/P29***
30.	Research proposal entitled **"*Reduced duration of eight versus twelve weeks of sofosbuvir-velpatasvir in treatment naive non-cirrhotic patients with chronic hepatitis C virus infection: A multicentric, open labeled, randomized, non-inferiority trial (RESOLVE)*"** sponsored by DHR, New Delhi submitted by Dr. Sumit Rungta, Head, Additional Professor, Department of Medicine Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. 1460/MedGastro/2022 dated 19th February, 2022. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** Approved ***Ref. code: 115th ECM IIA/P30***
31.	Research proposal entitled **"*Evaluation of nasolabial flap in oral defect created in oral squamous cell carcinoma patients*"** submitted by Prof. U.S. Pal, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 213/OMSF/2022 dated 25th February, 2022. ***Recommendation of Primary reviewer:*** • Kindly discuss in the meeting: Issue of Retrospective Ethical Clearance. For publication purposes. **EC Comment:** • Kindly remove the Consent form and apply for waiver of consent only. **EC Decision:** Approval subject to modification

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 2nd April, 2022

	Ref. code: 115th ECM IIA/P31
32.	Research proposal entitled "***To study the effectiveness of a tailored implementation strategy to improve adherence to a tuberculosis preventive treatment***" submitted by Dr. Sarika Gupta, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 472/Ped/2022 dated 26th February, 2022. ***Recommendation of Primary reviewer:*** • Kindly provide separate Assent Form. **EC Comment:** • As above **EC Decision:** Approval subject to modification *Ref. code: 115th ECM IIA/P32*
33.	Research proposal entitled "***A feasibility study for implementation of innovative RBSK-NTEP collaboration module for active case finding of tuberculosis among school students: Multicentric study***" submitted by Dr. Sarika Gupta, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 474/Ped/2022 dated 26th February, 2022. ***Recommendation of Primary reviewer:*** • Kindly provide separate Ascent Form. **EC Comment:** • As above **EC Decision:** Approval subject to modification *Ref. code: 115th ECM IIA/P33*
34.	Research proposal entitled "***Active screening & motivating the person with TB suggestive symptoms by trained youth club members of Nehru Yuva Kendra Sangathan (NYKS)***" submitted by Dr. Sarika Gupta, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 473/Ped/2022 dated 26th February, 2022. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** Approved *Ref. code: 115th ECM IIA/P34*
35.	Research proposal entitled "***Clinicoepidemiologic spectrum of hepatitis B patients at a tertiary care centre of North India and development of a simplified diagnostic and therapeutic algorithm***" submitted by Dr. Ajay Kumar Patwa, Prof. Jr. Grade, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 278/Med/22 dated 14th February, 2022. ***Recommendation of Primary reviewer:*** • Role of PI/Co-PIs not mentioned • Detailed methodology with Inclusion/Exclusion criteria not

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	mentioned. • Sample size not mentioned anywhere • Case record form / Demographic data form not attached **EC Comment:** • As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM IIA/P35***
36.	Research proposal entitled "***Generation of comprehensive methylome towards developing qPCR based epigenetic biomarker panel for early detection of buccogingival and tongue carcinoma***" submitted by Dr. Sameer Gupta, Additional Professor,, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/386/22 dated 26th February, 2022. ***Recommendation of Primary reviewer:*** • PI should be from parent institute , therefore Dr. Sameer Gupta of • Surgical Oncology Deptt will act as PI and Dr. Manisha Sachan from • Biotechnology Deptt of MNNIT site, Allahabad should be Co-PI • In Methodology ,study design and Exclusion criteria and grouping • not mentioned • Total sample size is not clear and not calculated (discrepancy between SOP form and Protocol • ICF clinical Investigator's Name must be there. • Budget from ICMR in SOP form is written as Rs. 38 lakhs/ and in protocol Rs.49,90,264/- Please justify. **EC Comment:** • As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM IIA/P36***
37.	Research proposal entitled "***Urine lipoarabinomannan antigen detection for diagnosis of pulmonary and extrapulmonary tuberculosis in adult population***" submitted by Dr. Ankit Kumar, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 283/22 dated 4th March, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation not done • ICF-H/E not similar ,should be revised • Structured questionnaire and Case record form not attached **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P37***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 2nd April, 2022

38.	Research proposal entitled "***A study of gaming disorder, social network addiction, sleep problems, coping styles, body esteem levels and emotionaldisturbances among undergraduate medical students***" submitted by Dr. Pawan Kumar Gupta, Additional Professor,, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 257/Psy dated 8th March, 2022. ***Recommendation of Primary reviewer:*** • Role of PI/Co-PIs not mentioned **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P38***
39	Research proposal entitled "***Retrospective study of vesico-vaginal fistulae associated with recto-vaginal fistulae repair***" submitted by Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 149/URO dated 9th March, 2022. • Inclusion/ Exclusion criteria –not mentioned • Sample size not mentioned • Why Patient information sheet is attached if direct patient involvement is not there, please justify. **EC Comment:** • As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM IIA/P39***
40	Research proposal entitled "***Impact of DNA methylation on proliferation of low vs high grade non-muscle invasive bladder cancer associated with autophagy in North Indian population***" submitted by Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 147/URO dated 9th March, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation not done (only formula is written) **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P40***
41	Research proposal entitled "***Assessment of nicotine dependence and readiness to change amongst patients attending Tobacco Cessation Clinic***" submitted by Dr. Vinay Kumar Gupta, Professor (Jr. Grade) Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 128/PHD/22 dated 9th March, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Ph.D. Scholar is not eligible for becoming Co-PI -Please remove the name (for discussion in open forum) • PI has mentioned the study design as Retrospective, but recruiting cases from TCC for observation, therefore the study will be Prospective observational study. **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P41***
IIB	**New Ph. D Proposal**
1.	Research proposal entitled "***Exploring the role of miRNA and epithelial mesenchymal transition (EMT) markers in prostate cancer***" sponsored by ICMR, New Delhi submitted by Mr. Gautam Prasad, Ph.D Scholar 2019, under the guidance Dr. Mohammad Kaleem Ahmad, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/682/22 dated 14th January, 2022. ***Recommendation of Primary reviewer:*** • Sample size discrepancy is there in total (350 in SOP form) and difference in grouping written in inclusion criteria (n=50) and sample size calculation (n=33). Please give exact total sample size and correct the discrepancy in number of cases in each group. (In methodology it is not clear that Blood and Tissue samples will be taken from same or different groups.) • Study design is not mentioned in protocol. • In Title there is only mention of Prostate cancer but in protocol BPH cases are also included- Please justify or correct. **EC Comment:** • As above **EC Decision:** Modify and re-submit (Tracking changes in word format) ***Ref. code: 115th ECM II B-Ph.D/P1***
2.	Research proposal entitled "***To assess the role of MTRR and MTHFR gene polymorphisms in rubella infected congenital heart disease patients aged between 0-11 months in North Indian population: A case-control study***" submitted by Ms. Sumedha Tripathi, Ph.D Scholar 2019, under the guidance Prof. Shally Awasthi, Head, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 77//Ped/22 dated 7th February, 2022. ***Recommendation of Primary reviewer:*** • Study design mentioned is Case control study, PI should mention details of study design in protocol that whether it is Prospective or Retrospective study (as Case-control studies are generally retrospective in nature). **EC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM II B-Ph.D/P2***
3.	Research proposal entitled ***"Ompact of a quality improvement intervention (QII) among nurses in terms of occurrence of nosocomial infection and client's satisfaction with Nursing care in PICU"*** submitted by Mrs. Anugrah Charan, Ph.D Scholar 2019, under the guidance Prof. Shally Awasthi, Head, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 475//Ped/22 dated 28th January, 2022. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** Approved ***Ref. code: 115th ECM II B-Ph.D/P3***
4.	Research proposal entitled ***"Efficacy of yogasana & meditation in the management of irritable bowel syndrome"*** submitted by Ms. Diksha Devi, Ph.D Scholar 2020, under the guidance Dr. Sunita Tiwari, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2403/PHY/22 dated 3rd March, 2022. ***Recommendation of Primary reviewer:*** • The current study must include a Co-PI who is an expert in Yoga/Meditation. • The study is funded by UGC, as per the PI. • No details of funding are given. • In the section on Privacy the PI has mentioned Direct identifiers and the ticked 'No' in confidential handling of data. This must be corrected. • Will suggest replacing the term 'Randomized Controlled Trial' with 'Randomized Controlled Study' **EC Comment:** • PI has superannuated-Change of guide needed **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM II B-Ph.D/P4***
II-B	**IMR-Faculty**
1.	Research proposal entitled ***"Genomic characterization of hepatitis C Virus infected patients who are non-responders to direct acting antiviral therapy in the tertiary Hospital care setup"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Suruchi Shukla, Assistant Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1806/22 dated 14th January, 2022. ***Recommendation of Primary reviewer:*** • Number of subjects is mentioned as 20 in the IEC form and as 15, and 25 in the Methods section of the proforma. Please correct this. **EC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM II B-IMR-F/P1***
2.	Research proposal entitled ***"Customized soft acrylic versus thermoplastic splint following release of post burn contracture of the hands: A comparative study"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Harsha Vardhan, Assistant Professor, Department of Plastic & Reconstructive Surgery , King George's Medical University, U.P., Lucknow vide letter no. 114/2022 dated 3rd February , 2022. ***Recommendation of Primary reviewer:*** • There are 3 Co-PIs from same Deptt (Plastic and Reconstructive Surgery) with same role-please justify • Sample size is only mentioned in SOP form (n =40) and not in Protocol and calculation not done • Child Assent Form not submitted (As recruitment of cases will be done from 12 year age group) **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Dr. D.N. Upadhyaya did not participate in discussion and making decision.*** ***Ref. code: 115th ECM II B-IMR-F/P2***
II-B	**Woman Scientist**
1.	Research proposal entitled ***"Bench to bedside: molecular evaluation and ex vivo validation of tetraspanin KAI-1 as a biomarker of metastatic progression in breast cancer "*** submitted by Dr. Richa Singh, under the guidance Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/139/22 dated 25th January, 2022. ***Recommendation of Primary reviewer:*** • Inclusion and Exclusion criteria are not mentioned. • Sample size calculation/justification not given. • Patient information sheet not attached. • ICF language should be easy to understand for the pay person/patient. • The language is too technical. **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM II B-WS/P1***
2.	Research proposal entitled ***"In vitro study on isolation and characterization of Human Antigen presenting cells and T cells and subsequent immune activation for immunotherapy application in Oral Cancer patients"*** submitted by Dr. Ruby Dwivedi,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Research Associate, Department of Oral Maxillofacial Surgery, FODS, King George's Medical University, U.P., Lucknow vide letter no. OMSD/RP/285/2022 dated 8th March, 2022. ***Recommendation of Primary reviewer:*** • Patient information sheet is not attached. • Language of ICF is to technical and not easy to understand for the common patient. • Sample size calculation/justification not done. • Role of Controls not defined. • Budget approval/allocation document not attached **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIB-WS/P2***
IIC	**Review of New Drug Trial**
1.	Research protocol no.082-20, Version no:1.0& Protocol amendment no.01 dated 14.01.2021 entitled ***"A prospective, open-label, multi-centered, non-randomized, non-comparative active post-marketing surveillance to test the safety and efficacy of diperoxochloric acid (DPOCL) topical solution in subjects with diabeticneuropathic ulcers of skin and subcutaneous tissue"*** sponsored by M/s Centaur House, Opp. Grand Hyatt, Vakola, Santacruz-East, Mumbai submitted by Dr. Kushagra Gaurav, Assistant Professor, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2155/2021 dated 2nd February, 2022. **Legal opinion:** • It does not include any of the mandatory provisions relating to Indemnification, Dispute Resolution, Force Majeure and Term and Termination. This needs to be revised as per other CTA formats followed by the University. **EC Comment:** • No reasoning for sample size of 'at least 200 participants' given • A payment clause is there in point number 19. How much amount and why the payment would be charged is not provided. • Insurance policy has expired. • Duration of study is incorrect, Subject participation is not mentioned • DSMB details missing • Ethical clearance form section 5 incomplete. **EC Decision:** Approval subject to modification and fulfillment Administrative formalities. ***Ref. code: 115th ECMIIC/P1***
2.	Research protocol no. GO42784 entitled ***"A phase III, randomized, open-label,***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	multicenter study evaluating the efficacy and safety of adjuvant giredstrant compared with physician's choice of adjuvant endocrine monotherapy in patients with estrogen receptor-positive, HER2-negative early breast cancer" sponsored by M/s F. Hoffmann-La Roche Ltd. submitted by Prof. Anand Kumar Mishra, HOD, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow, vide letter no. ES/08/2022 dated 22nd February, 2022. **Legal opinion:** • It does not include the mandatory provisions relating to Insurance, Dispute Resolution, and Force Majeure. This needs to be revised as per other CTA formats followed by the University. **EC Comment:** • Section 5, i, ii: not filled • DSMB details? • Why some elements of Consent have not been checked? **EC Decision:** Approval subject to modification and fulfillment Administrative formalities. ***Ref. code: 115th ECMIIC/P2***
3.	Research protocol no. ICR/19/007 entitled ***"A prospective, multi-center, single arm, phase IV study to assess the safety and efficacy of dienogest tablets in management of pelvic pain associated with endometriosis"*** sponsored by M/s Sun Pharma Laboratories Ltd submitted by Prof. Sujata Deo, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow, vide letter no. OG/495/2022 dated 28th February, 2022. **Legal opinion:** • A clause on Insurance may be added • In clause 22 the place of arbitration may be changed to Lucknow for convenience. **Comment:-** • How they reached sample size of around 232 peoples' not explained **EC Comment:** • The drug is New Drug, not IND: Wrongly checked in form • DSMB details? • Insurance policy is expiring in 3 months **EC Decision:** Approval subject to modification and fulfillment Administrative formalities. ***Ref. code: 115th ECMIIC/P3***
4.	Research protocol no. 20-03 (Protocol version No. 00; Dated 17-03-2022) entitled ***"A prospective, randomized, parallel, three-arm, open-label, multicenter, phase IV clinical trial to evaluate the immunological non-interference of Typhoid VI conjugate vaccine with Measles and Rubella vaccine administered to healthy infants"*** M/s Cadila Healthcare Ltd., Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

(Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway Ahmedabad submitted by Dr. Nishant Verma, Additional Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow, vide letter no. 410/Ped/2022 dated 19th February, 2022.

Legal opinion:

- I have reviewed Mr Verma's CTA. It does not have important provisions related to Insurance, Dispute Resolution and Force Majeure.
- We may include the aforementioned issues before moving forward with this CTA.

EC Comment:

- Section 5-1-2 Consent form Missing
- How they reached sample size of '900 children' not explained
- The drug is New Drug no IND: Wrongly checked in form DSMB details?
- Insurance has expired in March, 2022.

EC Decision: Approval subject to modification and fulfillment Administrative formalities.

Ref. code: 115th ECMIIC/P4

III **Modification**

1. Modification of Research protocol no. KCP-330-023 entitled: ***"BOSTON- A phase 3 randomized, controlled, open-label study of selinexor, bortezomib and dexamethasone (SVD) versus borterzomib and dexamethasone (Vd) in patients with relaplsed or refractory multiple myeloma (RRMM)"*** submitted by Dr. Shailendra Prasad Verma, Additional Professor, Department of Clinical Heamatology, King George's Medical University, U.P., Lucknow vide letter no. 43/CH/2021 dated 14th September, 2021.

The following documents were reviewed in the Meeting:

Sl. No.	List of Documents	Version/Date
1-	Informed Consent Form (ICF) – English ICF Summary of changes	India Master ICF Version # 5.0; Dated 22/Oct/2020 Final KCP-330-023 Version # 7.1; Dated 16/Oct/2020 Rest of World Master Template – Protocol Version 4.0 dated 17/Aug/2018 & IB ver 10.0 dated 21/sep/2020 Attached
2-	Translated ICF –Hindi	India Hindi Master ICF Final Version 5.0, Date 06/Nov/2020

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			Based on India Master ICF Version # 5.0 Dated 22/Oct/2020 Translated From English to Hindi on 06/Nov/2020
	3-	Translation Certificate of ICF–English to Hindi	Date of translation: 06/Nov/2020 Issued on: 06/Nov/2020
	4-	Back Translated ICF – Hindi to English	Back Translation of Hindi master ICF Based on India Master ICF Version # 5.0 Dated 22/Oct/2020 final Translated from English to Hindi on 06/Nov/2020 Back Translated From Hindi to English on 03/Dec/2020
	5.	Back Translation Certificate of ICF– Hindi to English	Date of Back translation: 03/Dec/2020 Issued on: 03/Dec/2020

EC Decision: Approved

Ref.code:87th ECMIIC/P4

2. Modification of Research protocol no. 5030801/GOPI Study entitled "***Prospective, non-interventional, multi-centre, post marketing surveillance study to evaluate the safety and tolerability of gaviscon oral suspension for the management of symptoms of gastroesophageal reflux disease***" sponsored by Reckitt United Kingdom submitted by Dr. Ajay Kumar Patwa, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 06/MED/2022 dated 2nd March, 2022.

The following documents were reviewed in the Meeting:

S. No	Documents
1.	**Informed consent forms (ICFs) in English:** Core Study ICD Version No. 3.1, dated 26-Nov-2021
2.	**Informed consent forms (ICFs) Translations:** Core Study ICD Version No. 3.1, dated 26-Nov-2021 Translated from English to Hindi Version 2.0 dated 30-Nov-2021
3.	**Back Translations of Informed consent forms (ICFs):** Core Study ICD Version No. 3.1, dated 26-Nov-2021 Translated from English to Hindi Version 2.0 dated 30-Nov-202 Back Translated from Hindi to English Version 2.0 dated 01-Dec-2021
4.	**Translation & Back Translation Certificates of ICF:** ICD - Translation and Back-Translation Certificates for Hindi dated 13-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Dec-2021.	
S. No	Table of Contents	

The following documents were reviewed in the Meeting:-

S. No	Documents ver. & date
1.	**Informed consent forms (ICFs) in English:** Core Study ICD Version No. 3.1, dated 26-Nov-2021
2.	**Informed consent forms (ICFs) Translations:** Core Study ICD Version No. 3.1, dated 26-Nov-2021 Translated from English to Hindi Version 2.0 dated 30-Nov-2021
3.	**Back Translations of Informed consent forms (ICFs):** Core Study ICD Version No. 3.1, dated 26-Nov-2021 Translated from English to Hindi Version 2.0 dated 30-Nov-202 Back Translated from Hindi to English Version 2.0 dated 01-Dec-2021
4.	**Translation & Back Translation Certificates of ICF:** ICD - Translation and Back-Translation Certificates for Hindi dated 13-Dec-2021.
S. No	Table of Contents

EC Decision: Approved

Ref.code:111th ECMIIC/P2

IV — Other Matter with the permission of Chair

1- Reg. request for re-approval of research proposal entitled ***"Outcomes of vital pulp therapy using various pulp capping agents"*** funded by CST, Lucknow submitted by Prof. Rakesh Kumar Yadav, Department of Conservative Dentistry & Endodontics, Faculty of Sciences, K.G's Medical University, UP, Lucknow vide letter no. 589/2022 dated 10th February, 2022.

Previous EC Decision: Approved

EC Decision: The approval has been sent. The same can be forwarded to sponsor.

Ref. code: 91st ECM II A/P4

2- Declaration regarding Conflict of Interest in CTA signature under the research protocol no. EX9536-4773 entitled "***Effect of semaglutide 2.4 mg once-weekly on function and symptoms in subjects with obesityrelated heart failure with preserved ejection fraction, and type 2 diabetes***" sponsored by M/s Novo Nordisk India Pvt. Ltd. submitted by Dr. Pravesh Vishwakarma, Professor Junior Grade, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 2133/Cardio/Res/2022 dated 16th March, 2022.

EC Comment:

- The PI may forward the letter of approval given by the Ethics Committee to the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Sponsor. This should be sufficient.
VI	**Brought to Ethics Committee after IX-PGTSC held on 15th March, 2022**
	Minutes of IX PG Thesis sub Committee" of "Institutional Ethics Committee" Meeting ***virtually*** held on 15th March, 2022 from 03.00 P.M. ***The following Members were present in the Meeting:*** 1. Dr. G.G. Agarwal -Member 2. Dr. A.A. Mahdi -Member 3. Dr. Rajendra Nath -Member 4. Dr. Anita Rani Singh -Member 5. Dr. D.N. Upadhyaya -Member 6. Dr. Shally Awasthi -Convener
I-A	**Action Taken**
1-	Clarification of research proposal entitled ***"To assess the role of VITAMIN D levels as a risk factor and prognostic marker in patients of acute ischemic stroke at a tertiary care centre in northern India"*** submitted by Dr. Kislaya Kamal, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 229/MED/2022 dated 4th February, 2022. **Previous PGTSC Comment:** • Patient record form needed ***The above comment forwarded to the P.I., Reply has given by P.I. which was forwarded to the Primary reviewer.*** ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P31***
2-	Clarification of research proposal entitled ***"A comparative study of plasma CYSTATIN C with renal resistive index as an early predictor of acute kidney injury in critically ill patients"*** submitted by Dr. Himanshu Mishra, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 390/MED/22 dated 26th February, 2022. **Previous PGTSC Comment:** • Kindly provide in ICF clear, understandable description of study procedure in simple language instead of writing study design. ***The above comment forwarded to the P.I., Reply has given by P.I. which was forwarded to the Primary reviewer.*** ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P14***
3-	Clarification of research proposal entitled ***"A cross-sectional study of***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

immunophenotypic profile in adult acute lymphoblastic leukaemia and its association with clinic-hematological parameters and treatment response" submitted by Dr. Kumar Varunanidhi, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 82/22 dated 24th January, 2022.

Previous PGTSC Comment:	PI response
Risk association with collection of bone marrow samples may be mentioned in the consent forms.	As bone marrow samples shall be collected during the diagnostic procedure and consent is taken each case, there is no additional risk associated with the study.

The above comment forwarded to the P.I., Reply has given by P.I. which was forwarded to the Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: IV PGTSC-IIA/P23

4- Clarification of research proposal entitled ***"Retrospective and prospective outcomes of transarterial chemoembolization in gestational trophoblastic diseases"*** submitted by Dr. Durga Singh, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 53/RD/22 dated 27th January, 2022.

Previous PGTSC Comment:

- TACE is an already established treatment modality. Why another study?
- Risk is not reasonable has been declared in the proforma. Please check this.
- Involvement of Vulnerable Participant-Not mentioned in proforma.
- Conflict in the number mentioned in the form (100) and in the proforma (32). Please check.
- Risks have not been explained in the consent. TACE will have risks of failed embolization, bleeding, hematoma etc. These must be mentioned.
- Check boxes in the proforma are not ticked. Please correct in ICF.
- Direct identifiers and Completely Anonymized are both ticked. Please correct in Privacy & confidentiality.
- Provisions for Medical / Psychosocial Support-Not mentioned
- Provisions for Treatment of Study-related injuries-Not mentioned
- Provision for Compensation-Not mentioned
- The study has eight co-supervisors besides one supervisor. Please mention the role of each supervisor in the project or curtail the number of names.

The above comment forwarded to the P.I., <u>Reply has given by P.I.</u> was reviewed by Primary reviewer.

Recommendation of Primary reviewer with <u>second opinion:</u>

- Query 1- Satisfactory response. Proforma not attached.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Query 2 and 3: Incomplete response. Does not mention if changes in the proforma have been done.
- Query 4- Satisfactory response. Proforma not attached
- Query 5- Incomplete response. Does not mention if changes in the proforma have been done.
- Query 6,7 and 8- Satisfactory response- Proforma not attached.
- Query 9 and 10- Incomplete response. Does not mention if changes in the proforma have been done.
- Query 11- Unsatisfactory response. Number of Co-PIs must be decreased.

Recommendation:-

- Revise and resubmit with altered proforma

The above comment again forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer with third opinion.

Their opinion of PR	PI Response
In the section on subject selection, vulnerable subjects has been ticked and handicapped and mentally challenged categories have been ticked. If this is true consent of a legally authorized representative will be required. Please confirm if this is true.	Changes in the ethical proforma have been done.
In the section on risks and benefits, answer to the query is the risk is reasonable has not been given?	Changes in the ethical proforma have been done.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: IV PGTSC-IIA/P38

5- Clarification of research proposal entitled ***"Conservative versus tube thoracostomy in patients with selected blunt injury chest-A prospective observational study"*** submitted by Dr. Shreedhar Shandilya, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no.296/22 dated 22nd January, 2022.

Previous PGTSC Comment:

- Kindly provide complete methodology.
- Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website. Use simple day to day Hindi language.

The above comment forwarded to the P.I., Reply has given by P.I. which was forwarded to the Primary reviewer.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

PI response Pending:

PGTSC Decision: Forwarded for first reminder

Ref. code: V PGTSC-IIA/P16

6- Clarification of research proposal entitled ***"Clinicopathological correlation of programmed death Ligand-1 (PDL-1) and HER2/neu expression in in lung carcinomas"*** submitted by Dr. Mohammad Arif, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.509/PCCM/22 dated 2nd January, 2022.

Previous PGTSC Comment:	PI response
Departmental affiliation of Dr. Esha Jafa shall be corrected in "Undertaking by Principal Investigator"	Departmental affiliation of Dr. Esha Jafa has been changed from Surgical Oncology to Medical Oncology.
Details of techniques and their reference shall be provided in Methodology.	Details of techniques and its reference has been added on page no.28

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: V PGTSC-IIA/P20

7- Clarification of research proposal entitled ***"Diagnostic yield of medical thoracoscopy in cases of exudative pleural effusion of undiagnosed etiology"*** submitted by Dr. Hemant Kumar, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.508/PCCM/22 dated 2nd January, 2022.

Previous PGTSC Comment:	PI response
Informed consent form states some minor complications including bleeding during the procedure. It shall be ensured that this point is also mentioned in the consent being from the subject.	Mentioned in **page no. 15** (English consent) and **page no. 17** (Hindi consent)
Explain from where is the bleeding likely to occur?	Bleeding from pleural biopsy site. **Page no. 11, 12, 14, 15 and 17.**
In the Methods section it is mentioned that Biochemical and cytological examination of pleural fluid will be carried out. However, no details or	biochemical like Protein, Sugar, adenosin deaminase (ADA), LDH etc and cytological examination like Total and differential Cell counts, Malignant

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	methodology is provided.	cytology etc **page no. 22**

The above comment forwarded to the P.I., Reply has given by P.I. which was forwarded to the Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: V PGTSC-IIA/P21

8- Clarification of research proposal entitled ***"Transfusion support in COVID-19 suspects"*** submitted by Dr. Anurag Singh, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no.498/21 dated 13th October, 2021.

Previous PGTSC Comment:

- Department Review Committee has only 3 members.
- There are 3 Co-PIs from the same department which seems superfluous. Please decrease the number of Co-supervisors or define their roles.
- IEC form doesn't mention –
  a. Type of study (Clinical/Epidemiological)
  b. Advertised or not?
  c. Contact person details in Consent Form d. Study involves blood sample collection which is not mentioned in the IEC form.
- The topic doesn't reflect the Objectives, please reconsider.
- IEC needs to be modified and resubmitted.

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer with his second opinion.

Comment:

- The response is not through proper channel and has not been forwarded through the office of the Head, Department of Transfusion Medicine.
- There is no response to Query number 1 (Insufficient members in Review Committee) and the DRC approval has not been attached.
- Response to queries number 2, 3, 4, and 5 are acceptable but the new proforma needs to be attached.
- Query number 6 has not been satisfactorily answered. The study involves human tissue and this must be mentioned in the proforma.
- Response to query number 7 is acceptable.

Recommendation:

- The application must be forwarded through the office of the HOD.
- The modified proforma must be attached to the response letter.
- Revise and resubmit

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PI response Pending. • Forwarded first reminder **PGTSC Decision:** Forwarded for First reminder ***Ref. code: V PGTSC-IIA/P28***
9-	Clarification of research proposal entitled ***"Clinicopathological study of non haematological paediatric tumors"*** submitted by Dr. Rohit Singh, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.208/22 dated 21st February, 2022. **Previous EC Comment:** • 1 supervisor and 4 co-supervisors are from the same department. Please reduce the number or mention each one's unique contribution. • Following sections in IEC form are incorrect/unfilled/erroneous – a. Privacy and confidentiality b. Use of biological material c. details of Consent d. Risks and Benefits. ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer with his second opinion.***

Second opinion of PR	PI Response
The number of C0-PIs has not been reduced.	For data collection from different labs in this department. Prof. Suresh Babu-Neuropathology Lab. Prof. Rashmi Kushwaha-Hematology Lab Dr. Malti Maurya-Cytology Lab Dr. Madhu Kumar-Cytology Lab
The number of Co-PIs has not been reduces 2 Co-PIs are from the same lab. (Cytology lab)	Both Co-PIs are on rotation basis to histopathology Lab and Cytolopathology Lab.
The incomplete sections mentioned in the last letter (Privacy and Confidentiality, Use of Biological Material, Details of Consent and Risks and Benefits) have again been incompletely filled.	Attached separately

	The above comment again forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer. ***Recommendation of Primary reviewer:*** • Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

PGTSC Decision: Approval ratified

Ref. code: V PGTSC-IIA/P30

10- Clarification of research proposal entitled ***"A fluoroscopic comparison between video laryngoscope and macintosh laryngoscope for assessment of cervical spine mobility during tracheal intubation in patients with cervical spine injury"*** submitted by Dr. Muthunagarathinam. M, JR-I, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1114/2021 dated 13th December, 2021.

Previous PGTSC Comment:	PI response
1 Supervisor & 3 cosupervisors from the same department please decrease the number or mentioned their unique roles.	Attached Separately
Sponsor information incorrect	Attached separately
Vulnerable/ special groups not ticked in IEC form	Attached separately
Privacy/ confidentiality section filled incorrectly	Attached separately
Use of biological material not filled	Attached separately
Detailed of consent not filled in IEC form.	Attached separately
Risk is mentioned as not reasonable	Attached separately
Benefits of video laryngoscopy are already known. Why this study	As most of the studies with videolaryngoscopy involved only normal patient. There are very few studies which compared videolarynoscope and macintosh laryngoscope during tracheal intubation in patients with cervical spine injury.
Conventional laryngoscopy in patients with cervical spine injury increases the risk of further trauma. Having video laryngoscopy which is less risky and still	Conventional laryngoscopy is still the standard of care in most of the centres with proper safety measures such as MILS. In this study both the groups with

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

doing laryngoscopy with a technique which is risky, will be unethical. Suggest this study be conducted in patients who may not be at risk of spinal trauma.	videolaryngoscope and conventional laryngoscope the safety measure is followed to reduce complications due to movement of spine.
Informed consent doesn't mentioned details of complications due to spine movement and due to fluoroscopy usage.	Attached separately

The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer with his second opinion.

Comment:

- The roles of investigators are still overlapping
- The PI proposes to document spinal movement during intubation in patients with spinal injury while knowing that spinal motion will be by viewers to the patient's wellbeing. Manual inline stabilization, if applied well, will not permit movement and thus the PI will not be able to document spinal movement for his thesis. If it is not applied well and movement is documented on fluoroscopy the PI will be threatening the patient's will being. This is UNETHICAL and cannot be permitted.

The above comment forwarded to the P.I.

PI response Pending.

- Forwarded for First reminder

Ref. code: V PGTSC-IIA/P31

11- Clarification of research proposal entitled ***"Outcome of patients with blunt trauma chest and possible risk factors affecting mortality in critical care unit"*** submitted by Dr. Neetu Pal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/51/22 dated 17th January, 2022.

Previous PGTSC Comment:	PI response
1 supervisor and 2 co-supervisors are from the same department. Please define their unique roles or decrease their number.	Yes, as per your advice remove-1 Co-Supervisor (Dr. Manoj Kumar Chaurasiya) 1 supervisor-Prof. Dinesh Singh and 1 Co-supervisor-Dr. Vipin Kumar Singh (Anesthesiology) 2 Co-supervisor- Dr. Vaibhav Jaiswal (Trauma Surgery)
Sponsor information incorrectly filled.	Sponsor information nil.

The above comment forwarded to the P.I., Reply has given by P.I. which was forwarded to the Primary reviewer.

Recommendation of Primary reviewer:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Approved

PGTSC Decision: Approval ratified

Ref. code: V PGTSC-IIA/P32

12- Clarification of research proposal entitled ***"Comparison of infraclavicular brachial plexus block and combination of infraclavicular brachial plexus block with suprascapular nerve block for shoulder surgeries: A randomized control trial"*** submitted by Dr. Parul Saxena, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/08/22 dated 3rd January, 2022.

Recommendation of primary reviewer:

The fundamentals of performing RCT are not completely Specified:

(a) Clinical Trial Registry
(b) Is blinding needed?
(c) Research hypothesis is not properly defined: whether it is (i) inferior, (ii) superior or (iii) equivalence trial?
(d) The sample size will depend on the research hypothesis. Statistical Analysis section should be more specific.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer with second opinion.

- The revised version of is incomplete.
- You have not addressed the points raised earlier.
- The sample size formula is also not clear.

Previous PGTSC Comment:	PI response
The fundamentals of performing RCT are not completely Specified: (a) Clinical Trial Registry (b) Is blinding needed? (c) Research hypothesis is not properly defined: whether it is (i) inferior, (ii) superior or (iii) equivalence trial?	As per your advice: a. Yes, After ethical clearance applied. b. Single blinded study c. Equivalence trial
(d) The sample size will depend on the research hypothesis. Statistical Analysis section should be more specific.	Sample size has been calculated as 88. The formula used is: **Sample size=Z^2 x (p) x (1-p)C^2** Where, Z=1.65 for 90 percent confidence level p (prevalence)= 17% C (margin of error) =0.1 Wiegel M et al (2017)

PI response incomplete- Pending

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

PGTSC Decision:

- Forwarded for First reminder

Ref. code: VI PGTSC-IIA/P5

13- Clarification of research proposal entitled ***"Prospective observational study on hyponatremia in acute encephalitic syndrome in children: its occurrence and effect on the outcome"*** submitted by Dr. Nikita Diwan, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 79/Ped/22 dated 12th January, 2022.

Previous PGTS Comment	PI response
Number of subjects is 200 or 215?	Number of subject 200 enrolled in the study
Vulnerable subjects have not been ticked even though it is a study on children.	Attached separately
Section on Consent is incomplete.	Attached separately
Answer to 'Risk is reasonable' is NO. 5. Assent form for children is not attached.	Attached separately

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer with second opinion.

- Vulnerable/Special group subject's section has still not been edited.
- Section on Consent is still incompletely filled.
- Answer to the question 'Risk is reasonable' is still ticked as 'No'

The above comment forwarded to the P.I.

PI response Pending

- Forwarded first reminder

Ref. code: VI PGTSC-IIA/P30

14- Clarification of research proposal entitled ***"Prospective study of complications after post traumatic decompressive craniectomy"*** submitted by Dr. Pritesh Bharatkumar Yadav, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/93/22 dated 27th January, 2022.

Previous PGTSC Comments	Clarification
There is no research hypothesis	Hypothesis: It Is a prospective observational study ,so we will be studying the complication following post traumatic decompressive craniectomy for traumatic brain injury. Complication will be noted in tabular form in terms of clinical , radiological and psychological form .

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Sample size calculation is missing	All patients who will undergo post traumatic decompressive craniectomy in tertiary care centre (Department of neurosurgery KGMU lucknow) between 1st july 2021 to 31st may 2022.
	There is no Statistical analysis section	It is an observational study . If needed : • The data will be summarized using medians for continuous variables, and counts and percentages for categorical variables. • Differences in continuous variables will be analyzed using the Student t-test, while categorical variables will be evaluated using the chi-square test. • Values with $p < 0.05$ will be considered statistically significant.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P2

15- Clarification of research proposal entitled ***"Prevalence and predictors of persistent pulmonary hypertension of neonates in hospitalised hypoxemic new born infants: A prospective hospital based study"*** submitted by Dr. Barnika Nath, JRI, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no.530/Ped/22 dated 3rd March, 2022.

Previous PGTSC Comment:

- This is an observational study primarily for finding prevalence of persistent pulmonary hypertension of neonates.
- It should not be used for predicting the risk factors.
- One use of a cross-sectional study is to determine the association between an outcome variable and some **explanatory variables**, for example to estimate the prevalence of a disease, perhaps as a function of some explanatory variables. An association between outcomes and explanatory variables may suggest causality, although a causal link usually cannot be established from a single cross-sectional survey because such studies give no information on the temporal ordering of possibly causal events.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P3

16- Clarification of research proposal entitled ***"Cerebello-pontine angle tumors: A 10 years experience at a tertiary care center"*** submitted by Dr. Ravi Prakash Verma, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/94/22 dated 27th January, 2022.

Previous PGTSC Comments	PI response
Sample size is missing	The study will take all cerebello-pontine angle cases admitted in tertiary care centre (Department of Neurosurgery KGMU Lucknow) from 1 Jan 2011 to 31 Dec 2020. 345 cases were admitted with average 0f 30 patients per year.
Statistical analysis is missing	• The data will be summarized using medians for continuous variables, and counts and percentages for categorical variables. • Differences in continuous variables will be analyzed using the Student t-test, while categorical variables will be evaluated using the chi-square test. • Values with $p < 0.05$ will be considered statistically significant.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P4

17- Clarification of research proposal entitled ***"Retrospective study of paediatric head injury: an institute experience from past 5 years"*** submitted by Dr. Vishal Kumar, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.NS/95/22 dated 27th January, 2022.

Previous PGTSC Comments	PI response

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Research hypothesis is missing	This study is retrospective observational study . This study will evaluate factors(demographic, clinical,radiological) determining the outcome of paediatric head injury patients.
sample size calculation is missing	The study will take all cases of paediatric head injury admitted in Department of Neurosurgery KGMU from 1 jan 2016 to 30 jun 2021. 1250 cases were admitted with average 0f 250 patient per year.
statistical analysis is missing	The data will be summarized using medians for continuous variables, and counts and percentages for categorical variables. Differences in continuous variables will be analyzed using the Student t-test, while categorical variables will be evaluated using the chi-square test. Values with $p < 0.05$ will be considered statistically significant.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P5

18- Clarification of research proposal entitled ***"Study on association of occurrence of oral mucormycosis with severity of COVID-19 infection, demographics and co-morbidities in COVID-19 patients"*** submitted by Dr. Nikhil Gupta, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.505/OP/22 dated 1st February, 2022.

Previous PGTSC Comments	PI response
It is a retrospective observational study however in methodology it is given that participants will be screened and detailed history will be taken and clinical examination will be carried out. Thereafter, biopsy samples will be taken.	All the tissue biopsy reports of the patients from the departmental data registers will be screened. The finally selected reports of the participants that meet all the inclusion criteria will be included in the present study. Thereafter,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 2nd April, 2022

	From where patients will be recruited? It is not clear.	the participants will be screened by taking the details from their case history sheets. The tissue specimens of the finally selected participants submitted for histopathological examination will be observed by naked eye and stereomicroscope during grossing. The specimens will then undergo routine tissue processing. Tissue sections of 3-4 µm will be cut using microtome and stained using Haematoxylin and Eosin stain, PAS stain and KOH. The slides will be observed under compound microscope.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P11

19- Clarification of research proposal entitled ***"Characteristics and factors affecting flares in spondyloarthritis patients and its impact on functional limitation"*** submitted by Dr. Abilash Krishnan V, JRI, Department of Clinical Immunology and Rheumatology, King George's Medical University, U.P., Lucknow vide letter no.Rh/47/22 dated 25th January, 2022.

Previous PGTSC Comments	PI response
Start date of the project is given as July ,2021 .Without IEC approval how was the project initiated? A clarification may be taken.	The project was expected to start by July 2021. No initiatives related to the project have been undertaken, pending approval of the IEC. So it is changed in the executive summary that ' The study will be conducted 1 year in Department of Rheumatology in King George's Medical University, Lucknow from date of ethical clearance.'

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Primary reviewer.
Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P14

20- Clarification of research proposal entitled ***"Effect of dexmedetomidine infusion on post operative cognitive dysfunction in elderly patients after oral cancer surgery and its correlation with ADRA2A genotype: A double blinded randomized controlled study"*** submitted by Dr. Swati Srivastava, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/123/22 dated 5th February, 2022.

Previous PGTSC Comments	PI response
Kindly mention from which department oral cancer patient swill be enrolled. As the study subjects are patients undergoing surgery for oral cancers, kindly add a clinician who performs such surgeries or declare who among the investigator will perform such surgeries or declare who among the investigators will perform such surgery.	All oral cancer patients will be enrolled from the Departments of General Surgery and Surgical Oncology, KGMU, Lucknow. Clinicians added in both departments. General Surgery-Dr. Jitendra Kushwaha (Added) Surgical Oncology-Dr. Sameer Gupta
If the patient is not being operated by the Co-guide, the surgeon must be informed about the inclusion of the patient in the study.	Yes, Surgeon will be informed about the inclusion of the patients in the study if the patient is not being operated by the co-guide.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.
Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P15

21- Clarification of research proposal entitled ***"Clinical profile, treatment modalities and outcome of takayasu arteritis patients attending rheumatology tertiary care centre in Northern India"*** submitted by Dr. Dogga Prasanna Kumar, SRI, Department of Clinical Immunology and Rheumatology, King George's Medical University, U.P., Lucknow vide letter no.Rh/85/22 dated 10th February, 2022.

Previous PGTSC Comments	PI response
Submit for waiver of consent	Waiver of consent is being submitted
Keep patient identifiers anonymous	Patients details in the data collected is

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 2nd April, 2022

		entirely anonymized. No photograph or material disclosing personal patient information will be included in and future publication. Kindly refer to the study design and method attached.
	Calculate power of the study on samples accrued in your department	Ours is a retrospective observational study whereby we have included all patients from our records from 2017 to 2021 whosoever fulfilled the inclusion criteria as defined in the proposal using convenient sampling. Hence power of the study was not calculated.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P16

22- Clarification of research proposal entitled ***"Infection profile of patients and utility of neutrophil CD64 expression, presepsin, procalcitonin, neutrophil to lymphocyte ratio and crp in differentiating infections from flares in systemic lupus erythematosus"*** submitted by Dr. Mukesh Kumar Maurya, SR, Department of Clinical Immunology and Rheumatology, King George's Medical University, U.P., Lucknow vide letter no.Rh/46/22 dated 25th January, 2022.

Previous PGTSC Comments	PI response
1) Kindly calculate power in your recruitment of 100 patients.	After discussion with Dr. V. K. Singh (Statistician cum Associate Professor (NM) to Research Cell, In the present study if we recruit minimum 100 patients for $\alpha = 5\%$, the power will be 85%. Reference: PASS sample size software, test for proportion. Intramural grant will be utilized for procurement of the Neutrophil CD 64 Expression (flow cytometry), presepsin and procalcitonin kits. Rest all the investigations are routine in

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	2) Please state clearly that all the investigations are routine in nature and no additional cost will be borne by any participant and in case it is no so, kindly mention the same in the informed consent form.	nature and no additional cost will be borne by any participant.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P18

23- Clarification of research proposal entitled ***"Comparative study between quadratus lumborum versus transverse abdominis plane block in laparoscopic pyeloplasty for post-operative pain relief"*** submitted by Dr. Manoj Kumar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.60/22 dated 19th January, 2022.

Previous PGTSC Comments	PI response
Kindly explain the study procedure to the patient in simple language instead of writing study design.	Attached separately.
Kindly follow the SOP provide by IEC, available on Website.	Attached separately.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Benefit of the study states that QLB is better than TAP in hysterectomy patients. Kindly explain the benefit of current study, in which patients is participating.

The above comment forwarded to PI.

PI response pending.

- Forwarded to First reminder.

Ref. code: VII-PGTSC-IIA/P19

24- Clarification of research proposal entitled ***"Impact of disease perception education on health-related quality of life, mental health and disease activity in patients with rheumatoid arthritis"*** submitted by Dr. Ankush P.M, SR, Department of Clinical Immunology and Rheumatology, King George's Medical University, U.P., Lucknow vide letter no.Rh/50/22 dated 25th January, 2022.

Previous PGTSC Comments	PI response

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated. 2nd April, 2022

	Kindly justify the role of Child Psychologist for psycho education of subject>18 years.	Dr. Pooja Mahour is a registered Clinical Psychologist under RCI. She has done her M.Phil and PhD in Clinical Psychology. She sees patient of all age groups (i.e Children, Adolescent, Adults and elderly)

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

Ref. code: VII-PGTSC-IIA/P20

25- Clarification of research proposal entitled ***"Incidence of post operative low back pain with median and paramedian approach in obese women patients undergoing surgery in spinal anaesthesia"*** submitted by Dr. Robin Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/99/22 dated 1st February, 2022.

Previous PGTSC Comments	PI response
Kindly tabulate the known advantages and disadvantages of 2 methods.	Attached separately
Who among the investigators will enroll the patients?	All patients will be enrolled by the Principal-Investigator.
Who among the investigators will perform the procedure?	Consultant In charge on the day of surgery will perform the procedure.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P22

26- Clarification of research proposal entitled ***"A comparative study of characteristics and outcomes in patients of interstitial pneumonia with autoimmune features(IPAF) and connective tissue disease associated interstitial lung disease (CTD-ILD) in a tertiary teaching center in northern India"*** submitted by Dr. Kamble Nishant Gautam, SR, Department of Rheumatology, King George's Medical University, U.P., Lucknow vide letter no.Rh/62/22 dated 31st January, 2022.

Previous PGTSC Comments	PI response
In subject Volunteers instead of patients	Corrected[Type of subject, Patient

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	has been ticked.	ticked]
	No option is selected in 'Vulnerable subject' section.	Corrected [Seriously ill and ill]
	Confidential handling of data has been ticked 'No'	Corrected [Yes]
	Sample size calculation not done.	Calculated, separately mentioned under Material and method section.
	Methods section in Proforma is inadequate/incomplete and has no details of data handling image acquisition/data usage/statistical methods applied etc.	Details of data handling, data usage and statistical methods applied mentioned.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P24

27- Clarification of research proposal entitled ***"Correlation of serum endocan level in preterm labour"*** submitted by Dr. Anamika Shahi, JRII, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. 1202/ OG/21 dated 31st December, 202.

Previous PGTSC Comments	PI response
Use of blood/body fluids has not been ticked in Proforma	I am resubmitting annexure after completion

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Inclusion criteria unclear.	**Inclusion criteria-** • All pregnant women who have been admitted with complaint of preterm labour pain from antenatal clinic will be enrolled for the study. • According to ACOG definition Preterm labor is defined as onset of regular uterine contractions with progressive cervical changes between period of gestation of 20 weeks to 37 weeks.
No mention of statistical analysis/how data will be analyzed	**Statistical analysis-** The statistical analysis will be done using latest version of SPSS (Statistical Package for Social Sciences) statistical analysis software version 23rd. categorical variables will be presented as mean ± SD. Quantitative variables will be compared using unpaired-t-test. Qualitative variables will be compared by using chi- square test/Fischer's exact test. Correlational coefficient will be used to check the strength of linearity.
Too many Co-PIs case management is not reason enough to be part of a research project; one has to actively participate in it. Justify.	Your advice to reduce my co-PIs has been very well taken but these documents have been submitted to Dean Office long time back. So, if possible please consider the same with continuing with same Co-PIs for this time. Your suggestion will be very much considered in future correspondence.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P25

28- Clarification of research proposal entitled ***"Correlation of body mass index and postoperative pain in patients undergoing abdominal hysterectomy under spinal anaesthesia"*** submitted by Dr. Bhagyesh Pratap Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/102/22 dated 1st February, 2022.

Previous PGTSC Comments	PI response
Age specification in Inclusion criteria not mentioned	Age 30 years- 60 years included in the study.
VAS Score chart -not attached	Attached separately

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P35

29- Clarification of research proposal entitled ***"Comparative evaluation of dexmedetomidine and butorphanol on perioperative Hemodynamics, sedation and postoperative analgesia for patients undergoing lower abdominal surgery"*** submitted by Dr. Avinash Kumar Yadav, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/128/2022 dated 7th February, 2022.

Previous PGTSC Comment:	PI response
VAS Score chart for pain and Ramsay Sedation score (RSS) chart	Attached separately

The above comment forwarded to the P.I., Reply has given by P.I.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: VII-PGTSC-IIA/P37

30- Clarification of research proposal entitled ***"A study on treatment regimen outcome and ADR monitoring in adult patients with tubercular meningitis at tertiary care Centre"*** submitted by Dr. Ajit Kumar Mishra, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 216/Pharma/22 dated 7th March, 2022.

Previous PGTSC Comment	PI response
There are eight Co-PIs including one from RML Institute-Justify their roles.	5 Co-PIs removed in this study Prof. Rajendra Nath (Removed) Prof. Surya Kant (Removed) Dr. Rishi Pal (Removed) Dr. Arpita Singjh (Removed) Dr. Narendra Kumar (Removed)
Study variables and population parameters are to be properly chosen.	Parameters is given in sample size calculation part (Attached separately)
Research hypothesis is to be defined in term of population parameters.	Attached Separately
Methodology section is poorly written.	Improved and Attached separately
Sample size calculation is inaccurate. Sample size formula picked arbitrarily	Attached separately
Statistical Analysis section is not specific to the study. It is written arbitrarily.	Attached separately

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Dr. Rajendra Nath did not take part in discussion and making decision.

Ref. code: VIII-PGTSC-IIA/P2

31- Clarification of research proposal entitled ***"A prospective study of perioperative and quality of life outcomes after endoscopic groin hernia repair by extended totally extraperitoneal repair"*** submitted by Dr. Sheefali Chandra, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no.633/22 dated 2nd March, 2022.

Previous PGTSC Comment:	PI response
Patient Information Sheet Not attached,	Attached separately

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Sample Size: kindly confirm 30/35, Duration of study: kindly confirm 1 year/2 years, ICF: Kindly explain the study procedure to the patient in simple language instead of writing study design.	Total sample size is 30 (using convenient sampling) Duration of study: 1 year
	Kindly follow the SOP provided by IEC, available on Website.	Attached separately

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VIII-PGTSC-IIA/P9

32- Clarification of research proposal entitled ***"Role of micro RNA expression as biomarker in breast cancer"*** submitted by Dr. Nijarth Shahi, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 662/22 dated 5th March, 2022.

Previous PGTSC Comment:

- Sample size calculation is not clear. Justify the sample size of 60 patients. Methodology is not properly described. ICF: Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website.

The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.

Recommendation of Primary reviewer:

- Still the procedure is not explained properly in ICF. "What will be done with her RNA" should be told to the patient before taking her consent

PGTSC Decision: Approval subject to modification.

Ref. code: VIII-PGTSC-IIA/P11

33- Clarification of research proposal entitled ***"Study of single nucleotide polymorphism in MGMT gene promoter region and correlation with MGMT methylation status and prognosis in glioblastoma"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Krachi Agarwal, JR-I through her Mentor Dr.Shivanjali Raghuvanshi, Associate Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.295/2022 dated 8th March, 2022.

Previous PGTSC Comment:

- Total 6 Co-PIs , 2 from Pathology and 2 from Neurosurgery with same role,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	please reduce the number of Co-PIs or justify the same and correct the name of Department of Prof. B K Ojha (HOD , Neurosurgery Deptt.). • Age specificity not mentioned in Inclusion criteria • Revise SOP form as not filled properly leaving parts of the question no.-5 ,8 & 10 unanswered. ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:*** • Age specificity is mentioned but it includes pediatric subjects. • As pediatric subjects are to be included in this study, therefore, Guardian and Child Assent Form should be submitted along with ICF. **PGTSC Comment:** • As pediatric subjects are to be included in the study therefore Guardian consent and Child's assent **forms needed.** **PGTSC Decision:** Approval subject to modification ***Ref. code: VIII-PGTSC-II B IMR-R/P5***
34-	Clarification of research proposal entitled ***"Impact of life style modification behaviour (LSMB) on physiological parameters, sleep pattern and quality of life among patients with poly cystic ovarian syndrome (PCOS) in tertiary care Hospital"*** submitted by Ms. Pratibha Singh under the guidance Dr. Suchana Roy Bhowmik, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.376/X.51/22 dated 25th February, 2022. **Previous EC Comment:** • The proforma has not been signed by the Co-PI from Deptt. of Obst. & Gynaecology ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIC/P2***
35-	Clarification of research proposal entitled ***"Effect of infrared radiation on post-operative pain and wound healing of patient who underwent sternotomy in tertiary care Hospital"*** submitted by Ms. Sneha Angel Solomon under the guidance Mrs. Rashmi P. John, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.379/x.51/22 dated 25th February, 2022. **Previous EC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Will suggest changing 'Infrared Radiation' to 'Infrared Light' or 'Infrared therapy' to avoid misconceptions. ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIC/P7***
36-	Clarification of research proposal entitled ***"Effectiveness of educational package on knowledge regarding care of children receiving chemotherapy among caregivers of tertiary care Hospital"*** submitted by Ms. Nandita under the guidance Mr. Subin.S, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.380/X.51/22 dated 25th February, 2022. **Previous PGTSC Comment:** • Name and phone number of contact person not mentioned on consent form. • Consent and assent for children are both required. • Under vulnerable subjects 'Elderly' is ticked ***The above comment forwarded to the P.I., Reply has given by P.I.*** ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIC/P8***
37-	Clarification of research proposal entitled ***"Effectiveness of the premature infant oral motor intervention on oral feeding among preterm infants in tertiary care Hospital"*** submitted by Ms. Divya Chakraverty under the guidance Mr. Subin.S, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.377/X.51/22 dated 25th February, 2022. **Previous PGTSC Comment:** • Hindi consent form shall be in simple language. • Annexure-I Need of the study shall be re-written in future tense as it seems the study has already been done. • "My study" used everywhere needs to be corrected to in the "proposed study" ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIC/P9***
38.	Clarification of research proposal entitled ***"Assess the awareness and attitude towards maternal rights among reproductive age women in tertiary care Hospital"*** submitted by Ms. Alka Bharti under the guidance Mrs. Sudha Mishra, Assistant Professor, KGMU

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.370/X.51/22 dated 25th February, 2022. **Previous PGTSC Comment:** • Hindi consent form shall be in simple language. • "Client awareness" "grahak" needs to be changed ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIC/P10***
39-	Clarification of research proposal entitled ***"Efficacy of hands-on-training on performance of use of incentive spirometry and oxygen saturation among hospitalized patients in respiratory ward at tertiary care Centre"*** submitted by Ms. Priya under the guidance Dr. Suchana Roy Bhowmik, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.375/X.51/22 dated 25th February, 2022. **Previous PGTSC Comment:** • Hindi consent form shall be in simple language ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIC/P11***
40-	Clarification of research proposal entitled ***"Effectiveness of splint on peripheral intravenous therapy among hospitalized children in tertiary care Hospital"*** submitted by Ms. Chaudhari Amrita Singh under the guidance Mr. Subin. S, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.378/X.51/22 dated 25th February, 2022. **Previous PGTSC Comment:** • Very poorly written. • Hindi consent form shall be in simple language • Study group is mentioned as an experimental group and needs to be corrected. ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIC/P12***
41-	Clarification of research proposal entitled ***"A study to assess the work-family conflict***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	and its association with psychological distress among working women" submitted by Ms. Shweta Ranjan under the guidance Mrs. Sudha Mishra, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.372/X.51/22 dated 25th January, 2022. **Previous PGTSC Comment:** • Hindi consent form shall be in simple language ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIC/P13***
42-	Clarification of research proposal entitled ***"Assess the quality of life and emotional distress among infertile women in tertiary care Centre"*** submitted by Mrs. Deeksha under the guidance Mrs. Sudha Mishra, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.371/X.51/22 dated 25th February, 2022. **Previous PGTSC Comment:** • Hindi consent form shall be in simple language ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIC/P14***
43-	Clarification of research proposal entitled ***"Impact of Nurse led renal Rehabilitation information module (NLRRIM) on quality of life, activity of daily living and renal function among hemodialysis patients in tertiary care hospital"*** submitted by Mrs. Preeti Singh under the guidance Dr. Suchana Roy Bhowmik, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.373/X.51/22 dated 25th February, 2022. **Previous PGTSC Comment:** • Hindi consent form shall be in simple language ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIC/P15***
44-	Clarification of research proposal entitled ***"Effect of education related to danger signs of pregnancy on knowledge among pregnant mothers in tertiary care hospital"***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	submitted by Ms. Nidhi Sachan under the guidance Dr. Suchana Roy Bhowmik, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no. 374/X.51/22 dated 25th February, 2022. **Previous PGTSC Comment:** • Hindi consent form shall be in simple language • In the questionnaire "Nuclear family' is translated to "Parmanu pariwar" needs to be corrected and Hindi translation needs to be improved. ***The above comment forwarded to the P.I., Reply has given by P.I. was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:*** • In the Hindi consent form Participant is mentioned as "ग्राहक" ; it shall be changed to "प्रतिभागी". **PGTSC Comment:** As above **PGTSC Decision:** approval subject to modification ***Ref. code: VIII-PGTSC-IIC/P16***
45-	Clarification of research proposal entitled ***"Microbial contamination of surgical scrubs & mobile phones in the operating theatre- A pilot study"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Mr. Vaibhav Singh through his Mentor Dr. Sheetal Verma, Associate Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 2251/2022 dated 26th February, 2022. **Previous PGTSC Comment:** Sample size calculation not done (it is a Pilot study) **Previous PGTSC Decision:** Approved **PGTSC Decision:** Noted ***Ref. code: VIII-PGTSC-II B IMR-S/P1***
IB	**Expedited review**
1-	Expedited review of research proposal entitled ***"ER and PR receptor expression in case of endometrial hyperplasia and malignancy: A cross-sectional study"*** submitted by Dr. Manju Singh Sirohi, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.114 dated 28th January, 2022. ***The above research proposal forwarded to two Primary reviewers.*** **Recommendation of First Primary reviewer:** • Wrong informed consent form is attached (that of Dr. Hemant Kumar from Pulmonary Critical Care Medicine Department) • Incomplete performa attached and that too not properly photocopied, please sent it again. ***The above comment forwarded to the Principal-Investigator, response received by PI.*** **PGTSC Decision:** • The above comment forwarded to both Primary reviewers for review. ***Ref. code: IX-PGTSC-IB/P1***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

II-A	New Thesis-Resident
1.	Research proposal entitled ***"Study to evaluate accuracy and surface reproducibility of conventional and virtual denture bases"*** submitted by Dr. Deep Shikha Tripathi, JRI, Department of Prosthodintics and Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.1066/22 dated 31st January, 2022. ***Recommendation of Primary reviewer:*** • The Study objective is not formulated into a proper research hypothesis. • This is not "observational design". There are two comparison groups. So, it should be prospective cohort study. • The sample size calculation is not given. This is because of absence of research hypothesis. • The method of distribution of subjects in the two groups is not mentioned. • The statistical analysis section should be more specific. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Assessment of snakebites reporting to emergency medicine Department"*** submitted by Dr. Utsav Anand Mani, SR, Department of Emergency Medicine, King George's Medical University, U.P., Lucknow vide letter no.17/EM/22 dated 5th February, 2022. ***Recommendation of Primary reviewer:*** • This seems to be a prevalence study. The primary objective and corresponding research hypothesis should be written in that light. • The numerator and denominator should be properly defined. • The sample size calculation should be done for the prevalence study. Simply giving number 500 is not enough. • There are variety of "Major objectives". It should be split into primary and secondary objectives. • For achieving some of these objectives, the proper questionnaire would be required. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Molecular mechanism of preventable causes of Oral cancer and precancer in patients with tobacco product habit"*** submitted by Dr. S. Ezhilarasi, JRI, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. OMSD/125/22 dated 21st January, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The study design is not mentioned. • The sample size calculation uses formula for two groups. What are the two groups? What are the different quantities (parameters) used in the formula? • There is no statistical analysis section **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Comparative evaluation of platelet rich fibrin (PRF) and amniotic membrane (AM) in necrotic immature permanent teeth: A rendomised clinical trial"*** submitted by Dr. Pallavi Yadav, SR, Department of Paediatric & Preventive Dentistry Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/18/22 dated 19th February, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Desision:** • Approved ***Ref. code: IX-PGTSC-IIA/P4***
5.	Research proposal entitled ***"To elucidate the neuro -protective effect of omega-3 fatty acid supplementation in acute spinal cord injury subjects: A prospective longitudinal cohort study"*** submitted by Dr. Khurshid Alam Ansari, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no.1685/OS/22 dated 2nd February, 2022. ***Recommendation of Primary reviewer:*** • Number of subjects to be included in different groups is not clear. • For biochemical investigations methods are not given as also where these estimations will be carried out? **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Analysis of functional and radiological short term outcomes of uncemented total HIP replacement-A prospective cohort study"*** submitted by Dr. Upendra Kumar Patel, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no.210/OS/22 dated 18th January, 2022. ***Recommendation of Primary reviewer:*** • It is not clear if outdoor or indoor patients will be recruited as the source population; it is mentioned that patients visiting KGMU Orthopedic OPD will be taken into study while in the consent form it is mentioned that all patients admitted in the Orthopedic Department will be the study subjects. • In consent form complications relating to hip replacement shall be mentioned.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-IIA/P6***
7.	Research proposal entitled ***"To elucidate the role of magnesium as predictor of neurological recovery in the acute traumatic spinal cord injury (ATSCI): A prospective longitudinal cohort study"*** submitted by Dr. Virendra Kumar, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no.1275/OS/21 dated 28th December, 2021. ***Recommendation of Primary reviewer:*** • For biochemical investigations (Serum Magnesium levels) methods are not given as also where these estimations will be carried out? Where will it be done? **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Assessment of nutrition status and its effect on outcome in patient with limb in jujries by subjective global assessment as a screening tool"*** submitted by Dr. Divya Bhanu, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no.1274/OS/21 dated 28th December, 2021. ***Recommendation of Primary reviewer:*** • For biochemical investigations (biomarkers) methods are not given as also where these estimations will be carried out? Where will it be done? **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-IIA/P8***
9.	Research proposal entitled ***"Retrospective and prospective outcome analysis of surgical management of spinal tuberculosis patient"*** submitted by Dr. Kishore Parihar, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no.1687/OS/22 dated 2nd February, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation has not been done. • Details of treatment/surgical protocol not mentioned. • Details of follow up not mentioned. • Clinical end point mentioned. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-IIA/P9***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

10.	Research proposal entitled ***"NAFLD profile in patients with type 2 diabetes mellitus"*** submitted by Dr. Ravi Rai, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.389/MED/22 dated 26th February, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: IX-PGTSC-IIA/P10***
11.	Research proposal entitled ***"An evaluation of lingual split vs buccal guttering technique in extraction of lingually placed impacted mandibular third molars- A randomized control trial"*** submitted by Dr. Reading Well Kharmawlonh, JRII, Department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.184/OMSD/22 dated 19th February, 2022. ***Recommendation of Primary reviewer:*** • Suggest changing 'a Randomized Controlled Trial' to 'A comparative study' since the research work is not a 'Trial' **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-IIA/P11***
II-B	**IMR-Resident**
1.	Research proposal entitled **"*A comparative study to evaluate masticatory performance and satisfaction level of the patient with conventional and three appointment complete denture*"** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Deep Shikha Tripathi, JRI, Through her Mentor Prof. Niraj Mishra, Department of Prosthodintics and Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 980/22 dated 6th January, 2022. ***Recommendation of Primary reviewer:*** • Study design should be blinded Randomized Controlled Study instead of Trial . • Sample size calculation details not mentioned • ICF –Hindi / English not similar –should be revised **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-II B IMR-R/P1***
2.	Research proposal entitled **"*Expression pattern of MUC1 and MUC4 in (OPMD) oral premalignant disorders and oral squamous cell carcinoma (OSCC) and normal oral mucosa in an attempt to analyze its role played in oral carcinogenesis*"** sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Sharon John, JRI, Through her Mentor Prof. Shalini Gupta, Department of Oral Pathology & Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 464/OP/22 dated 24th January, 2022. ***Recommendation of Primary reviewer:*** • There are 6 Co-PIs -(2 from Oral Pathology & Microbiology apart from Chief Guide

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	+ 2 from Oral and Maxillofacial Surgery) with almost similar roles – please justify. • As all age gp patients will be recruited in the study therefore ,Guardian and child Assent form is also needed apart from general ICF, which has not been submitted. • Study design not mentioned • SOP Form not filled completely –should be revised **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-II B IMR-R/P2***
3.	Research proposal entitled "***Contribution of GHR, IGF1R and IGF2R in determining the craniofacial pattern and proportions- A genetic study***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Gulnaz Husain, JRII, Through her Mentor Prof. Amit Nagar, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 609/Ortho/22 dated 27th January, 2022. ***Recommendation of Primary reviewer:*** • Age group of recruited subjects are between 14 to 24 years, therefore Child Assent form is needed which has not been submitted. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-II B IMR-R/P3***
4.	Research proposal entitled "***A comparative evaluation of efficacy of Different irrigants on smear layer in root canals of deciduous teeth with conventional irrigation Vs. passive ultrasonic irrigation: An in-vitro SEM study***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Alisha S. Jadhav, JRI, Through her Mentor Dr. Richa Khanna, Jr. Grade, Department of Paediatric and Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Ped/45/22 dated 19th January, 2022. ***Recommendation of Primary reviewer:*** • SEM in the title should be expanded/elaborated • Literature regarding use of Morinda citrifolia as irrigant should be submitted. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: IX-PGTSC-II B IMR-R/P4***
5.	Research proposal entitled "***Association of polymorphisms in IGF-1, GHR and PAX-9 genes with tooth size in different malocclusions***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Varun Gupta, JRII, Through her Mentor Dr. Dipti Shashtri, Associate Professor, Department of Orthodontics and Dentofacial

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 661/22 dated 18th February, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: IX-PGTSC-II B IMR-R/P5***
6.	Research proposal entitled "***Effect of beetroot juice rinse on oxidative stress on microbial profile of patients with oral lichen planus***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Ms. Snehlata Kaushik, BDS IV Year Student Through her Mentor Dr. Rameshwari Singhal, Additional Professor, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2249/P/22 dated 28th February, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: IX-PGTSC-II B IMR-R/P6***
III	**Modification**
1.	Modification of research proposal entitled ***"A study of handwriting sample in geriatric population with cognitive impairment"*** submitted by Dr. H.V. Suresh, SR-III, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 1446/DGMH/2022 dated 11th February, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref.code:100th ECM II B-Thesis/P17***
2.	Modification of research proposal entitled ***"Etiology and diagnosis of bacterial meningitis in neonates: an observational study at a University Hospital"*** submitted by Dr. Amber Azim, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1366/2021 dated 9th November, 2021. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: 107th ECM II B-Thesis/P14***
IV	**Other Matter**
1	Due to current Covid pandemic, it will be difficult for the PI to complete a sample size of 85 as he is not receiving enough surgically resected specimen of gall bladder diagnosed a Adenocarcinoma, in the Department of Pathology, KGMU, as requested by the kindly permission to change the work for use tissue blocks only after proper reporting and dispatch of the report of the **received sample for Waiver** under the research proposal entitled ***"Expression of ALDH1A1 in gall bladder carcinoma and its correlation with clinicopathological profile"*** submitted by Dr. Prashant Verma, JRI,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Department of Pathology of King George's Medical University, U.P., Lucknow vide letter no. 95 dated 25th January, 2022. **Previous PGTSC Decision:** Approved ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: 107th ECM II B-Thesis/P27***
5.	Research proposal entitled "***Association of polymorphisms in IGF-1, GHR and PAX-9 genes with tooth size in different malocclusions***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Varun Gupta, JRII, Through her Mentor Dr. Dipti Shashtri, Associate Professor, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 661/22 dated 18th February, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: IX-PGTSC-II B IMR-R/P5***

Next Meeting scheduled will be on 28th May, 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 116th ECM held on 28th May, 2022

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of 116th "Institutional Ethics Committee" Meeting ***virtually*** held on 28th May, 2022 from 10.30 AM.

The following Members were present in the Meeting:-

1. Prof. Alok Dhawan -Chairman
2. Prof. G.G. Agarwal -Member
3. Prof. Shubha R Phadke -Member
4. Mrs. Vasundhara Kumar -Member
5. Mrs. Akansha Dubey -Member
6. Mr. Ujjawal Krishna -Member
7. Dr. Akash Agarwal -Member
8. Dr. K.K. Yadav -Member
9. Prof. A.A. Mahdi -Member
10. Prof. Rajendra Nath -Member
11. Prof. Anupam Mishra -Member
12. Prof. Anita Rani Singh - Member
13. Dr. D.N. Upadhyaya -Member
14. Dr. Shally Awasthi -Member-Secretary, IEC

I-A	Action taken
1-	Clarification of research proposal entitled "***Formulation, optimization and evaluation of apigenin and cardamom essential oil based emulgel for mitigation of oral submucous fibrosis***" sponsored by ICMR, New Delhi submitted by Ms. Sarita Pal, Ph.D. Scholar 2019 under the guidance Dr. N.P. Yadav & Prof. U.S. Pal, Co-PI, Department of Oral and Maxillofacial Surgery, FODS, K.G's Medical University, U.P., Lucknow vide letter no. 463/OMFS/22 dated 20th May, 2022.

Previous EC Decision	PI response
Budget not mentioned	15 Lacs sanction by ICMR
Risk is not reasonable, why do the study?	The biopsy is advised in any potentially malignant lesion and oral submucous fibrosis (OSMF) is also a potentially malignant disorder so, to rule out any

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	malignancy biopsy should be advised, despite having minor risk.
Biopsy is an invasive procedure with discomfort, risk of complications: need to have a compensation policy.	The biopsy will be taken as routine treatment of OSMF. It will be divided into two pieces. One piece will be sent to the research laboratory (CSIR-CIMAP) for the development of a new drug. Another one will be sent to the pathology department (KGMU) for a histopathology examination. Diagnosis will be made and treatment will be given accordingly.
KGMU should have its own PI answer researcher outside KGMU will not be interaction with patients.	This study is conducted with the help of Dr. U. S. Pal (Prof., Department of Oral and Maxillofacial surgery). He is also serving as a Co-PI in this study.
Right to participation (Consent form): tissue sample is patient's property and rights can't be waived off.	We agreed with the comment. The consent for the tissue excised from the patient will remain to the patient.
Outcome measures are not in sync with aim/objectives.	This project belongs to the ICMR and the funding agency has already evaluated the aim and objective of the project and the project has been sanctioned in 2019. The aim of our present study is 'To evaluate the therapeutic potential of emulgel prepared from apigenin or cardamom essential oil in a human buccal mucosal sample of Oral Submucous Fibrosis'.

The above comment forwarded to the P.I. which was reviewed by PR:-
Recommendation of PR.

- List of queries raised previously and their clarifications have not been attached. Please ask the researcher to do the needful.

EC Comment:

- As procedure is carried out regularly, no additional risk. Can be approved.

EC Decision: Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: 107th ECM II B-Ph.D/P1

2- Clarification of research proposal entitled ***"Study of T regulatory cells, soluble cytotoxic T lymphocyte associated antigen-4 and transforming growth factor-β1 in patients of chronic myeloid leukemia on dasatinib therapy"*** sponsored by ICMR submitted by Dr. Akanksha Singh, Ph.D. Scholar 2019 under the guidance Prof. Rashmi Kushwaha, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.573 dated 26th April, 2022.

Previous EC Decision	PI response
Hindi translation of ICF needs correction so that it is meaningful.	Attached separately

EC Decision: Approved

Ref. code:110th ECM IIB-Ph.D./P1

3- Clarification of research proposal entitled ***"Skin flap necrosis after knife or electrocautery in patients undergoing inguinal lymph node dissection (SNAKE): a double blind randomized clinical trial"*** submitted by Dr. Shiv Rajan, Assistant Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no.SONC/788/2022 dated 21st May, 2021.

Previous EC Decision	PI response
Since only patient is blinded but not be investigator, this can be a single blind trial only.	This is a double blinded trial as mentioned in the protocol section under the heading blinding. Because among the patient, operating surgeon and outcome accessor only operating surgeon will know the surgical intervention. The patient and the outcome accessory will remain blinded to the surgical intervention (Treatment assigned). We believe doing this study as double blind research will add strength to it. Therefore we would like to continue it as a double blind study

The above comment forwarded to PI reply received. <u>The above proposal already approved by PR but above is EC objection.</u>

EC Decision: Approved

Ref. code:113th ECM IIA/P19

4- Clarification of research proposal entitled ***"Management of ROCM: A clinico-radiological study- An institutional experience"*** submitted by Dr. Rajat Jain, Assistant Professor, Department of Otorhinolaryngology, Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no.240/ENT/R/22 dated 23rd May, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Decision	PI response
The title has short form which is not explained. I do not know what is ROCM. On the page 11 of 13, the full form is mentioned. Rhino Oculo Cerbral Mucormycosis.	All the abbreviations used in this research proposal proforma have been explained under the heading "Abbreviation used'
5-vi-No answer about vulnerable subjects.	It is a retrospective study there will be no direct involvement of subject during the course of the study.
It is mentioned on point 8, that the written consent will be taken and patient information brochure is attached. But there is neither of them	Patients presented to us curing the epidemic of nucormycosis. All clinically and mocroboloially confirmed cases were admitted and written informed consent was taken from each patient before surgery. Since the study is a retrospective analysis of data there is no requirement of consent forms. Hence not attached.
It is retrospective analysis of data. Please confirm if consent will be taken or not. If the answer is 'yes' provide appropriate document.	-----
It is mentioned that the patient will be directly benefited. How?	This is the first episode of mubcormycosis epidemic all over India till date. No definitive management protocol has been established till date in the country. This is a single centre study. We have formulated management protocol which will benefit mucormycosis patients in for coming years.

The above comments forwarded to PI which was reviewed by Primary reviewer with following comments.

Second opinion of PR	PI response
Abbreviation should not be used in the title	The Title has been changed entitled ***"Management of Rhino-orbito-cerebral mucormycosis (ROCM) : A clinic-radiological study- An institutional experience"***
Written consent for surgery is different from the written consent for participation	Since this is the Retrospective study, consent for research purposes was taken

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

of the study	alongwith consent for surgery. So, we are using the same consent for the study.
Management was done based on the protocol is helpful for the patient. But study is not benefitting the patient directly.	Mucormycosis epidemic happened during covid pandemic. Never before in the history of mankind such use mucormycosis patient have been dealt with. So no proper protocol was available in literature thus we have developed a protocol for management of patients of mucormycosis which will benefit forthcoming generations.
The permission for the retrospective data analysis should be taken, Appropriate modifications in the application are needed.	The permission for data analysis was taken at the time of admission/ surgery.

EC Decision: Approved

Ref. code: 114th ECM IIA/P3

5- Clarification of research proposal entitled "***Antifungal sensitivity based management of COVID-19 associated Rhino-Orbital-cerebral mucormycosis (C-ROCM)- an outcome-based pilot analysis***" submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.831/MED/22 dated 27th April, 2022.

Previous EC Decision	PI response
Details of medical/surgical management protocol missing.	Possible C-ROCM will be evaluated by nasal endoscopy. Based on imaging and laboratory evidences the ROCM will be divided into probable and definite form. Surgical management will be done on the basis of different stages given by Malhotra et al (8). The scope of surgery may vary from local resection to radical resection of the involved segment/area.
Details of follow-up missing.	The patient will be called for follow up after one month till 6 months.
Clinical end point of treatment/follow-up missing.	For treatment of ROCM either parenteral or oral forms of Isavuconazole are

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		recommended. Posaconazole has also been used for treatment though it is preferred as a prophylactic agent for mucormycosis in transplant patients. Other than these two novel azoles, Itraconazole and Terbinafine have also been tested for their efficacy. Glycaemic control is also an important factor in management of patients with mucormycosis.
	ICF does not details of consent person	Supportive document - ANNEXURE: 8-RV-1/2019 (SOP-IEC-KGMU) ANNEXURE: 9-RV-1/2019 (SOP-IEC-KGMU) has been attached

The above comment forwarded to PI was reviewed by PR: Provisionally approved

EC Decision: Approved

Ref. code: 114th ECM IIA/P6

6- Clarification of research proposal entitled ***"International severe Asthma registry (ISAR)"*** submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no.403/RES/MED/22 dated 29th March, 2022.

Previous EC Decision	PI response
It is a multi country, multicentre observational study with a sample size of just 20-25 subjects. Sample size calculation shall be mentioned.	In International severe Asthma registry (ISAR) study, primary data collection (via eCRFs) will contribute to the development of a web-based platform to host the ISAR. Being a registry there is no sample size calculated for this specific initiative but the minimum expected **site-specific** sample size is between 20-25 patients.

The above comment forwarded to PR.

Recommendation of PR: Provisionally approved.

EC Decision: Approved

Ref. code: 114th ECM IIA/P7

7- Clarification of research proposal entitled ***"Comparison of percutaneous vs open hamstring lengthening in patients of spastic diplegic cerebral palsy"*** submitted by Dr. Syed Faisal Afaque, Assistant Professor, Department of Paediatric Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no.1749/Paed.ortho/22 dated 10th May, 2022.

The above comments forwarded to PI reply have given by PI which was reviewed by PR with following opinion.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	RV-1/2019 (SOP-IEC-KGMU) ANNEXURE: 9-RV-1/2019 (SOP-IEC-KGMU) has been attached

The above comment forwarded to PI was reviewed by PR: Provisionally approved

EC Decision: Approved

Ref. code: 114th ECM IIA/P6

6- Clarification of research proposal entitled "***International severe Asthma registry (ISAR)***" submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no.403/RES/MED/22 dated 29th March, 2022.

Previous EC Decision	PI response
It is a multi country, multicentre observational study with a sample size of just 20-25 subjects. Sample size calculation shall be mentioned.	In International severe Asthma registry (ISAR) study, primary data collection (via eCRFs) will contribute to the development of a web-based platform to host the ISAR. Being a registry there is no sample size calculated for this specific initiative but the minimum expected **site-specific** sample size is between 20-25 patients.

The above comment forwarded to PR.

Recommendation of PR: Provisionally approved.

EC Decision: Approved

Ref. code: 114th ECM IIA/P7

7- Clarification of research proposal entitled "***Comparison of percutaneous vs open hamstring lengthening in patients of spastic diplegic cerebral palsy***" submitted by Dr. Syed Faisal Afaque, Assistant Professor, Department of Paediatric Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no.1749/Paed.ortho/22 dated 10th May, 2022.

The above comments forwarded to PI reply have given by PI which was reviewed by PR with following opinion.

Sl. no.	Previous EC Comments	PI response
01	In executive summary, the formula for sample size calculation is indicated but not the sample size	**6.2.5 Sample size**: 100 (50 in each group) All the patients meeting the inclusion criteria and giving consent will be included in the sample size within the study period The sample size formulae used are as follows:(Bernard, 5th edition)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

n=

$$\frac{(\sigma_1^2 + \sigma_2^2 / \kappa)(z_{1-\alpha/}}{\Delta^2}$$

n= Sample size
σ = Standard Deviation
Δ = Difference of means
κ= Ratio
$Z_{1-\alpha/2}$= Two sided Z value
$Z_{1-\beta}$= Power

Confidence Interval (2-sided)	90%		
Power	80%		
Preoperative/Postoperative difference in PA (Turhan et al., 2019)	**OHL Group**	**PHL Group**	**Difference***
Mean	21	23.75	-2.75
Standard deviation	5.4	5.59	
Variance	29.16	31.24	
Total sample size	**100 (50 in each group)**		

OHL: Open hamstring lengthening, PHL: Percutaneous hamstring lengthening, PA: Popliteal angle

References:

1. Bernard Rosner. Fundamentals of Biostatistics (5th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			edition). (based on equation 8.27). 2. Turhan Y, Arican M. Clinical Comparison of Percutaneous and Open Hamstring Lengthening in Children with Spastic Cerebral Palsy. Medeniyet Med J. 2019;34:182-7.
	2.	In budget section Rs 10,000/- is indicated under "Research Associate" – Is that just for one time or for every month considering the duration of project to be 1.5 years. In later case, the yearly head would be 120000. Also check the salary for a research associate. It must be at par with ICMR norms	In budget section, Rs 20,000 is indicated under "Research Associate" which is just for one time.
	3.	Many points in Annexure 1 need to be filled up	Duly filled
	4.	This type of study seems to be more of outcome of surgical comparison than epidemiological as indicated. Hence, clinical category would be more appropriate	Author agrees with suggestion and now choose clinical type of study.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

5.	Type of patients should be patients instead of volunteers as indicated	Rectified
6.	Patient information sheet is not attached	Attached

Second opinion of PR:

- The PI has clarified majority of points except that the rationale for one time single payment of Rs.20,000/- to Research Associate does not correlate with ICMR norms. Moreover the Hindi version of patient information sheet will needs to be incorporated.

The above comment again forwarded to the PI reply received by PI with following:

- The Principal-Investigator will manage the work of Research Associate therefore Research Associate is not required and the PI will ensure that it will not affect the quality of work.

EC Decision: Approved

Ref. code: 114th ECM IIA/P16

8- Clarification of research proposal entitled ***"Correlation of serum angiopoietin-1&2 & endothelin-1 with severity of pulmonary hypertension (PH) in patients of chronic obstructive pulmonary disease (COPD)"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 540/22 dated 4th May, 2022.

Previous comment	PI response
This is correlation study. The sample size formula is inaccurate as it is for prevalence study	We are thankful to reviewer for correcting us, as suggested we have re-calculated the sample size and mentioned the study variables. Also, we have merged the answers of first three comments for easy

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The study variables (variables for finding correlations) are not properly identified.	understanding. Pulmonary hypertension (PH) is a fatal disease, and chronic lung disease viz COPD can cause PH. The co-existence of COPD and cardio vascular disease (CVD) is frequent and perhaps be inter-related via inflammation-related processes reflected by specific markers like endothelin-1, angiopoietin 1 and angiopoietin-2. Here, we wish to detect a simple correlation r (r=0.4) of N observations between PH and COPD patients. Here, we want to determine the serum levels of endothelin-1, angiopoietin 1 and angiopoietin-2 in three study groups- COPD (without PH), COPD+PH(with PH), and healthy individuals. Additionally, we will see the correlation of these markers with COPD and PH disease staging; as we know that PH is divided into three groups on the basis of mean pulmonary artery pressure(mPAP) [mild (20-40 mmHg), moderate(41-55mmHg), severe(>55mmHg)], and COPD has also mild (predicted FEV_1%, ≥80%), moderate (predicted FEV_1%, ≥50% to <80%), severe (FEV_1%, ≥30% to <50%), and very severe (predicted FEV_1% , <30%) category. Hence, using a two sided test, 5% significance level test (α=0.05) with power 80% power (β=0.2). Putted the value of r, α, and β in online available software:
Sample size can be calculated after identifying variables only.	

Second opinion of PR

- Outcome measures have to be mentioned.
- Has data already been collected?
- I.C.F. and patient information sheet to be submitted.
- Define role of KGMU.

The above comment forwarded to the PI was reviewd by PR:- Provisionally approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

EC Decision: Approved

Ref. code: 114th ECM II B-IMR-F/P1

9- Clarification of research protocol no.CKJX839B12302 entitled "***A randomized, double-blind, placebo-controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT)***" sponsored by M/s Novartis Healthcare Pvt. Ltd submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no.04/Cardio/Res/22 dated 7th April, 2022.

Previous EC Decision:

- To the question 14-the answer is that the type of genetic testing to be done has not been decided yet. In that case the investigators cannot collect the samples of patients for genetic testing without telling what type of genetic test will be done. In that case the consent for DNA testing cannot be taken and staples cannot collect.

The following documents were reviewed in the EC Meeting:-

Sr. No	Documents
1.	Clinical Trial Protocol (Version Number: 00; Dated: 08-Jul-2021)
2.	Investigator's Brochure (Edition 15; release date 23 Dec 2020)
3.	eCRF Template
4.	Patient Information and Informed Consent Form (Version 1.0, Dated 05 Aug 2021)
5.	Patient Information and Informed Consent Form (Version 1.0, Dated 05 Aug 2021) translated from English to Hindi on 20 Aug 2021
6.	Patient Information and Informed Consent Form (Version 1.0, Dated 05 Aug 2021) back translated from Hindi to English on 31 Aug 2021
7.	Translation and back translation certificate for Patient Information and Informed Consent Form (Version 1.0, Dated 05 Aug 2021): • Hindi
8.	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 05 Aug 2021)
9.	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 05 Aug 2021) translated from English to Hindi on 20 Aug 2021
10.	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 05 Aug 2021) back translated from Hindi to English on 31 Aug 2021
11.	Translation and back translation certificates for Informed Consent Form: Pregnancy Follow-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	up for Pregnant Participants (Version 1.0, Dated 05 Aug 2021): • Hindi
12.	Informed Consent Form: Pregnancy Follow-up for Pregnant Partnerof Male Participant (Version 1.0, Dated 27 Aug 2021)
13.	Informed Consent Form: Pregnancy Follow-up for Pregnant Partner of Male Participant (Version 1.0, Dated 27 Aug 2021) translated from English to Hindi on 02 Sep 2021
14.	Informed Consent Form: Pregnancy Follow-up for Pregnant Partner of Male Participant (Version 1.0, Dated 27 Aug 2021) back translated from Hindi to English on 08 Sep 2021
15.	Translation and back translation certificates for Informed Consent Form: Pregnancy Follow-up for Pregnant Partner of Male Participant (Version 1.0, Dated 27 Aug 2021): • Hindi
16.	Female Partner Information Sheet ICF (Version 1.0, Dated 25 Aug 2021)
17.	Female Partner Information Sheet ICF (Version 1.0, Dated 25 Aug 2021) translated from English to Hindi on 27 Aug 2021
18.	Female Partner Information Sheet ICF (Version 1.0, Dated 25 Aug 2021)back translated from Hindi to English on 01 Sep 2021
19.	Translation and back translation certificate for Female partner Information Sheet ICF (Version 1.0, Dated 25 Aug 2021): • Hindi
20.	Informed Consent for Exploratory Genetic Research (Version 1.0, Dated 5 Aug 2021)
21.	Informed Consent for Exploratory Genetic Research (Version 1.0, Dated 5 Aug 2021) translated from English to Hindi on 20 Aug 2021
22.	Informed Consent for Exploratory Genetic Research (Version 1.0, Dated 5 Aug 2021) back translated from Hindi to English on 31 Aug 2021
23.	Translation and back translation certificates for Informed Consent for Exploratory Genetic Research (Version 1.0, Dated 5 Aug 2021): • Hindi
24.	Audio-Video Informed Consent Form (Version 1.0, Dated 1 Apr 2021)
25.	Audio-Video Informed Consent Form (Version 1.0, Dated 1 Apr 2021) translated from English to Hindi on 23 Jun 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Audio-Video Informed Consent Form (Version 1.0, Dated 1 Apr 2021) back translated from Hindi to English on 25 Jun 2021
26.	Translation and back translation certificates for Audio-Video Informed Consent Form (Version 1.0, Dated 1 Apr 2021): • Hindi
27.	Patientcard_English
28.	Patient card translated to Hindi
29.	Patient card back translated from hindi to english
30.	Certificate of translation for Patient Card -Hindi
31.	ParticipantThankyouLetter
32.	Insurance certificate
33.	Draft CTA
34.	CTRI
35.	PI – CV, GCP and MRC
36.	IU
37.	FinantialDisclosure Form

The above clarification forwarded to the PI-Following reply given by PI:

- We will not take consent for DNA testing". So, we will make sure of it and will not obtain consent and sample for genetic test or DNA analysis.

EC Decision: Approved

Ref. code: 114th ECMIIC/P4

10- Clarification of research protocol no. MLLFT/10/2020 Version/Date: Version1.0 Dated 21 October, 2020 entitled "***A randomized, double blind, parallel group, active controlled, multicentric, phase III study comparing the efficacy, safety and tolerability of lifitegrast 5% eye drops in patients with dry eye disease***" sponsored by M/s Micro Labs Limited submitted by Dr. Pramod Kumar, Additional Professor, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no.799/OPH/22 dated 30th March, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous comment	PI response
Is the sample size is based on 32% of general population suffering from dry eye. This is incorrect.	Sample size justification: $\mathbf{n = Z_{\alpha/2}^2 * p*(1-p) / MOE^2}$, and $Z_{\alpha/2}$ is the critical value of the Normal distribution at $\alpha/2$. For a confidence level of 95%, α is 0.05 and the critical value is 1.96, MOE is the margin of error, p is the sample proportion. MOE is considered 0.05 to produce good precision and smaller error of estimate. Considering p= 0.32, n= 334 and with 10% dropout sample size is approximately 370. Additionally, difference in eye dryness score was reported to be 12.55-unit between treatment groups computed as mean change from baseline to week-12 and a common standard deviation (SD) of 28.6 units were assumed on the basis of findings from a previous phase III trial. This yielded a sample size of 206 in both arms with a power of 90% and 10% dropout. However, when this sample size was submitted to DCGI for approval, they requested a larger sample size considering the product is newly introduced in the Indian market. Hence, the former sample size estimation was used for the trial. If the power is increased to 99% this assumed difference between the two arms would yield a sample size of 370 subjects.
Sample size calculation: Statistician to give opinion.	Stated above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Agreement signed copy not attached.	Fully executed CTA after obtaining signatures of all concerned signatories will be notified to EC prior to SIV. However, draft CTA was submitted for EC review.

The following documents were reviewed in the EC Meeting:-

S.No:	DOCUMENTS	VERSION AND DATE
01.	Covering Letter	NA
02.	Annexure : 1-RV-1/2029	(SOP-IEC-KGMU)
03.	Review Committee Approval Letter	NA
04.	Responsibilities Letter of PI and CO-PI	NA
05.	Clinical Trial Protocol	Version 1.0 Dated 21 October 2020
06.	Investigator's Brochure	Version 1.0 Dated 21 October 2020
07.	Informed Consent Document(ICD)-(English)	Version 1.0 Dated 21 October 2020
08.	Informed Consent Document (Site Specific)(ICD)- English	Version 1.0 Dated 21 October 2020
09.	Translated Informed Consent Document (English to Hindi) With Translation Certificate	Version 1.0 Dated 21 October 2020
10.	Translated Informed Consent Documents Certificate (Site Specific) English to Hindi (Translated on- 03 Jan 2022) with Translation Certificate	Version 1.0 Dated 21 October 2020
11.	Back Translated Informed Consent Document (Hindi to English) With Back Translation Certificate	Version 1.0 Dated 21 October 2020
12.	Subject Diary –English	Version 1.0 Dated 21 October 2020
13.	Translated Subject Diary Cards (English to Hindi) with Translation	Version 1.0 Dated 21 October 2020

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Certificates	
14.	Case Report Form	Version 1.0 Dated 21 October 2020
15.	DCGI Approval Letter	Dated 15 July 2021
16.	Draft CTA	N.A.
17.	Insurance Policy [Valid Till-07/09/2021-06/09/2022]	N.A
18.	CTRI [Registered on-08/10/2021]	N.A.
19.	Investigator's Undertaking	N.A.
20.	PI's CV	N.A.
21.	PI's MRC	N.A.
22.	PI's GCP	N.A.

The above comment forwarded to the PR:

- Approved

EC Decision: Approved

Ref. code: 114th ECMIIC/P5

11- Clarification of research proposal under the Expedited review entitled "***Smartphone-based COVID-19 cough detection with artificial intelligence***" submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/718/22 dated 6th May, 2022.

Previous EC Comment	PI response
Patient information sheet should be as per the SOP both in English & Hindi.	Patient information sheet is being attached with this revision. Though we have attached the same with the initial protocol submission as a part 1 of main informed consent form.

EC Decision: Approved

Ref. code:115h ECM IB/P4

12- Clarification of research proposal entitled "***Matrix metalloproteinases in angiogenesis and tumor invasion: clinicopathological impact in urothelial bladder carcinoma***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

patients" submitted by Prof. Apul Goel, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 248/URO/2022 dated 6th May, 2022.

The following Comment forwarded to PI response has given by PI which was forwarded to PR vide this office letter no.281/Ethics/2022 dated 6th May, 2022.

Previous EC Comment	PI response
Patient information sheet (Part-I) has no information about sample collection. It has to be modified in both English & Hindi.	Patient information sheet (Part-I) with information about sample collection has been modified in both English and Hindi and two hard copies of the same are being submitted at the Research Cell for Ethical approval.

Reply pending by PR, the first reminder forwarded to PR by email dated 19th May, 2022 at 1:35 PM.

Second recommendation of PR:

- The patient information brochure does not mention the title of the study.
- What is TURBT, BHP? No full form is given.
- There should be information brochure for controls.
- There is consent form and guidelines for patient information sheet. The patient information sheet has mentioned that the the samples collected as a part of surgical procedure will be used at point number 11 of patient info brochure but not in consent form.
- This should be clearly mentioned in both, the patient info brochure and consent form in the beginning --what will happen if i take part... Consent for using the part of specimen removed during surgery as a part of management

The above comment forwarded to PI: Reply pending by PI

EC Decision: Defer to the next Meeting

Ref. code: 115th ECM IIA/P3

13- Clarification of research proposal entitled "***Indian trial of tranexamic acid in spontaneous intracerebral haemorrhage (Intrinsic Trial)***" sponsored by ICMR, New Delhi submitted by Dr. Praveen Kumar Sharma, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 176/Neuro/2022 dated 25th April, 2022.

Previous EC Comment:

- Clarify what compensation will be given? What are the criteria for giving compensation?

The above comment forwarded to PI which was reviewed by PR.

Recommendation of PR:-

- Provisionally approved

EC Decision: Approved

Ref. code: 115th ECM IIA/P5

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

14- Clarification of research proposal entitled "***To assess sociodemographic, clinical and serological profile of allergic bronchopulmonary aspergillosis (ABPA) patients***" submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 561/22 dated 7th May, 2022.

The following Comment forwarded to PI response has given by PI which was forwarded to PR vide this office letter no.319/Ethics/2022 dated 10th May, 2022.

Previous EC Comment	PI response
No case report from is there.	Case report form is attached
Patient information sheet has to give more details.	More illustrated patient information sheet is attached.

Recommendation of Primary reviewer:

- Provisionally approved

EC Decision: Approved

Ref. code: 115th ECM IIA/P6

15- Clarification of research proposal entitled "***The HOLD study-stomach cancer elective surgery morbidity and mortality at 90-Day: A TUGS multinational audit***" sponsored by University of Sunderland, NHS Foundation Trust, England submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/717/2022 dated 6th May, 2022.

Previous EC Comment:

- Complete the protocol check list of KGMU.

The above comment forwarded to PI response which was reviewed by PR:

Recommendation of PR:

- Provisionally approved

EC Decision: Approved

Ref. code: 115th ECM IIA/P7

16- Clarification of research proposal entitled "***The outlive study-Oesophageal and Junctional cancer elective surgery morbidity and mortality at 90-Day: A TUGS multinational audit***" sponsored by University of Sunderland, NHS Foundation Trust, England submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/716/22 dated 6th May, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comment	PI response
Kindly attach patient information sheet as per SOP of EC KGMU. It is indicated in the annexure last page that patient information sheet is attached but no such enclosure is submitted.	Patient Information Sheet is being attached with this revision. Though we have attached the same with the initial protocol submission as a part 1 of main informed consent form.
Kindly enclose the protocol for data collection and explain the procedure in methodology. There is no indication of mortality parameters to be assessed as well as the anticipated	All the data of the OUTLIVE study will be collected directly in the Excel file. Google drive link to the Excel file has been provided by the study sponsor. To maintain the confidentiality of the link/data, we have provided the data collection points in the MS Word file exactly as per the excel file information given in the Google Drive link. This study will not change patient treatment given at any point. Whilst in hospital, we will collect some routinely held medical data from the patient hospital file about the operation and post operative period. At 90-day follow up visit we will ask the patient some extra questions, regarding his/her health. All the above mentioned information will be collected by the PI/Co-PI in the Excel Sheet as explained as above. The parameters/factors for the mortality will be analysed from the study data (Clinical, Oncological, Surgical, Pathological, 90 days Post surgery data) collected from the patients. The Mortality is defined as Grade V of "Clavien Dindo Classification" of complications which will be used to indicate mortality in the study. This parameter is the standard definition of mortality worldwide for the surgical patients. Kindly find attached data dictionary for the same.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	data collection and explain the procedure in methodology. There is no indication of mortality parameters to be assessed as well as the anticipated factor as per second aim.	of the link/data, we have provided the data collection points in the MS Word file exactly as per the excel file information given in the Google Drive link. This study will not change patient treatment given at any point. Whilst in hospital, we will collect some routinely held medical data from the patient hospital file about the operation and post operative period. At 90-day follow up visit we will ask the patient some extra questions, regarding his/her health. All the above mentioned information will be collected by the PI/Co-PI in the Excel Sheet as explained as above. The parameters/factors for the mortality will be analysed from the study data (Clinical, Oncological, Surgical, Pathological, 90 days Post surgery data) collected from the patients. The Mortality is defined as Grade V of "Clavien Dindo Classification" of complications which will be used to indicate mortality in the study. This parameter is the standard definition of mortality worldwide for the surgical patients. Kindly find attached data dictionary for the same.
	Kindly attach some document/ correspondence from the sponsor (University of Sutherland)	Response to the comment has been attached.
	Kindly indicate the anticipated number of subjects to be recruited in study.	We anticipate to include around 20 patients for this study from our site.
	No case report form is enclosed as indicated on last page of annexure	The copy of Case Report form has been attached.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	one. Kindly attach a copy.	

The above comment forwarded to PI response which was reviewed by PR:
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 115th ECM IIA/P8

17- Clarification of research proposal entitled "***A comparative prospective study of the various parameters of the wave like involuntary movements in scrotum in apparently normal individuals and patients of hydrocele, varicocele and primary idiopathic infertility***" submitted by Prof. D. Dalela, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 242/URO/22 dated 4th May, 2022

Previous EC Comment	PI response
This is a pilot study. It should be mentioned in the title.	New Title: '**A Comparative Prospective Pilot Study of the Wave Characteristics of the Involuntary Movements in Scrotum in Apparently Normal Individuals and patients of Hydrocele, Varicocele**
The term "various parameters" is vague. Research hypothesis should be defined properly after identifying the parameters.	New Title: **'A Comparative Prospective Pilot Study of the Wave Characteristics of the Involuntary Movements in Scrotum in Apparently Normal Individuals and patients of Hydrocele, Varicocele and Primary Idiopathic Infertility'**
Sample size is not required, as it is a pilot study.	No sample size is being calculated.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		like movements of scrotum will be analysed. For further statistical analyses, SPSSv23 software will be and ANOVA test will be used. P<0.05 will be considered significant.

The above comment was reviewed by PR-

- Provisionally approved

EC Decision: Approved

Ref. code: 115th ECM IIA/P15

18- Clarification of research proposal entitled ***"Outcomes of surgically addressed impacted injury in the patients of acetabulum fracture"*** sponsored by ICMR, New Delhi submitted by Dr. Dharmendra Kumar, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2100/OS/2022 dated 6th May, 2022.

Previous EC Comment	PI response
Title should be "Assessment of outcomes".	Response: With due respect it is to inform you that the project title has been approved by SERB, DST (funding agency), therefore it is very difficult to us to change the titled of the project. **Note:** Funding agency of this project is SERB, New Delhi. Kindly Do Needful As It Was Written, ICMR, New Delhi
The proposal is incomplete. There is no research hypothesis, no sample size calculation, no methodology, no statistical analysis section.	Response: The proposal summary including-Hypothesis, sample size calculation, methodology, statistical analysis section is attached.

The above comment forwarded to PI was reviewed by PR:
Recommendation of PR: Provisionally approved

EC Decision: Approved

Ref. code: 115th ECM IIA/P16

19- Clarification of research proposal entitled ***"Study on patient satisfaction and***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

psychological well-being of patients on oral anticoagulant therapy after a trial fibrillation (AF), arterial or venous thromboembolism (VTE)" submitted by Dr. Sujita Kumar Kar, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 559/Psy/22 dated 2nd April, 2022.

Previous EC Comment	PI response	Page no.
The primary objective and secondary objectives are being mixed.	The secondary objectives are now removed	Page 1 section 7.1.2 Secondary objectives
The primary objective uses cross-sectional (observational) design, whereas the secondary objective uses prospective comparative study.	The primary objectives will use the cross-sectional (observational) study design.	Page 1, Section 8 study design and methods.
The focus should be on primary objective, as the sample size, methodology etc. will be different for two kind of designs.	The focus is changed to only primary objectives. The sample size, methodology is aligned accordingly.	Page 1, Section 8 Study design and methods, Subsection 8.2 Study design.
Sample size calculation is not clear. What is the formula used?	The formula used for sample size calculation is included along with a detailed description.	Page-4. Section 14 Sample xize.
Data analysis section is also vague. It just give the terms: Ftests- ANOVA: Repeated measures, within factors. This makes no sense	The data analysis section is revised and aligned with the primary objectives.	Page-5, Section 16 Data analysis.

The above comment was reviewed by PR-

- Provisionally approved

EC Decision: Approved

Ref. code: 115thECM IIA/P17

20- Clarification of research proposal entitled ***"To explore the role of vitamin K1 in osteoporosis and correlate the synergistic interplay with Vitamin D: A randomized control study"*** sponsored by ICMR, New Delhi submitted by Dr. Dharmendra Kumar, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2024/OS/2022 dated 20th April, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comment	PI response
It is a randomized control study in which neither methodology; hypothesis or any references have been included.	Brief summary of the proposal including methodology, hypothesis and references is attached.
Where biochemical estimations will be carried out?	The biochemical test in this proposed study will be carried out in the host Institute (KGMU, Lucknow) and ESIC hospital, Lucknow
Consent form needs correction as going through it seems as if the study has already been completed.	Revised Hindi and English consent form is attached

The above comment forwarded to PI was reviewed by PR.
Recommendation of PR: Provisionally approved
EC Decision: Approved

Ref. code: 115th ECM IIA/P23

21- Clarification of research proposal entitled "***To develop and validate the protocol for post-operative rehabilitation in acetabulum fracture cases: A prospective case control study***" sponsored by ICMR, New Delhi submitted by Dr. Dharmendra Kumar, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2101/OS/2022 dated 6th May, 2022.

Previous EC Comment	PI response
Consent form needs correction as going through it seems as if the study has already been completed.	Modified as per suggestions
Methodology and references not provided	Incorporated and attached below in details.
Correct the affiliation of Dr. Urmila.	Revised (Department of Clinical Immunology and Rheumatology, KGMU), although she is not a co-investigator in this project.
Hypothesis and Methodology is missing	Added in details
Justify whether the Investigations	All the biochemical estimations will be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

can be done in ESIC Hospital	carried out at the Institutional laboratory. **Note:** ASIC hospital, Sarojini Nagar, Lucknow is not a collaborative centre in this project.
There are no references.	Added

EC Decision: Approved

Ref. code: 115th ECM IIA/P24

22- Clarification of research proposal entitled "***A comparative study of patients from UP and Bihar for assessing surgical outcomes in obese and non-obese patients***" sponsored by ICMR, New Delhi submitted by Dr. Dharmendra Kumar, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2102/OS/2022 dated 6th May, 2022.

Previous EC Comment	PI response
Consent form needs correction as going through it seems as if the study has already been completed.	Modified as per suggestions
Objectives/hypothesis not clear.	Modified and incorporated given below.
Methodology and references not provided	Incorporated and given below.
In metal ions why carbon monoxide has been included?	We didn't include Carbon monoxide in our study. Instead we will measure Chromium & Cobalt.
Where biochemical estimations will be carried out?	All the biochemical estimations will be carried out at the Institutional laboratory and ASIC hospital, Sarojini Nagar, Lucknow (Collaborative centre)
Entire proposal is sketchy.	Modified.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Consent form in English and Hindi missing	Attached
There are no references	Incorporated

EC Decision: Approved

Ref. code: 115th ECM IIA/P25

23- Clarification of research proposal entitled "***Evaluation of long term complications, their spectrum and magnitude in ICU survivor being followed in critical care follow up clinic***" submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 95/CCU/22 dated 5th May, 2022.

Previous EC Comment	PI response
Kindly provide outcome parameters.	The primary outcome parameter is the complication developed after discharge.
Without knowing, what information is retrieved from the patient, waiver cannot be confirmed.	The other data retrieved will be age and gender of the patient, reason/diagnosis at admission length of ICU stay and complications after discharge from ICU.
Also, as the time frame has been fixed, it would be better to consider calculation of sample size.	As this is a pilot study we don't have previous studies to calculate the sample size, so will include all the patients enrolled for OPD visit in one year duration. The power of study will be calculated later during statistical analysis.

The above comment was reviewed by PR:-

- The proposal is approved for waiver

EC Decision: As above

Ref. code: 115th ECM IIA/P28

24- Clarification of research proposal entitled "***To study the effectiveness of a tailored implementation strategy to improve adherence to a tuberculosis preventive treatment***" submitted by Dr. Sarika Gupta, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1149/Ped/22 dated 19th April, 2022.

Previous EC Comment:

- Kindly provide separate Assent Form

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment was reviewed by PR:- • Provisionally approved **EC Decision:** Approved ***Ref. code: 115th ECM IIA/P32***
25-	Clarification of research proposal entitled "***A feasibility study for implementation of innovative RBSK-NTEP collaboration module for active case finding of tuberculosis among school students: Multicentric study***" submitted by Dr. Sarika Gupta, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1148/Ped/22 dated 19th April, 2022. **Previous EC Comment:** • Kindly provide separate Assent Form ***The above comment was reviewed by PR:-*** • Provisionally approved **EC Decision:** Approved ***Ref. code: 115th ECM IIA/P33***
26-	Clarification of research proposal entitled "***A study of gaming disorder, social network addiction, sleep problems, coping styles, body esteem levels and emotionaldisturbances among undergraduate medical students***" submitted by Dr. Pawan Kumar Gupta, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 628/Psy dated 12th May, 2022. **Previous EC Comment:** • Role of PI/Co-PIs not mentioned ***The above comment was reviewed by PR:-*** • Provisionally approved **EC Decision:** Approved ***Ref. code: 115th ECM IIA/P38***
27-	Clarification of research proposal entitled "***Exploring the role of miRNA and epithelial mesenchymal transition (EMT) markers in prostate cancer***" sponsored by ICMR, New Delhi submitted by Mr. Gautam Prasad, Ph.D. Scholar 2019 under the guidance Dr. Mohammad Kaleem Ahmad, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/97/22 dated 11th May, 2022.

Previous EC Comment	PI response
Sample size	The sample size is calculated as per the ICMR statistics of 7.5% incidence

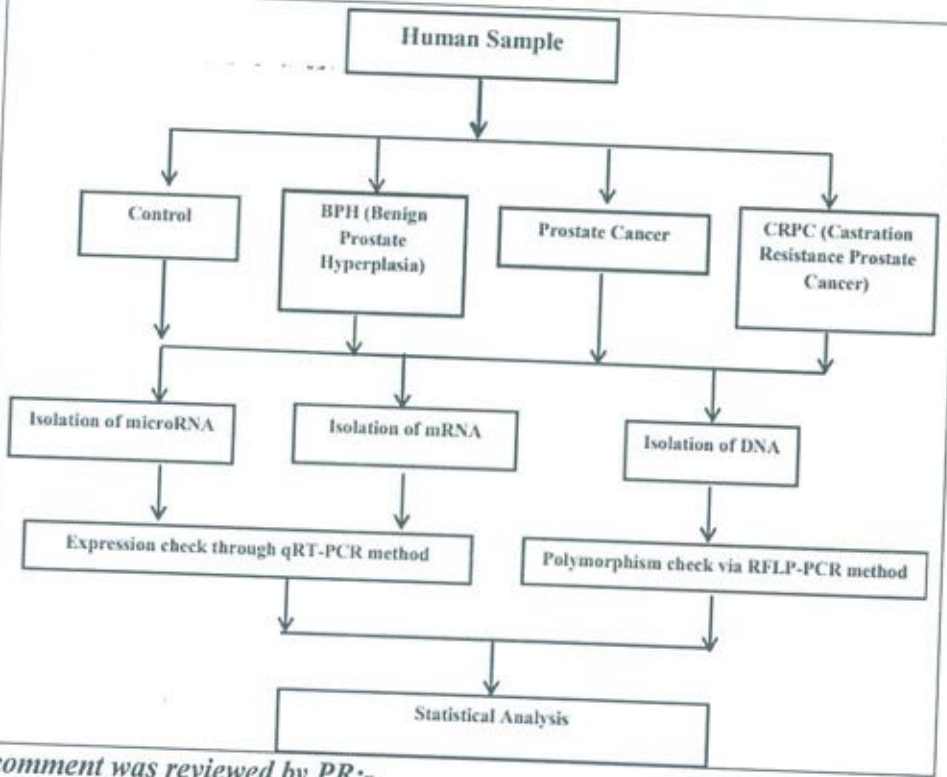
(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Sample size discrepancy is there in total (350 in SOP form) and difference in grouping written in inclusion criteria (n=50) and sample size calculation (n=33). Please give exact total sample size and correct the discrepancy in number of cases in each group. (In methodology it is not clear that Blood and Tissue samples will be taken from same or	The sample size is calculated as per the ICMR statistics of 7.5% incidence and consulted with the statistician. It has been calculated that each group i.e, BPH, Prostate Cancer, and CRPC must *include 33 cases*. However, we *increased the sample size in each group from n=33 to n= 50* to *validate the* significance of the study. As per our study design, we will take blood and tissue samples from BPH and Prostate Cancer and only blood samples from control and CRPC. From the same individual BPH patient, adjacent tissue will be taken as control to compare miRNA expression with diseased tissue. As mentioned in our ethical proposal, we will take adjacent healthy tissue samples from BPH patients (operated by TURP) as control and compare them with BPH tissue (operated by TURP) and prostate cancer tissue (operated by TRUS) of the cases. The tissue samples are significant for study since Epithelial-Mesenchymal Transition (EMT) is a tissue-based phenomenon and we are trying to explore and correlate its significance in a less invasive manner by comparing miRNA tissue expression with blood.	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	different groups.)	
	Study design is not mentioned in protocol.	As per the suggestion of the reviewer, we have mentioned the study design (case-control study) in the executive summary on page no.7
	In Title there is only mention of Prostate cancer but in protocol BPH cases are also included- Please justify or correct.	

The above comment was reviewed by PR:-

- Provisionally approved

EC Decision: Approved

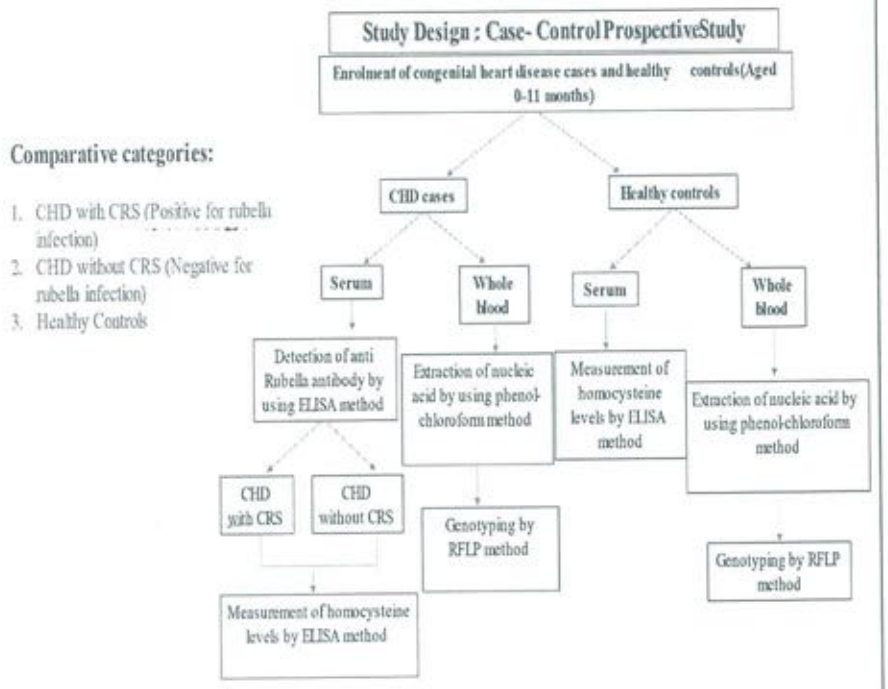
Ref. code: 115th ECM II B-Ph.D/P1

28- Clarification of research proposal entitled "***To assess the role of MTRR and MTHFR gene polymorphisms in rubella infected congenital heart disease patients aged between 0-11 months in North Indian population: A case-control study***" submitted by Ms. Sumedha Tripathi, Ph.D. Scholar 2019 under the guidance Prof. Shally Awasthi, Head,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. CHD/02/2022 dated 10th May, 2022.

Previous EC Comment	PI response
Study design mentioned is Case control study ,PI should mention details of study design in protocol that whether it is Prospective or Retrospective study (as Case-control studies are generally retrospective in nature)..	Study design is Case- Control Prospective study. 

The above comment was reviewed by PR:-

- Provisionally approved

EC Decision: Approved

Ref. code: 115th ECM II B-Ph.D/P2

29- Clarification of research proposal entitled ***"Genomic characterization of hepatitis C Virus infected patients who are non-responders to direct acting antiviral therapy in the tertiary Hospital care setup"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Suruchi Shukla, Assistant Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 181/Micro/22 dated 18th April, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comment	PI response
Number of subjects is mentioned as 20 in the IEC form and as 15, and 25 in the Methods section of the proforma. Please correct this.	The document is updated as per suggestion. The changes are highlighted. Page 4, 10.

The above comment was reviewed by PR:-

- Provisionally approved

EC Decision: Approved

Ref. code: 115th ECM II B-IMR-F/P1

30- Clarification of research proposal entitled "***In vitro study on isolation and characterization of Human Antigen presenting cells and T cells and subsequent immune activation for immunotherapy application in Oral Cancer patients***" submitted by Dr. Ruby Dwivedi, Research Associate, Department of Oral Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. OMSD/RP/325/22 dated 25th April, 2022.

Previous EC Comment	PI response	Page number
Patient information sheet is not attached.	Patient information sheet is now attached as annexure.	9-17
Language of ICF is to technical and not easy to understand for the common patient.	Language of the Informed Consent Form is modified accordingly.	18-22
Sample size calculation/justification not done.	Sample size calculation is now added to the project proposal.	23
Role of Controls not defined.	Role of control is added in the project.	24
Budget approval/allocation document not attached.	Budget approval / allocation document is attached now along with copy of sanction	29

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	order.	

The above comment was reviewed by PR:-

- Provisionally approved

EC Decision: Approved

Ref. code: 115th ECM IIB-WS/P2

31- Clarification of research protocol no. GO42784 entitled ***"A phase III, randomized, open-label, multicenter study evaluating the efficacy and safety of adjuvant giredstrant compared with physicians cholce of adjuvant endocrine monotherapy in patients with estrogen receptor-positive, HER2-negative early breast cancer"*** sponsored by M/s F. Hoffmann-La Roche Ltd. submitted by Prof. Anand Kumar Mishra, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow, vide letter no. ES/24/2022 dated 7th May, 2022.

Previous EC Comment	PI response
Section 5, i, ii: not filled	Completed & attached
DSMB details?	The Independent Data Monitoring Committee (iDMC) for GO 42784 study is planned to be composed of the following members: • Peter Dubsky, iDMC Chairman, Hirslandenn Klinik, Luzern, Switzerland. • Tiffany Traina, iDMC Member, MSKCC, NY, USA • Prof. Daniel Gillen, iDMC Member, UC Irvine, California, USA,
Why some elements of Consent have not been checked?	The Main ICF v2.0 dated 24th August, 2021 have been reviewed against all the elements as per table 3 of schedule 3 of New Drugs and Clinical Trial Riles, 2019. The site specific ICFs were translated and submitted to EC for review and approval.
Legal opinion: It does not include the mandatory provisions relating to Insurance, Dispute Resolution, and Force	**Insurance:** The sponsor shall maintain reasonable insurance in accordance with applicable law to cover its obligations it terms of this Agreement for the duration of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Majeure. This needs to be revised as per other CTA formats followed by the University.	the Trial. **Dispute Resolution:** Dispute resolution clause already mention on point no.-21.3. **Force Majeure:** In the event a party is unable to comply with obligations under this Agreement due to circumstances beyond its control, such as an earthquake, hurricane, blizzard, flood, tornado, fire, act of God, other similar catastrophe, war, riots, terrorism or other debilitating action of a third party, such party shall be excused from such obligation for such period of inability, provided that the excused party shall take reasonable steps to remedy such noncompliance once it is able.

- The above comment was forwarded to PR.
- Why alternative to treatment not offered in IEC form?
- Why contact information not checked?
- IEC form mentions that no biological material will be taken from the patient. However, the consent form mentions, explicitly, that biological samples will be collected/ stored for further use(pg 23 of 37). Please explain
- The following documents were reviewed in the Meeting:-

Sr. No.	Document/Language	Version No. and Date
1.	Protocol No: GO42784	Protocol Version 2.0, 30 Jun 2021 (Controlled Copy No: PPD/ GO42784/ Protocol Version 2.0, 30 Jun 2021 / 022- 028)
2.	Investigators Brochure: RO7197597 (Giredestrant, GDC-9545)	Investigator's Brochure for RO7197597 (Giredestrant, GDC-9545), version 5, 31 May 2021 (Controlled Copy No: PPD/ Investigator's Brochure/ version 5 dated 31 May 2021/ 022- 028)
3.	Insurance Certificate & Policy	Policy Number- OG- 22- 2001-3306- 00000019 Effective from 02 Jan 2022 to 01 Jan 2023
4.	Draft CTA & Budget	Attached
5.	Case Report Form (CRF)	PRD_R1.0_001_27JUL2021_SKN - Master Forms

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

6.	DCGI Submission Acknowledgement	Application No. GCT/CT04/FF/2021/27266 Cover Letter signed and dated 30Jul2021
7.	English Main Informed Consent Form	GO42784_Main_ICF_v2.0_India_English_Dr Anand Kumar Mishra _24Aug2021
8.	Hindi Main Informed Consent Form	GO42784_Main_ICF_v2.0_India_Hindi_ Dr Anand Kumar Mishra _24Aug2021 Translation Certificate Attached
9.	Hindi to English Main Informed Consent Form	GO42784_Main_ICF_v2.0_India_English Back Translated from Hindi_ Dr Anand Kumar Mishra _24Aug2021 Translation Certificate Attached
10.	English Pregnant Partner Authorization Form	GO42784_Pregnant Partner Authorization Form_Version 2.0_India_English_ Dr Anand Kumar Mishra _31Aug2021
11.	Hindi Pregnant Partner Authorization Form	GO42784_Pregnant Partner Authorization Form_Version 2.0_India_Hindi_ Dr Anand Kumar Mishra _31Aug2021 Translation Certificate Attached
12.	Hindi to English Pregnant Partner Authorization Form	GO42784_Pregnant Partner Authorization Form_Version 2.0_India_English Back Translated from Hindi_ Dr Anand Kumar Mishra _31Aug2021 Translation Certificate Attached
13.	English COVID-19 ICF Addendum	GO42784_COVID-19 ICF Addendum 1_India_English_ Dr Anand Kumar Mishra _04Aug2021
14.	Hindi COVID-19 ICF Addendum	GO42784_ COVID-19 ICF Addendum 1 India_Hindi_ Dr Anand Kumar Mishra _04Aug2021 Translation Certificate Attached
15.	Hindi to English COVID-19 ICF Addendum	GO42784_ COVID-19 ICF Addendum 1 India_English_Back Translated from Hindi_ Dr Anand Kumar Mishra _04Aug2021 Translation Certificate Attached
16.	English Infant Authorization Form	GO42784_ Infant Authorization Form _v2.0_India_English_Dr Anand Kumar Mishra _31Aug2021 Translation Certificate Attached
17.	Hindi Infant Authorization Form	GO42784_ Infant Authorization Form _v2.0_India_Hindi_ Dr Anand Kumar Mishra _31Aug2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Translation Certificate Attached
18..	Hindi to English Infant Authorization Form	GO42784_ Infant Authorization Form _v2.0_India_English Back Translated from Hindi_ Dr Anand Kumar Mishra _31Aug2021 Translation Certificate Attached
19.	English Audio Video Recording ICF	GO42784_Audio Video Recording ICF_v1.0_India_English_ Dr Anand Kumar Mishra _04Aug2021
20.	Hindi Audio Video Recording ICF	GO42784_Audio Video Recording ICF_v1.0_India_Hindi_ Dr Anand Kumar Mishra _04Aug2021 Translation Certificate Attached
21.	Hindi to English Audio Video Recording ICF	GO42784_Audio Video Recording ICF_v1.0_India_English Back Translated from Hindi_ Dr Anand Kumar Mishra _04Aug2021 Translation Certificate Attached
22.	English Patient Card	Patient Card INDIA English v1.0.0 04 MAR 2021
23.	Hindi Patient Card	Patient Card INDIA Hindi v1.0.0 04 MAR 2021 Translation Certificate Attached
24.	Hindi to English Patient Card	Patient Card INDIA Hindi v1.0.0 04 MAR 2021 Translation Certificate Attached
25.	English GO42784 lidERA Patient Study Medication Diary	GO42784 lidERA Patient Study Medication Diary V3.0_ Giredestrant Tamoxifen Letrozole Anastrozole Exemestane_dated 28May2021
26.	Hindi GO42784 lidERA Patient Study Medication Diary	GO42784 lidERA Patient Study Medication Diary V3.0_ Giredestrant Tamoxifen Letrozole Anastrozole Exemestane _ dated 28May2021_ Hindi Translation Certificate Attached
27.	Hindi to English GO42784 lidERA Patient Study Medication Diary	GO42784 lidERA Patient Study Medication Diary V3.0_ Giredestrant Tamoxifen Letrozole Anastrozole Exemestane _ dated 28May2021_English Back Translated from Hindi Translation Certificate Attached
28.	English EORTC QLQ-BR23	1994 EORTC Quality of Life Group. Version 1.0
29.	Hindi EORTC QLQ-BR23	1994 EORTC Quality of Life Group. Version 1.0 Translation Certificate Attached
30.	English EORTC QLQ-C30	1995 EORTC Quality of Life Group. Version 3.0
31.	Hindi EORTC QLQ-C30	1995 EORTC Quality of Life Group. Version 3.0

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

32.	English EQ-5D-5L Health Questionnaire	India (English) © 2010 Translation Certificate Attached
33.	English GP5_FACT-G	GP5_FACT-G (Version 4), 16 November 2007
34.	Hindi GP5_FACT-G	GP5_FACT-G (Version 4), 11 October 2011 Translation Certificate Attached
35.	English NCI PRO-CTCAE ™ ITEMS	NCI PRO-CTCAE ™ ITEMS, Item Library Version 1.0, Form created on 03 March 2021
36.	Cancer Therapy Satisfaction Questionnaire, India English	CTSQ - India English © Pfizer Inc. 2007 Translation Certificate Attached
37.	Cancer Therapy Satisfaction Questionnaire, India Hindi	CTSQ – Hindi for India © Pfizer Inc. 2007 Translation Certificate Attached
38.	English MedCom_Welcome Email Template	MedCom_Welcome Email Template Version 26-Jul-2021
39.	Hindi MedCom_Welcome Email Template	MedCom_Welcome Email Template Version 26-Jul-2021_Hindi Translation Certificate Attached
40.	Hindi to English MedCom_Welcome Email Template	MedCom_Welcome Email Template Version 26-Jul-2021_Back Translated From Hindi Translation Certificate Attached
41.	English MedCom_Unable to Reach Email Template	MedCom_Unable to Reach Email Template Version 15-Jul-2021
42.	Hindi MedCom_Unable to Reach Email Template	MedCom_Unable to Reach Email Template Version 15-Jul-2021_Hindi Translation Certificate Attached
43.	Hindi to English Med Com_Unable to Reach Email Template	MedCom_Unable to Reach Email Template Version 15-Jul-2021_Back Translated From Hindi Translation Certificate Attached
44.	Safety Memo	Safety Memo- Newly Identified Giredestrant Adverse Drug Reactions dated 14Jul2021
45.	Investigator Undertaking_Dr Anand Kumar Mishra	Signed and Dated 17Jul2021
46.	CV and MRC_ Dr Anand Kumar Mishra	CV Signed and Dated 26Feb2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

47.	DCGI Approval Letter	Application No. GCT/CT04/FF/2021/27266 (GCT/87/21) and dated 30Jul2021
48.	CTRI	CTRI/2022/01/039625 (Registered on 21/01/2022)

Legal opinion: - Approved

EC Decision: Approved

Ref. code: 115th ECMIIC/P2

32- Clarification of research protocol no. ICR/19/007 entitled ***"A prospective, multi-center, single arm, phase IV study to assess the safety and efficacy of dienogest tablets in management of pelvic pain associated with endometriosis"*** sponsored by M/s Sun Pharma Laboratories Ltd. submitted by Prof. Sujata Deo, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. GO/CT/05/22 dated 4th May, 2022.

Previous EC Comment	PI response
Legal opinion: A clause on Insurance may be added.	Insurance clause will be incorporated in the CTA in section 13.3. stating that **Sponsor/CRO will provide and insurance policy to cover conduct of Clinical Trial, in accordance with applicable national laws, is in place.**
Legal opinion: In clause 22 the place of arbitration may be changed to Lucknow for convenience.	**Lucknow** has been added in the arbitration clause of the clinical trial agreement.
How they reached sample size of around 232 peoples' not explained	Kindly refer **Statustical method** section mentioned in page number **14** in the **study protocol** stating that " A Proportion Test using Normal Approximation with a 5% two-sided significance level assuming 6.5% margin of error and incidence rate for adverse event of 31.5%, a sample size of 232 subjects will be required. Attrition rate due to various reasons were factored up to 15" To achieve enrollment target number, 14 sites across PAN India would be taken and there would be competitive enrollment across all the site.
The drug is New Drug, not IND:	This has been rectified, was checked

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Wrongly checked in form.	inadvertently. Please fine attached corrected form for your reference.
DSMB details?	This has been recrifed, was checked inadvertently, Please find attached corrected form for our reference.
Insurance policy is expiring in 3 months.	Insurance will be renewed before 30-Jun-2022, the study end date is mentioned in the insurance policy.

The above comment was forwarded to PR. Provisionally approved

The following documents were reviewed:-

Sl.No.	Documents	Date & version
1	Clinical Trial Protocol	1.0 dated 13 Jan 2021
2	Protocol Signature Page	27-Jan-2021
3	Note to File to document 'specified analysis' for 'Safety endpoint' in Section 13.1 in Protocol Version No. 1.0; Dated 13/JAN/2021	Dated 12 Oct 2021
4	Patient Information Sheet and Informed Consent Form in English	Version 1.0, Dated: 22 Jan 2021
5	Patient Information Sheet and Informed Consent Form translated from English to Hindi	Version 1.0, Dated: 31 Dec 2021
6	Patient Information Sheet and Informed Consent Form in English back translated from Hindi to English	Version 1.0, Dated: 03 Jan 2022
7	Translation and Back-Translation Certificates for Informed consent form.	Dated: 12-Jan-2022
8	Investigator Brochure/ Amendment	Version No. 1.0, Dated 11 Jan 2021
9	e-Case Report Form	Version No. 1.0 Date: 13 Jan 2021
10	Clinical Trial Protocol	1.0 dated 13 Jan 2021
	10 PI Documents	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	10.1 Curriculum Vitae	27-Jan-2021
	10.2 MRC	15-Feb-2012
	10.3 GCP Training records	10-Oct-2021
	10.4 Investigator Undertaking	27-Jan-2021
11	11 Lab Documents	
	11.1 CV & MRC of Lab Director	26-Nov-2021
	11.2 Local lab accreditations	28-Sep-2020
	11.3 Reference ranges	26-Nov-2021
12	Draft Investigator's Agreement with the Sponsor	25-Jan-2022
13	Insurance Policy/ Compensation for participation and for serious adverse events occurring during the study participation.	01 Jul 2021
14	Compensation to the patient per visit for voluntary participation in the clinical trial	INR 500
15	Subject related documents (subject diary)	Version No. 1.0 Date 05 Feb 2021
16	Subject diary translated from English to Hindi	Version 1.0, Dated: 03 Jan 2022
17	Subject diary in English back translated from Hindi	Version 1.0, Dated: 04 Jan 2022
18	Translation & Back translations Certificates of patient diary	12 Jan 2022
19	**19. DCGI Submission and Approval Letter**	08 Jul 2021
	19.1 DCGI Approval Letter	

Legal opinion: - Approved

EC Decision: Approved

Ref. code: 115th ECMIIC/P3

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

33- Research protocol no. 20-03 (Protocol version No. 00; Dated 17-03-2022) entitled ***"A prospective, randomized, parallel, three-arm, open-label, multicenter, phase IV clinical trial to evaluate the immunological non-interference of Typhoid VI conjugate vaccine with Measles and Rubella vaccine administered to healthy infants"*** M/s Cadila Healthcare Ltd., Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway Ahmedabad submitted by Prof. Nishant Verma, Additional Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. PED/CT/02/2022 dated 4th May, 2022.

Previous EC Comment	PI response
Legal Query: • I have reviewed Mr Verma's CTA. It does not have important provisions related to Insurance, Dispute Resolution and Force Majeure. • We may include the aforementioned issues before moving forward with this CTA	**Response:** As suggested by your good office, please find enclosed the revised draft CTA with *Force Majeure* clause included as section no. 25 of CTA for your kind perusal (**Encl. 2**). The provisions related to insurance and dispute resolution have already been covered in section 12.2 and section 28 in this CTA.
Section 5-1-2 Consent form Missing	Response: Please find enclosed the informed consent document for this clinical trial including the subject information sheet and informed consent form for your kind perusal. Please also find its translation in and back-translation of *Hindi* language along with translation and back-translation certificates for your kind perusal.
How they reached sample size of '900 children' not explained	Response: The sample size justification

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	certificate was already enclosed as an appendix to the clinical trial protocol submitted to your good office (refer section no. 20.8 of protocol). Please find enclosed the same sample size justification certificate for your kind reference.
The drug is New Drug no IND: Wrongly checked in form DSMB details?	Response: We wish to kindly inform your good office that both typhoid Vi conjugate vaccine (TCV) and Measles & Rubella vaccine (MR) of M/s. Cadila Healthcare Ltd. have already approved by the Central Licensing Authority for marketing in the country. Please find enclosed proofs of approval of both the vaccines for kind reference. Therefore, both these vaccines are not considered as either IND or new drug; and hence, according to us, there should be no requirement of the DSMB in this phase IV clinical trial. This has been rectified, was checked inadvertently. Please find attached corrected form for your reference.
Insurance has expired in March, 2022.	Response: Please find enclosed renewed clinical trial insurance policy valid from 20th March, 2022 to 19th March, 2023. The above clinical trial is included at Sr. No. 1 in the annexed list of clinical trials covered under this insurance policy.

The above comment was forwarded to PR & legal expert: - both were reviewed.

- Provisionally approved

The following documents were reviewed in the Meeting:-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Sr. No.	List of Documents Enclosed		
1-	Details of Investigator, Site and Sponsor		
2-	Protocol No. 20-03 (Version No. 00; Dated 17/03/2020) with Appendices		
	Appendix 1	Case Report Form (CRF)	Version No. 00; Dated 17/03/2020
	Appendix 2	Unscheduled Visit Form	Version No. 00; Dated 17/03/2020
	Appendix 3	Subject Diary Card (TCV and MR vaccine co-administration)	Version No. 00; Dated 17/03/2020
	Appendix 4	Subject Diary Card (TCV administration)	Version No. 00; Dated 17/03/2020
	Appendix 5	Subject Diary Card (MR vaccine administration)	Version No. 00; Dated 17/03/2020
	Appendix 6	Informed Consent Document (Including Subject Information Sheet and Informed Consent Form)	Version No. 00; Dated 17/03/2020
	Appendix 7	Serious Adverse Event (SAE) Reporting Form	Version No. 00; Dated 17/03/2020
	Appendix 8	Biostatistician's Certificate for Sample Size Justification	Dated 29/02/2020
3-	Translation Documents:		
	A. Informed Consent Document [Including Subject Information Sheet and Informed Consent Form] (Version No. 00; Dated 17/03/2020): (In English and its Translation in & Back translation in Hindi Language)		
	B.Subject Diary Card (TCV and MR vaccine co-administration) (Version No. 00; Dated 17/03/2020): (In English and its Translation in & Back translation in Hindi Language)		

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		C. Subject Diary Card (TCV administration) (Version No. 00; Dated 17/03/2020): (In English and its Translation in & Back translation in Hindi Language)
		D. Subject Diary Card (MR vaccine administration) (Version No. 00; Dated 17/03/2020): (In English and its Translation in & Back translation in Hindi Language)
		E. Translation and Back-Translation Certificates for Informed Consent Document, and Subject Diary Cards for HindiLanguage
		B.Subject Diary Card (TCV and MR vaccine co-administration) (Version No. 00; Dated 17/03/2020): (In English and its Translation in & Back translation in Hindi Language)
	4.	Undertaking by the Investigator
	5.	Curriculum Vitae (CV) and Medical Council Registration Certificate (MRC) of the Principal Investigator
	6.	Regulatory Authority's (DCGI's) Permission for the Clinical Trial
	7.	Investigator's Brochure - Typhoid Vi Conjugate Vaccine I.P. of M/s. Cadila Healthcare Ltd. (Version No. 02; Dated 28/01/2019)
	8.	Investigator's Brochure - Measles and Rubella Vaccine (Live), I.P. (Freeze Dried) of M/s. Cadila Healthcare Ltd. (Version No. 01; Dated 18/03/2020)
	9.	Prescribing Information of the Study Vaccine (ZyVac TCV and MR vaccine)
	10.	Clinical Trial Insurance Policy (2022 – 2023)
	11.	Proposed methods for Subject Recruitment
	12.	Draft Clinical Trial Agreement

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

13.	CTRI Dated CTRI/2022/02/040274 [Registered on: 14/02/2022] -

EC Decision: Approved

Ref. code: 115th ECMIIC/P4

34- Clarification of Extension of research proposal entitled "***Nanostring nCounter based screening for molecular typing and target based therapeutics of TNBC in the Indian population***" sponsored by C.S.I.R., New Delhi submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, K.G's Medical University, U.P., Lucknow vide letter no. SONC/763/22 dated 12th May, 2022.

Previous EC Comment	PI response
Whether Prof. Vijay Kumar, Surgical Oncology, KGMU UP, Lucknow was the part of original Research Protocol?	Yes, Prof. Vijay Kumar, Surgical Oncology, KGMU UP, Lucknow was a part of the original Research Protocol as a CO-PI in the project.
In absence of PI (Dr. Neetu Singh) the approval of change or addition of PI & Co-PIs will have to be taken first from sponsoring authority (CSIR, New Delhi)?	The approval of change of PI (Prof. Vijay Kumar in place of Dr. Neetu Singh) and addition of Dr. Naseem Akhtar, Additional Professor, Surgical Oncology Department, KGMU as a CO-PI in the project has been approved by the sponsoring authority. The letter of approval is enclosed with this letter.
Approval for extension can only be given after it has been approved by sponsoring authority and also submitting the Original protocol with sponsor documents.	The request for extension has been approved by the sponsoring authority CSIR-CDRI. The proof of the same is enclosed with this letter.

The above comment was forwarded to PR & legal expert: - both were reviewed.

- Provisionally approved

EC Decision: Approved

Ref. code: 93rd ECM II A/P5

35- Clarification of research protocol no. MLTSP/04/2019 Version/Date: 2.0 Dated 21 September, 2020 entitled "***An open label, multicentric, phase III, prospective study to evaluate the efficacy, safety and tolerability of triple fixed dose combination of Timolol 0.5% + Brimonidine 0.2% + Brinzolamide 1% eye drops in patients with open angle glaucoma/ocular hypertension not responding to dual drug therapy***" sponsored by M/s

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Micro Labs Limited submitted by Prof. S.K. Bhasker, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no.191/OPH/22 dated 7th May. 2022.

Recommendation of Primary reviewer:

- Insurance policy should be revised as it is ending on 03-02-2022.

Legal opinion

- 1-There is no provision relating to Force Majeure in this agreement. This may be added to cover any unforeseen situation in the future.
- There is no Dispute Resolution clause in the agreement. This may be added to ensure that arbitration is the primary mode of dispute resolution.
- In Clause 26 of the Agreement the exclusive jurisdiction of Mumbai is referred to while this may be changed to Lucknow.

The above comment forwarded to the PI was reviewed by legal expert:-

Recommendation of legal expert: Approved

Also the insurance is valid till February, 2023.

S.No:	DOCUMENTS	VERSION AND DATE
01.	Covering Letter	NA
02	Annexure : 1-RV-1/2029	(SOP-IEC-KGMU)
03	Review Committee Approval Letter	NA
04	Responsibilities Letter of PI and CO-PI	NA
05	Clinical Trial Protocol	Version 2.0 Dated 21 September 2020
06	Investigator's Brochure	Version 2.0 Dated 21 September 2020
07	Informed Consent Document(ICD)-(English)	Version 2.0 Dated 21 September 2020
08	Informed Consent Documents (Site Specific) (ICD)- English	
09	Translated Informed Consent Document	Version 2.0 Dated 21 September 2020

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		(English to Hindi) With Translation Certificates	
	10	Translated Informed Consent Document (Site Specific) (English to Hindi) (Translated on- 03 Jan 2022) along With Translation Certificates	Version 2.0 Dated 21 September 2020
	11	Back-Translated Informed Consent Document (Hindi to English) along with translation certificate	Version 2.0 Dated 21 October 2020
	12	Subject Diary –English	Version 2.0 Dated 21 September 2020
	13	Back Translated Subject Diary Cards with Back Translation Certificates	Version 2.0 Dated 21 September 2020
	14	Case Report Form	Version 2.0 Dated 21 September 2020
	15	DCGI Approval Letter	Dated 27 Nov 2020
	16	Draft CTA	N.A.
	17	Insurance Policy [Valid Till-04/02/2021-03/02/2022]	N.A

EC Decision: Approval after fulfillment of Administrative Formalities

Ref. code: 114thECMIIC/P6

36.	**Minutes of ADR Sub Committee held on 28-05-2022**
A	**DCGI**
	Minutes of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting ***virtually*** held on 28th May, 2022 from 10.00 AM. ***The following Members were present in the Meeting:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	1. Prof. Alok Dhawan -Chairman 2. Mrs. Akansha Dubey -Member 3. Mrs. Vasundhara Kumari -Member 4. Mr. Ujjawal Krishna -Member 5. Prof. Rajendra Nath -Member 6. Dr. D.N. Upadhyaya -Member 7. Prof. Shally Awasthi -Member-Secretary, IEC
1-	ADR of research protocol no. EX9536-4388 SELECT-***"Semaglutide effects on cardiovascular outcomes in people with overweight or obesity"*** submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 64/Cardio/Res/22 dated 30th April, 2022. **Death** **Subject ID no. 253703** **Subject Initial:** A-K-Y **Gender:** M **Age:** 58 years-01-10-1964 **Date of enrollment:** 28th May, 2018 **Patient follow up under study:** Randomization visit 2, visit 3, visit 4, visit 5, visit 6, visit 7, visit 8, visit, 9, visit, 10, visit, 11, visit, 12, visit, 13, visit, 14, visit, 15, visit, 16, visit, 17 **Weight:** 64.0 KG **Height:** 157.0 cm **Subject History:** Site staff made a follow-up call to the subject on 30th April, 2022 around 12:30 hrs. Subject's family member revealed that the patient passed away on 3rd March, 2022 at 11:00 AM. Subject's relative informed that subject had a severe headache for which he was taken to the nearby hospital on 25th February, 2022, his CT scan report showed intracranial hemorrhage, his condition was serious, life-threatening, and untreatable, So the subject was discharged on 2nd March, 2022 and next day expired at home. No autopsy was done and family members destroyed all papers after cremation. ***Recommendation of Primary reviewer:*** • SAE (death) of the patient seems to be due to disease outcome (FUC of Inferior wall +RVMI/STK+) and sudden intracranial hemorrhage (by CT Report) and not due to intervention (Semaglutide SC) as patient had taken intervention for about 3 years and was followed up to 17th visit and was planning for 18th visit on 23-04-2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Causal relationship cannot be established as death occurred after developing intracranial hemorrhage and he expired next day at home. No autopsy was done. (Death certificate attached) **ADR sub Committee Decision:** • Submit to DCGI ***Ref. code: 92nd ECM IIC/P1***
B	**NON-DCGI**
	Minutes of **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting ***virtually*** held on 28th May, 2022 from 10.00 AM. ***The following Members were present in the Meeting:*** 1. Prof. Alok Dhawan -Chairman 2. Mrs. Akansha Dubey -Member 3. Mrs. Vasundhara Kumari -Member 4. Mr. Ujjawal Krishna -Member 5. Prof. Rajendra Nath -Member 6. Dr. D.N. Upadhyaya -Member 7. Prof. Shally Awasthi -Member-Secretary, IEC
I	ADR of research protocol entitled ***"A global registry to study the demographics, socioeconomic and clinical factors, etiologies, pathophysiology, management, barriers to outcomes"*** submitted by Prof. Sharad Chandra, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 24/Cardio/Res/22 & 25/Cardio/Res/22 dated dated 20th April, 2022.
a	**Death** **Subject ID no. 0653021** **Subject Initial:** S D **Gender:** F **Age:** 70 years **Date of enrollment:** 28th May, 2018 **Patient follow up under study:** Enrolment (Baseline) Month 6, Month 12, Month 18, Month 24, Long term consent, Tel. Month 30, Tel. Month 42, Tel Month 54, Tel Month 66, Tel Month 78. **Weight:** 55.0 KG **Height:** 154.0 cm

Shally Awasthi

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Subject History: The contact was made to get long term follow up Site person made several long term extension calls for follow-up visit but call was not answered. They tried again on 7th April, 2022 around 11:15 AM. Subject's LAR informed that she passed away on 4th October, 2021 at around 5:00 PM. The LAR revealed that patient had a complaint of weakness, and breathlessness for which she was taken to the hospital and expired on the way to the hospital. She was not hospitalized hence no papers are available and autopsy was not done. Only Death Certificate received. ***Recommendation of Primary reviewer:*** • The subject was enrolled on 28-05-2018. According to this her 30th month follow up would have fallen in November, 2021. The SAE was, however detected on 7th April, 2022. Explanation may be sought for the skipped follow up. • The SAE (death) doesn't seem to be related to the study **ADR sub Committee Decision:** • Ask for explanation **Death** **Subject ID no. 0653022**
b	**Subject Initial:** R-K **Gender:** M **Age:** 70 years **Patient enrolled date:** 28th May, 2018 **Patient follow up under study:** Enrolment (Baseline) Month 6, Month 12, Month 18, Month 24, Long term consent, Tel. Month 30, Te;. Month 42, Tel Month 54, Tel Month 66, Tel Month 78. **Weight:** 59.0 KG **Height:** 157.0 cm **Subject History:** Site person made a follow-up call to subject on 7th April, 2021 around 11:45 AM, Subject's LAR informed that the subject passed away on 31st March, 2021 at 8:00 PM. LAR said that patient was not feeling well for last 10 days. He had a complaint of weakness, and breathlessness and suddenly expired at home. Local medical person confirmed his death. Autopsy was not done and no documents are available. Only Death Certificate received.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: 1. The subject was enrolled on 28th May, 2018. According to this his 30th month follow-up would have fallen in November, 2021. The SAE was, however detected on 8th April, 2022. Explanation may be sought for the skipped follow-up. **ADR sub Committee Decision:** • Ask for explanation ***Ref. code: 86th ECM IIC/P3***
II	ADR of research protocol entitled ***"International study of comparative health effectiveness with Medical and invasive approaches"*** submitted by Prof. Sharad Chandra, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 45/Cardio/Res/22 dated 26th April, 2022. **Death** **Subject ID no. 091019-502** **Subject Initial:** S-S **Gender:** F **Age:** 52 years-01-01-1970 **Date of enrollment:** 28th May, 2018 **Patient follow up under study:** Randomization visit, Month 1.5, Month 3 Month 6,Month 12, Month 18, every month telephonic Follow up till 5 Years. **Weight:** 76.0 KG **Height:** 160.0 cm **Subject History:** Site person has made a scheduled monthly follow-up call to the subject on 15 April, 2022 at 11:00 hrs. Subject's LAR informed that subject passed away on 18th January, 2022 at around 16:00 hrs. LAR said that subject had severe bleeding for which she was taken to the nearby hospital, her creatinine was highly elevated, and her condition was not good so they took the patient against medical advice. From there and on the way from hospital to Cardiology KGMU emergency she expired. No autopsy was done and family members destroyed all papers after cremation. ***Recommendation of Primary reviewer:*** • SAE (Death) is most likely due to disease outcome (FUC Non ST Elevation MI with CKD) and excessive vaginal bleeding and not due to intervention (99 mm Tc-Sestamibi) as patient intervened almost 3 year 11 month back and completed 47

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Month telephonic follow-up visit without any complaint. • Causal relationship cannot be established as the subject after having severe vaginal bleeding was taken back against medical advice (LAMA) from nearby hospital and on the way to Cardiology emergency, KGMU she expired. No autopsy was done and family members destroyed all papers after cremation, so no records were found. • PI to submit Death certificate as it is missing **ADR sub Committee Comment:** • Clarify if the patient is on anti-platelet drugs and could it be related to excusive vaginal bleeding. What could be the possible etiology of excusive vaginal bleeding? ***Ref. code: 86th ECM IIC/P3***
I-B	**Expedited review**
1.	Expedited review of research proposal entitled "***Diagnostic and epidemiological study of brucellosis in northern India and to construct a clinical prediction rule***" sponsored by ICMR submitted by Prof. Raj Kumar Kalyan, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 88/2022 dated 12th April, 2022. ***The above research proposal forwarded to the two Primary reviewers:*** ***Recommendation of both Primary reviewers:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 116th ECM IB/P1***
2.	Expedited review of research proposal entitled "***Development of a Pediatric Trauma resuscitation Module (PTRM) and assessment of impact of simulation-based training on outcome of Pediatric Trauma patients at Level I, Trauma Centre in Northern India***" sponsored by ICMR, New Delhi submitted by Prof. Samir Misra, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. TS/208/2022 dated 4th April, 2022. ***The above research proposal forwarded to the two Primary reviewers:*** ***Recommendation of both Primary reviewers:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 116th ECM IB/P2***
3.	Expedited review of research proposal entitled "***Effect of time restricted feeding (TRF) on circulating miRNAs and mRNA expression levels in prediabetic patients with eveningness chronotype: emerging nutritional challenges***" sponsored by ICMR New Delhi submitted by Dr. B. Anjum, Research Associate, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/42/2022 dated 12th April, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above research proposal forwarded to the two Primary reviewers: ***Recommendation of First Primary reviewer-***Approved ***Recommendation of Secondary reviewer:-*** -Study design not mentioned. -Sample size calculation not done -Patient information sheet contents to matched with the study -Self-administered brief diet history questionnaire (BDHQ) not attached -Budget applied-not mentioned ***The above comment forwarded to PI which was reviewed by PR.*** ***Recommendation of Secondary reviewer:-*** • Provisionally approved **EC Decision:** Approved ***Ref. code: 116th ECM IB/P3***
4.	Expedited review of research protocol entitled ***"Impact of modern lifestyle dimensions on mental health and cognition in hostel versus home residing females at the University of Lucknow"*** sponsored by ICMR, New Delhi submitted by Ms. Preeti Gupta, under the guidance Prof. Narsingh Verma, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.2493/Phy/22 dated 13th April, 2022. ***The above research proposal forwarded to the two Primary reviewers:*** ***Recommendation of First primary reviewer:*** Provisionally approved **EC Decision:** Approved ***Ref.code:116th ECMIB/P4***
5.	Expedited review of research proposal entitled ***"Association of blood and salivary lead and cadmium with their concentration in chemical formulations used in the oral cavity- a cross sectional study"*** sponsored by ICMR, New Delhi submitted by Dr. Anupama Pathak, under the guidance Prof. Saumyendra V. Singh, Department of Prosthodontics, Faculty of Dental Science, King George's Medical University, U.P., Lucknow vide letter no. 44/22 dated 19th April, 2022. ***The above research proposal forwarded to the two Primary reviewers:*** ***Recommendation of first Primary reviewer-*** **Provisionally approved** ***Recommendation of Secondary reviewer:-*** • The patient information sheet should be in prescribed institutional format. The one provided by researcher is the proforma for collecting information from the patient in various outcomes. • The researcher may be communicated for approval and instructed to mandatorily submit required patient information sheet.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to PI was reviewed by PR: ***Recommendation of Secondary reviewer:*** • Provisionally approved **EC Decision:** Approved ***Ref. code: 116th ECM IB-FS/P5***
6.	Expedited review modification of research protocol no. 02-COV entitled ***"An open-label, multicentre, randomized, adaptive platform trial of the safety and efficacy of several therapies, including antiviral therapies, versus control in mild cases of COVID-19"*** sponsored by (DNDi) & ICMR India submitted by Prof. Avinash Agrawal, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/211/2022 dated 25th March, 2022. ***The above research proposal forwarded to the two Primary reviewers:*** ***Recommendation of both Primary reviewer:*** • Provisionally approved **EC Decision:** Approved ***Ref.code:114th ECMIB/P6***
II-A	**New Proposal**
1.	Research proposal entitled ***"Analysis of the existing policies & programs of the central and various state governments of India with respect to the 'mental health needs of older adults"*** submitted by Dr. Akanksha Sonal, Assistant Professor, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 1512/DGMH/2022 dated 8th March, 2022. ***Recommendation of Primary reviewer:*** • This is the evaluation of certain programs • The exclusive list of the programs should be provided. • How the data for last 10 years will be collected? • The questionnaire for evaluating the programs is required. • How the "qualitative analysis" will be performed? • What software shall be used for performing "qualitative analysis?" **EC Comment:** As above **EC Decision:** Revise and Re-submit with corrections in tabular format in word file. ***Ref. code: 116th ECM IIA/P1***
2.	Research proposal entitled ***"To study the volume of biomedical waste generated in a healthcare facility"*** sponsored by Centre for Chronic Disease Control submitted by Dr. Nitin Dutt Bhardwaj, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/87/2022 dated 10th March, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • To make the study useful, couple of private as well as government healthcare facilities should be included in the facility. If possible. • The questionnaire is required to measure the various categories of waste. **EC Comment:** As above **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECM IIA/P2l***
3.	Research proposal entitled ***"Study of incidence and prevalence of electric burn injuries in North India at tertiary burn care Centre"*** submitted by Dr. Ravi Kumar, Assistant Professor, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 237/2022 dated 10th March, 2022. ***Recommendation of Primary reviewer:*** • The numerator and denominator are different for "incidence" and "prevalence". • These should be exclusively specified, which shall require target population, sampling frame etc. • The term "North India" will require the target population of whole north India. Do they really mean to do it? • The questionnaire is required. • The sample size is given to be 100. How this figure is arrived at? • Basically, this is a descriptive statistics to find out rates. How this can be used for doing survival analysis is not clear. **EC Comment:** As above **EC Decision:** Revise and Re-submit with corrections in tabular format in word file. ***Ref. code: 116th ECM IIA/P3***
4.	Research proposal entitled ***"Searching safer options for delivery of pedicle of free flaps into the neck in minimal access neck incisions"*** submitted by Dr. Ravi Kumar, Assistant Professor, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 236/2022 dated 10th March, 2022. ***Recommendation of Primary reviewer:*** • By the title, the proposal looks to be a "comparative study". • This is not an observational descriptive study, as mentioned in the proposal. • The aim and the corresponding research question should be formulated properly after identifying the study parameters and variables. • It is wrong contention that "sample size calculation not required for observational

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	study" as mentioned in the proposal. • Anyway, sample size calculation should be done after properly defining the research hypothesis. • The statistical analysis section shall be accordingly written. **EC Comment:** As above **EC Decision:** Revise and Re-submit with corrections in tabular format in word file. ***Ref. code: 116th ECM IIA/P4***
5.	Research proposal entitled "***Comparison of stress and anxiety levels among pregnant women on the basis of gender of the first living child***" submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/605/2022 dated 9th March, 2022. ***Recommendation of Primary reviewer:*** • Aims and objectives are not given. • The corresponding research hypothesis is required, • This is a prospective cohort study for comparing two group. The two groups should be clearly identified. • The sample size calculation is not given. • The questionnaire is required. • The statistical analysis section is required. **EC Comment:** As above **EC Decision:** Revise and Re-submit with corrections in tabular format in word file. ***Ref. code: 116th ECM IIA/P5***
6.	Research proposal entitled "***Development of blueprint for setting Anatomy question paper in Colleges affiliated to King George's Medical University***" submitted by Dr. Garima Sehgal, Additional Professor, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 668/ANAT/2022 dated 11th March, 2022. **EC Decision:** Approved ***Ref. code: 116th ECM IIA/P6***
7.	Research proposal entitled "***Mechanisms of autophagy-mediated cell survival in breast cancers and its implication in therapeutics and diagnostics***" submitted by Prof. M.L.B. Bhatt, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 219/RT/2022 dated 14th March, 2022. **EC Comment:** • No patient information brochure. • Hindi translation of title of proposal is incorrect.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Approval subject to modification ***Ref. code: 116th ECM IIA/P7***
8.	Research proposal entitled "***Evaluation of shear bond strength of composite resin, bonded to laser and bur prepared dentine surface using low level laser application before bonding***" sponsored by ICMR, New Delhi submitted by Dr. Vijay Kumar Shakya, Additional Professor, Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 698/2022 dated 26th March, 2022. **EC Comment:** • No patient information sheet. • Hindi ICF needed. **EC Decision:** Approval subject to modification ***Ref. code: 116th ECM IIA/P8***
9.	Research proposal entitled "***To determine the role of infection control nurse (ICN) in prevention and control of Hospital acquired infections***" submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/426/2022 dated 17th March, 2022. **EC Comment:** • Define role of ICF • Research proposal very sketchy give details clearly. • Patient information sheet/Consent not clear. • Is the routine work or research? **EC Decision:** Revise and Re-submit with corrections in tabular format in word file. ***Ref. code: 116th ECM IIA/P9***
10.	Research proposal entitled "***To study the determinants of mortality in critically ill obstetric patients admitted in Intensive Care Unit***" submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/427/2022 dated 17th March, 2022. **EC Comment:** • The inclusion criteria should be more precise as will the researcher include if a pregnant woman is admitted in ICU before delivery? After delivery till what duration will it be considered as an obstetric case? **EC Decision:** Approved for waiver of consent after modification ***Ref. code: 116th ECM IIA/P10***
11.	Research proposal entitled "***Spectrum of supraclavicular lymph node diagnosis on fine needle aspiration cytology in a tertiary care Hopsital***" submitted by Dr. Sumaira Qayooom, Associate, Professor, Department of Pathology, King George's Medical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	University, U.P., Lucknow vide letter no. 350/Patho/2022 dated 21st March, 2022. **EC Comment:** • Kindly fill the human subject review waiver form of KGMU's ethics committee rather than ICF itself, as it is a retrospective study. **EC Decision:** Re-submit ***Ref. code: 116th ECM IIA/P11***
12.	Research proposal entitled ***"Hospital Based Cancer Registries in India"*** sponsored by National Centre for Disease Informatics and Research submitted by Prof. Kirti Srivastava, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 277/RT/2022 dated 22nd March, 2022. **EC Decision:** Approved ***Ref. code: 116th ECM IIA/P12***
13.	Research proposal entitled ***"The stanmore study-necrotising soft tissue infection of abdominal wall-30-day mortality & morbidity outcome: A TUGS multinational audit"*** submitted by Dr. Ajay Kumar Pal, Associate Professor, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 981/2022 dated 7th April, 2022. **EC Comment:** • Give CV of two member's site investigators. • Mention other sites with their PIs. • Correct the recruitment time. • On the page of "Contribution of PIs and Co-PIs" researchers have mentioned 4 PIs and Co-PIs while on page of "Undertaking by the PI" two more names are added. And CVs are also not attached to these two researchers if they are from outside of KGMU. • Since this is a multinational and multicentric study. Researchers have to mention the complete name of other site's PI and site addresses. **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECM IIA/P13***
14.	Research proposal entitled ***"Management of open fractures in tertiary care centre: an epidemiological, regional and comparative study of COVID-19 pandemic and non-pandemic phases"*** submitted by Dr. Ravindra Mohan, Assistant Professor, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 1931/OS/2022 dated 29th March, 2022. **EC Comment:** • Submit ICF waiver form as it is a retrospective study • Kindly fill the human subject review waiver form of KGMU's ethics committee as

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	it is a retrospective study. **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECM IIA/P14***
15.	Research proposal entitled "***Effect of pumpkin seed on anthropometric, biochemical and genetic marker of metabolic syndrome***" sponsored by ICMR, New Delhi submitted by Prof. Dileep Kumar Verma, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2483/PHY/2022 dated 8th April, 2022. **EC Comment:** • Method of randomization not given. • Blinding not mention. • Since it is a randomized trial, get it registered it in CTRI portal. • Include an Ayurvedic doctor in the project. • Method of randomization is not mentioned. **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECM IIA/P15***
16.	Research proposal entitled "***Development of Indian TNBC patients-derived organoid (PDO) and xenograft (PDX) models to understand its therapeutic vulnerabilities***" sponsored by ICMR, New Delhi submitted by Prof. Dipak Datta, Head, Cancer Biology Division Central Drug Research, Co-PI Prof. Anand Kumar Mishra, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/145/2022 dated 21st February, 2022. ***Recommendation of Primary reviewer:*** • ICF: study procedure has to be explained to the patient properly. **EC Comment:** • Since it is a trial, get it registered at CTRI **EC Decision:** Approval subject to modification. ***Ref. code: 116th ECM IIA/P16***
17.	Research proposal entitled "***Role of amplitude integrated electroencephalogram (aEEG) in prediction of neurodevelopmental outcome in near-term neonates with moderate to severe encephalopathy due to perinatal asphyxia***" submitted by Dr. Shalini Tripathi, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1106/Ped/2022 dated 13th April, 2022. ***Recommendation of Primary reviewer:*** • As the Budget shown is NA and research is not sponsored, kindly assure that cost of Investigations (aEEG and MRI) is part of standard protocol and patients will not be charged for the same.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Approved ***Ref. code: 116th ECM IIA/P17***
18.	Research proposal entitled "***Study on knowledge, attitude and practice of psychiatrists in India regarding sudden unexpected death in epilepsy (SUDEP)***" submitted by Dr. Sujita Kumar Kar, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 512/Psy/2022 dated 19th April, 2022. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 116th ECM IIA/P18***
19.	Research proposal entitled "***The grace study-30-Day morbidity and mortality of surgery for perforated peptic UICEr: A TUGS multinational Audit***" submitted by Dr. Ajay Kumar Pal, Associate Professor, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 983/2022 dated 7th April, 2022. ***Recommendation of Primary reviewer:*** • Study Duration mentioned in the proforma is from 1st Jan to 30th June 2022. Which should be mentioned as 6 months from the date of ethical approval? Proforma has been submitted on 7th April, 22. It appears that work has already been started and procuring ethical clearance is a secondary issue. • Researcher has not provided any sample size and neither has mentioned the study design as pilot. • The data of mortality and morbidity will be utilized by collaborators in the UK. Kindly highlight the status of publication of data from KGMU. • ICF: all points must be clearly stated in simple language as study procedure. **EC Comment:** As above **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECM IIA/P19***
20.	Research proposal entitled "***The aroma study- 30-Day morbidity and mortality of emergency surgery for abdominal hernia- A TUGS multinational audit***" submitted by Prof. Harvinder Singh Pahwa, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 982/2022 dated 7th April, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation is needed for an audit of this nature. • This may be discussed in the IEC meeting and decided upon accordingly. • Roles of PI and Co-PI are the same. • They may be modified.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The study period is form Jan-Jun 2022 while the EC permission is being sought in May. This has to be extended. **EC Comment:** As above **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECM IIA/P20***
21.	Research proposal entitled "***Measuring impact of COVID-199 pandemic at our Teaching Hospital in north India***" submitted by Dr. Harish Gupta, Associate Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 722/MED/2022 dated 8th April, 2022. ***Recommendation of Primary reviewer:*** • The PI wants to retrospectively analyze hospital attendance data of one year to measure its impact on student education. What data is required and how it will be used is not mentioned. • No sample size has been mentioned. • If the study is using only anonymized patient data from OPD the PI may be encouraged to apply for IEC waiver. **EC Comment:** • Very sketchy protocol **EC Decision:** Re-write & Re-submit after departmental Scientific review. ***Ref. code: 116th ECM IIA/P21***
22.	Research protocol entitled "***Management of chronic Achilles tendon tear by reverse gastrocnemius turn down flap and augmentation with FHL tendon***" submitted by Dr. Devarshi Rastogi, Associate Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2006/OS/2022 dated 13th April, 2022. ***Recommendation of Primary reviewer:*** • Sample size is not mentioned • Exclusion criteria, discontinuation and withdrawal criteria not mentioned. **EC Comment:** As above **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref.code:116th ECMIIA/P22***
23.	Research protocol entitled "***Total hip arthroplasty for failed osteosynthesis of proximal femoral fractures: clinical outcome from a low-and middle-income country***" submitted by Dr. Devarshi Rastogi, Associate Professor, Department of Orthopaedic Surgery, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. 2002/OS/2022 dated 13th April, 2022. ***Recommendation of Primary reviewer:*** • Sample size is not mentioned. **EC Comment:** As above **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref.code:116th ECMIIA/P23***
24.	Research protocol entitled "***Retrospective evaluation of ankle arthritis managed surgically***" submitted by Dr. Devarshi Rastogi, Associate Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2003/OS/2022 dated 13th April, 2022. **EC Comment:** • Incomplete proposal **EC Decision:** Re-submit ***Ref.code:116th ECMIIA/P24***
25.	Research proposal entitled "***Cost-effectiveness of pradhan mantra janaushadhi pariyojna (PMJP) and its impact on financial risk protection in India***" sponsored by Department of Health Research Ministry of Health and Family Wekfare, Indian Red Cross Society Building submitted by Prof. Divya Mehrotra, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. OMSD/295/2022 dated 12th March, 2022. **EC Comment:** • Proposal is sketchy. • References not given. **EC Decision:** Re-submit ***Ref. code: 116th ECM IIA/P25***
26.	Research proposal entitled "***Management of meniere's disease: an institutional experience***" submitted by Dr. Rajat Jain, Assistant Professor, Department of Otorhinolaryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 64/ENT/2022 dated 30th April, 2022. **EC Comment:** • Sample size calculation not given • References not provided. • Sketchy proposal **EC Decision:** Re-submit

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 116th ECM IIA/P26
27.	Research proposal entitled "***Dosimetric impact of model-based dose-calculation algorithms in high dose rate brachytherapy of cervical carcinoma***" submitted by Dr. Shraddha Srivastava, Associate Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 415/RT/2022 dated 2nd May, 2022. **EC Comment:** • Proposal details missing **EC Decision:** Re-submit
	Ref. code: 116th ECM IIA/P27
28.	Research proposal entitled "***Randomized controlled trial to assess the feasibility of delivering psycho-social interventions and effectiveness in improving the common psychological problems of the non-clinical population: a multi-centric and multi-setting study from central India***" submitted by Dr. Amit Singh, Assistant Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 606/Psy/2022 dated 6th May, 2022. **EC Comment:** • Calculation of sample size is not clear. It is mentioned that in total 173 cases will be recruited and in each group there will be 43 subjects. Why? • In the setting of the study section it is mentioned that subjects will be recruited from Bhopal too. Which institution and who will be the Co-PI from there is not mentioned. **EC Decision:** Approval subject to modification with corrections in tabular format in word file.
	Ref. code: 116th ECM IIA/P28
29.	Research proposal entitled "***Bone marrow metastasis in retinoblastoma: A retrospective study of hemato-morphological features***" submitted by Dr. Geeta Yadav, Associate Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 575 dated 26th April, 2022. **EC Comment:** • Sample size calculation missing. **EC Decision:** Approval subject to modification with corrections in tabular format in word file.
	Ref. code: 116th ECM IIA/P29
II-B	**RA/SRF/ Ph.D Proposal**
1.	Research proposal entitled "***Impact of BCG failure on FGFR3, TP53 gene and blood metabolite alteration in non-muscle invasive bladder cancer***" sponsored by ICMR New Delhi submitted by Mr. Mukul Kumar Singh, Ph.D. Scholar 2019 under the guidance Prof.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no.148/URO/22 dated 9th March, 2022. **EC Decision:** Approved ***Ref. code: 116th ECM II B /P1***
2.	Research proposal entitled "***Deciphering the role of genetic complexity in Japanese encephalitis patients***" sponsored by DBT Ramalingamswami Grant submitted by Ms. Anjali Singh, Ph.D. Scholar 2019 under the guidance Dr. Himanshu Dandu, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.223/MED/22 dated 3rd February, 2022. ***Recommendation of Primary reviewer:*** • What are the outcome measures briefly describe. • The sample size calculation missing. • Also outline the anticipated statistical analysis. It is mentioned that "clinical symptoms were analysed by chi-square test - is the data already analysed and if clinical data is collected then ICF is required. • The sponsor is DBT with 87 lakhs budget but the project names or different • For any genetic / molecular analysis of patients or control blood (human) samples on individual basis, informed consent form is required. Since this is not analysis of units (as claimed in the waiver form), either ICF and patient information sheet may be submitted or justify in which way does the PI consider this as units? • What is the role of KGMU? Is this just for collecting blood samples or clinical data? Also kindly specify as what percentage of clinical or molecular work will be carried out at KGMU and SGPGI ? **EC Comment:** As above **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECM II B /P2***
3.	Research proposal entitled "***Screening of lifestyle mitigated circadian disruptions in metabolic diseases and differential effect of plant derived omega 3, ALA, DHA & Palmitate blend supplementation on circadian pattern of metabolic markers***" sponsored by ICMR New Delhi submitted by Dr. Kshitij Bhardwaj, Ph.D. Scholar under the guidance Prof. Narsingh Verma, Head, Department of Physiology, King George's Medical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	University, U.P., Lucknow vide letter no.2485/Phy/22 dated 11th April, 2022. **EC Comment:** • Since it is a trial, get it registered at CTRI **EC Decision:** Approval subject to modification ***Ref. code: 116th ECM II B /P3***
4.	Research proposal entitled "***A case control study to assess the effect of alpha linolenic acid on tobacco craving in various tobacco users***" sponsored by ICMR New Delhi submitted by Miss. Anjali Singh, Ph.D. Scholar under the guidance Prof. Narsingh Verma, Head, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2482/Phy/22 dated 8th April, 2022. **EC Comment:** • Is linolenic and a drug (Flex seeds)? • Give standard care of such patient. • What exactly is being done? • Justify why this intervention is being given proposal sketchy-Does is justify as Ph.D work. **EC Decision:** Revise & Re-submit with corrections in tabular format in word file. ***Ref. code: 116th ECM II B /P4***
5.	Research proposal entitled "***Assessment of neuroprotective efficacy of camel-α-lactalbumin and oleic acid in parkinson's disease-targeting silent information regulator 1 (SIRT 1)***" submitted by Ms. Saba Ubaid, Ph.D. Scholar under the guidance Dr. Shivani Pandey, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/38/22 dated 11th April, 2022. ***Recommendation of Primary reviewer:*** • PI has proposed a lab study without involvement of human participants and has applied for IEC Waiver. **EC Decision:** Approved ***Ref. code: 116th ECM II B-Ph.D/P5***
6.	Research proposal entitled "***To study the formulation of human alpha-lactalbumin-oleic acid complex and investigation of its tumoricidal effect on notch signaling pathway during cell death process on leukemia cell lines***" submitted by Mr. Vivek Singh, Ph.D. Scholar 2016, under the guidance Dr. Ranjana Singh, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/51/22 dated 20th April, 2022. ***Recommendation of Primary reviewer:*** • Kindly provide information in detail for procuring HUMAN MILK. **EC Comment:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECM II B-Ph.D/P6***
II-B	**IMR-Faculty Proposal**
1.	Research proposal entitled ***"Standardization of multiplex real time PCR for detection of M leprae"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Parul Jain, Assistant Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1801/22 dated 13th January, 2022. ***Recommendation of Primary reviewer:*** • The sample size calculation may be added • The patient information sheet in Hindi to be added. • Also provide a brief outline paragraph of outcome measures. • No scientific committee approval is attached but it is expected that the proposal has been scientifically approved before sanction. **EC Comment:** • Give approval letter from Research Cell. **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECM II B-IMR-F/P1***
2.	Research proposal entitled ***"Determination of micrometastatic cells and their sensitization by radiotherapy and estimation of DNA damage repair in breast cancer patient"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Satyendra Kumar Singh, Associate Professor, Department of Centre For Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/439/22 dated 21st March, 2022. ***Recommendation of Primary reviewer:*** • No justification for sample size has been provided. **EC Comment:** As above **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECM II B-IMR-F/P2***
II-B	**Fellowship**
1.	Research proposal entitled ***"A study to explore the mechanism of FGD5-AS1 in oral cancer"*** sponsored by ICMR, New Delhi submitted by Dr. Manjari Sonam, under the guidance Dr. Fahad Mansoor Samadi, Additional Professor, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.672/OP/22 dated 8th April, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • Sample size calculation may be added • Patient information sheet to be attached • The methodology for statistical analysis is missing and needs to be added • The outcome measures need to be mentioned- will there be any clinical parameters for assessment? • Kindly provide inputs for points: 1. No. 5 related to subject selection in annexure 1, 2. No. 8 related to consent in annexure 1. 3. No. 9,10 and 11 related in annexure 1. • The study procedure can be elaborated in ICF in a language for patient to be a to understand better (in both English and Hindi versions) **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 116th ECM II B-FS/P1***
2.	Research proposal entitled ***"Exploration of co-regulatory network of microRNA200 and microRNA31 in tumor progression in OSCC and elucidating its effect on efficacy of chemotherapeutic agents"*** sponsored by ICMR, New Delhi submitted by Dr. Purnima Radesh under the guidance Prof. Shalini Gupta, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.676/OP/22 dated 11th April, 2022. ***Recommendation of Primary reviewer:*** • Sponsor information missing in annexure 1 where as it is written as ICMR sponsored. No budget is indicated. • Regarding point number 4 in annexure 1 : 1. Outcome measures and statistical analysis needs to be briefed. 2. References need to be added while quoting the literature on miRNA in cancer. 3. What is the full form of TNBC ? 4. How will this study initiate the target genes and pathways associated with miR-31 and examine the mechanism underlying the function of miR-31? 5. Also elaborate the use of bio informatics tools in this study • No inclusion or exclusion criteria mentioned despite quoted in annexure 1. If type of subjects are only Patients (annexure 1) then what about controls? Are there any

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	controls as well? • The patient information sheet not attached • Kindly fill up the gaps in annexure 1 • If there is a plan for reporting adverse effect in this basic science study as mentioned in annexure 1, kindly brief about those anticipated adverse effects. These need mention in ICF as well. • Furthermore, the ICF needs revision in such a way that the 'purpose of the study' and 'study procedures' are understandable to the patient who is giving consent. • The review of literature should be more relevant to the concerned study and re-written according to the objectives proposed. • Kindly elaborate in detail about the methodology for the three objectives separately in different paragraphs. • What chemotherapeutic agents are targeted in this study? • Which different genes will be explored? • Regarding expected outcomes as mentioned at the end of the submitted proposal, kindly brief as to what clinical or pathological data will be collected. There is no case sheet attached for the clinical or pathological data that is intended to be registered. Kindly elaborate. • What will be the criteria for efficacy of chemotherapeutic agents? Will it be clinical or molecular or both? kindly elaborate. • What will be the source of normal oral squamous samples? Will it be from matched Control subjects? The ICF from controls need to be obtained and accordingly ICF for controls should be formatted as well. **EC Comment:** As above **EC Decision:** Re-write & Re-submit with corrections in tabular format in word file. ***Ref. code: 116th ECM II B-FS/P2***
3.	Research proposal entitled ***"Integrated transcriptomics and metabolomics analysis of metabolomics disturbances in triple negative breast cancer cells"*** sponsored by ICMR, New Delhi submitted by Mr. Ankit Pateriya under the guidance Dr. Ashutosh Shrivastava, Associate Professor, Department of Canter For Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 417/CFAR/22 dated 19th April, 2022. ***Recommendation of Primary reviewer:*** • The clinical assessment in material in method section should include collection of survival data and mention it • Regarding metabolic profiling of TNBC cell kindly include the list of metabolites that is being intended to study or the anticipated metabolic pathways involved (that will be tested for) • Depending upon customised metabolic profiling the corresponding names of genes

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	need to be mentioned as well • What is the rational of selecting sample size of 50 • The "study procedure" section in Hindi version of ICF is inadequate and does not match with corresponding English version. Also the versions need to be exact replica translation of each other. • In ICF it is mentioned that compensation will be as per funding agency norms. What are those norms and what amount is permissible? kindly elaborate • Kindly include patient information sheet in Hindi language as well. • Kindly complete many left entries of annexure 1. • While this is mentioned as government-funded ICMR project, another entry states that National industry is also involved in this project but no mention of this industry is mentioned in the text • Will just 20,000/- INR (twenty thousand rupees) be sufficient for this project? **EC Comment:** As above **EC Decision:** Re-write & Re-submit with tabular format in word file. ***Ref. code: 116th ECM II B-FS/P3***
4.	Research proposal entitled ***"Estimation of various inflammatory markers levels in poly cystic ovarian syndrome (PCOS) patients and effect of metformin and furostanolic saponins on granulose cells in PCOS"*** sponsored by ICMR, New Delhi submitted by Mrs. Aparna Shukla, under the guidance Dr. Satyendra K Singh, Associate Professor, Department of Cantre for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 470/CFAR/22 dated 16th April, 2022. ***Recommendation of Primary reviewer:*** • The sample size calculation may be added • Briefly describe the quantifications of a specific molecular marker expression as one of the outcome variables in blood samples of PCOS patient • Who will retrieve follicular fluid and granulosa cell from 20 patients with PCOS and 10 normal folliculogenesis subjects of 20 to 35 age. This is not mentioned in the role of investigator. • Oocyte retrieval in OBGYN is usually done in in vitro fertilisation (IVF) procedures under general anaesthesia and transvaginal sonographic guidance- this may be possible only if 20 females with PCOS undergo oocyte retrieval for IVF in the time period of the study. Kindly include a paragraph regarding justification and feasibility of such issues. • It has to be explained that why would a female with normal folliculogenesis undergo oocyte retrieval and hyper stimulation of ovary. • For IVF procedures women are given large doses of gonadotropins for hyper stimulation of ovaries. How will they get follicular fluid and granulosa cells from

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	women with normal folliculogenesis? • The statistical analysis should be described quoting the various outcome parameters as well. • Many entries in annexure 1 need to be done. • Justify inclusion of normal women. **EC Comment:** As above **EC Decision:** Re-write & Re-submit with corrections in tabular format in word file. ***Ref. code: 116th ECM II B-FS/P4***
II-C	**Review of New Drug Trial**
1.	Research protocol no. EX6018-4758 Study Phase:3a entitled **"ZEUS - *Effects of ziltivekimab versus placebo on cardiovascular outcomes in participants with established atherosclerotic cardiovascular disease, chronic kidney disease and systemic inflammation*"** sponsored by Novo Nordisk India Private Ltd. submitted by Prof. Rishi Sethi, Department of Cardiology King George's Medical University, U.P., Lucknow, vide letter no. 2156/Cardio/Res/2022 dated 29th March, 2022. ***Recommendation of Primary reviewer:*** • Multiple deficiencies in IEC form • Sec 3 • Approval/marketing is incorrect • What is the change in route? Where is the attached certificate from DCGI? • Is this IND? • No of subjects? • Why use direct identifiers? • What samples will be sent abroad? • Where is the permission attached? • Why alternative treatment option not given? • Why consent form is not provided in English? • Risk benefits- fields filled wrongly • Compensation- fields wrongly filled • Conflict of interest? • Separate consent form for study participation and biomarker collection has to be provided, as mentioned in protocol. **EC Comment:** • We have no patient search agency. **EC Decision:** Approval subject to modification ***Ref. code: 116th ECMIIC/P1***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

2.	Research protocol no. LIB003-005 entitled ***"Randomized, double-blind, placebo-controlled, phase 3 study to evaluate the long-term efficacy and safety of LIB003 in patients with cardiovascular disease on stable lipid-lowering therapy requiring additional low-density lipoprotein cholesterol reduction (LIBerate-CVD)"*** sponsored by LIB Therapeutics, LIC. submitted by Prof. Akahyaya Pradhan, Professor Jr, Department of Cardiology King George's Medical University, U.P., Lucknow, vide letter no. 2157/Cardio/Res/2022 dated 29th March, 2022. ***Recommendation of Primary reviewer:*** • The drug approval for marketing in any country- contradictory statements in IEC from and patient information form. • Document from DCGI about change in route of administration is missing. • The patient information sheet and IEC form are providing conflicting information about patient benefit. • Why use direct identifiers? • Risk benefits- fields filled wrongly, conflicting information from that provided in patient information sheet. • If biological samples are not being collected(as mentioned in IEC form), what is being sent abroad? • Letter of permission to send samples abroad? • Consent section doesn't check compensation for study related injury. **EC Comment:** • From will Covid-19 patients are obtained. **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECMIIC/P2***
3.	Research protocol no. 0135-0347 entitled ***"A phase IIB/III operationally seamless open label, randomized, sequential, parallel group adaptive study to evaluate the efficacy and safety of daily intervenous alteplase treatment given up to 5 days on the standard of care (SOC) compared with SOC alone, In patients with acute respiratory distress syndrome (ARDS) triggered by COVID-19"*** sponsored by PAREXEL International Clinical Research Private Limited submitted by Prof. R.A.S Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 468/Res/2022 dated 11th April, 2022. ***Recommendation of Primary reviewer:*** • Study duration and participation details missing • Why use direct identifiers? • Why will data not be handled confidentially by staff? • Why is there no physical discomfort?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: As above **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECMIIC/P3***
4.	Research protocol no. CA-170-302 entitled ***"A phase IIB/III, randomised, double-blind, placebo-controlled, study title: A multicentre, study of CA-170 in combination with chemotherapy in patientswith stage IV non-squamous non-small cell lung cancer (ASIAD-3)"*** sponsored by M/s Aurigene Discovery Technologies Limited submitted by Dr. Sudhir Singh, Associate Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 374/RT/2022 dated 13th April, 2022. ***Recommendation of Primary reviewer:*** • KGMU is not a study site in submitted documents • Blood will be collected, it's a biological material. • Duration of study and subject participation not mentioned. • Why will direct identifiers be used? • Physical discomfort not filled • Benefit to participants not clarified. **EC Comment:** As above **EC Decision:** Approval subject to modification with corrections in tabular format in word file. ***Ref. code: 116th ECMIIC/P4***
5.	Research protocol no. HCR/III/DENOSOL/12/2019 entitled ***"A randomized, multiple-dose, multicenter, comparative parallel study to evaluate the pharmacokinetic, pharmacodynamic, efficacy and safety of subcutaneous injection of denosumab (Hetero) and reference medicinal product (Denosumab, Amgen Inc.) in patients with bone metastases from solid tumours"*** sponsored by Hetero Biopharma Limited submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/367/2022 dated 3rd March, 2022. ***Recommendation of Primary reviewer:*** • DCGI doesn't mention KGMU as a study site. • No insurance policy attached **EC Comment:** As above **EC Decision:** Approval subject to modification with corrections in tabular format in

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	word file. ***Ref. code: 116th ECMIIC/P5***
III	**Modification**
1.	Modification of research protocol no.LRP/LUBT010/2016/008 entitled ***"A global, phaseIII, double blind, randomized controlled study to compare the efficacy, safety & immunogenicity of LUBT010 with lucentis® in patients with neovascular age-related macular degeneration"*** sponsored by Lupin Limited (Biotechnology Division) submitted by Dr. Sandeep Saxena, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no.709/OPH/2022 dated 10th March, 2022. ***Recommendation of Primary reviewer:*** ICF latest version 2.0 E/H and back translation certificate not attached 1. DCGI cover letters and Notifications not attached 2. CTRI Registration and Draft CTA not attached 3. Insurance update certificate not attached **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref.code:105th ECMIIC/P1***
2.	Modification of research protocol no. EX9536-4388 SELECT entitled ***"Semaglutide effects on cardiovascular outcomes in people with overweight or obesity"*** sponsored by M/s Novo Nordisk Ltd submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.2132/Cardio/Res/2022 dated 16th March, 2022. ***Recommendation of Primary reviewer:*** Noted ***The following documents were reviewed in the EC Meeting:-***

Sr. No	Document
1-	Protocol Version-6.0, Dated 04-Jan-2021
2.	Updated ICF Version 5.0
a	In English Version 5.0 Dated 18 Aug 2021
b	In Hindi Version 5.0 Dated 22 Sep 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	c	In Back Translation of Hindi to English Version 5.0 Dated 30 Sep 2021
	3.	Track Change/ strike out copy of approved protocol from version 3.0 to version 6.0.

EC Decision: Approved

Ref.code:92th ECMIIC/P1

3. Modification of research protocol entitled ***"A study to assess the impact of "Group motivational enhancement therapy" on clinical outcome and quality of life among patients with opioid dependence undergoing maintenance treatment"*** submitted by Mrs. Sudha Mishra, Ph.D. Scholar under the guidance Prof. Vivek Agrawal, Head, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 519/Psy/2022 dated 19th April, 2022.

Recommendation of Primary reviewer:

Noted

EC Decision: Approved

Ref. code: 111th ECM II B-Ph.D/P2

4. Modification of research protocol no.5030801/GOPI Study entitled ***"Prospective, non-interventional, multi-centre, post marketing surveillance study to evaluate the safety and tolerability of gaviscon oral suspension for the management of symptoms of gastroesophageal reflux disease"*** sponsored by Reckitt United Kingdom submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/10/2022 dated 6th May, 2022.

Recommendation of Primary reviewer:

Updated insurance-Missing.

Office note: Insurance valid till 19th November, 2022.

The following documents were reviewed in the Meeting:-

S. No.	Table of Contents
1.	**Study Protocol:** Clinical Trial Protocol version 2.0, dated 28-Feb-2022
2.	**Substantial Protocol Amendment** Substantial Protocol Amendment Number 01, Version 1.0 dated 28-Feb-2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	3.	**Case Report Form (CRF):** Case Report Form version 2.0 dated 07-Apr-2022.
	4.	**Informed consent forms (ICFs):** 4.1 English Core Study ICD Version No. 4.0, dated 24-Mar-2022 4.2 Core Study ICD Version No. 4.0, dated 24-Mar-2022, Translated from English to Hindi Version No. 3.0, dated 28-Mar-2022 4.3 Core Study ICD Version No. 4.0, dated 24-Mar-2022, Translated from English to Hindi Version No. 3.0 dated 28-Mar-2022, Back Translated from Hindi to English Version No. 3.0 dated 28-Mar-2022
	5.	**Translation & Back Translation Certificates:** ICD - Translation Certificates for English to Hindi & Hindi to English signed on 01-Apr-2022.
	6.	Protocol Signature Page signed on 31 Mar 2022
	7.	Undertaking by the Investigator signed on 31 Mar 2022
	8.	**Regulatory Documents:** 8.1 DCGI notification and acknowledgment (Protocol amendment 01) dated 27 Apr 2022

EC Decision: Approved

Ref. code: 111th ECM II C/P2

IV	**Extension Study**
1-	Extension of research proposal entitled ***"Infant traumatic brain injury: A hidden epidemic in India"*** sponsored by Albert Einstein College of Medicine submitted by Prof. Chandrakanta, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1171/Ped/22 dated 21st April, 2022. ***Recommendation of Primary reviewer:*** • Enrolment of cases is over in this Project, but further Extension of this Project is required. • for the purpose of Data analysis and Publication. • Since this Project is going on from 08-09-2015 after approval from IEC and reapproved on 03-02-21 ,why PI and his team did not analyzed the Data and published the papers in almost 6 and a half years of ongoing Project –Please justify. **EC Decision:** Noted ***Previous Ref. code: 73rd ECM IIA/P10*** ***Current Ref. Code 100 ECM IIE/P1***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

2.	Extension of research proposal entitled ***"A prospective, single-arm, multi-centre, observational, real world registry to evaluate safety and performance of the BioMime™ Morph-Sirolimus eluting coronary stent system for very long coronary lesion"*** M/s Meril Life Science Pvt. Ltd. submitted by Prof. Sharad Chandra, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 59/Cardio/Res/22 dated 29th April, 2022. ***Recommendation of Primary reviewer:*** • Protocol Clarification, DCGI submission letter and amended CTA document not attached. **EC Comment:** As above **EC Decision:** Re-submit ***Ref. code: 83rd ECM IIC/P5***
V	**Other Matter with the permission of Chair**
1-	Due to the 2021 Floods in Lucknow, the lab facilities of Cadmus Laboratories were enundated and all the laboratory was suspended., Hence it was decided to change the lab facilities from Cadmus to Parrk Diagnostics which is also a NABL accredited under the Research Protocol no.MC/BAN/21-001,Version/Date: Version 1.0 Dated 22 March, 2021 entitled ***"A prospective, randomized, parallel group, double blind, multicentric, active controlled, School based study to evaluate the efficacy and safety of albendazole 400 mg & Ivermectin 3 mg/6 mg/12 mg combination vs albendazole 400 mg in reduction of soil-transmitted helminth infections in children"*** sponsored by Pvt. Ltd. submitted by Prof. Shally Awasthi, Head, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. Bandyplus/017/04/22 dated 18th April, **EC Decision:** Noted ***Ref. code: 112th ECM IIC/P2***
2-	Reg. issue of new ethical approval letter because Prof. Sunita Tiwari has superannuated on 20th January, 2022, so kindly issue a new ethical approval letter through new guide-Prof. Narsing Verma, Department of Physiology, K.G's Medical University, U.P., Lucknow under the research proposal entitled ***"Efficacy of dietary intervention of flax seeds (Linum usitatissimum) on signs and symptoms associated with perimenopausal syndrome"*** submitted by Ms. Rashmi Shrivastava, Ph.D. Scholar, through Prof. Narsing Verma, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.2508/PHY/2022 dated 26th April, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above research proposal was already approved in the EC Meeting held on 7th August*, 2021.** **EC Decision:** Noted ***Ref. code: 110th ECM II B-Ph.D/P5
3-	Reg. initially ethical approval was taken dated 10th December, 2020 but funding agency i.e. ICMR asked for new ethical clearance (not more than 6 months old) under ICMR SRF scheme of the research proposal entitled **"*Forensic 3D craniofacial reconstruction using facial anthropometry and soft tissue thickness in India*"** submitted by Mr. Anurag Dubey, Ph.D. Scholar, 2019 Batch, under the guidance Prof. Anoop Kumar Verma, Head, Department of Forensic Medicine & Toxicology of this University via letter no. 110/FMT/2022 dated 20th May, 2022. **EC Decision:** Noted ***Ref. code: 102nd ECM II B-Ph.D/2***
VI	**Brought to Ethics Committee after X-PGTSC held on 19th May, 2022**
	Minutes of X **"PG Thesis sub Committee"** of "Institutional Ethics Committee" Meeting ***virtually*** held on 19th May, 2022 from 3:00 PM. ***The following Members were present in the Meeting:*** 1. Prof. G.G. Agarwal -Member 2. Prof. A.A. Mahdi -Member 3. Prof. Rajendra Nath -Member 4. Prof. Anita Rani Singh -Member 5. Prof. Shally Awasthi -Member
I-A	**Action taken**
1-	Clarification of research proposal entitled ***"To estimate the prevalence of celiac disease in refractory iron deficiency anemia among children: prospective observational study"*** submitted by Dr. Samrat Chirag Singh, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1109/Ped/22 dated 13th April, 2022. **Previous PGTSC Comment:** • How will be Iron deficiency be assessed. • Where and how will Serum Zinc level be assessed. ***The above comment again forwarded to PI response given by PI was reviewed by PR with following recommendation:*** ***Recommendation of PR:*** The clarification provided on Iron deficiency assessment is not clear as there are many factors other than serum iron levels which may affect Hb. If proper clarification is provided then it may be approved. Moreover, it will be better if Serum Zn levels are

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	estimated by Atomic absorption spectroscopy (AAS) or by ICP-MS. ***The above comment forwarded to PI-Reply pending:-*** **PGTSC Decision:** Defer in the next Meeting ***Ref. code: III PGTSC-IIA/P20***
2-	Clarification of research proposal entitled ***"Utility of lung ultrasonography in the evaluation of ≤34 weeks preterm neonates admitted in a neonatal intensive care unit with clinical suspicion of respiratory distress syndrome within 12 hours of birth"*** submitted by Dr. Shivendra Rai, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.1180/Ped/22 dated 21st April, 2022. **Previous PGTSC Comment:** • 'No' has been ticked in response to 'Reasonable risk' question in form. • Involvement of Vulnerable Participants-Not mentioned • Voluntary, Non-coercive Recruitment of Participants-Not mentioned • Voluntary, Non-coercive Recruitment of Participants-Not mentioned • Direct identifiers and completely anonymized are both ticked ***The above comment again forwarded to PI response given by PI was reviewed by PR with following recommendation:*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IV PGTSC-IIA/P39***
3-	Clarification of research proposal entitled ***"Conservative versus tube thoracostomy in patients with selected blunt injury chest-A prospective observational study"*** submitted by Dr. Shreedhar Shandilya, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no.761 dated 14th March, 2022.

Previous PGTSC Comment:	PI response
Kindly provide complete methodology.	Attached separately
Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website. Use simple day to day Hindi language.	Attached separately

The above comment forwarded to PI response given by PI was reviewed by PR.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Second opinion of PR / **PI response** Still allocation of patients for different treatment modalities is not clear. In ICF procedure part of the above mentioned proposal part is not clear. Patients has the right tobe properly informed about different steps including treatment modality, in clear and simple language / Attached separately ***The above comment again forwarded to PI response given by PI was reviewedby PR with following recommendation:*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P16***
4-	Clarification of research proposal entitled ***"Transfusion support in COVID-19 suspects"*** submitted by Dr. Anurag Singh, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no.600(A)/2021 dated 18th November, 2021. **Previous PGTSC Comment:** • Department Review Committee has only 3 members. • There are 3 Co-PIs from the same department which seems superfluous. Please decrease the number of Co-supervisors or define their roles. • IEC form doesn't mention – a. Type of study (Clinical/Epidemiological) b. Advertised or not? c. Contact person details in Consent Form d. Study involves blood sample collection which is not mentioned in the IEC form. • The topic doesn't reflect the Objectives, please reconsider. • IEC needs to be modified and resubmitted. ***The above comment forwarded to PI response given by PI was reviewed by PR.*** ***Recommendation of PR:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: V PGTSC-IIA/P28***
5-	Clarification of research proposal entitled ***"A fluoroscopic comparison between video laryngoscope and macintosh laryngoscope for assessment of cervical spine mobility during tracheal intubation in patients with cervical spine injury"*** submitted by Dr. Muthunagarathinam. M, JR-I, Department of Anaesthesiology, King George's Medical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

University, U.P., Lucknow vide letter no. Anaes/626/21 dated 19th April, 2022.

Previous PGTSC Comment:

- 1 Supervisor and 3 co-supervisors from the same department. Please decrease the number or mention their unique roles.
- Sponsor information incorrect
- Vulnerable/Special groups not ticked in IEC form.
- Privacy/Confidentiality section filled incorrectly.
- Use of biological material not filled.
- Details of Consent not filled in IEC form.
- Risk is mentioned as not reasonable.
- Benefits of Video laryngoscopy are already known. Why this study?
- Conventional laryngoscopy in patients with cervical spine injury increases the risk of further trauma. Having Video laryngoscopy which is less risky and still doing laryngoscopy with a technique which is risky, will be UNETHICAL. Suggest this study be conducted in patients who may not be at risk of spinal trauma.
- Informed consent doesn't mention details of complications due to spine movement and due to fluoroscopy usage.

The above comment forwarded to PI response given by PI was reviewed by PR.

Second recommendation of PR:

Second opinion of PR	PI response
Research project maybe accepted of the study is being carried out in patient without cervical spine injury.	As recommended by IEC, the study will be now carried out in patients without cervical spone injury. (Corrected proforma attached separately)

The above comment forwarded to PI response given by PI was reviewed by PR.

Third recommendation of PR:

- Approved with modified title

PGTSC Decision: Approval ratified

Ref. code: V PGTSC-IIA/P31

6- Clarification of research proposal entitled ***"Comparison of infraclavicular brachial plexus block and combination of infraclavicular brachial plexus block with suprascapular nerve block for shoulder surgeries: A randomized control trial"*** submitted by Dr. Parul Saxena, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/594/22 dated 8th April, 2022.

Previous PGTSC Comment:	PI response
The fundamentals of performing RCT are not completely Specified:	a. Yes, in process

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

(a) Clinical Trial Registry (b) Is blinding needed? (c) Research hypothesis is not properly defined: whether it is (i) inferior, (ii) superior or (iii) equivalence trial?	b. Yes, Single blinding needed c. My research hypothesis proposes that, there is o difference between "Infraclavicular brachial plexus block and combination of infraclavicular brachial plexus block with supracaplular nerve block for shoulder surgeries". Hence it is an equivalence trial.
The sample size will depend on the research hypothesis. Statistical Analysis section should be more specific	Sample size has been calculated as 31 in each group. Attached separately

The above comment forwarded to PI response given by PI was reviewed by PR.
Third recommendation of PR:

- Approved

PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/P5

7- Clarification of research proposal entitled ***"Radiological evaluation of spinal dysraphism with ultrasonography and its comparison with magnetic resonance imaging in children UPTO 1 year of age"*** submitted by Dr. Dhiraj Kumar Gupta, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no.398/RD/22 6th May, 2022.

Previous PGTSC Comment:	**PI response**
In aims and objectives it is mentioned that biopsy will be performed but it is not mentioned in the consent form.	Corrected Aims and Objectives: 1. To see the distribution of different kinds of spinal dysraphism in and around Lucknow in children upto 1 year of age 2. To assess the diagnostic value of spinal ultrasound in evaluation of SD when compared to MRI which is gold standard of imaging in this condition 3. To compare the radiolgocal diagnosis with clinical diagnosis
Although the study will be performed on	Dr. Shalini Tripathi, Associate Professor

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

children less than one year of age, no cosupervisor has been taken from the Pediatric Department, Otherwise there are a lot many co-supervisors.	Department of Paediatric, KGMU, Lucknow chosen has Co-supervisor.

The above comment forwarded to PI response given by PI was reviewed by PR.

Second opinion of PR	**PI response**
The first two points have not been addressed (Rectification of the consent form)	

The above comment forwarded to PI response given by PI was reviewed by PR.
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: VI PGTSC-IIA/P19

8- Clarification of research proposal entitled ***"Diagnostic yield of trans-vaginal ultrasound in post menopausal females and correlation with CA 125 levels"*** submitted by Dr. Vasav Tyagi, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no.399/RD/22 dated 6th May, 2022.

Previous PGTSC Comment:	**PI response**
How Ca 125 levels will be measured? Sample collection/Methodology/ References are not given.	Attached separately
Who will do the test?	Lab Technician posted at Gynaecology OPD in QMH Hospital, KGMU, Lucknow.

The above comment forwarded to PI response given by PI was reviewed by PR.
Recommendation of PR:-

- Gone through the clarification. Still neither the reference of method which will be used for Ca 125 measurement is given nor is a satisfactory response for under whose supervision it will be carried out is mentioned. The candidate has written that blood will be collected by a Lab. technician. Name of the Faculty under whose supervision it will be carried out shall be mentioned. May be approved at your end after the above two clarifications are provided.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The above comment forwarded to PI response given by PI was reviewed by PR.
Recommendation of PR:-

- However, in the project of Dr. Vasav Tyagi, they still mention that laboratory investigation will be carried out under the supervision of a Gynaecologist which I cannot understand why they are insisting on this? Supervision of a person from a diagnostic department (Pathology/Biochemistry) must be there.

PGTSC Comment: As above
PGTSC Decision: Approval subject to modification with tabular format in word file.

Ref. code: VI PGTSC-IIA/P20

9- Clarification of research proposal entitled ***"Prospective observational study on hyponatremia in acute encephalitic syndrome in children: its occurrence and effect on the outcome"*** submitted by Dr. Nikita Diwan, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 989/Ped/22 dated 1st April, 2022.

Previous PGTSC Comment:	**PI response**
Number of subjects is 200 or 215?	Number of subjects 200 enrolled in the study.
Vulnerable subjects have not been ticked even though it is a study on children	Attached separately
Section on Consent is incomplete.	Attached separately
Answer to 'Risk is reasonable' is NO. 5.	Attached separately
Assent form for children is not attached.	Attached separately

The above comment again forwarded to PI response given by PI was reviewed by & he has given his <u>Second Opinion</u>.

Previous PGTSC Comment:	**PI response**
Vulnerable subjects section has still not been edited/ attaché for verification.	Attached separately
Section on Consent is incomplete.	Attached separately
Answer to 'Risk is reasonable' is NO	Attached separately

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment again forwarded to PI response given by PI was reviewed by PR-Recommendation of PR:- • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VI PGTSC-IIA/P30***
10	Clarification of research proposal entitled ***"Comparative study between quadratus lumborum versus transverse abdominis plane block in laparoscopic pyeloplasty for post-operative pain relief"*** submitted by Dr. Manoj Kumar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/228/22 dated 3rd March, 2022. **Previous PGTSC Comment:** • Kindly explain the study procedure to the patient in simple language instead of writing study design. • Kindly follow the SOP provide by IEC, available on Website. ***The above comment again forwarded to PI response given by PI was reviewed by PR-Recommendation of PR:-*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VII-PGTSC-IIA/P19***
11-	Clarification of research proposal entitled ***"Retrospective study of demographic and clinical profile of patients of chronic rhinosinusitis with polyposis at tertiary care Centre"*** submitted by Dr. Neha Agarwal, JRI, Department of OTO-Rhino-Laryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no.63/ENT/21 dated 28th April, 2022. **Recommendation of Primary reviewer:** • IEC form incompletely/incorrectly filled • Sample size calculation not done • Too many Co-PIs included in a project which requires only retrospective data handling. Please justify. ***The above comment again forwarded to PI response given by PI was reviewed by PR-Recommendation of PR:-*** • The objections to the study were raised I November, 2021 and the clarification has been received in April, 2022. • The IEC form was incompletely filled in proposal which has not been corrected and attached for examination. • Sample size calculation still needs to be done in retrospective studies. • Point on Consent waiver is well taken. • Individual roles of all C-PIs have to be defined. 'Patients managed by all consultants' cannot be a criterion to be a part of research proposal. ***The above comment again forwarded to PI response is not given by PI-Pending***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Defer in the next Meeting ***Ref. code: VII-PGTSC-IIA/P30***
12-	Clarification of research proposal entitled ***"Three dimensional evaluation of palatal plane in different vertical facial patterns-a CBCT study"*** submitted by Dr. Sharon K Sabu, JRII, Department of Orthodontics and Dentofacial Orthopaedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 4133/2022 dated 9th March, 2022. **Previous PGTSC Comment:** • Research hypothesis is not defined. • Study design and sampling method are not mentioned. • Study variables and parameters are not given. • Sample Size calculation is not given. • Statistical Analysis section is vague. ***The above comment again forwarded to PI response given by PI was reviewed by PR-Recommendation of PR:-*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIA/P1***
13	Clarification of research proposal entitled ***"To study the association of early biomarkers of acute kidney injury in hepatitis B induced chronic liver disease on tenofovir treatment"*** submitted by Dr. Shivani Rani, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 573/MED/22 dated 16th March, 2022. **Previous PGTSC Comment:** • Research hypothesis is not defined. It should be defined after properly identifying the study variables and population parameters of the study. • Sample size calculation is out of context. It is not specific to the study. • Statistical Analysis section is missing. ***The above comment again forwarded to PI response given by PI was reviewed by PR-Recommendation of PR:-*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIA/P4***
14.	Clarification of research proposal entitled ***"A comparison of internal jugular vein cannulation by anatomical landmark and ultra sound guided technique in operation theater and Intensive care unit (ICU)"*** submitted by Dr. KRL Chetan, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/713/22 dated 5th May, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Sample size calculation is not given. Sample size of 100 picked arbitrarily. • Sampling method is not mentioned. • Statistical Analysis section is not specific to the study. ***The above comment again forwarded to PI response given by PI was reviewed by PR-*** ***Recommendation of PR:-*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIA/P5***
15-	Clarification of research proposal entitled ***"Predictor of outcome in children with tuberculous meningitis and effect of leukotriene A4 hydrolase gene polymorphism on outcome of tuberculous meningitis in children: A prospective observational study"*** submitted by Dr. Dhruvi Rai, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1284/Ped/21 dated 5th May, 2022. ***Recommendation of Primary reviewer:*** • Since the objective of the study is to find predictors of short-term outcome, outcome has not been defined. • Research hypothesis is not given. • Sample size formula is arbitrarily chosen and not specific to the study. • Statistical Analysis section is missing. ***The above comment again forwarded to PI response given by PI was reviewed by PR-*** ***Recommendation of PR:-*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIA/P6***
16-	Clarification of research proposal entitled ***"An observational prospective analysis of suspected poisoning cases admitted in Medicine and Pediatrics Departments of a North-Indian Teaching Medical University"*** sponsored by Research Cell, KGMU UP, Lucknow submitted by Ms. Yashita Khulbe & Mr. Yash Chandani, both are MBBS students through their Mentor Dr. Raja Rupani, Additional Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 60/FMT/22 dated 4th April, 2022. **Previous PGTSC Comment:** • As the patients will also be taken from Paediatric Deptt. –therefore Guardian and Child Assent form is needed apart from general ICF • Cutting of written matter in SOP form is not required (Only ticks against the written matter in every point is permissible) ***The above comment again forwarded to PI response given by PI was reviewed by PR-*** • Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approval ratified ***Ref. code: VIII-PGTSC-IIB IMR-S/P2***
17-	Clarification of research proposal entitled "***CD44 expression in different histological grades of renal cell carcinoma and its clinicopatholgical correlation***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Ms. Varsha Singhal, MBBS 2019 through her Mentor Dr. Atin Singhai, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.408/22 dated 28th March, 2022. **Previous PGTSC Comment:** • Justification for including HSRW Form along with ICF (E/H) • JRs cannot act as Co-PIs in Research Projects? ***The above comment again forwarded to PI response given by PI was reviewed by PR-*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-II B IMR-S/P3***
18-	Clarification of research proposal entitled "***Diphtheria: A prospective study of incidence of diphtheria in the emergency unit of the department of Pediatrics in a hospital of a medical University of Northern India***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Mr. Shubhajeet Roy & Ms. Aditi Singh both are MBBS students through their Mentor Dr. Sciddhartha Koonwar, Prof. Jr. Grade, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.651/Ped/22 dated 11th March, 2022. **Previous PGTSC Comment:** • Exact sample size and its calculation not done • PI has made several cuts of contents in SOP Form –which is not required therefore Revised SOP Form should be submitted with only necessary Ticks • Title has been altered in Protocol and ICF by erasing the few words by whitener which is not permissible. Please give exact title. • Child Assent form not submitted along with ICF ***The above comment again forwarded to PI response given by PI was reviewed by PR-*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-II B IMR-S/P4***
19-	Clarification of research proposal entitled "***Study of single nucleotide polymorphism in MGMT gene promoter region and correlation with MGMT methylation status and prognosis in glioblastoma***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Krachi Agarwal, JR-I through her Mentor Dr. Shivanjali Raghuvanshi, Associate Professor, Department of Pathology, King George's Medical University, U.P., Lucknow

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	vide letter no.Anaes/228/2022 dated 3rd March, 2022. **Previous PGTSC Comment:** • Total 6 Co-PIs, 2 from Pathology and 2 from Neurosurgery with same role, please reduce the number of Co-PIs or justify the same and correct the name of Department of Prof. B K Ojha (HOD , Neurosurgery Deptt.). • Age specificity not mentioned in Inclusion criteria • Revise SOP form as not filled properly leaving parts of the question no.-5 ,8 & 10 unanswered. ***The above comment again forwarded to PI response given by PI was reviewed by PR-*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-II B IMR-R/P5***
20-	Clarification of research proposal entitled ***"Effect of education related to danger signs of pregnancy on knowledge among pregnant mothers in tertiary care hospital"*** submitted by Ms. Nidhi Sachan under the guidance Dr. Suchana Roy Bhowmik, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.622/X.51/22 dated 11th April, 2022. **Previous PGTSC Comment:** Hindi consent form shall be in simple language • In the questionnaire "Nuclear family' is translated to "Parmanu pariwar" needs to be corrected and Hindi translation needs to be improved. ***The above comment again forwarded to PI response given by PI was reviewed by PR-*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: VIII-PGTSC-IIC/P16***
IB	**Expedited review**
1-	Expedited review of research proposal entitled ***"ER and PR receptor expression in case of endometrial hyperplasia and malignancy: A cross-sectional study"*** submitted by Dr. Manju Singh Sirohi, JRI, T.S. Mishra Medical University, Amousi under the guidance of Prof. U.S. Singh, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.114 dated 28th January, 2022. ***The above research proposal forwarded to two Primary reviewers.*** **Recommendation of First Primary reviewer:** • Wrong informed consent form is attached (that of Dr. Hemant Kumar from Pulmonary Critical Care Medicine Department) • Incomplete performa attached and that too not properly photocopied, please sent it again.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to the Principal-Investigator, response received by PI. • The above comment forwarded to both Primary reviewers for review. ***Dr. Anita Rani has given her reply with following recommendation:-*** • In the attached ICF, the procedure is mentioned as Immnunohistochemistry. Proper explanation in simple language is needed. ***The above comment forwarded to the PI through her guide Prof. U.S. Singh, Department of Pathology, KGMU UP, Lucknow vide this office letter no.255/Ethics/2022 dated 28th April, 2022.*** ***Reply received on 18th May, 2022 which is forwarded to Primary reviewer vide this office letter no.342/Ethics-2022 dated 18th May, 2022.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: IX-PGTSC-IB/P1***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"The prevalence of internet gaming and its predictors in adolescents in a district of UP"*** submitted by Dr. Gunjan Bhargava, JRII, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1253/CM/22 dated 2nd March, 2022. ***Recommendation of Primary reviewer:*** • This is supposed to be a cross-sectional study to find the prevalence. • The objective "prevalence of internet gaming" is not clear. The parameter should be properly identified and then objective should be properly stated. • This is a descriptive study. The problem of distinguishing whether exposure preceded outcome or vice versa, is unique to the cross-sectional studies and constitutes major limitations in analytic research. In other words, using it for finding "predictors" should be avoided. • The proposed "district" is not mentioned. • The proposal should be more specific and pinpointed. The objectives should be for a descriptive study and not for an analytic study. In the present format, these are mixed. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Evaluation of non-endoscopic and endoscopic assisted platysma flap- A randomized control trial"*** submitted by Dr. Sandeep Kumar, JRII,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 202/OMFS/22 dated 5th March, 2022. ***Recommendation of Primary reviewer:*** • The aim and objectives are stated separately. There should be one only. • The research hypothesis is not stated. • It it is actually RCT, it should be properly planned. • The fundamentals of performing RCT are not completely Specified: Clinical Trial Registry, method of randomization, blinding, follow-up, outcome event, efficacy or effectiveness trial, Statistical and methodological issues in RCT. • The sample size calculation, statistical analysis section etc. are missing **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P2***
3.	Research proposal entitled ***"A comparative study on lung function of post tuberculosis obstructive pulmonary disease (TOPD) versus chronic obstructive pulmonary disease patient"*** submitted by Dr. Bishal Debbarma, JR, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 284/22 dated 4th March, 2022. ***Recommendation of Primary reviewer:*** • The objectives should be very specific. The first objective is to find our prevalence, whereas the other objectives are pointing toward "Comparative study". • Research hypothesis should be properly defined after identifying the parameters of the study. • The sample size calculation is inadequate. It should be for "Comparative study" not for prevalence. • Statistical analysis section is missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Amniotic membrane as a therapeutic agent for pulpotomy in permanent molars: A randomized controlled trial"*** submitted by Dr. Saumya Johri, SR, Department of Conservative Dentistry & Endodontics, King George's Medical University, U.P., Lucknow vide letter no. 604/22 dated 17th February, 2022. ***Recommendation of Primary reviewer:*** • Aims and objectives are stated in two different statements. These statements should be combined to make it "efficacy trial". • Research hypothesis should be defined in terms of properly identified parameters of the study.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The fundamentals of performing RCT are not completely specified: Clinical Trial Registry, method of randomization, blinding, follow-up, outcome event, efficacy or effectiveness trial, Statistical and methodological issues in RCT. • Since, the research hypothesis is not defined, the sample size calculation is not clear. • Statistical analysis section should be stated only after properly defining the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P4***
5.	Research proposal entitled ***"Comparison of HRCTV delineation in brachytherapy of carcinoma cervix using CT imaging with the gold standard MRI delineation"*** submitted by Dr. Mohammad Ahtesham Khan, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 223/RT/22 dated 14th March, 2022. ***Recommendation of Primary reviewer:*** • Research hypothesis is missing. • The variables and parameters should be explicitly identified for the study. • Research hypothesis should be stated in terms of the parameters of the study. • In the absence of proper research hypothesis, the sample size calculation has no meaning. • The statistical analysis section is missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Comparative evaluation of the nasal cavity and pharyngeal airways in cleft LIP and palate individuals with normal subjects- A cone beam computed tomography study"*** submitted by Dr. Mehak Dobhal, JRII, Department of Orthodontics and Dentofacial Orthopaedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 719/22 dated 16th March, 2022. ***Recommendation of Primary reviewer:*** • Aims and objectives are stated in two different statements. These statements should be combined to make it "comparative study". • Research hypothesis is missing. • The variables and parameters should be explicitly identified for the study. • Research hypothesis should be stated in terms of the parameters of the study. • In the absence of proper research hypothesis, the sample size calculation has no meaning. • The statistical analysis section is missing.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: As above **PGTSC Decision:** Revise & Re-submit with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P6***
7.	Research proposal entitled ***"Effect of platelet-rich fibrin and concentrated growth factor on the regenerative potential of human induced pluripotent stem cells (HIPSCS): A comparative analysis"*** submitted by Dr. Anisha, JRII, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 680/22 dated 23rd March, 2022. ***Recommendation of Primary reviewer:*** • Research hypothesis is missing. • The variables and parameters should be explicitly identified for the study. • Research hypothesis should be stated in terms of the parameters of the study. • Sample size calculation and statistical analysis section are missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Evaluation of hypo-fractionated radiotherapy versus conventionally fractionated radiotherapy for the adjuvant management of resected Head and Neck squamous cell cancers"*** submitted by Dr. Aman Verma, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 222/RT/22 dated 14th March, 2022. ***Recommendation of Primary reviewer:*** • Aims & objectives section is not clear. It has the definition of primary and secondary end points, which should be in methodology section. • The variables and parameters should be explicitly identified for the study. • Research hypothesis should be stated in terms of the parameters of the study. • In the absence of proper research hypothesis, the sample size calculation has no meaning. • The statistical analysis section is missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P8***
9.	Research proposal entitled ***"To study the comparison of six fractions per week chemoradiation versus five fractions per week of conventional chemoradiation locally advanced carcinoma cervix"*** submitted by Dr. Mahan Lal Jat, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	220/RT/22 dated 14th March, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: X-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Evaluation of HIF-1ALPHA and CCND1 expression as a biomarker of treatment outcome in locally advanced Head and Neck cancer patients undergoing chemo-radiotherapy"*** submitted by Dr. Mansi Shukla, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 224/RT/22 dated 14th March, 2022. ***Recommendation of Primary reviewer:*** • Start date of the project is given as June 2021 and the project is to be completed by June, 2022. Without IEC approval how was tha project initiated? A clarification may be taken. • Sample size is 100, why this number of subjects will be taken is not mentioned. If it is a pilot study then it may mentioned. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Post operative residual corneal astigmatism in patients undergoing phacoemulsification with steep axis clear corneal incision, guided by android app"*** submitted by Dr. Shilpi Arya, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 829/OPH/22 dated 31st March, 2022. ***Recommendation of Primary reviewer:*** • Sample size is 81, why this number of subjects will be taken is not mentioned. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P11***
12.	Research proposal entitled ***"Retrospective prospective comparative analysis of reconstruction of ACL TEAR with quadruple hamstring graft and quadruple hamstring graft internally braced with fibertape"*** submitted by Dr. Suraj Saxena, JRI, Department of Orthopardics, King George's Medical University, U.P., Lucknow vide letter no. 1990/OS/22 dated 7th April, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: X-PGTSC-IIA/P12***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

13.	Research proposal entitled ***"Study of dysphagia-optimised intensity-modulated radiotherapy (Do-IMRT) versus standard in tensity-modulated radiotherapy (S-IMRT) in head and neck squamous cell cancer patients"*** submitted by Dr. Shally Batham, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 221/RT/22 dated 14th March, 2022. ***Recommendation of Primary reviewer:*** • In each group 25 patients will be taken, why/on what basis this number of subjects will be taken is not mentioned. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P13***
14.	Research proposal entitled ***"A prospective study to find out the association of IL-18 (-607) C/A and (-137) G/ Gene polymorphism with primary varicose vein disorder and its clinical implication in diagnosis & severity of primary varicose vein disorder"*** submitted by Dr. Nishant Upadhyay, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 303/22 dated 22nd January, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: X-PGTSC-IIA/P14***
15.	Research proposal entitled ***"Localisation of sentinel lymph node, using flouroscent indocyanin green dye by using enhanced visualistion & quality-of life assessment in elective inguinal lymphadenectomy in carcinoma penis"*** submitted by Dr. Jaideep Singh Soni, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 405/22 dated 30th February, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: X-PGTSC-IIA/P15***
16.	Research proposal entitled ***"Serial estimation of urinary trypsinogen-2 levels in patients of acute pancreatitis: A new prognostic indicator"*** submitted by Dr. Rinki Meena, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 302/22 dated 22nd January, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: X-PGTSC-IIA/P16***
17.	Research proposal entitled ***"Assessment of quality of life (Qol) in a case of***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	thoracomyoplasty done after window thoracostomy for chronic empyema thoracis an observational study" submitted by Dr. Atreyee Saha, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 300/22 dated 22nd January, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: X-PGTSC-IIA/P17***
18.	Research proposal entitled ***"Diagnostic accuracy of clinical evaluation and conditional imaging to detect urgent conditions in acute abdominal pain: A prospective cohort study"*** submitted by Dr. Ashi Verma, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 304/22 dated 22nd January, 2022. ***Recommendation of Primary reviewer:*** • ICF: Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on website. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P18***
19.	Research proposal entitled ***"Evaluation of the outcome of video assisted thoracoscopic decortications in cases of early pleural empyema: A prospective observational study"*** submitted by Dr. Piyush, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 301/22 dated 22nd January, 2022. ***Recommendation of Primary reviewer:*** • ICF: different in Hindi and English • Explain the procedure of method for dividing the patients into A and B groups. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P19***
20.	Research proposal entitled ***"Horizontal recti down displacement for unilateral dissociated vertical deviations-A case series"*** submitted by Dr. Akshay Mohan, SRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 788/OPH/22 dated 28th March, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: X-PGTSC-IIA/P20***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

21.	Research proposal entitled ***"Micro-ct evaluation of efficacy of CA(OH)2 paste removal from root canals using laser activated, ultrasonic activated and sonic activated irrigation methods-An in-vitro study"*** submitted by Dr. Adarsh K.S, JRII, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 20/Cons&Endo/22 dated 6th March, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: X-PGTSC-IIA/P21***
22.	Research proposal entitled ***"Comparative evaluation of bone regeneration with L-PRF, amniotic membrane and simvastatin using CBCT after endodontic surgery: A randomized clinical trial"*** submitted by Dr. Niharika Singh, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 37/Cons&Endo/22 dated 6th March, 2022. ***Recommendation of Primary reviewer:*** • Please provide the cost of treatment. • Explain to the patient about 3 bone healing materials that may be used for his/her treatment in ICF and also that any of these 3 materials may be used in the ICF. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P22***
23.	Research proposal entitled ***"Mechanical and chemical changes in root canal dentine by various chelating agents: An in-vitro study"*** submitted by Dr. Anvesha Kumar, JRII, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 81/Cons&Endo/22 dated 23rd March, 2022. ***Recommendation of Primary reviewer:*** • Approved for waiver **PGTSC Comment:** • Please specify where will scanning E.M. be done? Who will perform it. **PGTSC Decision:** Approved for waiver ***Ref. code: X-PGTSC-IIA/P23***
24.	Research proposal entitled ***"A comparative evaluation of efficacy of ethylenediaminetetraacetic acid, citric acid and glycolic acid as final root canal irrigant: An in-vitro study"*** submitted by Dr. Prachi Jha, JRII, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	U.P., Lucknow vide letter no. 685/Cons&Endo/22 dated 23rd March, 2022. ***Recommendation of Primary reviewer:*** • Approved for waiver **PGTSC Decision:** Approved for waiver ***Ref. code: X-PGTSC-IIA/P24***
25.	Research proposal entitled ***"Effect of depth on the amount of degree of conversion and microhardness of dual cure and light cure composites resins-A fourier transform infrared spectroscopy (FTIR) study"*** submitted by Dr. Khushboo Gupta, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 41/Cons&Endo/22 dated 20th April, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: X-PGTSC-IIA/P25***
26.	Research proposal entitled ***"Kinesiophobia in young adults after anterior crutiate ligament reconstruction in a tertiary care centre of northern India: A prospective study"*** submitted by Dr. Ankit Kumar, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 2034/OS/22 dated 22nd April, 2022. ***Recommendation of Primary reviewer:*** • Sections of IEC form regarding consent/Advertising/Risk & benefits and not filled. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P26***
27.	Research proposal entitled ***"Vascular pattern on narrow band imaging bronchoscopy and its relationship with histological type of lung cancer"*** submitted by Dr. Nivedita, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.539/PCCM/22 dated 23rd March, 2022. ***Recommendation of Primary reviewer:*** • Section on use of biological material does not mention biopsy specific harvesting. • There is no mention of how NBI bronchoscopy findings will be quantified/recorded/correlated with HPE results. • Ideally Co-PI cannot be a member of the departmental Scientific Research Committee. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P27***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

28.	Research proposal entitled ***"Endobronchial ultrasound elastography in the evaluation of mediastinal and hilar lymph nodes"*** submitted by Dr. Maqsumi Reza, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.540/PCCM/22 dated 23rd March, 2022. ***Recommendation of Primary reviewer:*** • No mention of tissue sample collection in the section on 'Use of Biological Material' • Sample size in mentioned as 60 at one place and 30 at another. • Ideally Co-PI cannot be member of the departmental Scientific Research Committee. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P28***
29.	Research proposal entitled ***"A study of prevalence of obstructive sleep apnea in population with metabolic syndrome"*** submitted by Dr. Syed Ahmed Hussain Kazmi, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.545/PCCM/22 dated 23rd March, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation has not been done although the sample is mentioned as 60 patients. • In 'Subject Selection' section on vulnerable subject has been left out. • Ideally Co-PI cannot be part of the committee approving the research proposal. **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P29***
30.	Research proposal entitled ***"Clinical and etiological study of hyponatremia in patients admitted in respiratory intensive care unit in a Tertiary Care Hospital"*** submitted by Dr. Shivam Gupta, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.544/PCCM/22 dated 23rd March, 2022. ***Recommendation of Primary reviewer:*** • Sample size in mentioned as 70 at one place and 100 at another. • Involvement of vulnerable subjects has to be mentioned. • Ideally Co-PI cannot be part of the committee approving the proposal. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P30***
31.	Research proposal entitled ***"Role of ultrasound guided IVC-CI versus central venous pressure in assessing fluid status in critically ill patients"*** submitted by Dr. Shubham Jain, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	University, U.P., Lucknow vide letter no.541/PCCM/22 dated 23rd March, 2022. ***Recommendation of Primary reviewer:*** • Study uses seriously ill patients as subject but the IEC proforma does not mention use of vulnerable subjects modify. • Sample size is mentioned as 70 at one place and 100 at another. • Ideally Co-PI cannot be part of committee approving the proposal. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P31***
32.	Research proposal entitled ***"Sedation in flexible fibreoptic bronchoscopy in non intubated patients: midazolam versus midazolam with fentanyl"*** submitted by Dr. Ankit D. Patel, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.543/PCCM/22 dated 23rd March, 2022. ***Recommendation of Primary reviewer:*** • Ideally Co-PI cannot be part of committee approving the proposal. • Suggest changing design of study from 'Randomized Trial' to 'Randomized controlled study'. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P32***
33.	Research proposal entitled ***"Validation of cancer tatio (Serum pleural fluid ADA ratio) for malignant pleural efusion"*** submitted by Dr. Jitendra Agarwal, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.542/PCCM/22 dated 23rd March, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation has not been done. • Co-PI cannot be part of committee approving the proposal. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P33***
34.	Research proposal entitled ***"Clinical findings and lab parameters in cases of acute lymphoblastic leukemia with thrombocytosis at initial diagnosis"*** submitted by Dr. Anurag Singh, SR, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.382 dated 24th March, 2022. ***Recommendation of Primary reviewer:*** • Sample size justification has not been done. • Sections on use of Biological material are not properly filled.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• IEC waiver has been requested since non-identifiable date will be used. • Waiver may be accepted for this research proposal since it is retrospective review of data without identifying features. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-IIA/P34***
II-B	**MHA**
1.	Research proposal entitled ***"A study on patient waiting time in outpatient department in a tertiary care government Teaching Hospital"*** submitted by Dr. Swati Rai under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/53/22 dated 15th February, 2022. **PGTSC Comment:** **Methodology:-** • **Study design-**Observational descriptive study. • **Variables-** • A- Patient arrival time in the queue for registration –Patient registration time. • B- To determine the patient waiting time for consultation with doctor-Time for consultation? • C- To identify the reasons which are responsible for increased waiting time? **Inclusion criteria:** • New patients on working days from OPD of- Endocrinology, Rheumatology, Surgical Oncology and Radiotherapy (Age/sex specificity not mentioned) **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X PGTSC-II B-MHA/P1***
II-B	**MBBS Student**
1.	Research proposal entitled ***"Evaluation of growth parameters and compliance score in transfusion dependent thalassemia major patients enrolled in a tertiary care hospital in Lucknow"*** submitted by Ms. Ishita Shukla, MBBS 2018 Batch, Through her Mentor Dr. Nishant Verma, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 564/Ped/22 dated 5th March, 2022. ***Recommendation of Primary reviewer:*** • As the pts taken care of age gp between 2-18 yrs ,therefore Guardian consent and Child Assent form should also be submitted apart from general ICF. • Mention Role of PI and Co-PI not mentioned **Informed Consent form:-**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Hindi & English-General attached, but as the patients taken are of age group between 2-18 yrs, therefore Guardian consent and child assent form should also be submitted. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-II B MBBS-S/P1***
2.	Research proposal entitled **"*Trends of utilization of Ayushman Bharat Pradhan mantra Jan AROGYA Yojana (AB-PMJAY)*"** sponsored by ICMR submitted by Mr. Bobby Patel, BDS, Through her Mentor Prof. Balendra Pratap Singh, Department of Prosthodontics & Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1238/22 dated 15th March, 2022. ***Recommendation of Primary reviewer:*** • Sample size not mentioned • Role of PI/Co-PI not mentioned • Structured Questionnaire not submitted **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-II B BDS-S/P2***
3.	Research proposal entitled **"*Correlation of chemotherapy induced response in serous ovarian carcinoma with P53 expression and serum CA125 levels*"** submitted by Ms. Fiza Akhtar, MBBS, 2019 through her Mentor Dr. Riddhi Jaiswal, Additional Professor, Department of **Pathology**, King George's Medical University, U.P., Lucknow vide letter no. 416/22 dated 29th March, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation not mentioned (if pilot study ,PI should clear) • HSRW form is attached but in protocol's inclusion criteria, it is mentioned that consent for participation will be initiated by telephonic conversation –Justification should be given by PI. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-II B MBBS-S/P3***
4.	Research proposal entitled **"*Investigating normal size of spleen in patients of various age groups appearing in tertiary health care centre using ultrasonography (USG)*"** submitted by Mr. Abhinav Shukla, MBBS, 2020, Through his Mentor Dr. Nitin Arun Dikshit, Assistant Professor, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 275/RD/22 dated 7th April, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • Sample size not mentioned in Protocol (Only mentioned in SOP Form as 2000 subjects)-Please include calculated sample size in Protocol • As all age group patients will be taken therefore Guardian consent and Child Assent form should be submitted along with regular consent form. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: X-PGTSC-II B MBBS-S/P4***
5.	Research proposal entitled ***"Antibiotic prescription practice in febrile: a hospital based ovservational study"*** submitted by Ms. Radhda Mateen, MBBS, 2020, Through his Mentor Dr.Sarika Gupta, Prof. Jr. Grade, Department of Paediatics, King George's Medical University, U.P., Lucknow vide letter no.1232/Ped/22 dated 29th April, 2022. ***Recommendation of Primary reviewer:*** • Role of PI / Co-PI not mentioned **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: X-PGTSC-II B MBBS-S/P5***
II-C	**Nursing KGMU Institute**
1.	Research proposal entitled ***"Effectiveness of structured teaching plan on knowledge and attitude regarding self-care management of gestational diabetes mellitus among antenatal women"*** submitted by Mr. Sunny Kumar Pathrol under the guidance Mrs. Rashmi P. John, Head, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.563/X.51/21 dated 30th March, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: X-PGTSC-IIC/P1***
III-A	**Additional Document**
1.	Additional of research protocol entitled ***"An epidemiological study of substance abuse among youth in Lucknow district"*** submitted by Dr. Hariom Singh, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 31/22 dated 4th April, 2022. ***Recommendation of Primary reviewer:*** • The name of Dr. Abhishek Gupta, Associate Professor, Department of Community Medicine, TSM Medical College, Lucknow as a Co-PI (CV-Attached) in this study

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	may be approved. **PGTSC Decision:** As above ***Ref. code: VI-PGTSC-IIA/P18***
2.	Additional of research protocol entitled ***"Randomised controlled single blind trial of transcranial direct current stimulation (tDCS) as early augmentation in major depressive disorder"*** submitted by Dr. Babli Kumari, JR, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 495/Psy/22 dated 13th April, 2022. ***Recommendation of Primary reviewer:*** • Additional the name of Dr. Amit Singh, DM, Assistant Professor, Department of Psychiatry, KGMU, Lucknow for the purpose of reaching target sample size has been approved. • This is the project to be taken under the IEC Meeting. **PGTSC Decision:** As above ***Ref. code: 107th ECM-IIB-Thesis/P53***
III-B	**Modification**
1.	Modification of research protocol entitled ***"Study the effect of melatonin on psychological and physical outcome in older adults with acute ischemic stroke"*** submitted by Dr. Prerak Kumar, SRI, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 1546/DGMH/2022 dated 30th March, 2022. ***Recommendation of Primary reviewer:*** • Modification in protocol has been done and explained will-Noted **PGTSC Decision:** As above. ***Ref. code: VII-PGTSC-IIA/P32***
	Other Matter
1	Reg. typographical error in protocol section under the research proposal entitled ***"Randomised controlled single blind trial of transcranial direct current stimulation (tDCS) as early augmentation in major depressive disorder"*** submitted by Dr. Babli Kumari, JR, Department of Psychiatry, King George's Medical University, U.P., Lucknowletter no. 251/Psy dated 7th March, 2022. ***Already approved in the PGTSC Meeting held on 26th June, 2021.*** **PGTSC Decision:** Noted ***Ref. code: 107th ECM II B-Thesis/P53***
2-	Reg. Due to COVID-19 conditions, the permission to change the study design from "Randomized Control trial" to "prospective observational study" under the research proposal entitled ***"Comparison of two weaning methods, T-piece method vs continuous***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	positive airway pressure (CPAP) methods, in mechanically ventilated patients admitted to a paediatric intensive care unit department of Paediatrics of a medical university in northern India Respective cohort study" submitted by Dr. Dhirendra Pratap Yadav, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1277/Ped/2022 dated 5th May, 2022. ***Already approved in the PGTSC Meeting held on 26th June, 2021.*** **PGTSC Comment:** Title modified **PGTSC Decision:** Approval subject to modification ***Ref. code: 107th ECM II B-Thesis/P29***

The Next Meeting will be held on 30th July, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 117th IEC Meeting held on 30th July, 2022

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of 117th "Institutional Ethics Committee" Meeting ***virtually*** held on 30th July, 2022 from 10:30 AM***The following members were present in the Meeting:***

1. Prof. Alok Dhawan -Chairman
2. Prof. Shubha R Phadke -Member
3. Dr. Akash Agarwal -Member
4. Mrs. Vasundhara Kumari -Member
5. Mr. Ujjwal Krishna -Member
6. Dr. K.K. Yadav -Member
7. Prof. Rajendra Nath -Member
8. Prof. Anupam Mishra -Member
9. Prof. Anita Rani Singh -Member
10. Dr. D.N. Upadhyaya -Member
11. Mrs. Akansha Dubey -Member
12. Prof. Shally Awasthi -Member-Secretary, IEC

The following Member could not attend the Meeting:

1. Prof. A.A. Mahdi –He has not given his comment
2. Prof. G.G. Agarwal-He has given his written comment

IA	Action Taken
1	Clarification of research proposal entitled "***Missed injury associated with maxillofacial trauma: An observational study***" submitted by Dr. Arunesh Kumar Tiwari, Associate Professor, Department of Oral and Maxillofacial Surgery, King George's Medical University, U.P., Lucknow vide letter no.585/OMF/2021 dated 15th July, 2022

Previous EC Comment:	PI response

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The protocol appears to be a part of manuscript prepared for publication. Kindly resend the proposal in proper format.	Sending a fresh protocol along with.
	Apply as fresh proposal for waiver	No waiver approval required for now.

The above Comment forwarded to PI was reviewed by PR:-

Recommendation of PR:

- Role of Co-PI seems incorrect.
- Patient Information sheet has not been provided. In the ICF, the procedure is not explained properly.

EC Comment:

- As above

EC Decision: Re-submit

Ref. code: 111th ECM IIA/P14

2 Clarification of research proposal entitled "***Matrix metalloproteinases in angiogenesis and tumor invasion: clinicopathological impact in urothelial bladder carcinoma patients***" submitted by Prof. Apul Goel, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 385/URO/2022 dated 15th July, 2022.

Previous EC Comment:

- Patient information sheet (Part-I) has no information about sample collection. It has to be modified in both English & Hindi.

Previous EC Decision: Approval subject to modification

The above Comment forwarded to Primary reviewer for review:-

Recommendation of PR:

Approved

EC Decision: As above

Ref. code: 115th ECM IIA/P3

3 Research proposal entitled "***Assessment of trends and factors influencing smokeless tobacco use in Lucknow***" submitted by Dr. Gaurav Mishra, Associate Professor, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 450/PHD/2022 dated 27th July, 2022.

Previous EC Comment:	PI response
Patient information sheet as per SOP EC KGMU to be attached	Attached
Annexure 1 needs to be complete. Many information are not available such as.	Completed (copy attached)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	information are not available such as. a- Sponsor information (yes or no) b- In 'subject selection' kindly indicate types of special group subjects c- Give response regarding risk and benefit d- Give response regarding data monitoring e- Give response regarding "Is their compensation for injury"	
	Give a brief detail about statistical analysis	Detail mentioned (Attached)

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:

- Kindly provide patient information sheet in Hindi.

The above comment forwarded to PI was reviewed by Primary reviewer:
Recommendation of Primary reviewer:
Provisionally approved
EC Decision: Approved

Ref. code: 115th ECM IIA/P11

4 Research proposal entitled "***Knowledge, attitudes, and practices of School Teachers toward Oral Health in Uttar Pradesh, India***" submitted by Dr. Sumit Kumar, Associate Professor, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 407/PHD/22 dated 12th July, 2022.

Previous EC Comment:	**PI response**
Kindly attach patient information sheet as per SOP EC KGMU (mentioned as attached in annexure)	Attached
Kindly complete following details of an excel in subject selection kindly indicate which special group subjects in risk benefit kindly indicate is there social physical risk discomfort.	Corrected (Copy attached)
Give a brief account of how sampling will be done how will the division or schools be selected whether age will be a criteria for randomly selected teachers.	With respect to the sampling corrections have been done. Age is not a criteria in my study for collection of teachers.
Give a brief account of statistical analysis	Mentioned/attached

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Kindly provide patient information sheet in Hindi ***The above comment again forwarded to PI was reviewed by Primary reviewer:*** ***Recommendation of Primary reviewer:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 115th ECM IIA/P12***
5	Clarification of research proposal entitled ***"Knowledge, attitude and practice of Paediatric trauma management among the health care workers providing trauma care in government run major Hospitals of Lucknow: A questionnaire based study"*** submitted by Dr. Vikas Verma, Associate Professor, Department of Paediatric Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no.1782/PaedOrtho/2022 dated 31st May, 2022.

Sl.No.	Previous EC Comment:	PI response
1-	The title should be "Development and validation of a questionnaire to assess Knowledge, attitude modify accordingly.	Title changed as advised to "Development and validation of a questionnaire to assess knowledge, attitude and practice about paediatric trauma management among health care workers providing trauma care in major government run hospitals of Lucknow "
2-	The methodology to develop, assess reliability and validity of the questionnaire should be given in detail. For example, what kind of "validity" is required for the present situation?	The methods section has been rewritten as Questionnaire would be developed using the following steps:- Step 1: To summarize the structure and extent of questionnaire – Literature will be reviewed for defining the questions related to management of paediatric trauma. Meeting of experts in the field of paediatric trauma will be conducted. Telephonic interviews will be conducted with experts in the field. Information gathered will be used to design a questionnaire assessing the demography, educational status, current designation, knowledge, attitude and practice about paediatric trauma among doctors managing trauma.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

				Step 2: Development and precision of questionnaire items - To ensure precision and agreement the questionnaire will be evaluated by an expert panel (n=5) to identify the dimensionality of the construct, determine the questionnaire format (self or researcher administered), determine the item format (open ended or closed ended), develop the items, determine the length of the questionnaire, and review and revise the initial item pool. Any new questions suggested by the expert panel will be added to the questionnaire. Content validation of the questionnaire would be done at this stage. For this a meeting of internal and external experts shall be called. Each question as well as the overall questionnaire will be scored for content validity and clarity; with response options given as l="not", 2="Somewhat", 3="rather" Or 4:"highly" relevant or clear. Responses will be summed and averaged to determine a mean score for the relevancy and clarity of each question. Questions with low mean score will be removed and revisions will be made. Step 3: Cognitive interviews: Cognitive interviews would be conducted with health care workers (n=10) trauma in the trauma centre of KGMU. Written informed consent would be obtained from the enrolled health care workers. During the interviews, which will range in duration from 15-30 min each, participants will be instructed to complete the questionnaire by 'thinking out loud" as they read and answer each question. Commentary will be encouraged around interpretation of wording, arrival at answers, and available response options. Comments will be	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

				recorded and later analyzed to identify common themes. Time taken to fill one form will be recorded. Based on this feedback, a **2.0 version** of the questionnaire will be finalized. This will complete the development stage of the study. Step 4: Pilot testing: For pilot testing a convenient sample size of 30 will be taken. Participants would be recruited from the health care workers managing trauma in the trauma centre of KGMU. Written informed consent would be obtained from the participants. The same set of participants would fill the questionnaire thrice with a gap of 24 hours between each time. Questions would be assessed for floor effect and ceiling effect. Those with high floor effect and ceiling effect would be removed from the questionnaire. The questionnaire items would be revised upon reviewing the results of the preliminary pilot testing. No incentive will be provided to the participants. **Step 5: Validation:** The questionnaire would be validated by calculating estimates of reliability and validity. Reliability: Would be assessed by determining the internal consistency, test retest reliability and inter-rater reliability. Internal consistency of the questionnaire would be calculated using Cronbach's α for the questionnaire as well as each of the items in the questionnaire. An α value of ≥ 0.80 will be taken as internally consistent. Test-retest reliability of the questionnaire would be calculated using intra-class correlation coefficient. Inter-rater reliability would be estimated using kappa for agreement (would be done if whole or part	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

				of the questionnaire is researcher administered). Validity: Content validity would be estimated as detailed in step 2. Construct validity cannot be estimated as pre-existing instruments to measure knowledge, attitude and practice about paediatric trauma in health care workers is not available. Once a precise questionnaire has been developed, it will be used in the second stage of the study. The questionnaire will be used to assess the knowledge, attitude and practice about paediatric trauma in health care workers involved in trauma care at government run major hospitals of Lucknow namely Ram Manohar Lohia institute, King George Medical University, Lucknow, Sanjay Gandhi Post graduate institute, Lucknow Balrampur Hospital and Civil Hospital. All types of paediatric trauma cases are admitted in the department of trauma surgery at the trauma centre of KGMU. Once primarily managed and stabilized they are transferred to other departments for definitive management. Paediatric orthopaedic injury patients are transferred to the department of Paediatric Orthopaedics. Paediatric head injury cases are transferred to the department of neurosurgery. Paediatric thoracic injures and abdominal injuries are managed in the department of trauma surgery itself. Questionnaire would be designed by involving internal as well as external experts from the department of trauma surgery, neurosurgery and paediatric orthopaedics.	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 115th ECM IIA/P18

6 Clarification of research proposal entitled "***Evaluation of nasolabial flap in oral defect created in oral squamous cell carcinoma patients***" submitted by Prof. U.S. Pal, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 477/OMSF/2022 dated 28th May, 2022.

Previous EC Comment	PI response
Kindly discuss in the meeting: Issue of Retrospective Ethical Clearance. For publication purposes.	This Ethical clearance is needed for publication purpose only.
Kindly remove the Consent form and apply for waiver of consent only.	Waiver of consent form has been attached removing the consent form as this is a retrospective study.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved for waiver
EC Decision: As above

Ref. code: 115th ECM IIA/P31

7 Clarification of research proposal entitled "***Clinicoepidemiologic spectrum of hepatitis B patients at a tertiary care centre of North India and development of a simplified diagnostic and therapeutic algorithm***" submitted by Dr. Ajay Kumar Patwa, Prof. Jr. Grade, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1384/Med/22 dated 20th July, 2022.

Previous EC Comment	PI response
Role of PI/Co-PIs not mentioned	Role of PIs mentioned
Detailed methodology with Inclusion/Exclusion criteria not mentioned.	Detailed methodology given and inclusion and exclusion criteria mentioned
Sample size not mentioned anywhere	Calculated and mentioned
Case record form / Demographic data form not attached	Case record form attached

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Change in title as suggested by the team)

Previous title	Current title
Clinico-epidemiologic spectrum of hepatitis B patients at a tertiary care centre of North India and development of a simplified diagnostic and therapeutic algorithm.	Development of KGHeBTA: a simple comprehensive diagnostic and therapeutic algorithm for hepatitis for hepatitis B and its clinic-epidemiological spectrum.
The changes are highlighted	

The above comments forwarded to PR with following comments:-

- Sample size calculation is still not mentioned but in comments- answer table PI has mentioned that Sample size calculation has been done (In Protocol PI has mentioned that it is a Retrospective study therefore Sample size is not needed)-Please clarify.
- This is a retrospective study of data collection of the patients between 2014 to 2019, then why this time in protocol PI has included a patient information sheet, and an Informed consent form (In the previous protocol PI has submitted a Human subject review waiver form [HSRWF] instead of ICF)- Please clarify
- This time the Title has been changed - whether it has been approved by the Scientific Review Committee of the department. Please clarify

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 115th ECM IIA/P35

8 Clarification of research proposal entitled "***Generation of comprehensive methylome towards developing qPCR based epigenetic biomarker panel for early detection of buccogingival and tongue carcinoma***" submitted by Dr. Sameer Gupta, Additional Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/161/22 dated 13th July, 2022.

Previous EC Comment:

- PI should be from parent institute , therefore Dr. Sameer Gupta, Deptt of Surgical Oncology will act as PI and Dr. Manisha Sachan from Biotechnology Deptt of MNNIT site, Allahabad should be Co-PI.
- In Methodology, study design and Exclusion criteria and grouping not mentioned
- Total sample size is not clear and not calculated (discrepancy between SOP form and Protocol
- ICF clinical Investigator's Name must be there.
- Budget from ICMR in SOP form is written as Rs.38 lakhs/ and in protocol Rs.49,90,264/- Please justify.

The above comments forwarded to PI, reply has given by PI was again reviewed PR

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

with following comments:-

- **Methodology and Exclusion criteria have been given but** Study design still not mentioned
- Sample size -PI has mentioned that around 100 tissue samples will be taken **-PI should give the flow chart of methodology including different tissue samples with numbers, as it is not clear. Please also mention how you have calculated this sample size.**

The above Comment forwarded to PI was reviewed by PR:-

Recommendation of PR:

Provisionally approved

EC Decision: Approved

Ref. code: 115th ECM IIA/P36

9- Clarification of research proposal entitled "***Retrospective study of vesico-vaginal fistulae associated with recto-vaginal fistulae repair***" submitted by Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter nos. 305/URO dated 6th June, 2022 & 323/URO dated 20th June, 2022.

Sl.No.	Previous EC Comment:	PI response
1-	Inclusion/ Exclusion criteria –not mentioned	**Inclusion criteria:** All rectovaginal fistulas associated with vesicovaginal fistula underwent repair at our center. **Exclusion criteria:** Isolated rectovaginal fistula (RVF) and isolated Vesicovaginal Fistula (VVF).
2-	Sample size not mentioned	The proposed study is **retrospective review** of records from patients of vesicovaginal fistula (VVF) associated with rectovaginal fistula (RVF) underwent to fistula repair in which we will analyse previously stored records from patients in

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		department of Urology, KGMU, Lucknow, during last two decades (2001-2021).**Therefore the sample size was not being mentioned.**
3-	Why Patient information sheet is attached if direct patient involvement is not there, please justify	We have removed the patient information sheet. Since it is retrospective review of records this sheet is not needed.

The above Comment forwarded to PI- was reviewed by PR.

Second recommendation of PR:

Second opinion of PR	**PI response**
Sample size calculation still not given-saying that is is the retrospective study: the retrospective study also needs sample size, you have no mention that whether it is convenience, quota, or systematic sampling. Which are normally done in retrospective studies to do data analysis.	In this retrospective study we use convenience sampling method for data analysis of vesicovaginal fistula (VVF) associated with rectovaginal fistula (RVF) underwent to fistula repair. The sample size was calculated for this study based on the previous study (Gulati et al.2011) that reported the average prevalence of combined vesicovaginal fistula (VVF) and rectovaginal fistula (RVF) is **1.85%** in India, **95%** level of confidence and Error rate, usually set at **0.05. Minimum 30** Patients data will be included in this study. **$n= Z^2 P(1-P)/d^2$** Where, • n = Sample size, • Z = Z Statistic for level of confidence, for the level of confidence of 95%, which is conventional, Z value is 1.96. • P = Expected prevalence of proportion (in proportion of one; if 1.85%, P = ~0.02). • d = Precision (in proportion of one; if 5%, d = 0.05).

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		$n = 1.96x1.96x0.02x0.98/0.05^2$ **n = 30.11** **n = 30** **Total 30 samples will be included in this study.** **Reference:** Gulati BK, Unisa S, Pandey A, Sahu D, Ganguly S. Correlates of Occurrence of Obstetric Fistula among Women in Selected States of India: An Analysis of DLHS-3 Data. Facts Views Vis Obgyn. 2011;3(2):121-8. PMID: 24753857; PMCID: PMC3987485.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 115th ECM IIA/P39

10 Clarification of research proposal entitled ***"Impact of DNA methylation on proliferation of low vs high grade non-muscle invasive bladder cancer associated with autophagy in North Indian population"*** submitted by Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 304/URO dated 6th June, 2022.

Previous EC Comment:	**PI response**
Sample size calculation not done (only formula is written)	The Sample size was calculated based on the previous study that reported that the prevalence of urinary bladder cancer is **5.5%** in globally, **95%** level of confidence and Error rate, usually set at **0.05. Total 80** Patients will be included in this study. **$n= Z^2 P(1-P)/d^2$** Where, • n = Sample size, • Z = Z Statistic for level of confidence, for the level of confidence of 95%, which is conventional, Z value is 1.96.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		• P = Expected prevalence of proportion (in proportion of one; if 5.5%, P = 0.055). • d = Precision (in proportion of one; if 5%, d = 0.05). **$n = 1.96 \times 1.96 \times 0.055 \times 0.945 / 0.05^2$** **n = 79.866864** **n = 80** **Total 80 samples will be included in this study.**

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:-
Provisionally approved
EC Decision: Approved

Ref. code: 115th ECM IIA/P40

11 Clarification of research proposal entitled "***Assessment of nicotin dependence and readiness to change amongst patients attending Tobacco Cessation Clinic***" submitted by Dr. Vinay Kumar Gupta, Prof. Jr. Grade, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 364/PHD/22 dated 16th June, 2022.

Previous EC Comment	PI response
Ph.D. Scholar is not eligible for becoming Co-PI -Please remove the name (for discussion in open forum)	Ph.D. scholar name as Co-PI has been removed.
PI has mentioned the study design as Retrospective, but recruiting cases from TCC for observation; therefore the study will be Prospective observational study.	Study design has Change to Prospective observational study.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 115th ECM IIA/P41

12 Clarification of research proposal entitled "***Bench to bedside: molecular evaluation and ex vivo validation of tetraspanin KAI-1 as a biomarker of metastatic progression in breast cancer***" submitted by Dr. Richa Singh under the guidance Prof. Vijay Kumar, Head, Department of Surgical Oncology,King George's Medical University, U.P., Lucknow vide letter no. SONC/1231/22 dated 13th July, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comment	PI response
Inclusion and Exclusion criteria are not mentioned.	It has been mentioned at page no. 5.
Sample size calculation/justification not given.	It has been mentioned at page no. 5.
Patient information sheet not attached.	It has been attached as annexure VII at page number in both Hindi and English languages.
ICF language should be easy to understand for the pay person/patient.	The ICF Language has been simplified.
The language is too technical.	An attempt has been made to simplified.

The above comments forwarded to PI was reviewed by PR:-
Recommendation of PR:-
Provisionally approved

EC Decision: Approved

Ref. code: 115th ECM II B-WS/P1

13 Clarification of research proposal entitled "***Efficacy of yogasana & meditation in the management of irritable bowel syndrome***" submitted by Ms. Diksha Devi, Ph.D Scholar 2020 under the guidance Dr. Sunita Tiwari, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2580/PHY/22 dated 23rd June, 2022.

Previous EC comment	PI response
The current study must include a Co-PI who is an expert in Yoga/ Meditation	I have added a Co-PI who is an expert in Yoga/ Meditation. Dr Umesh Kumar Shukla PhD in Yoga, Yoga Instructor Lucknow University, Lucknow
The study is funded by UGC, as per the PI.	Yes, it is funded by UGC as per the PI
No details of funding are given.	Study is funded by UGC (New-Delhi). Award letter of UGC-Junior Research Fellowship (JRF) has been attached
In the section on privacy the PI has mentioned direct identifiers and ticked 'No' in confidential	It has been corrected in the attached SOP ethical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	handling of data. This must be corrected.	sheet.
	Will suggest replacing the term 'Randomized Controlled Trial' with 'Randomized Controlled Study'	Thanks for the suggestion. I have replaced the term with 'Randomized Controlled Study'. Please find in the attached sheet.
	PI has superannuated- Change of guide needed	Guide has been changed. Dr. Sandeep Bhattacharya is my new guide. Change of guide letter has been attached.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 115th ECM II B-Ph.D/P4

14 Clarification of research proposal entitled "***To study the volume of biomedical waste generated in a healthcare facility***" sponsored by Centre for Chronic Disease Control submitted by Dr. Nitin Dutt Bhardwaj, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/231/2022 dated 24th June, 2022.

Previous EC comment	PI response
To make the study useful, couple of private as well s government healthcare facilities should be included in the facilities. If possible.	This is a **multicentric** study. Below mentioned hospital are part of this study and the list is already attached in annexure 2 of the ethical review. **a) Bharat Hospital, Delhi (Pvt)** **b) PSG, Coimbatore (Pvt)** **c) Arvind Eye Care, Pondicherry (Pvt)** **d) Sehgal Neo Hospital, Delhi (Pvt)** **e) KGMU, Lucknow, tertiary care Govt Hospital**
The questionnaire is required to measure the various categories of waste	**Observational checklist is attached for assessment of various categories of waste along with protocol.**

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 116th ECM IIA/P2

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

15 Clarification of research proposal entitled "***Comparison of stress and anxiety levels among pregnant women on the basis of gender of the first living child***" submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1307/22 dated 11th June, 2022.

Previous EC Comment	PI response
Aims and objectives are not given.	Aims and objectives mentioned (in executive summary) **Primary objective:** To find out levels of stress and anxiety among females during their second pregnancy and compare the levels between women whose first child was male versus whose first child was female. **Secondary objectives:** 1. To ascertain the psychosocial aspect on the gender preference of children present in Indian population. 2. To determine whether the gender preference of children is more prevalent among certain sections of the society on the basis of place of residence, socioeconomic status, religion, caste, literacy, etc. 3. To correlate stress and anxiety of women with social support from family, friends and significant other. 4. To comment on the subjective well-being of the women of the two groups.
The corresponding research hypothesis is required,	Research hypothesis mentioned (in executive summary) 1. Women whose first child was female are likely to have higher levels of stress and anxiety in regards to the general idea of preference of male child in Indian population. 2. This difference is more likely to be present in women coming from rural areas, low socioeconomic status or low literacy.
This is a prospective cohort study for comparing two group. The two groups should be clearly identified.	Details of two groups added (in executive summary) Group 1: women in their second pregnancy who's first living child is male.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Group 2: women in their second pregnancy who's first living child is female.
	The sample size calculation is not given.	Sample size calculation mentioned (in executive summary and annexure 1) Sample size was calculated to be 104 (51 for each group) (Noncentrality parameter δ = 2.5248762, critical t = 1.6602343, Df = 100) with the following parameters Tail(s) = One Effect size d = 0.5 α err prob = 0.05 Power (1-β err prob) = 0.8 Allocation ratio N2/N1 = 1
	The questionnaire is required.	Questionnaire attached
	The statistical analysis section is required.	Statistical analysis mentioned (in executive summary) The data obtained from the filled forms will be fed into MS Excel 2016. Statistical analysis will be done using Statistical Package for the Social Sciences (SPSS) version 22. Descriptive analysis will be performed to determine the percentage of individuals exhibiting similar levels of depression-anxiety-stress, subjective well-being & perceived social support. Unpaired t-test will be used to compare the mean scores of the three scales in the two groups to determine if there is a statistically significant difference between them. Correlational analysis will also be done to determine if there exists an association among variables.
	The above Comment forwarded to PI was reviewed by PR:- ***Recommendation of PR:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 116th ECM IIA/P5***	
16	Clarification of research proposal entitled "***Evaluation of shear bond strength of composite resin, bonded to laser and bur prepared dentine surface using low level laser application before bonding***" sponsored by ICMR submitted by Dr. Vijay Kumar Shakya, Additional Professor, Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	letter no. 127/CONS & ENDO2022 dated 4th July, 2022. ***Recommendation of Primary reviewer:*** • The part 1 of the consent form has information. the second point - method of research / study in Hindi - the translation in not correct • दाँत - need to be written correctly. • स्वेच्छा - INCORRECTLY TYPED. • Hindi should be simple and of good quality. **EC Decision:** Approval subject to modification. ***Ref. code: 116th ECM IIA/P8***
17	Clarification of research proposal entitled "***To determine the role of infection control nurse (ICN) in prevention and control of Hospital acquired infections***" submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 133/CCU/22 dated 21st June, 2022.

Previous EC Comment	PI response
Define role of ICF	The role of An Infection Control Nurse role is to identify, create, and employ best practices for sanitation and infection management. Whether it's a contained infection or a global pandemic, ICN should eliminate infectious threats that may be present.
Research proposal very sketchy give details clearly.	**Objective:** 1. **Primary Objective** – To study the role of Infection Control Nurse (ICN) in prevention and Control of Hospital Acquired infection 2. **Secondary Objective** – To study the incidence of Ventilator Associated Pneumonia (VAP), Central line-associated bloodstream infections (CLABSI), Catheter-Associated Urinary Tract Infections (*CAUTI*) in Critical Care Unit (CCU). **Method:** All patient admitted in CCU will be enrolled in study. At admission will be following parameters will be noted- 1. APACHE 2. Indwelling in situ

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		3. Culture Sensitivity reports 4. Days Mechanical Ventilation 5. SOFA score (daily) 6. All Routine Investigation ICN will DO the Check list review of the standard ICU protocol and assure there compliance. Compliance to various ICU Bundles will be assured. **Design:** To Study The Effectiveness Of ICN (Infection Control Nurse) in Infection Preventing Control in Critical Care Unit. Patient admitted in ICU during 1 year duration will include in the study. The data will be compared with the previous year data when ICN were not appointed. 1 year Prospective cohort study of Infection Control Nurse (ICN) **Intervention:** No Intervention **Participants:** Patients admitted in ICU over a period of one year. **Setting:** Infection Control Nurse (ICN), King George's Medical University, Lucknow India **Result:** we will collected and analyse. Before analyzing, the data will be anonymised. We will compare the incidence of hospital Acquired Infection (HAI) in 1 year period with previous year data.
	Patient information sheet/Consent not clear.	The data will be anonymised. Request is for consent waiver.
	Is the routine work or research?	These activities in critically ill patients must be performed by the nursing officer looking after the patient. ICN will ensure that these activities are performed according the protocol in every patient. He/she will ensure the implementation of ICU Care bundles and will collect the data of these patients. One dedicated person assign for this task may improve the patient's outcome. The primary outcome measure is whether appointment of ICN in ICU can result in decrease in infection rate and

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		which in turn can be translated in term of decrease mortality and morbidity.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 116th ECM IIA/P9

18 Clarification of research proposal entitled "***To study the determinants of mortality in critically ill obstetric patients admitted in Intensive Care Unit***" submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 134/CCU/22 dated 21st June, 2022.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 116th ECM IIA/P10

19 Clarification of research proposal entitled "***Effect of pumpkin seed on anthropometric, biochemical and genetic marker of metabolic syndrome***" sponsored by ICMR, New Delhi submitted by Prof. Dileep Kumar Verma, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2566/PHY/2022 dated 11th June, 2022.

Previous EC Comment:	**PI response**
Method of randomization not given.	Simple random sampling will be used in the study by Random number table method. **Simple random sampling-** Simple random sampling is a type of probability sampling in which the researcher randomly selects a subset of participants from a population. Each member of the population has an equal chance of being selected. **Random number table method-** A random number table is a table of digits. The digit given in each position in the table was originally chosen randomly from the digits 1,2,3,4,5,6,7,8,9,0 by a random process in which each digit is equally likely to be chosen.
Blinding not mention.	There is no blinding in the study. Therefore, it is mentioned in the project proposal that the study is Unblinded or open label (Both researcher and the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		enrolled patients will be aware of the treatment(s).
	Since it is a randomized trial, get it registered it in CTRI portal.	Yes, we know that but for registering a trial in *Clinical Trials Registry- India (CTRI)* portal ethical clearance certificate is required to be uploaded on the portal.
	Include an Ayurvedic doctor in the project.	**Dr. Naresh Patel,,**BAMS,,Emergency Medical Officer, Nishat Hospital,,Lalbagh,,Lucknow **Tel No.-** 0522-2334035 **Mobile No.-** 9839184703,9450110180
	Method of randomization is not mentioned.	Simple random sampling will be used in the study by Random number table method. **Simple random sampling-** Simple random sampling is a type of probability sampling in which the researcher randomly selects a subset of participants from a population. Each member of the population has an equal chance of being selected. ▪ **Random number table method-** A random number table is a table of digits. The digit given in each position in the table was originally chosen randomly from the digits 1,2,3,4,5,6,7,8,9,0 by a random process in which each digit is equally likely to be chosen.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 116th ECM IIA/P15

20 Clarification of research proposal entitled "***Development of Indian TNBC patients-derived organoid (PDO) and xenograft (PDX) models to understand its therapeutic vulnerabilities***" sponsored by ICMR submitted by Prof. Dipak Datta, Head, Cancer Biology Division Central Drug Research, Co-PI Prof. Anand Kumar Mishra, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/145/2022 dated 21st February, 2022.

Previous EC Comment:	**PI response**
Since it is trial, get it registered at CTRI	The aim of the study is to develop the in-vitro

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Patient-derived organoid (PDO). For this purpose Tissue samples from Triple negative breast cancer patient (TNBC) will be screened by approved chemotherapeutic drugs in the lab. So, there is no in vivo clinical trial involved. Hence, not registered at CTRI.
	ICF: Study procedure has to be explained to the patients properly	Detailed study procedure re-written and highlighted. Please find the attached file and it will be explained to the patient's properly.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:

- No Informed Consent Form and Patient Information sheet is attached for review.
- Kindly provide required documents in local and English.

EC Comment:
As above
EC Decision: Approval subject to modification

Ref. code: 116th ECM IIA/P16

21	Clarification of research proposal entitled "***Measuring impact of COVID-19 pandemic at our Teaching Hospital in north India***" submitted by Dr. Harish Gupta, Associate Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1211/MED/2022 dated 13th June, 2022. **Previous EC Comment:** • No sample size has been mentioned. • If the study is using only anonymized patient data from OPD the PI may be encouraged to apply for IEC waiver. • If the study is using only anonymized patient data from OPD the PI may be encouraged to apply for IEC waiver. • Very sketchy protocol ***Tabular format has not given by PI.*** ***The above Comment forwarded to PI was reviewed by PR:-*** **Second opinion of PR:-** • The response is inadequate and does not answer the queries raised. Research proposal cannot be approved in its current form. ***The above Second opinion forwarded to PI –Reply is pending:-*** **EC Decision:** • Dr. Harish Gupta to present his proposal in the Next EC Meeting. ***Ref. code: 116th ECM IIA/P21***
22	Clarification of research protocol entitled "***Management of chronic Achilles tendon tear by reverse gastrocnemius turn down flap and augmentation with FHL tendon***"

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

submitted by Dr. Devarshi Rastogi, Associate Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2322/OS/2022 dated 13th June, 2022.

Previous EC Comment:	PI response
Sample size is not mentioned	*The present study is retrospective study (Jan* 2017 to Jan 2021*), all the subjects who meet our inclusion criteria within the mentioned duration will be included in the study, Every year total 30 to 40 patients of chronic TA rupture visited the hospital, so our target is to enrolled at least 54 subjects or above.*
Exclusion criteria, discontinuation and withdrawal criteria not mentioned.	Patients were given written informed consent previously. Before being recruited, all patients will be diagnosed with a full-thickness tear by Ultrasonography (USG) and a physical examination that include heel raise and ankle movement. Patients were unable to complete a single-limb heel-rise because of a neglected or chronic TA rupture with a ruptured gap of more than 6 cm. Patients with a history of local infection near tendon rupture, open Achilles tendon rupture, a concomitant disease with fracture, poor skin condition, Acute Achilles tendon rupture, varicose vein, DVT, ruptured gap of less than 6 cm, blood vessel rupture, or nerve rupture were ruled out. Subjects have right to withdraw from the study.

Second opinion of PR:-

- The response is inadequate and does not answer the queries raised. Research proposal cannot be approved in its current form.

The Second opinion was forwarded to PI –Reply is pending:-

EC Decision: First reminder to be sent to Principal Investigator.

Ref.code:116th ECMIIA/P22

23 Clarification of research protocol entitled "***Total hip arthroplasty for failed osteosynthesis of proximal femoral fractures: clinical outcome from a low-and middle-income country***" submitted by Dr. Devarshi Rastogi, Associate Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

no. 2321/OS/2022 dated 13th June 2022.

Previous EC Comment:	PI response
Sample size is not mentioned	The present study is retrospective study (January 2016 to June 2020), all the subject who meet our inclusion criteria within the mentioned duration will be included in the study, Although according to hospital record every year near about 120 subjects visited the hospital so according to prevalence rate we will enrolled near about 60 subjects or above.

Second opinion of PR:-

- The response is inadequate. Sample size calculation is a must for the study to have scientific validity.

The Second opinion was forwarded to PI –Reply is pending:-

EC Decision: First reminder to be sent to Principal Investigator.

Ref.code:116th ECMIIA/P23

24 Clarification of research proposal entitled "***Cost-effectiveness of pradhan mantra janaushadhi pariyojna (PMJP) and its impact on financial risk protection in India***" sponsored by Department of Health Research Ministry of Health and Family Wekfare, Indian Red Cross Society Building submitted by Prof. Divya Mehrotra, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 556/OMSD/22 dated 25th June, 2022.

Previous EC Comment:	PI response
Proposal is sketchy.	Brief description of proposal has been re-written.
References not given.	References have been added

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally approved

EC Decision: Approved

Ref. code: 116th ECM IIA/P25

25 Clarification of research proposal entitled "***Management of meniere's disease: an institutional experience***" submitted by Dr. Rajat Jain, Assistant Professor, Department of Otorhinolaryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 218/ENT/2022 dated 27th June, 2022.

Previous EC Comment:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Sample size calculation not given • References not provided. • Sketchy proposal ***The above Comment forwarded to PI:-Reply pending .*** **EC Decision:** Defer for the next Meeting. ***Ref. code: 116th ECM IIA/P26***
26	Clarification of research proposal entitled "***Dosimetric impact of model-based dose-calculation algorithms in high dose rate brachy therapy of cervical carcinoma***" submitted by Dr. Shraddha Srivastava, Associate Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 713/RT/22 dated 11th July, 2022. **Previous EC Comment:** • Proposal details missing ***The above comment forwarded to PI response received by PI was forwarded to PR:-*** ***Recommendation of PR with following comments:*** PI has stated that the work will be carried out between March 2021 to April, 2022. The study time is over then why goes in for Ethical clearance now? ***The Member Secretary has Provisionally approved.*** **EC Decision:** Approved ***Ref. code: 116th ECM IIA/P27***
27	Clarification of research proposal entitled "***Randomized controlled trial to assess the feasibility of delivering psycho-social interventions and effectiveness in improving the common psychological problems of the non-clinical population: a multi-centric and multi-setting study from central India***" submitted by Dr. Amit Singh, Assistant Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 817/Psy/22 dated 16th June, 2022.

Previous EC Comment:	PI response
Calculation of sample size is not clear. It is mentioned that in total 173 cases will be recruited and in each group there will be 43 subjects. Why?	The estimated minimum sample size for the study is 170. Thus, in each of the 4 study settings (two general hospital settings and two community setting) around 43 participants will be required. Considering them to be divided equally into intervention arm and control arm we have proposed to recruit 22 participants in each arm.
In the setting of the study section it is mentioned that subjects will be recruited from Bhopal too. Which institution and who will be the Co-PI from there is not mentioned.	The details of the institution and Co-PI from Bhopal site are as follows:- **Name of the Institution:** All India Institute of Medical Sciences, Bhopal, Madhya Pradesh.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		PI (Bhopal Site): Dr. Snehil Gupta Assistant Professor, Department of Psychiatry, all India Institute of Medical Sciences, Bhopal (CV of the PI was submitted along with the study proposal)

The above Comment forwarded to Primary reviewer for review:-
Recommendation of PR:
Pending
EC Decision: Defer for the next Meeting because Primary reviewer was absent.
Ref. code: 116th ECM IIA/P28

28 Clarification of research proposal entitled "***Screening of lifestyle mitigated circadian disruptions in metabolic diseases and differential effect of plant derived omega 3, ALA, DHA & Palmitate blend supplementation on circadian pattern of metabolic markers***" sponsored by ICMR New Delhi submitted by Dr. Kshitij Bhardwaj, Ph.D. Scholar under the guidance Prof. Narsingh Verma, Head, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.2561/Phy/22 dated 9th June, 2022.

Previous EC Comment:	**PI response**
Since it is a trial, get it registered at CTRI	Attached separately

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved
Ref. code: 116th ECM II B /P3

29 Clarification of research proposal entitled "***A case control study to assess the effect of alpha linolenic acid on tobacco craving in various tobacco users***" sponsored by ICMR New Delhi submitted by Miss. Anjali Singh, Ph.D. Scholar under the guidance Prof. Narsingh Verma, Head, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2562/Phy/22 dated 9th June, 2022.

Previous EC Comment:

- Is linolenic and a drug (Flex seeds)?
- Give standard care of such patient.
- What exactly is being done?
- Justify why this intervention is being given proposal sketchy-Does is justify as Ph.D work.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Provisionally approved **EC Decision:** Approved ***Ref. code: 116th ECM II B /P4***
30	Clarification of research proposal entitled "***To study the formulation of human alpha-lactalbumin-oleic acid complex and investigation of its tumoricidal effect on notch signaling pathway during cell death process on leukemia cell lines***" submitted by Mr. Vivek Singh, Ph.D. Scholar 2016 under the guidance Dr. Ranjana Singh, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/152/22 dated 9th May, 2022.

Previous EC Comment:	PI response
Kindly provide information in detail for procuring HUMAN MILK.	We didn't required human milk for our research purpose. We had purchased human a-Lactalbumin from human milk (Sigma-CAS Number: 9051-29-0) from app lab biosciences. Human a-Lactalbumin is a protein which was isolated from the milk and commercialized in market by different companies. So, in this study we didn't use any human subject and also does not any ethical clearance for that.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:-
Provisionally approved
EC Decision: Approved
Ref. code: 116th ECM II B-Ph.D/P6

31	Clarification of research proposal entitled ***"Standardization of multiplex real time PCR for detection of M leprae"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Parul Jain, Assistant Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.395/22 dated 15th June, 2022.

Previous EC Comment:	PI response
Comment 1: The sample size calculation may be added	We have taken a convenient sample size based on the average number of samples received annually in the laboratory.
Comment 2: The patient information sheet in Hindi to be added.	The sheet has been attached.
Comment 3: Also provide a brief outline	The following outcome measures will be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	paragraph of outcome measures.	considered: Correlations between C_T values and bacilloscopy, Correlations between C_T values and grading (paucibacillary and multibacillary samples), Correlations between C_T values and histopathological grades, standard curve using Ct values versus serial DNA concentrations, Sensitivity, specificity, concordance, positive predictive value, and negative predictive value of the newly developed PCR
	Comment 4: No scientific committee approval is attached but it is expected that the proposal has been scientifically approved before sanction.	Letter is attached
	Comment 5: Give approval letter from Research Cell	Letter is attached

The above comment forwarded to PI was reviewed by Primary reviewer:-
Provisionally approved
EC Decision: Approved

Ref. code: 116th ECM II B-IMR-F/P1

32 Clarification of research proposal entitled ***"Determination of micrometastatic cells and their sensitization by radiotherapy and estimation of DNA damage repair in breast cancer patient"*** sponsored by Research Cell KGMU Lucknow submitted by Dr. Satyendra Kumar Singh, Associate Professor, Department of Centre For Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/530/22 dated 16th June, 2022.

Previous EC Comment:	**PI response**
No justification for sample size has been provided.	20 lymph node negatives, 20 lymph node positive and 20 metastatic breast cancer patients will be taken. In each group ER, PR, HER-2 status will we considered to make subgroups on the basis of patients availability. 10 ml blood will be withdrawn at the time of radiotherapy.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

<table>
<tr><td></td><td>Provisionally approved
EC Decision: Approved
Ref. code: 116th ECM II B-IMR-F/P2</td></tr>
<tr><td>33</td><td>Clarification of research proposal entitled "A study to explore the mechanism of FGD5-AS1 in oral cancer" sponsored by ICMR, New Delhi submitted by Dr. Manjari Sonam, under the guidance Dr. Fahad Mansoor Samadi, Additional Professor, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.798/OP/22 dated 5th July, 2022.
<table>
<tr><th>Previous EC Comment:</th><th>PI response</th></tr>
<tr><td>Sample size calculation may be added</td><td>Sample size calculation for Oral Cancer lesions has been distributed according to age and sex distribution. However, the study and control group were categorized as - 110 confirmed oral cancer cases, and the control group comprised 50 samples of healthy tissue. The study group is oral cancer lesions with 110 samples which are further categorized into - well-differentiated OSCC (70), Moderately differentiated (30), and Poorly differentiated OSCC (10), and control groups with 50 samples. Thus, the combined sample of the study and control group is 160. The assessment indicated: - range from 100 percent below 1 percent. On average sample collection in the study and control groups is 80%. This is called a reliability check. The sample size was estimated using the formula: n = Z 2 p (1 − p) d 2 where $n = Samplesize Z = 1.96\ for\ 95\%\ CIp = 0.50\ (Expectedproportionof functionalCSCs)\ d = 0.09\ (precisionof\ 80\%)$

Sample size: 160 cases

$n = \frac{2(Z\alpha + Z1-\beta)^{2\sigma 2}}{\Delta^2}$

Where
Z1-α = normal deviate for an error (two-sided test uses Z1-α/2)
Z1-β = normal deviate for b error
2 indicates two groups (sources of variability) i.e., the treatment group
Δ = least difference between the treated and non-treated group that is considered clinically significant
n = sample size of each group</td></tr>
<tr><td>Patient information sheet to be attached</td><td>Statistical software STATA 15 was applied and univariate</td></tr>
</table>
</td></tr>
</table>

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		and bivariate analysis was used. Possible tests that can be applied in the present study would be:- As the present study is present in Clinical data sets and it is a parametric statistical test, an assumption about the population parameters and the distributions of the data can be made with the following included includes T-***tests, Z tests and ANOVA tests, which assume data is from normal distribution*** **1. T test formula** One-sample t-test is expressed using the observed sample mean, the theoretical population means, sample standard deviation, and sample size. Mathematically, it is represented as, $t = (\bar{x} - \mu) / (s / \sqrt{n})$ **2. Z test** The formula for calculating a z-score is $z = (x-\mu)/\sigma$, where x is the raw score, μ is the population mean, and σ is the population standard deviation. As the formula shows, the z-score is simply the raw score minus the population mean, divided by the population standard deviation. **3. ANOVA Test** A one-way ANOVA uses the following null and alternative hypotheses: H_0 (null hypothesis): $\mu_1 = \mu_2 = \mu_3 = \ldots = \mu_k$ (all the population means are equal) H_1 (alternative hypothesis): at least one population mean is different from the rest.
	4:Outcome measures:	ANOVA, z -test, two-tailed t-test through Graphpad 7.0 and SPSS 22.0.
	5:	**(A)** **Subject selection** i. Number of subjects: 160 ii. Duration of a) Study: 24 months b) Subject participation: iii. Will subjects from both sexes be recruited

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			Yes √ No □
			iv. Inclusion/exclusion criteria given Yes √ No □
			v. Type of subjects Volunteers □ Patients √√
			vi. Vulnerable subjects Yes □ No √ (Tick the appropriate boxes) Pregnant Women □ Children □ Elderly □ Fetus□ Illiterate □ Handicapped □ Terminally ill □ Seriously ill □ Mentally Challenged □ Economically & socially backward □ Any other □
			vii. Special group subjects Yes □ No √ (Tick the appropriate boxes) Captives □ Institutionalized □ Employees □ Students □ Nurses / Dependent □ Armed Forces □ Any other □ Staff □
			(B) **8. Consent** * **Written** √

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Oral☐ Audio-Visual ☐ i. Patient Information Sheet attached: (Tick the included elements) Yes √ No☐ Understandable language √Alternatives to participation √ Statement that study involves research √Confidentiality of records √ Sponsor of study √Contact information √ Purpose and procedures √Statement that consent is voluntary √ Risks & discomforts √Right to withdraw √ Benefits √Consent for future use of material biological NA Compensation for participation NA☐Benefits if any on future commercialization e.g. Genetic basis for drug development NA Compensation for study related injury NA Translation of information sheet in local language ☐√ ii. If healthy volunteers will be included, information sheet for them attached NA iii. Consent form in English √ Hindi √ iv. Who will obtain consent (PI) √ Nurse / Cousellor☐ Research Staff ☐ Any other ☐

The above comment forwarded to the PI response has given by PI was reviewed by both PRs:-

Recommendation of both PRs:-

Provisionally approved

EC Decision: Approved

Ref. code: 116th ECM II B-FS/P1

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

34 Clarification of research proposal entitled ***"Integrated transcriptomics and metabolomics analysis of metabolomics disturbances in triple negative breast cancer cells"*** sponsored by ICMR, New Delhi submitted by Mr. Ankit Pateriya under the guidance Dr. Ashutosh Shrivastava, Associate Professor, Department of Canter For Advance Research, King George's Medical University, U.P., Lucknow vide letter no. nil dated 17th June, 2022.

Previous EC Comment:	**PI response**
The clinical assessment in material in method section should include collection of survival data and mention it.	The patients will be followed up for response to the chemotherapy and survival data will be recorded. The same has been mentioned in method section.
Regarding metabolic profiling of TNBC cell kindly include the list of metabolites that is being intended to study or the anticipated metabolic pathways involved (that will be tested for)	**Metabolites** Boric acid Carbonate Citrate lactic acid L-Valine Glycine Phosphoric acid Lactate Isocitrate Succinate Butanedioic acid Uracil Serine L-Threonine

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Tromethamine α-Ketoglutarate L-Aspartic acid L-Glutamic acid D-Fructofuranose D-Glucose Palmitic acid Myo-inositol	
	Depending upon customised metabolic profiling the corresponding names of genes need to be mentioned as well.	In this study we will also focused on the genes of TCA cycle, such as, IDH, SDH, CSY and MDH. Which are known to regulate the metabolite levels related to energy metabolism?	
	What is the rational of selecting sample size of 50?	**Sample Size:** The sample size was calculated based on a previous study that reported the average fold-changes of metabolites (Amino acid, bile acid, carbohydrates, vitamins and cofactors) in breast cancer is 3.3% (Park et al.,2019), 95% level of confidence and Error rate, usually set at 0.05 level is 4. Total 50 patients will be included in this study. We have used following statistical formula to calculate patient's sample size. Same has been mentioned in method section of research proposal on page on. 5. $n=Z^2P(1-P)/d^2$ Where, • n = sample size, • Z = Z statistic for a level of confidence,	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	for the level of confidence of 95%, which is conventional, Z value is 1.96. • P = expected prevalence or proportion (in proportion of one; if 3.3%, P = 0.033), • d = precision (in proportion of one; if 5%, d = 0.05). **n**=1.96x1.96x0.033x0.967/0.05^2 **n=49.04**
The "study procedure" section in Hindi version of ICF is inadequate and does not match with corresponding English version. Also the versions need to be exact replica translation of each other.	The corrected ICF is now incorporated.
In ICF it is mentioned that compensation will be as per funding agency norms. What are those norms and what amount is permissible? Kindly elaborate.	There is no compensation by the funding agency. The entry in the annexure 1 is corrected.
Kindly include patient information sheet in Hindi language as well.	We have now added the patient information sheet in Hindi language as well.
Kindly complete many left entries of annexure 1.	We have filled all the left entries of annexure 1.
While this is mentioned as government-funded ICMR project, another entry states that National industry is also involved in this project but no mention of this industry is mentioned in the text	This study is funded by Indian Council of Medical Research, Central Government of India.
Will just 20,000/- INR (twenty thousand rupees) be sufficient for this project?	The contingency amount of this ICMR funded project is 20,000/-. This study will be conducted in the laboratory of Dr. Ashutosh Shrivastava (mentor) already funded by Ministry of Ayush, Government of India. Sanction letter No.:**S-14015/6/2019-SCHEME** Total Project Cost: INR **59,91,281/-**

The above comment forwarded to PI was reviewed by PR:-
Recommendation of PR:-
Provisionally approved
EC Decision: Approved

Ref. code: 116th ECM IIB-FS/P3

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

35 Clarification of research proposal entitled ***"Estimation of various inflammatory markers levels in poly cystic ovarian syndrome (PCOS) patients and effect of metformin and furostanolic saponins on granulose cells in PCOS"*** sponsored by ICMR, New Delhi submitted by Mrs. Aparna Shukla, under the guidance Dr. Satyendra K Singh, Associate Professor, Department of Centre for Advance Research, King George's Medical University, U.P., Lucknow vide letter no.564/CFAR/22 dated 14th July, 2022.

1	The sample size calculation may be added.	The sample size was calculated based on previous studies that reported the prevalence of PCOS among reproductive women is 4-5%, 95% level of confidence and error state, usually set at .05 level is 4. So, by using following formula; $n = (Z)^2 \cdot p \cdot q / d^2$ where, n = Sample size, P = Expected prevalence= 4%, p=.04 d = Degree of freedom if 5%, d=.05 Z= Differentiation coefficient, for level of confidence of 95%; Z=1.96 $n=1.96*1.96*.04*.96/ (.05)^2$ n=59.0 Thus, the sample size comes out to be almost 60 females.
2	Briefly describe the quantifications of a specific molecular marker expression as one of the outcome variables in blood samples of PCOS Patients.	Emerging evidence suggests that PCOS might be linked to the presence of a low-grade chronic inflammatory state with increased levels of IL-6, IL-18 and TNF-alpha in women with PCOS when compared with control. However, we expect that levels of these parameters should go down after treatment of cells with furostanolic saponins

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			(furocyst) and metformin. In addition we will also check levels of few other possible markers such as IL-1, IL-2, IL-8, IL-13, IL-12, IL-10, IL-15, IL-22, NFkB in granulosa cells. Immune cells such as monocytes, lymphocytes, eosinophils and granulocytes are up regulated in PCOS as compared to control group. So, we will study whether levels of these immune cells go down or not after treatment with furocyst and metformin. We are using some different immune cell types those levels are not known in PCOS, which may be act as a novel factor.
	3	Who will retrieve follicular fluid and granulosa cell from 20 patients with PCOS and 10 normal folliculcogenesis subjects of 20-35 age group. This is not mentioned in the role of investigator.	Follicular fluid will be collected by Prof. Dr. Renu Singh, department of Obstetrics & gynaecology from PCOS patients only. We will not need follicular fluid from healthy females with normal folliculogenesis as it is clearly mention in titles itself that we will work on **"granulosa cells in PCOS"**
	4	Oocyte retrieval in OBGYN is usually done in in-vitro fertilization(IVF) procedures under general anesthesia and transvaginal sonographic guidance-this may be possible only if 20 females with PCOS undergo oocyte retrieval for IVF in the time period of the study. Kindly include a paragraph regarding justification and feasibility of such issues.	We have clearly mentioned that **we will try** to collect follicular fluid from almost 20 female patients, if available, with age group of 20-35 years old. If we will be able to establish granulosa cell line from the very first sample, we will not need any more no. of samples. We would like to mention that also if in case we will not be able to get success in establishing granulosa cell lines Or we don't get follicular fluid in the tenure of study we will take it from CSIR-Institute.
	5	It has to explained that why would a female with normal folliculogenesis undergo oocyte retrieval and hyperstimulation of ovary.	We will not need follicular fluid from healthy women with normal folliculogenesis. It has been corrected.
	6	For IVF Procedures women are given large does of gonadotropins for hyperstimulation of ovaries, how will	As previously mentioned, we don't need follicular fluid from healthy females. And it has

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		they get follicular fluid and granulosa cells from women with normal folliculogenesis.	been corrected in Modified copy.
	7	The statistical analysis should be describe quoting the various outcome parameters as well.	Unpaired/paired t-test will be used to determine statistical significance between groups. P value less than 0.05 will be considered as statistically significant. (*p≤0.05; *p≤ 0.01). Data will be represented as mean ±standard error. Two tailed Student's t-test will be used to compare two groups (means +-SD).
	8	Many entries in annexure 1 need to be done.	All the entries have been completed. Copy is attached with modifications.
	9	Justify inclusion of normal women.	Normal healthy women between age group 18-40 years will be included. With no other abnormalities such as diabeties, CLD, Hypertension, Pituatry disorders, etc. for the study of level of various inflammatory and bio-markers in **peripheral blood samples** of normal healthy females as compared to PCOS patients.

The above comment forwarded to PR:-

Recommendation of PR:-

Provisionally approved

EC Decision: Approved

Ref. code: 116th ECM II B-FS/P4

36 Clarification of research protocol no. EX6018-4758 Study Phase:3a entitled "**ZEUS - *Effects of ziltivekimab versus placebo on cardiovascular outcomes in participants with established atherosclerotic cardiovascular disease, chronic kidney disease and systemic inflammation***" sponsored by Novo Nordisk India Private Ltd. submitted by Prof. Rishi Sethi, Department of Cardiology King George's Medical University, U.P., Lucknow, vide letter no. 174/Cardio/Res/2022 dated 1st July, 2022.

Recommendation of Primary reviewer:

- Multiple deficiencies in IEC form
- Sec 3
- Approval/marketing is incorrect
- What is the change in route? Where is the attached certificate from DCGI?
- Is this IND?
- No of subjects?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Why use direct identifiers? • What samples will be sent abroad? • Where is the permission attached? • Why alternative treatment option not given? • Why consent form is not provided in English? • Risk benefits- fields filled wrongly • Compensation- fields wrongly filled • Conflict of interest? • Separate consent form for study participation and biomarker collection has to be provided, as mentioned in protocol. • We have no patient search agency. **The above comment forwarded to PR:-** ***Recommendation of PR:-*** • Section 7(ii) contradicts Section 7 (ix) • Approval for export of biological samples: not attached. There is a process and certificate for approval, as attached with proposal 720. • Section 8: consent: alternative to participation should be allowed. Without this, study is ethically not acceptable. **EC Comment:** Can samples send, if CDSCO approve. **EC Decision:** Approval subject to modification ***Ref. code: 116th ECMIIC/P1***
37	Clarification of research protocol no. LIB003-005 entitled "***Randomized, double-blind, placebo-controlled, phase 3 study to evaluate the long-term efficacy and safety of LIB003 in patients with cardiovascular disease on stable lipid-lowering therapy requiring additional low-density lipoprotein cholesterol reduction (LIBerate-CVD)***" sponsored by LIB Therapeutics, LIC submitted by Prof. Akahyaya Pradhan, Professor Jr, Department of Cardiology King George's Medical University, U.P., Lucknow, vide letter no. 190/Cardio/Res/2022 dated 12th July, 2022. ***Previous* EC Comment:***:* • The drug approval for marketing in any country- contradictory statements in IEC from and patient information form. • Document from DCGI about change in route of administration is missing. • The patient information sheet and IEC form are providing conflicting information about patient benefit. • Why use direct identifiers? • Risk benefits- fields filled wrongly, conflicting information from that provided in patient information sheet.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• If biological samples are not being collected(as mentioned in IEC form), what is being sent abroad? • Letter of permission to send samples abroad? • Consent section doesn't check compensation for study related injury. • From will Covid-19 patients are obtained. **The above comment forwarded to PR:-** ***Recommendation of PR:-*** • Section 3 (ii): PI states that trial drug LIB003 is approved for marketing in India, UK, Europe and US. This contradicts information provided in the brochure. Kindly explain. • Section 10: there is no intervention which will not cause discomfort. A subcutaneous injection is definitely a cause of discomfort. PI should refer to https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf. **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 116th ECMIIC/P2***
38	Clarification of research protocol no. 0135-0347 entitled "***A phase IIB/III operationally seamless open label, randomized, sequential, parallel group adaptive study to evaluate the efficacy and safety of daily intervenous alteplase treatment given up to 5 days on the standard of care (SOC) compared with SOC alone, In patients with acute respiratory distress syndrome (ARDS) triggered by COVID-19"*** sponsored by PAREXEL International Clinical Research Private Limited submitted by Prof. R.A.S Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 596/RT/2022 dated 22nd June, 2022.

Previous EC Comment:	PI response
Study duration and participation details missing	Duration of the study is of 90 Days (Completion of study) Is mentioned in protocol page no-70of 140 and subject participation is mentioned in the protocol page no-5 of 140 (Participation details-Inclusion/Exclusion Criteria)
Why use direct identifiers?	Direct identifiers are used because it is a new drug clinical trial.
Why will data not be handled confidentially by staff?	CDA attached
Why is there no physical discomfort?	It is a new clinical trial and physical exam will be done it includes BP measurements, Body

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		temperature, Respiratory rate, Pulse rate, ECG and Vital signs.

The above comment forwarded to PI was reviewed by PR:-

Recommendation of PR:-

- IEC From in corrected form is not attached.
- The fact that a new drug is being tested is not a valid reason for using direct identifiers. It's against patient privacy and confidentiality.
- Daily iv injection (the intervention arm) is a physical discomfort.
- Cannot be accepted in the current form.
- PS: All revised submissions should be accompanied with a new IEC form.

EC Comment:

As above

EC Decision: Approval subject to modification

This trial was terminated vide letter no. 855/22 dated 27th July, 2022.

Ref. code: 116th ECMIIC/P3

39 Clarification of research protocol no. CA-170-302 entitled ***"A phase IIB/III, randomised, double-blind, placebo-controlled, study title: A multicentre, study of CA-170 in combination with chemotherapy in patients with stage IV non-squamous non-small cell lung cancer (ASIAD-3)"*** sponsored by M/s Aurigene Discovery Technologies Limited submitted by Dr. Sudhir Singh, Associate Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 596/RT/2022 dated 22nd June, 2022.

Previous EC Comment:	PI response
KGMU is not a study site in submitted documents	DCGI notification of the will be done at the earliest and acknowledgment will be shared with you.
Blood will be collected, it's a biological material.	As per ICF pg no-8 of 30, it is a biological material will be taken for routine tests to check blood counts, chemistries.
Duration of study and subject participation not mentioned.	Duration of the study and subject participation is mentioned in the protocolv1.0., dated 21/ June / 2021, page no-24.
Why will direct identifiers be used?	Direct identifiers be used because it is new drug clinical trials.
Physical Discomfort not filled	As per ICF pg no-7 of 30 Point no-3.A complete physical examination will be done.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Benefit to participants not clarified.	Benefits to participants is mentioned in the Informed Consent form and its translations and back-translations.

The above comment forwarded to PI was reviewed by PR:-

Recommendation of PR:-

- Fresh IEC form has not been filled.
- A lot of information is present in the Investigator brochure. It's the PI's duty to fill it in the IEC form, not that of IEC to search for it in 100s of pages of documents.
- The fact that it's a new drug doesn't justify use of Direct Identifiers.
- PI should ensure that all the sections are filled properly.

EC Comment: As above

EC Decision: Approval subject to modification

Ref. code: 116th ECMIIC/P4

40 Clarification of research protocol no. HCR/III/DENOSOL/12/2019 entitled ***"A randomized, multiple-dose, multicenter, comparative parallel study to evaluate the pharmacokinetic, pharmacodynamic, efficacy and safety of subcutaneous injection of denosumab (Hetero) and reference medicinal product (Denosumab, Amgen Inc.) in patients with bone metastases from solid tumors"*** sponsored by M/s Hetero Biopharma Limited submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1152/2022 dated 13th July, 2022.

Recommendation of Primary reviewer:

Approved

The following documents were reviewed in the Meeting:-

1. Clinical Study Protocol Version 1.0 dated 03-Dec-2019
2. Draft Clinical Trial Agreement
3. Investigator Brochure version 1.0 dated 27 Dec 2019
4. Inform Consent Form (ICF) English version 1.0 dated 24 Dec 2019
5. Inform Consent Form (ICF) version 1.0 dated 24 Dec 2019 Translated from English to Hindi on 04 Feb 2021.
6. ICF Translation Certificate dated 04 Feb 2021.
7. Inform Consent Form (ICF) version 1.0 dated 24 Dec 2019 Back Translated from

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Hindi to English on 08 Feb 2021 8. ICF Back Translation Certificate dated 08 Feb 2021 9. DCGI Submission Acknowledgment Letter (SUGAM Portal) 10. DCGI Approval Letter dated 03 Feb 2021 11. Investigator Signature Page dated 24 Dec 2019 12. Investigator Undertaking dated 24 Dec 2019 13. Principal Investigator's CV & MRC 14. Draft Case Report Form (CRF) Version 1.0 dated 26 Dec 2019 **EC Decision:** As above ***Ref. code: 116th ECMIIC/P5***
41	Clarification of Extension under the research protocol no. BIO/MOR-II version 1.0.1 dated 28th August, 2018 entitled ***"A prospective, single-arm, multi-centre, observational, real world registry to evaluate safety and performance of the BioMime™ Morph-Sirolimus eluting coronary stent system for very long coronary lesion"*** M/s Meril Life Science Pvt. Ltd. submitted by Prof. Sharad Chandra, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 136/Cardio/Res/22 dated 14th June, 2022. ***Previous EC Comment:-*** • Protocol Clarification, DCGI submission letter and amended CTA document not attached. **The above comment forwarded to PI was reviewed by PR:-** ***Recommendation of PR:-*** Provisionally approved **EC Decision:** Approved ***Ref. code: 83rd ECM IIC/P5***
42	Clarification of research proposal entitled ***"Spectrum of supraclavicular lymph node diagnosis on fine needle aspiration cytology in a tertiary care Hospital"*** submitted by Dr. Sumaira Qayooom, Associate, Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 932/22 dated 25th July, 2022. **Previous EC Comment:** • Kindly fill the human subject review waiver form of KGMU's ethics committee rather than ICF itself, as it is a retrospective study. **The above comment forwarded to PI was reviewed by PR:-**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of PR:- Provisionally approved **EC Decision:** Approved ***Ref. code: 116th ECM IIA/P11***
43	Clarification of research proposal entitled "***A prospective, multicenter, observational study of bifurcation coronary stenting in India to determine clinical and angiographic outcomes (IBIS Registry)***" sponsored by Cardiovascular Research Society-Kerala submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 227/Cardio/Res/2022 dated 26th July, 2022. **Previous EC Comment:** • Patient information sheet as per SOP EC KGMU to be attached • Signed copy of Clinical registry agreement need to be submitted before initiation of project • If budget is 250 INR per subject as indicated in budget then it should also be indicated in sponsor letter- why this discrepancy? • How will the budget be channelized in KGMU? a policy copy needs to be attached • While annexure indicates it is a natural and national industry the sponsor letter states that it is not industry - why discrepancy ?? • While annexure states that adverse events will not be reported, point number 11 indicates otherwise - why this discrepancy? • Kindly fill the following information in annexure a- Confidentiality of records b- Contact information c- Right to withdraw d- Consent form in English and Hindi e- Plan for interim analysis • In ICF the right to participation should include right to withdraw at any stage both in English and Hindi versions. **The above comment forwarded to PI was reviewed by PR:-** *Recommendation of PR:-* • Kindly modify the Hindi ICF **EC Decision:** Approval subject to modification ***Ref. code: 115th ECM IIA/P9***
44.	**Minutes of ADR sub Committee Meeting (DCGI & Non DCGI)**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

a.	Minutes of the **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting held on 30th July, 2022 from 10:00 A.M. **(DCGI)** ***The following Members were present in the Meeting:-*** 1. Dr. Alok Dhawan -Chairman 2. Dr. Rajendra Nath -Member 3. Dr. D.N. Upadhyaya -Member 4. Mrs. Akanksha Dubey -Member 5. Mrs. Vasundhara Kumari -Member 6. Mr. Ujjwal Krishna -Member 7. Dr. Shally Awasthi -Member-Secretary, IEC
I	**SAEs**
1-	Research Protocol no. CTQJ230A12301entitled ***"A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease"*** sponsored by Novartis Health Care Pvt. Ltd. submitted by Prof. S.K. Dwivedi, Department of Cardiology King George's Medical University, U.P., Lucknow vide letter no. 112/Cardio/Res/22 dated 26th May, 2022. **Death** **Subject ID no. 1178-111** **Subject Initial:** L-B-S **Gender:** M **Age:** 73 years **Patient starting date:** 3rd March, 2022 **Patient follow up under study:** 1st Month, 2nd Month, 3rd Month, 4 Month 5, 6 Month, 9 Month, 12th Month, 15th Month, 18th Month, 21st Month, 24th Month, 27th Month and every three month Follow up till 4 year. **Weight:** 60 KG

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Height: 157 CM **Patient History:** A letter was received in the office of the Ethics Committee on 26th May, 2022. The letter stated that SAE occurred on 12th May, 2022 around 11:00. Earlier to that, telephonically called several times to remind the subject about follow up visit, but he had not replied. On 12th May, 2022 subject's son was telephonically called by the principal investigator. LAR had informed that **Subject expired on 25th March, 2022**. LAR said that on 25th March, 2022, subject was not feeling well since afternoon around 14:00 P.M., having weakness and pain in one and half of the body and was unable to move the limbs for which patient was brought to trauma centre, where he expired at around 9:00 PM on 25th March, 2022. Death Certificate is provided by subject's son. ***Recommendation of Primary reviewer:-*** • SAE (Death) is likely due to disease outcome (Acute Coronary Syndrome / Non ST Elevation MI) as patient was enrolled in Treatment arm (given Intervention in the form of Pelacarsen-TQZ230 –A Lipoprotein (a) lowering agent 80 mg monthly SC on 13th March, 2022) and 12 days has elapsed since taking the interventional drug. It has been told by LAR to PI that patient was not feeling well since afternoon on 25th March, 2022, having weakness and pain in one half of the body and was unable to move the limbs and expired in trauma centre around 9:00 pm on same date. • Causal relationship cannot be established as death occurs at hospital (trauma center) due to cardiopulmonary arrest with hemiplegia. • Death certificate is attached. **ADR sub Committee Comment:** As above **ADR sub Committee Decision:** Noted ***Ref. code: 101st ECMIIC/P18***
IIa	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc. submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter nos.132/Cardio/Res/2022 dated 9th June, 2022 & 138/Cardio/Res/2022 dated 16th June, 2022. **Death** **Subject ID no. 010-0086** **Subject Initial:** H-C **Gender:** M **Age:** 38 years

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Patient enrolled date: 24th November, 2018 **Patient follow up under study:** 1st Month, 6th Month, 12th Month and every 6th Month till 5 years **Weight:** 52 KG **Height:** 162 CM **Patient History:** A letter was received in the office of the Ethics Committee on 10th June, 2022. The letter stated that the several telephonically calls done by PI for scheduled follow up final visit (01-03-2022 to 31- 05-2022) but call was not received by the Subject. PI tried to again telephonically call the subject on 26th May, 2022 and this time call was answered by the subject's LAR. LAR informed that the subject passed away on 22nd February, 2022 at around 02:30 PM. Subject had developed mouth bleeding (Approx 200 ml) and breathlessness for which he consulted a local practitioner. He expired and could not be hospitalized anywhere. PI doesn't have any exact records to ascertain the cause of death. No autopsy was done. Hence causality assessment cannot be done. Also, Subjects was on telephonically contact from 31st December, 2020 and had stopped taking study drug (Rivroxaban 20mg) since he was taking treatment from outside. ***Recommendation of Primary reviewer:-*** • The SAE (Death) doesn't appear to be related to the study. **ADR sub Committee Decision:** Noted
IIb	**Death** **Subject ID no. 010-0074** **Subject Initial:** B-L **Gender:** M **Age:** 55 years **Patient enrolled date:** 27th September, 2018 **Patient follow up under study:** 1st Month, 6th Month, 12th Month and every 6th Month till 5 year **Weight:** 46 KG **Height:** 162 CM **Patient History:** A letter was received in the office of the Ethics Committee on 17th June, 2022. The letter stated that a telephonically call done by PI for scheduled follow up final visit (01-03-2022 to 31- 05-2022) on 2nd June, 2022. Subject's LAR answered that subject

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	passed away on 9th December, 2021 at around 08:35 PM. Subject had developed chest pain and breathlessness and after few minutes subject collapsed. LAR could not be hospitalized anywhere and a local practitioner visited to his place and confirmed Subject's death. PI doesn't have any exact records to ascertain the cause of death. No autopsy was done. Hence causality assessment cannot be done. ***Recommendation of Primary reviewer:-*** • The SAE (Death) doesn't appear to be related to the study. **ADR sub Committee Decision:** Noted ***Ref. code: 83rd ECM IIC/P6***
	Minutes of the **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting *virtually* held on 30th July, 2022 from 10:00 A.M. **(Non-DCGI)** ***The following Members were present in the Meeting:-*** 1. Dr. Alok Dhawan -Chairman 2. Dr. Rajendra Nath -Member 3. Dr. D.N. Upadhyaya -Member 4. Mrs. Akanksha Dubey -Member 5. Mrs. Vasundhara Kumari -Member 6. Mr. Ujjwal Krishna -Member 7. Dr. Shally Awasthi -Member-Secretary, IEC
I	ADR of research protocol entitled ***"A global registry to study the demographics, socioeconomic and clinical factors, etiologies, pathophysiology, management, barriers to outcomes"*** submitted by Prof. Sharad Chandra, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 198,199/Cardio/Res/22 dated 18th July, 2022.
a	**Death** **Subject ID no. 0653021** **Subject Initial:** S D

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Gender: F
Age: 70 years

Date of enrollment: 28th May, 2018

Patient follow up under study: Enrolment (Baseline) Month 6, Month 12, Month 18, Month 24, Long term consent, Tel. Month 30, Tel. Month 42, Tel Month 54, Tel Month 66, Tel Month 78.

Weight: 55.0 KG
Height: 154.0 cm

Subject History: The contact was made to get long term follow up

Site person made several calls for follow-up visit but calls were not answered. They tried again on 7th April, 2022 around 11:15 AM. Subject's LAR informed that she passed away on 4th October, 2021 at around 5:00 PM. The LAR revealed that patient had complaints of weakness, and breathlessness for which she was taken to the hospital and expired on the way to the hospital. She was not hospitalized hence no papers are available and autopsy was not done. Only Death Certificate received.

Previous ADR sub Committee Comment:

- The subject was enrolled on 28-05-2018. According to this her 30th month follow up would have fallen in November, 2021. The SAE was, however detected on 7th April, 2022. Explanation may be sought for the skipped follow up.
- The SAE (death) doesn't to be related to the study

Previous ADR sub Committee Decision:

- Ask for explanation

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved

ADR sub Committee Decision: Noted

Death

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

b	**Subject ID no. 0653022** **Subject Initial:** R-K **Gender:** M **Age:** 70 years **Patient enrolled date:** 28th May, 2018 **Patient follow up under study:** Enrolment (Baseline) Month 6, Month 12, Month 18, Month 24, Long term consent, Tel. Month 30, Te;. Month 42, Tel Month 54, Tel Month 66, Tel Month 78. **Weight:** 59.0 KG **Height:** 157.0 cm **Subject History:** Site person made a follow-up call to subject on 7th April, 2021 around 11:45 AM, Subject's LAR informed that the subject passed away on 31st March, 2021 at 8:00 PM. LAR said that patient was not feeling well for last 10 days. He had a complaint of weakness, and breathlessness and suddenly expired at home. Local medical person confirmed his death. Autopsy was not done and no documents are available. Only Death Certificate received. **Previous ADR sub Committee Comment:** 1. The subject was enrolled on 28th May, 2018. According to this his 30th month follow-up would have fallen in November, 2021. The SAE was, however detected on 8th April, 2022. Explanation may be sought for the skipped follow-up. **Previous ADR sub Committee Decision:** • Ask for explanation ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **ADR sub Committee Decision:** Noted ***Ref. code: 86th ECM IIC/P3***
IB	**Expedited review**
1-	Expedited review of research proposal entitled ***"Safe motherhood intervention app"*** submitted by Prof. Abbas Ali Mahdi, Head, Department of Biochemistry, K.G's Medical University, U.P., Lucknow vide letter no.TS/2022/150 dated 8th June, 2022. ***The above research proposal forwarded to both reviewers First PR- & Secondary***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	reviewer. ***Recommendation of First Primary reviewer-*** • **Study design not mentioned.** • Aim: • 1-Analysis of blood lead levels of pregnant women and their umbilical cord. • 2-Development of safe motherhood app. • Sample size and its calculation not given in Protocol (50 patients mentioned only is SOP form) • One Co-PI (Dr. Priyanka Chaurasia) is from foreign Institution as a collaborator. • There must be written collaboration document between KGMU and School of Computing, Ulster University, Coleraine, Co-Londonderry, BT52, 1SA, Northern Ireland for doing collaborative - research work-PI should specify. ***Recommendation of Secondary Primary reviewer-*** • Sample size calculation is not given. • Statistical analysis detail is not given. ***Reply have given by both reviewers -*** -Provisionally approved **EC Decision:** Approved ***Ref. code: 116th ECM IB/P1***
2-	Expedited review of research proposal entitled ***"Evaluation of the urinary and serum biomarkers for acute kidney injury in patients admitted to the intensive care unit at the tertiary care centre"*** submitted by Dr. M.L. Patel, Professor (Jr. Grade), Department of Medicine, K.G's Medical University, U.P., Lucknow vide letter no.1389/MED/2022 dated 15th July, 2022. ***The above research proposal forwarded to both reviewers.*** **EC Comment:** ***Reply pending from both reviewers.*** **EC Decision:** Defer to the next Meeting because both reviewers have not given their response till 3rd August, 2022. ***Ref. code: 116th ECM IB/P2***
3-	Expedited review of research proposal ***"Understanding the continuum of cancer care in selected Districts of UP: A qualitative case study"*** submitted by Prof. Kirti Shrivastava, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no.65/HBCR/22 dated 25th July, 2022. ***The above research proposal forwarded to two reviewers.*** ***Recommendation of both reviewers:*** Approved **EC Decision:** As above ***Ref. code: 116th ECM IB/P3***
II-A	**New Proposal**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 117th IEC Meeting held on 30th July, 2022

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

1.	Research proposal entitled ***"Prevalence of Hepatitis B and Hepatitis C among IDUs of Lucknow"*** submitted by Prof. S.K. Singh, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 147/CM/22 dated 10th May, 2022. ***Recommendation of PR:-*** • IDU – No fullform has been given anywhere. But I think they mean 'intravenous drug users'. The participants will be included from the hotspots. They are not the one who are coming to the hospitals. If the participant agrees to give written consent and give sample then there are probably no issues. But the participants are drug addicts and I don't know if they will accept it and let it know to others unless they are into some reforms centre. Will like others to give opinions. • The patient information document says that 'the participants are included as per inclusion criteria' in answer to the question of 'Why have I been chosen'. But the answer should include what are the inclusion criteria. Also to the question 'What I have to do'; the answer should be that you will have to give urine sample. • Dr Manish Manar is M Tech and is in community medicine. Please check. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM IIA/P1***
2.	Research proposal entitled ***"Prevalence of iodine deficiency disorder among-6-12 years School Children of Uttar Pradesh"*** submitted by Prof. S.K. Singh, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 148/CM/22 dated 10th May, 2022. ***Recommendation of PR:-*** • It is an epidemiological study to assess iodine level in about 27000 school children in villages in UP. Clinical examination for goitre and urine iodine levels will be measured in children from 6 to 12 years. Written consent will be taken. Who will be giving consent? Parents' consent and child assent are required. Don't know if written consent will be necessary for urine collection. How will the parents contacted. The patient information is there. But these are not patients. May be there can be information brochure for the parents of the participating children. The patient information document says that 'the participants are included as per inclusion criteria' in answer to the question of 'Why have I been chosen'. But the answer should include what are the inclusion criteria. Also to the question 'What I have to do'; the answer should be that you will have to give urine sample.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Dr Manish Manar is M Tech and is in community medicine. Please check. • As such there are o ethics related issues but if consent is to be taken it should be proper. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM IIA/P2***
3.	Research proposal entitled ***"Evaluation of Her2Neu expression in periampullary carcinoma in tertiary care centre of northern India-A retrospective data analysis"*** submitted by Dr. Preeti Agarwal, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 639/22 dated 12th May, 2022. ***Recommendation of PR:-*** • Retrospective study of anonymized samples of cancer. They have asked for waver of consent. That should be ok. But the secondary objective is to correlate the expression of Her2Neu with survivals. Please give opinion if this can be considered as a part of retrospective study and suitability for waver of consent. **EC Comment:** • Please clarify the budget. **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM IIA/P3***
4.	Research proposal entitled ***"Assessment of tobacco consumption habits and knowledge, attitude and practice of tobacco use in oral cancer patients"*** submitted by Dr. Parijat Suryavanshi, Professor (Junior Grade), Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1181/22 dated 10th May, 2022. ***Recommendation of PR:-*** • Questionnaire based study. No issues. • Patient information brochure is not there. **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 117th ECM IIA/P4***
5.	Research proposal entitled ***"A hybrid type-2 study of next generation pulse oximeters to support the integrated management of childhood illness in primary care settings"*** submitted by Prof. Shally Awasthi, Head, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. Hybrid/01/05/22 dated 10th May, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of PR:- • Is consent required? Whose? Caregivers- medical or relatives? Consent and information document should be for parents / guardian. **EC Decision:** Approved ***Dr. Shally Awasthi did not participate in discussion & decision making.*** ***Ref. code: 117th ECM IIA/P5***
6.	Research proposal entitled ***"Post COVID-19 sequelae registry (PCSR)"*** submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 599/Res Med/22 dated 13th May, 2022. ***Recommendation of PR:-*** • Neither PID nor questionnaires are provided. **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 117th ECM IIA/P6***
7.	Research proposal entitled ***"Psychological distress in patients with burn deformities: an observational study from a tertiary care center of North India"*** submitted by Dr. Harsha Vardhan, Assistant Professor, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 481/22 dated 13th May, 2022. ***Recommendation of PR:-*** • Approved **EC Decision:** As above ***Ref. code: 117th ECM IIA/P7***
8.	Research proposal entitled ***"A study of pattern of care and survival of Head & Neck, breast and cervical cancers in India HBCR of national cancer registry programme"*** sponsored by National Centre for Disease Informatics and Research & Indian Council of Medical Research, New Delhi submitted by Prof. Kirti Srivastava, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no.43/HBCR/22 dated 5th May, 2022. ***Recommendation of PR:-*** • Approved **EC Decision:** As above ***Ref. code: 117th ECM IIA/P8***
9.	Research proposal entitled ***"Psychosocial analysis in patients with brachial plexus injury in a tertiary care Hospital of Northern India"*** submitted by Dr. Harsha Vardhan, Assistant Professor, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 482/22 dated 13th May, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • There are too many objectives. There should be one primary objective, and the rest can be covered in secondary objectives. Actual, other objectives would be side products of main objective. • The sample size calculation is missing. • How the items were generated for the questionnaire. Do they come from previous scales/ clinical observations/expert opinion/research findings/theory? • How the scale will be evaluated for internal consistency (reliability)? • Does the scale have face validity/ content validity/ construct validity? **EC Comment:** As above **EC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: 117th ECM IIA/P9***
10.	Research proposal entitled ***"A prospective pilot study to analyze the changes in the angle of the penis from midline, and dimensions of the urethral meatus on pulling of the prepuce or the skin of the penis, in patients of a North Indian tertiary care Hospital"*** submitted by Prof. Divakar Dalela, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 243/Uro/22 dated 4th May, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 117th ECM IIA/P10***
11.	Research proposal entitled ***"Randomized multi-center study to evaluate the efficacy of single versus double drains in breast cancer patients undergoing surgery"*** submitted by Dr. Pooja Ramakant, Professor Junior Grade, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/161/22 dated 14th May, 2022. ***Recommendation of Primary reviewer:*** • Title and primary objectives do not match. • Title says: Randomized Multi-center study to evaluate the efficacy….. • Primary objective says: To document the rate of seroma formation in both the groups. • If it is really randomized multi-center study, all the pre-requisite should be mentioned properly. • There are protocols for RCT. All those be properly defined. • There are protocol/guidelines for Multi-center studies. All those should be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	mentioned. • Sample size calculation is arbitrary. It is ambiguous in the absence of proper research hypothesis. • Statistical Analysis section is also very general, not specific to the study. **EC Comment:** As above **EC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: 117th ECM IIA/P11***
12.	Research proposal entitled ***"Evaluation of needle tapping in the outcome of pneumoperitoneum in neonates and infants"*** submitted by Dr. Gurmeet Singh, Assistant Professor, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 370/PedSrg/22 dated 20th May, 2022. ***Recommendation of Primary reviewer:*** • Proper research hypothesis should be defined after identifying the study variables and population parameters involved. • Study design is not given. • Sample size calculation and statistical analysis are missing. **EC Comment:** As above **EC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: 117th ECM IIA/P12***
13.	Research proposal entitled ***"Mucormycosis: A comparative study between endoscopic and radiological features"*** submitted by Dr. Manish Chandra, Associate Professor, Department of Otorhinolaryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 120/ENT/MC/22 dated 20th May, 2022. ***Recommendation of Primary reviewer:*** • Proper research hypothesis should be defined after identifying the study variables and population parameters involved. • Study design seems to be case-control study. • All the fundamentals for case-control study should be clearly outlined. • Sample size calculation and statistical analysis are missing. **EC Comment:** As above **EC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: 117th ECM IIA/P13***
14.	Research proposal entitled ***"Using computer generated models (artificial intelligence) to predict mortality and outcome in hospitalized patients"*** submitted by Dr. Vivek

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Gupta, Additional Professor, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SG/260/22 dated 13th May, 2022. ***Recommendation of Primary reviewer:*** • Proper research hypothesis should be defined after identifying the study variables and population parameters involved. • What kind of model (Statistical) will be used? • I think, a statistician should be included in order to develop proper prediction model. • Study design mentioned is "observational". • How an observational study can be used for developing an prediction model. • Sample size calculation is missing. **EC Comment:** As above **EC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: 117th ECM IIA/P14***
15.	Research proposal entitled ***"Assessment of treatment outcomes for sebaceous cell carcinoma eyelid"*** submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/814/22 dated 24th May, 2022. ***Recommendation of Primary reviewer:*** • Proper research hypothesis should be defined after identifying the study variables and population parameters involved. • Study design is not clear. It says: single center, observation, retrospective case series study. • Sample size calculation is missing. • Statistical method section is very general, not specific to the study. **EC Comment:** As above **EC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: 117th ECM IIA/P15***
16.	Research proposal entitled ***"Assessment of treatment outcomes for carcinoma vulva"*** submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/789/22 dated 24th May, 2022. ***Recommendation of Primary reviewer:*** • The status of vulnerable subjects need to be clarified • What is the rationale of sample size of 30? • This is labeled as a retrospective data analysis of 30 patients treated between

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	2017-2022 and requires estimation of survival (disease free and overall). Hence a Prospective arm of follow-up for 3-5 year need to be undertaken and patient examined for disease free status. Hence ethical approval may need a consent process to be incorporated as well. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM IIA/P16***
17.	Research proposal entitled ***"Assessment of treatment outcomes for esophageal cancer"*** submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/790/22 dated 24th May, 2022. ***Recommendation of Primary reviewer:*** • The status of vulnerable subjects need to be clarified • What is the rationale of sample size of 65? • This is labeled as a retrospective data analysis of 65 patients treated between 2017-2022 and requires estimation of survival (disease free and overall) . Hence a Prospective arm of follow up for 3-5 year need to be undertaken and patient examined for disease free status. Hence ethical approval may need a consent process to be incorporated as well. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM IIA/P17***
18.	Research proposal entitled ***"Effectiveness of kinesio taping in management of low back pain"*** submitted by Dr. Narendra Singh Kushwaha, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2182/OS/22 dated 21st May, 2022. ***Recommendation of Primary reviewer:*** • Patient information sheet to be attached as per SOP • In ICF 'study procedures' and 'benefit of study' are written in past tense and therefore ICF needs to be revised • Sample size calculation need to be mentioned • The page where role of PI is mentioned it has to be clarified if investigator is from pulmonary medicine also or only from orthopedics

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM IIA/P18***
19.	Research proposal entitled ***"Local vs systemic tranexamic acid in total hip arthroplasty"*** submitted by Dr. Narendra Singh Kushwaha, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2181/OS/22 dated 21st May, 2022. ***Recommendation of Primary reviewer:*** • Patient information sheet to be attached as per SOP • In ICF 'study procedures' and 'benefit of study' are written in past tense and therefore ICF needs to be revised • Sample size calculation need to be mentioned • The page where role of PI is mentioned it has to be clarified if investigator is from pulmonary medicine also or only from orthopedics • To add subheadings of 'outcome variables' and 'statistical analysis' so as to make methodology section more explanatory **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM IIA/P19***
20.	Research proposal entitled ***"Premature greying of hair in children and adolescents-a case control study analysis of nutritional and biochemical parameters"*** submitted by Dr. Parul Verma, Associate Professor, Department of Dermatology Venerology & Leprosy, King George's Medical University, U.P., Lucknow vide letter no. 98/22 dated 25th May, 2022. ***Recommendation of Primary reviewer:*** • Patient information sheet to be attached as per SOP • Sample size calculation need to be elaborated step by step • The prospective outcome variables should be briefly mentioned and categorized as continuous and categorical before detailing the analytical method. • Does counting of hairs via hand lens constitutes an accepted method (mention reference) or an indigenous way adopted by the investigator? • Since the ICF has to be signed by the parents only, the language has to be modified somewhat.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM IIA/P20***
21.	Research proposal entitled ***"Evaluation of blood group in patients of congenital malformation"*** submitted by Dr. Piyush Kumar, Assistant Professor, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 402/Ped Sy/22 dated 3rd June, 2022. ***Recommendation of Primary reviewer:*** • To include sample size (and its calculation) • The ICF to be detailed in a simple way to make the patient understand the contents. • Give a brief account of anticipated statistical analysis • Which major types of congenital anomalies are likely to be targeted in this study. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM IIA/P21***
22.	Research proposal entitled ***"Variations in the outcome of various surgical procedures for fistula in ano: A prospective multicentre observational cohort study"*** submitted by Prof. Arshad Ahmad, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1383/22 dated 3rd June, 2022. ***Recommendation of Primary reviewer:*** • Patient information sheet to be attached as per SOP • Sample size calculation need to be mentioned. • What are the other centers involved • Incorporate the relevant papers from the central coordinating (main) center • ICF poorly written- revise as per the patient understanding • Briefly outline the anticipated outcome variables and incorporate the anticipated statistical analysis section. • Add the data collection proforma (case sheet) as approved by this multicentric study. • What and where is the 'national lead' and what is the central team – elaborate details • Complete the left out responses in the annexure

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: Kindly provide funding agency. **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM IIA/P22***
23.	Research proposal entitled ***"Demographic and clinicopathological profile of cutaneous tuberculosis: observational multicentric study"*** submitted by Dr. Parul Verma, Associate Professor, Department of Venereology Leprosy, King George's Medical University, U.P., Lucknow vide letter no. 106/Skin/22 dated 15th June, 2022. ***Recommendation of Primary reviewer:*** • Kindly provide Sponsor/ Budget information • Justification of sample size is needed. Kindly calculate sample size for the study. • How many subjects will be recruited from each center/ which centers will be enrolling patients? • Kindly describe all procedures involved in the study to the patient in easy and understandable local languages. Revise the ICF. ICF must clearly explain all procedures. "As per standard Protocol" is not accepted. • ICF must be translated to all local languages. • CV of Dr Dipak Patel is not enclosed. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM IIA/P23***
24.	Research proposal entitled ***"Assessment of the level of immediate and long term chemical pneumonitis in patients of trachea-esophageal fistula who have undergone surgery"*** submitted by Dr. Anand Pandey, Professor Junior Grade, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 445/PedSy/22 dated 18th June, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 117th ECM IIA/P24***
25.	Research proposal entitled ***"Evaluation of the histopathology of fistula in male patients with anorectal malformation"*** submitted by Dr. Anand Pandey, Professor Junior Grade, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 434/PedSy/22 dated 16th June, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: Approved **EC Decision:** As above ***Ref. code: 117th ECM IIA/P25***
26.	Research proposal entitled ***"A prospective study to assess the micronutrient levels in COVID-19 recovered patients in a tertiary care Hospital of Northern India"*** submitted by Dr. Arpit Singh, Associate Professor, Department of Orthopedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2342/OS/22 dated 17th June, 2022. ***Recommendation of Primary reviewer:*** • Kindly provide sample size calculation. • Are all investigations part of Standard protocol? Kindly provide documentary support. • For research purpose, researcher may not prescribe extra investigations leading to financial burden on the patient. **EC Comment:** As above **EC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: 117th ECM IIA/P26***
27.	Research proposal entitled ***"Evaluation of efficacy of a paste of refined wheat flour and zinc oxide versus coloplast 2650 in skin care for pediatric patients who have undergone ileostomy or colostomy- A non-randomized controlled trial"*** submitted by Dr. Anand Pandey, Professor Junior Grade, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 444/PedSy/22 dated 18th June, 2022. ***Recommendation of Primary reviewer:*** • The research is worth trying, because we need cost effective treatment modalities for our setups. • Please provide adequate evidence to support success of application of Maida and ZnO combination, may be at any other area. • If the combination does not work as expected, what would be the consequences? • Sample size calculation must be given according to the known prevalence of cases of ILEOSTOMY or colostomy. **EC Comment:** • Can be done as pilot study (30 in each group) • Define outcome measures and include microbiological out comes.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Approval subject to modification with tabular format in word file ***Ref. code: 117th ECM IIA/P27***
28.	Research proposal entitled ***"A multicentre prospective qualitative study on understanding the breast cancer and oral cancer patients"*** submitted by Dr. Pooja Ramakant, Additional Professor, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. EndoSurg/183/22 dated 13th June, 2022. ***Recommendation of Primary reviewer:*** • Kindly provide separate ICF for Oral cancer Patients. Use the term ORAL CANCER ie MUH KA CANCER instead of HEAD and NECK Cancer in PATIENT INFORMATION SHEET. **EC Comment:** As above **EC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: 117th ECM IIA/P28***
29.	Research proposal entitled ***"A survey among psychiatrists to assess the need for sud/super specialization courses in psychiatry in India"*** submitted by Dr. Amit Singh, Assistant Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 895/Psy/22 dated 1st July, 2022. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 117th ECM IIA/P29***
30.	Research proposal entitled ***"To assess the clinical characteristics, inflammatory markers and co-morbidities of patients with obstructive sleep apnea with chronic obstructive pulmonary diseases"*** submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 757/22 dated 30th June, 2022. **EC Decision:** Defer to the next Meeting because Primary reviewer was absent. ***Ref. code: 117th ECM IIA/P30***
31.	Research proposal entitled ***"Clinical course and outcome of electrical burn injury patients at tertiary care center. A single-center pilot study"*** submitted by Dr. Anshu Singh, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 617/22 dated 1st July, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Defer to the next Meeting because Primary reviewer was absent. ***Ref. code: 117th ECM IIA/P31***
32.	Research proposal entitled ***"Buprenorphine transderma patch versus fentanyl transdermal patch for acute pain management in burn patients. A comparative study"*** submitted by Dr. Anshu Singh, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 616/22 dated 1st July, 2022. **EC Decision:** Defer to the next Meeting because Primary reviewer was absent. ***Ref. code: 117th ECM IIA/P32***
33.	Research proposal entitled ***"Prospective study on Spectrum of Inhalation burn injury at a tertiary care center and role of prognostic factors and severity predictors in its management"*** submitted by Dr. Sandhya Pandey, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 613/22 dated 1st July, 2022. **EC Decision:** Defer to the next Meeting because Primary reviewer was absent. ***Ref. code: 117th ECM IIA/P33***
34.	Research proposal entitled ***"Use of HBOT for Limb salvageability and limiting the amputation level in electric burn injuries"*** submitted by Dr. Sandhya Pandey, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 615/22 dated 1st July, 2022. **EC Decision:** Defer to the next Meeting because Primary reviewer was absent. ***Ref. code: 117th ECM IIA/P34***
35.	Research proposal entitled ***"Use of HBOT in improving outcome of electrical burn injuries-experience at a tertiary care burn center"*** submitted by Dr. Sandhya Pandey, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 614/22 dated 1st July, 2022. **EC Decision:** Defer to the next Meeting because Primary reviewer was absent. ***Ref. code: 117th ECM IIA/P35***
36.	Research proposal entitled ***"Drug induce liver injury associated with treatment for COVID-19 (COVISILI): A nationwide study from India"*** submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1323/MED/22 dated 4th July, 2022. **EC Decision:** Defer to the next Meeting because Primary reviewer was absent.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 117th ECM IIA/P36
37.	Research proposal entitled ***"Anatomy of termination of popliteal artery and its association with peripheral vascular disease: A multidetector ct angiographic study"*** submitted by Prof. Jyoti Chopra, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 58/ANAT/22 dated 7th May, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above
	Ref. code: 117th ECM IIA/P37
38.	Research proposal entitled ***"A study to find the role of interactive session on self-directed learning in medical undergraduate and postgraduate students"*** submitted by Dr. Suyog Sindhu, Assistant Professor, Department of Pharmacology, King George's Medical University, U.P., Lucknow vide letter no. 336/Pharm/22 dated 11th May, 2022. ***Recommendation of Primary reviewer:*** • Statistical Methods to compare scores should be non parametric tests. Minor revision is needed. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file.
	Ref. code: 117th ECM IIA/P38
39.	Research proposal entitled ***"A prospective study to assess the levels of thrombogenic factors in patients of hematological malignancies admitted in a tertiary care Hospital of Northern India"*** submitted by Prof. A. K. Tripathi, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. 347/CH/22 dated 4th July, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above
	Ref. code: 117th ECM IIA/P39
40.	Research proposal entitled ***"Palato-lingual direct-cross wire maxilla-mandibular fixation: A comparative study"*** submitted by Dr. Amiya Agrawal, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 586//22 dated 9th July, 2022. ***Recommendation of Primary reviewer:*** • No review of literature to support the rationale of the study. **EC Comment:** As above **EC Decision:** Approval subject to modification

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 117th ECM IIA/P40
41.	Research proposal entitled ***"The every woman study in low and middle income countries identifying challenges and opportunities to improve survival and quality of life for women with ovarian cancer"*** submitted by Prof. Nisha Singh, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1519/22 dated 13th July, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 117th ECM IIA/P41***
II-B	**New Ph. D Proposal**
1.	Research proposal entitled ***"Charactarization and gene expression analysis of candida isolates from blood stream infection"*** submitted by Ms. Shivangi Tripathi, Ph.D Scholar 2020 under the guidance Prof. Gopa Banerjee, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 2022/DST/CAND/22 dated 11th May, 2022. ***Recommendation of Primary reviewer:*** • Budget column is crossed. It should be revised and give the detail of budget. **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 117th ECM II B-Ph.D/P1***
2.	Research proposal entitled ***"FOXO-1 &3 gene polymorphism as predisposing factor to critically ill sepsis patient with type II diabetes mellitus"*** submitted by Prof. Avinash Agarwal, Ph.D Scholar under the guidance Prof. R. K. Garg, Head, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. KGMU/CCM/0362/22 dated 11th May, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 117th ECM II B-Ph.D/P2***
3.	Research proposal entitled ***"Molecular characterization of multidrug resistance mechanisms and virulence factors in classical and hypervirulent klebsiella pneumonia clinical isolates in Northern India"*** sponsored by CSIR-UGC New Delhi submitted by Ms. Rashmi, Ph.D Scholar through her guide Prof. Vimala Venkatesh, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 322/22 dated 3rd June, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Approved **EC Decision:** As above ***Ref. code: 117th ECM II B-Ph.D/P3***
4.	Research proposal entitled ***"Antimicrobial resistance and biofilm formation in multidrug resistant acinetobacter baumannii in clinical isolates at a tertiary care center"*** sponsored by CSIR New Delhi submitted by Ms. Upma Singh, Ph.D Scholar, through her guide Prof. Vimala Venkatesh, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 323/22 dated 3rd June, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 117th ECM II B-Ph.D/P4***
5.	Research proposal entitled ***"Effect of LAABH (Lined-up Antenatal Approach to better health) on knowledge attitude and practice regarding perinatal care among pregnant women attending antenatal clinic)"*** submitted by Mrs. Sarita Dubey, Ph.D Scholar 2019 under the guidance Prof. Sujata Deo, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/985/22 dated 2nd May, 2022. ***Recommendation of Primary reviewer:*** • Several sections of the IEC forms like Consent, Privacy and Confidentiality, Compensation and Conflict of interest have not been filled. **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 117th ECM II B-Ph.D/P5***
6.	Research proposal entitled ***"Evaluation of dental implants with platelet rich in growth factor (PRGF) in smokers: A split mouth randomized controlled clinical trial"*** submitted by Dr. Aastha Singh, Ph.D. Scholar under the guidance Prof. Uma Shanker Pal, Department of Oral & Maxillofacial Surgery, FODS, King George's Medical University, U.P., Lucknow vide letter no. 547/OMSD/22 dated 18th June, 2022. ***Recommendation of Primary reviewer:*** • Sample size justification/calculation has not been done. • Patient information sheet in Hindi has not been attached. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 117th ECM II B /P6
7.	Research proposal entitled ***"Association of apoptotic pathway genes polymorphism with newly diagnosed chronic phase-chronic myeloid leukemia"*** submitted by Ms. Kaynat Fatima, Ph.D. Scholar under the guidance of Prof. Syed Tasleem Raza & Co GuideDr. Shailendra Prasad Verma, Associate Professor, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. 327/CH/22 dated 20th June, 2022. ***Recommendation of Primary reviewer:*** • Sectional on Vulnerable subject is incorrectly filled. • Patient information sheet is not attached to the proforma. • Dr. Shailendra Verma is Co-PI as well as member of the Scientific Review Committee. • This is conflict of interest and has to be corrected. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file.
	Ref. code: 117th ECM II B-Ph.D/P7
8.	Research proposal entitled ***"Mechanistic analysis of host-protein crosstalks during JE neuropathogenesis and development of therapeutic and preventive interventions"*** submitted by Mr. Swatantra Kumar, Ph.D. Scholar under the guidance Prof. Shailendra Kumar Saxena, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/544/22 dated 15th June, 2022. ***Recommendation of Primary reviewer:*** • Prof. Shailendra Kumar, Prof. A.K. Tripathi and Prof. Rashmi Kushwaha are Co-PIs as well as Doctoral Committee members. This may involve Conflicts of Interest. **The Members Secretary may take a call on this.** **EC Decision:** Waiver granted
	Ref. code: 117th ECM II B-Ph.D/P8
9.	Research proposal entitled ***"Pharmacological characterization of the neuroprotective properties of natural products against acute encephalitis syndrome"*** submitted by Mr. Vimal Kumar Maurya, Ph.D. Scholar under the guidance Prof. Shailendra Kumar Saxena, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/545/22 dated 15th June, 2022. **EC Comment:** • Add in title in vitro Neuroprotective **EC Decision:** Waiver granted

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 117th ECM II B-Ph.D/P9
10.	Research proposal entitled ***"To assess the association of blood lead level with dietary intake and cognitive performance of urban School going children in ten cities of India"*** submitted by Dr. Divas Kumar, Ph.D. scholar under the guidance Prof. Shally Awasthi, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2017/Ped/22 dated 5th July, 2022. ***Recommendation of Primary reviewer:*** • The PI has applied for ethical review waiver since this involves secondary data analysis from a previous study. **EC Decision:** Waiver may be granted ***Dr. Shally Awasthi did not take part in the discussion and making decision.*** ***Ref. code: 117th ECM II B/P10***
II-B	**Fellowship**
1.	Research proposal entitled ***"Genotype and phenotype characterization of mutations in GNAS, USP8, PIK3CA, H-RAS and TERT gene in patients with pituitary tumors"*** sponsored by DBT, New Delhi submitted by Dr. Poonam Tripathi under the guidance Prof. B. K. Ojha, Head, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/924/22 dated 29th June, 2022. ***Recommendation of Primary reviewer:*** • Patient information sheet in Hindi needs to be attached. • Sample size calculation has not been done. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM II B-FS/P1***
2.	Research proposal entitled ***"Micro-RNAs and their target expression profiling in pregnancy miscarriage"*** sponsored by ICMR New Delhi submitted by Dr. Rajesh Kumar Jha, Associate Professor, Endocrinology Division CSIR-Central Drug Research Institute, Lucknow Forwarded by Prof. Pushplata Sankhwar, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. nil dated 23rd May, 2022. ***Recommendation of Primary reviewer:*** • In SOP form PI ticked in the confidentiality column as NO –should be corrected. • In Inclusion criteria – Age matched women will be taken –Specific age group not mentioned. • Exclusion criteria – not mentioned.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Animal ethical clearance letter –if taken please attach (as Animals are also required in this study) • Patient information sheet –Hindi translation missing –Please attach • Technical approval letter for this fellowship study from ICMR, New Delhi not given– Please attach. • Budget for the project not mentioned. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM II B-FS/P2***
II-B	**Women Scientist**
1.	Research proposal entitled ***"To establish the molecular axis of inflammatory cytokines, circadian genes and their association with notch-1 signaling pathway in the pathogenesis of chronic myeloid leukemia"*** submitted by Ms. Nimra Habib under the guidance of Dr. Ranjana Singh, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/169/22 dated 17th June, 2022. ***Recommendation of Primary reviewer:*** • Budget not mentioned • No Co-PIs from collaborating Deptt (Deptt. of Clinical Hematology) has been included -please justify or include the Co-PI from respective department. • Inclusion criteria -Age and sex specificity – not mentioned. • If control patients will be taken then what will be the Inclusion and exclusion criteria. (In SOP form the PI mentioned that from total 60 pts -30 will be of CML cases and 30 as control) • Study design not mentioned in Protocol. • Methodology part not explained well (how grouping will be done) –PI should attach the Flow chart of methodology. • Approval letter of Fellowship and information about budget -may be attached **EC Comment:** As above **EC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: 117th ECM II B-WS/P1***
2.	Research proposal entitled ***"To investigate the endosomal pathway as a molecular***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	target in patients with T-cell acute lymphoblastic leukemia" submitted by Mr. Sandeep Pandey under the guidance of Dr. Ranjana Singh, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/170/22 dated 17th June, 2022. ***Recommendation of Primary reviewer:*** • Budget not mentioned • No Co-PIs from collaborating Deptt (Deptt. of Clinical Hematology) has been included -please justify or include the Co-PI from respective department. • Inclusion criteria -Age and sex specificity – not mentioned. • If control patients will be taken then what will be the Inclusion and exclusion criteria ((In SOP form the PI mentioned that from total 60 pts -30 will be of CML cases and 30 as control) • Sample size – In Protocol- total 50 pts (25 pts in each group) but in SOP form – total 60 pts (30 in each group) –Please explain and remove the discrepancy • Study design not mentioned in Protocol (only mentioned in SOP Form as Case control study) • Methodology part not explained well (how grouping will be done) –PI should attach the Flow chart of methodology • Approval letter of Fellowship and information about budget –may be attached **EC Comment:** As above **EC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: 117th ECM II B-YS/P2***
3.	Research proposal entitled ***"Determining the role of lipid-induced human hepatic cell derived extracellular vesicles (ectosomes and exosomes) in mediating pro-inflammatory and pro-fibrogenic response in vitro"*** submitted by Dr. Deepika Misra, under the guidance of Prof. Kauser Usman, Department of Internal Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1355/MED/22 dated 9th July, 2022. **EC Decision:** Approved ***Ref. code: 117th ECM II B-WS/P3***
4.	Research proposal entitled ***"Correlation of mitochondrial DNA (mtDNA) copy number with toxicity of heavy metals and pesticides in women with unexplained infertility"*** sponsored by ICMR, New Delhi submitted by Dr. Pratibha Kumari under the guidance of Prof. Sujata Deo, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1520/22 dated 13th July, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • Budget not mentioned • Sample size-total-63 is given (PI written that for statistical point of view we will enrolled 100 cases and 100 control subjects) .In SOP form –sample size given is 150-please clarify the sample size. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file. ***Ref. code: 117th ECM II B-WS/P4***
II-C	**Review of New Drug Trial**
1.	Research Protocol no. ODM-203-201 entitled ***"A phase II open-label trial evaluating the efficacy and safety of once daily Oral ODM-203 in patients with unresectable transitional cell urothelial carcinoma with FGFR3 mutation (TEJAS-1)"*** sponsored by M/s Aurigene Discovery Technologies Ltd. submitted by Dr. Sudhir Singh, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 278/RT/2022 dated 18th June, 2022. ***Recommendation of Primary reviewer:*** • PI form has multiple deficiencies: • Section 3 (ii, iii, iv) documents not attached, contradictory information. • Section 5: incomplete • Section 6, 7, 10: missing information/ wrong information ***The above comments forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:-*** • Fresh IEC form has not been filled. • A lot of information is present in the Investigator brochure. It's the PI's duty to fill it in the IEC form, not that of IEC to search for it in 100s of pages of documents. • The fact that it's a new drug doesn't justify use of Direct Identifiers. • PI should ensure that all the sections are filled properly. • Ethically not acceptable. • PI should make some effort and put in all the information in the IEC form mentioning that it's a revised protocol. **Legal opinion:** No legal observation. **EC Comment:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Modify and re-submit with tabular format in word file. ***Ref. code: 117th ECMIIC/P1***
2.	Research Protocol entitled ***"A randomized, multicentre, double blind, placebo controlled, parallel-group, study to evaluate the efficacy and safety of linaclotide once daily of Dr. Ready's laboratories limited in patients with chronic constipation"*** sponsored by M/s Dr. Reddy's laboratories limited submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/17/2022 dated 4th July, 2022. ***Recommendation of Primary reviewer:*** • PI has mentioned in point 10 that risks of doing this study are **not reasonable** compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed. **Legal opinion:** No legal observation. **EC Comment:** As above **EC Decision:** Modify and re-submit ***Ref. code: 117th ECMIIC/P2***
3.	Research Protocol no. AKPL/FDC/AT/02/18 entitled ***"A phase III, multi-centre, double-blind, randomized, parallel-group, active-controlled trial to compare efficacy and safety of fixed dose combination of alfuzosin 10mg/10mg ER plus tadalafil 2.5mg/5mg tablets versus alfuzosin 10mg ER tablets in patients with lower urinary tract symptoms (LUTS) associated with benign prostatic Hyperplasia (BPH)"*** sponsored by M/s Akums Drugs & Pharmaceuticals Limited submitted by Prof. Apul Goel, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. UR/CT/03/2022 dated 4th July, 2022. ***Recommendation of Primary reviewer:*** • PI has mentioned in point 10 that risks of doing this study are **not reasonable** compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed. • Departmental Scientific Committee Head is Co-PI in one document, Senior Resident is Co-PI in another. Both conditions are not acceptable. Cannot be accepted for review. **Legal opinion:** No legal observation. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 117th ECMIIC/P3
4.	Research Protocol no. QPT-ORE-006 entitled ***"A Phase2, Double-blind, placebo-controlled, multicenter clinical trial comparing chemoimmunotherapy (Paclitaxel-carboplatin-oregovomab) versus chemotherapy (Paclitaxel-carboplatin-Placebo) as neoadjuvant therapy in patients with advanced epithelial ovarian, fallopian tube or peritoneal carcinoma"*** sponsored by M/s Onco Quest Pharmaceuticals Inc submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/1063/2022 dated 7th July, 2022. ***Recommendation of Primary reviewer:*** • Section 7 (ii) states that body fluids will not be used. However, as per protocol, will be used. Need to clarify and give details. • Section 7 (ix) clarification and clearance are not attached. Contradicts information in Section 7 (ii) **Legal opinion:** No legal observation. **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format in word file.
	Ref. code: 117th ECMIIC/P4
5.	Research Protocol entitled ***"A randomized, double blind, multicenter, parallel, placebo controlled clinical trial to assess the efficacy, safety and tolerability of antiviral drug umifenovir with standard care vs. standard care therapy in mild COVID-19 patients"*** sponsored by M/s Midi Zest Pharmaceuticals Pvt. Ltd. submitted by Prof. V. Atam Head, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/15/2022 dated 4th July, 2022. ***Recommendation of Primary reviewer:*** • Departmental Scientific Committee Head is PI. Conflict of interest. Cannot be accepted for review. **Legal opinion:** No legal observation. **EC Comment:** As above **EC Decision:** Modify and re-submit
	Ref. code: 117th ECMIIC/P5
6.	Research Protocol no. BRADPL/CT/FDC/AZM/03/30 entitled ***"A multi-center, double-blind, randomized, active-controlled, comparative, parallel-group, phase III clinical study to evaluate the efficacy and safety of fixed dose combination of azelnidipine plus***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	metoprolol succinate tablets in the treatment of subjects with stage 2 Hypertension" sponsored by M/s Akums Drugs & Pharmaceuticals Ltd. submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/16/2022 dated 4th July, 2022. ***Recommendation of Primary reviewer:*** • PI has mentioned in point 10 that risks of doing this study are **not reasonable** compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed. **Legal opinion:** No legal observation. **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 117th ECMIIC/P6***
7.	Research Protocol no. nil entitled ***"A pilot observation study to assess the role of centralized monitoring in general medicine wards"*** sponsored by Turtle Shell Technologies Pvt. Ltd. submitted by Dr. Ambuj Yadav, Assistant Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/18/2022 dated 4th July, 2022. ***Recommendation of Primary reviewer:*** • Will data be anonimyzed? • How will you ensure that data will not be shared with third party? • Get an undertaking from Company. **Legal opinion:** No legal observation. **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 117th ECMIIC/P7***
8.	Research Protocol no. LIB003-006 entitled ***"Randomized, double-blind, placebo-controlled, phase 3 study to evaluate the long-term efficacy and safety of LIB003 in patients with cardiovascular disease, or at high risk for cardiovascular disease, on stable lipid-lowering therapy requiring additional low-density lipoprotein cholesterol reduction (LIB Berate-HR)"*** sponsored by LIB Therapeutics, LIC submitted by Dr. Akshayaya Pradhan, Additional Professor, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 175/Cardio/Res/2022 dated 4th July, 2022. ***Recommendation of Primary reviewer:*** • Section 3: Conflicting statements: If drug is approved for marketing worldwide,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	how come it's a IND/ND? • DGCI approval not attached • Why use direct identifiers? • Section 7: Conflicting statements on biological material. Clearance letter to transport samples out of India not attached. • Section 10 (ii) Is wrong **Legal opinion:** No legal observation. **EC Comment:** As above **EC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: 117th ECMIIC/P8***
9.	Research Protocol no. GLK-2101 entitled ***"A randomized, assessor-blind, placebo controlled, multi center, clinical endpoint bioequivalence study to compare the efficacy and safety of generic fluticasone propionate inhalation aerosol USP 44mcg (Glenmark Pharmaceuticals Ltd) to flovent HFA (Fluticasone propionate inhalation aerosol) 44mcg (GSK Group of Companies) in treatment of patients with bronchial asthma"*** sponsored by Glenmark Pharmaceuticals Ltd. B/2 Mahalaxmi Chamber submitted by Prof. R.A.S Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. RM/CT/04/2022 dated 6th July, 2022. ***Recommendation of Primary reviewer:*** • PI has mentioned in point 10 that risks of doing this study are **not reasonable** compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed. ***Ref. code: 117th ECMIIC/P9***
10.	Research Protocol no. BSV-01-2021 entitled ***"A real world prospective study to evaluate the geographical distribution of prevalence, sensitization rate, and utilization of prophylactic treatment of Rh-negative women in India"*** sponsored by Bharat Serum and vaccine limited submitted by Prof. Rekha Sachan, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/CT/08/2022 dated 13th July, 2022. ***Recommendation of Primary reviewer:*** • PI has mentioned in point 10 that risks of doing this study are **not reasonable** compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed. **EC Comment:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Approval subject to modification *Ref. code: 117thECMIIC/P10*
III	**Adverse Drug Event**
1.	ADE research protocol no. Prax A Study entitled ***"A post marketing surveillance study of prax a 75th (Fixed dose combination capsule containing prasugrel 10mg and sapirin 75mg) in patient with acute coronary syndrome (ACS) who are to be managed with percutaneous coronary intervention (PCI)"*** submitted by Prof. Sharad Chandra, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 118/Cardio/Res/2022 dated 1st June, 2022. **Subject ID-** 05070 **Subject initial:** M-D **Gender:** F **Age:** 66 years **Date of enrollment:** 09-12-2021 **Start date:** 18th May, 2022 **Stop date-** Ongoing **Date of awareness-** 18th May, 2022 **Severity-**Moderate **Causality-** Not done **Subject History:** A letter was received in the office of the Ethics Committee on 1st June, 2022. Subject came into the hospital OPD on 18th May, 2022 with the complaint of breathlessness, chest pain and angina on exertion from last 20 days; She was hospitalized for medical management. It is not related study drug. ***Recommendation of Primary reviewer:*** • The SAE (Hospitalization) is likely due to disease outcome (AWMI /TLT-ve(2019).P/PCI to LAD -09-12-21) and not due to intervention (Prax A 75 –Prasugrel 10 mg + Aspirin 75 mg) as subject completed 3 visits without any adverse drug event. She was hospitalized on 18-05-22 due to chest pain (angina) and underwent CART on 19-05-22 without any complications and was discharged (on 20-05-22) in hemodynamically stable condition. • Therefore causal relationship is unlikely due to intervention and patient managed successfully after the SAE (Hospitalization). **EC Decision:** Reviewed

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 73th ECM IIC/P3
IV-A	**Additional Document**
1.	Additional of research protocol entitled ***"Development of primary human microglial/astrocyte cell-based model for neurodegenerative diseases"*** sponsored by ICMR submitted by Prof. Shailendra Kumar Saxena, Head, Department of Centre for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/543/22 dated 15th June, 2022. ***Recommendation of Primary reviewer:*** • Patient information sheet and ICF should include language/ text compatible with the patient understanding • While annexure states that written consent will be obtained, the investigator has also submitted reviewer waiver form. • What sort of adverse events are anticipated in the study (as per the annexure)? • ICF to be renewed. For example compensation section should indicate Yes or No rather than irrelevant text. Moreover the patient has the right for his tissue to be included (or excluded) in the study. • What are the criteria of sample size of 100? **EC Comment:** As above **EC Decision:** Approval subject to modification *Ref. code: 104th ECMIIA/P31*
IV-B	**Modification**
1.	Modification of research protocol entitled ***"Tools for the integrated management of childhood illness evaluation of pulse oximetry and clinical decision support algorithms in primary care pragmatic cluster randomized controlled trial, with embedded mixed methods, cost and cost-effectiveness studies in India and tanzania"*** submitted by Prof. Shally Awasthi, Head, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 209/Paed/05/2022 dated 10th May, 2022. ***Recommendation of Primary reviewer:*** • This is the revised protocol of the already approved study and hence can be approved as submitted. ***The following documents were reviewed in the Meeting:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Abbreviations 5

1 Summary 7

Investigators 7

Collaborators 7

Funding agency 7

Background / rationale 7

Objectives 8

Study Design and Methods 9

Intervention 10

Setting 10

Inclusion and Exclusion Criteria 10

Sample Size for Primary Outcomes 11

Data Management and Analysis 11

Ethical Clearances 12

Time Line 12

2 General information 13

2.1 Trial registration 13

2.2 WHO Trial Registration Data Set 13

2.3 Funding 13

2.4 Roles & responsibilities 13

Protocol development 15

2.4.1 Project governance 16

3 Background & rationale 19

3.1 Rationale for pulse oximetry 19

3.2 Rationale for clinical decision support algorithm 21

3.3 The TIMCI project 22

4 Goal & objectives 23

5 Study design 24

5.1 Pilot phase 25

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

5.2 Pragmatic cluster randomised controlled trial 26
5.3 Service provision assessment 26
5.4 Facility-based process mapping and time-flow study 27
5.5 Healthcare providers' acceptability and perceptions of the intervention 27
5.6 Caregiver perceptions of the intervention and health-seeking behaviour 28
5.7 Stakeholder perceptions and project data review 29
5.8 Cost and cost-effectiveness study 29
6 Participants, interventions, and outcomes 31
6.1 Study setting 31
6.2 Eligibility criteria 32
6.2.1 Pragmatic cluster RCT (including pilot) 32
6.2.2 Other mixed methods studies 33
6.2.3 Cost and cost-effectiveness study 33
6.3 Interventions 33
6.4 Outcomes 38
6.4.1 Pilot phase 38
6.4.2 Pragmatic cluster RCT 39
6.4.3 Other mixed methods studies 41
6.4.4 Cost and cost-effectiveness study 41
6.5 Participant timeline 42
6.5.1 Pragmatic cluster RCT 42
6.5.2 Other mixed methods studies 47
6.5.3 Cost and cost-effectiveness study 48
6.6 Sample size 48
6.6.1 Pragmatic cluster RCT 48
6.6.2 Mixed methods studies 49
6.6.3 Cost and cost-effectiveness study 51
6.7 Recruitment 51

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

7 Assignment of intervention 53

7.1 Allocation 53

7.1.1 Sequence generation 53

7.1.2 Allocation concealment mechanism 53

7.1.3 Implementation 53

7.2 Blinding 53

8 Data collection, management and analysis 54

8.1 Data collection methods 55

8.1.1 Pragmatic cluster RCT 56

8.1.2 Routine data 57

8.1.3 Other mixed methods studies 58

8.1.4 Cost and cost-effectiveness study 59

8.2 Data management 62

8.2.1 Data flow, storage and transfer 62

8.2.2 Data entry, handling and validation 64

8.2.3 Data privacy protection 66

8.2.4 Data quality assurance and control 67

8.3 Statistical methods 68

8.3.1 Pragmatic cluster RCT 68

8.3.2 Other mixed methods studies 69

8.3.3 Cost and cost-effectiveness study 71

9 Monitoring 72

9.1 Harms 72

9.2 Auditing 72

10 Ethics and dissemination 73

10.1 Research ethics approval 73

10.2 Protocol amendments 73

10.3 Consent or assent 74

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

10.3.1 Pragmatic cluster RCT 74

10.3.2 Other mixed methods studies 74

10.3.3 Cost and cost-effectiveness study 75

10.4 Confidentiality 75

10.4.1 Pragmatic cluster RCT 75

10.4.2 Other mixed methods studies 75

10.4.3 Linking between pragmatic cluster RCT and mixed methods studies 76

10.4.4 Cost and cost-effectiveness study 76

10.5 Risk and benefits to participants 76

10.6 Access to data 77

10.7 Dissemination policy 77

11 References 79

12 Appendix 85

12.1 Study instruments appended to the protocol 85

12.2 Informed consent forms appended to the protocol 85

12.3 Budget and collaboration appended to the protocol 85

12.4 TIMCI Preliminary Theory of Change 86

EC Decision: Approved

Dr. Shally Awasthi did not take part in discussion & making decision.

Ref. code: 103rd ECM IIC/P2

2. Modification of research protocol no. GS-US-417-0304 entitled ***"A multicenter, open-label, long-term extension study to assess the safety and efficacy of filgotinib in subjects with rheumatoid arthritis"*** submitted by Dr. Puneet Kumar, Department of Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/308/2022 dated 19th May, 2022. –Amendment-7

Recommendation of Primary reviewer:

Noted

The following documents were reviewed in the meeting:

Sr. No.	Study Documents	Version No.	Date
1	Study Protocol	Amendment- 7	21 Jan -2022
2	Summary of Changes for study protocol amendment 7	NA	11-Feb-2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	3	Main ICF- Subject Information and Informed Consent Form India (Dr.Puneet Kumar) Translation and Back Translation	Version- 12.1.1	Eng 11-Feb-2022 Eng to Hin: 19-Feb-2022 Hin to Eng: 21-Feb-2022
	4	Main ICF- Subject Information and Informed Consent Form India (Dr.Puneet Kumar) Translation and Back Translation Certificates	Version- 12.1.1	Eng to Hin: 19-Feb-2022 Hin to Eng : 21-Feb-2022
	5	Summary of Changes of Informed Consent Form From Version 11.1.0 To Version 12.1.0	NA	11-Feb-2022

EC Decision: Approved

Ref. code: 83rd ECM IIC/P4

3. Modification of research protocol entitled ***"Multi-centric prospective cohort study of TB recurrence free cure among microbiologically confirmed new pulmonary tuberculosis patients treated under NTEP with the 4-Month moxifloxacin containing daily regimen"*** submitted by Prof. Rajiv Garg, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. MOXI/55/2022 dated 9th June, 2022.

EC Comment:

- Revised ICF to be submitted with earlier version tracking changes.

EC Decision: Approval subject to modification

Ref. code: 110th ECM IB/P4

4. Modification of research protocol entitled ***"A study to assess the impact of "Group motivational enhancement therapy" on clinical outcome and quality of life among patients with opioid dependence undergoing maintenance treatment"*** submitted by Mrs. Sudha Mishra, Ph.D. Scholar under the guidance Prof. Vivek Agrawal, Head, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 811/Psy/2022 dated 16th June, 2022.

EC Decision: Approved

Ref. code: 111th ECM IIB Ph.D/P2

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

5. Modification of research protocol no. RI-01-006 entitled ***"A randomized, double-blind, parallel- group, phase III study to compare the efficacy, safety, and immunogenicity of proposed rituximab biosimilar (DRL- RI) with MAB THERA® in subjects with previously untreated, stage II- IV, cluster of differentiation (CD)20- positive, low tumour burden follicular lymphoma"*** sponsored by M/s Dr. Reddy's Laboratories S.A submitted by Dr. Sudhir Singh, Additional Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 606/RT/2022 dated 27th June, 2022.

Recommendation of Primary reviewer:

- The Amendment allows the incorporation of various measures taken to adapt for conduct of the clinical study in the Coronavirus disease pandemic situation including adaptations of the study results analysis based on discussion with the USA, FDA during Biological Product Development type-2 meeting on 02 July, 2021.

The following documents were reviewed in the Meeting:-

Sl.No.	Name of the document	Version number	Version date
1-	RI-01-006 Protocol	5.0	27-10-2021
2-	Protocol summary of changes	For V5.0	27-10-2021
3-	Investigator's Brochure	9.0	21-09-2021
4-	Investigator's Brochure summary of changes	For V9.0	18-10-2021
5-	Blank CRF	7.0	28-10-2021

EC Decision: Approved

Ref. code: 101st ECM IIC/P2

V **Other Matter with the permission of Chair**

1 With refer to the letter no. DCGI/2022/0534 dated 14th July, 2022, PI has informed that DSMB meeting held on 24th February, 2022, it has been recommended to not open Nitazoxaninde + Ciclesonide treatment arm for Anticov-India study based on the futility results received from Antocov-Africa study interim analysis. As Anticov-India study is platform-based study with provisions for adding and deleting different treatment arms (depending on the result of the interim analysis), amendment to the protocol is not required. The effective version will be 4.0 with two treatment arms (Paracetamol and Fluoxetine + Budesonide). for this reason, the inclusion/exclusion criteria specific to this

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	arm will not be considered when patients will be screened under the research protocol no. 02-COV entitled ***"An open-label, multicentre, randomized, adaptive platform trial of the safety and efficacy of several therapies, including antiviral therapies, versus control in mild cases of COVID-19"*** sponsored by (DNDi) & ICMR India submitted by Prof. Avinash Agrawal, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow. **EC Decision:** Reviewed ***Ref. code: 114th ECM IB/P6***
2-	Correction in the name of funding agency from **'ICMR' to 'SERB'** on ethical approval letter under the research proposal entitled ***"Outcomes of surgically addressed impacted injury in the patients of acetabulum fracture"*** submitted by Dr. Dharmendra Kumar, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2346/OS/2022 dated 17th June, 2022. **EC Decision:** Revised letter to be issued ***Ref. code: 115th ECM IIA/P16***
3-	Regarding typo error in the translation date of main Inform Consent Form (Hindi & Back translation) the correct dates of the documents under the research protocol entitled no.LIB003-004 entitled ***"Randomized, double-blind, placebo-controlled, phase 3 study of evaluate the long-term efficacy and safety of LIB003 in heterozygous familial hypercholesterolemia patients on stable lipid-lowering therapy requiring additional low-density lipoprotein cholesterol reduction (LI Berate-HeFH)"*** sponsored by M/s LIB Tharapestics, LLC submitted by Dr. Akshyaya Pradhan, Professor Junior Grade, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.177/Cardio/Res/2022 dated 5th July, 2022. ***The following point wise corrections were reviewed in the Meeting:-***

Sr. No.	Document	Version	Version/Document Date
8-	Participant Information Sheet and Informed Consent form in **Hindi** with translation certificate dated **21 January, 2022.**	Master: 1.0 India: 1.0 Site-specific: 2.0	Master: 20 Oct 2020 India: 17 June 2021 Site-specific: 20 Jan 2022
9	Participant Information Sheet and Informed Consent Form: Back translation from **Hindi to English** with Back-translation certificate	Master: 1.0 India: 1.0 Site-specific: 2.0	Master: 20 Oct 2020 India: 17 June 2021 Site-specific: 20 Jan 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		dated 21 January, 2022		

EC Decision: Reviewed

Ref. code: 113th ECM IIC/P2

4- Add the related documents under the research protocol no. CLNA043A1 2202 entitled "***A 5-year, randomized, double-blind, placebo-controlled, multi-center study assessing the efficacy, safety, and tolerability of intra-articular regimens of LNA043 versus placebo in patients with symptomatic knee osteoarthritis (ONWARDS)***" sponsored by M/s Novartis Healthcare Pvt. Ltd. submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow.

The following documents were reviewed in the Meeting:-

Sl.No.	Documents
1-	Patient Retention Material_English a) ONWARDS_Thank you card 1_V1_04May21_English (UK) b) ONWARDS_Thank you card 2_V1_04May21_English (UK) c) ONWARDS_Thank you card 3_V1_04May21_English (UK) d) ONWARDS_Thank you card 4_V1_04May21_English (UK) e) ONWARDS_Study Visit Guide_V1_04May21_English (UK) f) ONWARDS_Patient compliance animation_V1_11June21_English (UK) Novartis ONWARDS Langland Materials Description_Cover letter_11June21
2-	Patient Retention Material_Hindi a) ONWARDS_Thank you card 1_V1_04Jun2021_Hindi (India) b) ONWARDS_Thank you card 1_V2_04Jun2021_Hindi (India) c) ONWARDS_Thank you card 1_V3_04Jun2021_Hindi (India) d) ONWARDS_Thank you card 1_V4_04Jun2021_Hindi (India) e) ONWARDS_Study Visit Guide_V1_04Jun2021_Hindi (India) f) ONWARDS_Patient compliance animation_V1_04Jun2021_Hindi (India) Novartis ONWARDS Langland Materials Description_Cover letter_24June21
3-	Certificate of translation for Patient retention material_Hindi
4-	Participant Guide to Activity Monitoring System_ActiGraph • English Hindi
5-	Patient Global Impression of Change (PGIC)_English_India_V1_23 Mar 2021
6-	Certificate of translation _ Patient Global Impression of Change (PGIC)_English_India
7-	Patient Global Impression of Change (PGIC)_Hindi_India_Vi_15 Apr 2021
8-	Certificate of translation _ Patient Global Impression of Change

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	(PGIC)_Hindi_India
9-	Patient Global Impression of Severity (PGIS)_English_India_V1_23 Mar 2021
10-	Certificate of translation _ Patient Global Impression of Severity (PGIS)_English_India

EC Decision: Reviewed

Ref. code: 114th ECM IIC/P3

VI **Brought to Ethics Committee after XI-PGTSC held on 23rd July, 2022**

1 Minutes of XI **"PG Thesis sub Committee"** of "Institutional Ethics Committee" Meeting ***virtually*** will be held on 23rd July, 2022 from 12.00 noon.

The following Members were present in the Meeting:

1. Dr. G.G. Agarwal -Member
2. Dr. Anita Rani Singh -Member
3. Dr. Rajendra Nath -Member
4. Dr. A.A. Mahdi -Member
5. Dr. Shally Awasthi -Member

The following Member was not present in the Meeting:

1. Dr. D.N. Upadhyaya - Sent his written comments

IA **Action Taken**

1- Clarification of proposal entitled ***"A study to assess the knowledge and attitude regarding hand washing among mothers of under five children in pediatric ward, KGMU"*** submitted by Ms. Shalini Chaudhary, Ms. Shalini Maurya, Ms. Sharon Tressler, Ms. Shefali Gautam, Ms. Shikha Gupta, Ms. Shivani Yadav, Ms. Shreya Bajpai, Ms. Shreya Mishra, under the guidance Mr. Nayan Paul & Mrs. Versha Rani Verma, Department of KGMU College of Nursing, King Georg's Medical University, U.P., Lucknow vide letter no.886/X.51/22 dated 8th June, 2022.

Previous PGTSC Comment:	**PI response**
Content and tool validation certificate - without signature attached	Attached
Why content and tool validation certificate -without signature is attached	It was by mistakenly attached in the previous performa as it was supposed to be send with Tool for its validation but now the tool is validated so we are attaching the signed content and tool validation.

The above comment forwarded to PI was reviewed by PR.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of PR:- Approved **PGTSC Decision:** Approval ratified ***Ref. code: II-PGTSC-IIB /P4***
2-	Clarification of research proposal entitled ***"To estimate the prevalence of celiac disease in refractory iron deficiency anemia among children: prospective observational study"*** submitted by Dr. Samrat Chirag Singh, JRI, Department of Paediatrics, King Georg's Medical University, U.P., Lucknow vide letter no. 1918/Ped/22 dated 24th June, 2022. **Previous PGTSC Comment:** • How will be Iron deficiency be assessed. • Where and how will Serum Zinc level be assessed. ***The above comment forwarded to PI was reviewed by PR.*** ***Recommendation of PR:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: III PGTSC-IIA/P20***
3-	Clarification of proposal proposal entitled ***"Diagnostic yield of trans-vaginal ultrasound in post menopausal females and correlation with CA 125 levels"*** submitted by Dr. Vasav Tyagi, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no.557/RD/2022 dated 24th June, 2022.

Previous PGTSC Comment:	**PI response**
However, in the project of Dr. Vasav Tyagi, they still mention that laboratory investigation will be carried out under the supervision of a Gynaecologist which I cannot understand why they are insisting on this? Supervision of a person from a diagnostic department (Pathology/ Biochemistry) must be there.	*As per your advice added co-supervisor from Department of Pathology –* Dr. Wahid Ali Additional professor

The above comment forwarded to PI was reviewed by PR.
Recommendation of PR:-
Approved
PGTSC Decision: Approval ratified
Ref. code: VI PGTSC-IIA/P20

4-	Clarification of proposal entitled ***"Salivary and serum estrogen level assessment in oral***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Research hypothesis and objective are not in conformity. Research hypothesis mentions it as a "comparative study", whereas the objective mentions it as a "correlation study".	As per your advice this study as an correlation study. Evaluation of correlation between Bispectral index and Riker sedation agitation scale in Intensive care unit.
Sample size calculation is not clear. There is no or poor justification for selecting the values in the formula.	Sample size calculation attached separately.
Statistical Analysis section is very general and not specific to the study.	Statistical analysis will be done using the Software Statistical Package for the Social Sciences (IBM SPSS statistics version 23rd IBM Corp, Armonk, NY). The dichotomous variables will be presented in number/frequency and will be analyzed using Chi-square or Fisher Extract test. For comparison of the means between the two groups, analysis by Student t-test, Mann-Whitney U test, with 95% confidence interval will be used.Spearman's squared rank correlation coefficient (r^2) & the Kendall rank correlation coefficient will be calculated.

The above comment forwarded to PI was reviewed by PR:-
Recommendation of Primary reviewer:
Approved
PGTSC Decision: Approval ratified

Ref. code: VIII-PGTSC-IIA/P3

7- Clarification of proposal proposal entitled ***"Study of correlation of clinic-pathological features of extremity squamous cell carcinoma developing over scar (Marjolin ulcer) with lymph node metastasis"*** submitted by Dr. Deepak Kumar Gupta, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1527 dated 22nd June, 2022.

Previous PGTSC Comment:	**PI response**
Patient Information Sheet Not attached, Sample Size: kindly confirm 50/60, ICF:	Attached separately

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	lichen planus patients and its correlative analysis with oral lichen planus and stress" submitted by Dr. Heena Agrawal, JRI, Department of Oral Medicine and Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter dated 4th June, 2022.

Previous PGTSC Comment:	PI response
In Inclusion criteria specific age group not mentioned	Female patients of reproductive age and post menopausal age (16-55 years) with clinically diagnosed Oral Lichen Planus
Stress scale not attached	Enclosed within

The above comment forwarded to PI was reviewed by PR:-
Recommendation of Primary reviewer:
Approved
PGTSC Decision: Approval ratified

Ref. code: VI PGTSC-IIA/P32

5-	Clarification of proposal entitled ***"Retrospective study of demographic and clinical profile of patients of chronic rhinosinusitis with polyposis at tertiary care Centre"*** submitted by Dr. Neha Agarwal, JRI, Department of OTO-Rhino-Laryngology, Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no.181/ENT/22 dated 10th June, 2022.

Previous PGTSC Comment:

- IEC form incompletely/incorrectly filled
- Sample size calculation not done
- Too many Co-PIs included in a project which requires only retrospective data handling. Please justify.

The above comment forwarded to PI was reviewed by PR.
Recommendation of PR:-
Approved
PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-IIA/P30

6-	Clarification of proposal entitled ***"Evaluation of correlation between the sedation-agitation scale and the bispectral index in ventilated patients in the intensive care unit"*** submitted by Dr. Pralobh Kumar Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/756/2022 dated 18th May, 2022.

Previous PGTSC Comment:	PI response

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on Website	

The above comment forwarded to PI was reviewed by PR:-
Recommendation of Primary reviewer:
Pending. PI to discuss with EC member and correct the IEC again.
PGTSC Decision: Approved

Ref. code: VIII-PGTSC-IIA/P8

8- Clarification of research proposal entitled ***"Role of micro RNA expression as biomarker in breast cancer"*** submitted by Dr. Nijarth Shahi, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no.1291/22 dated 26th May, 2022.

Previous PGTSC Comment:	PI response
Still the procedure is not explained properly in ICF. What will be done with her RNA should be told the patient before taking her consent.	RNA will be used in Breast cancer diagnostic procedure and its use as biomarker. ICF attached separately

The above comment forwarded to PI was reviewed by PR.
Recommendation of PR:-
Approved
PGTSC Decision: Approval ratified

Ref. code: VIII-PGTSC-IIA/P11

9- Clarification of research proposal entitled ***"To elucidate the neuro -protective effect of omega-3 fatty acid supplementation in acute spinal cord injury subjects: A prospective longitudinal cohort study"*** submitted by Dr. Khurshid Alam Ansari, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no.2171/OS/22 dated 19th May, 2022.

Previous PGTSC Comment:	PI response
Number of subjects to be included in different groups is not clear.	Child assent form attached.
For biochemical investigations methods are not given as also where these	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	estimations will be carried out?

The above comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved

PGTSC Decision: Approval ratified

Ref. code: IX-PGTSC-IIA/P5

10- Clarification of research proposal entitled ***"Analysis of functional and radiological short term outcomes of uncemented total HIP replacement-A prospective cohort study"*** submitted by Dr. Upendra Kumar Patel, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no.2344/OS/22 dated 14th June, 2022.

Previous PGTSC Comment:	PI response
It is not clear if outdoor or indoor patients will be recruited as the source population; it is mentioned that patients visiting KGMU Orthopedic OPD will be taken into study while in the consent form it is mentioned that all patients admitted in the Orthopedic Department will be the study subjects.	All patients visiting KGMU Orthopaedics OPD will be recruited as the source population. All indoor patients admitted in the Department of Orthopaedics, KGMU, Lucknow having primary and secondary arthritis of hip will be the study subjects.
In consent form complications relating to hip replacement shall be mentioned.	Attached separately.

The above comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: Approval ratified

Ref. code: IX-PGTSC-IIA/P6

11- Clarification of research proposal entitled ***""To elucidate the role of magnesium as predictor of neurological recovery in the acute traumatic spinal cord injury (ATSCI): A prospective longitudinal cohort study"*** submitted by Dr. Virendra Kumar, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no.2345/OS/22 dated 14th June, 2022.

Previous PGTSC Comment:	PI response
For biochemical investigations	*Biochemical investigation i.e*

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	(Serum Magnesium levels) methods are not given as also where these estimations will be carried out? Where will it be done?	*Magnesium will be carried out* for 12 weeks. During the study at the time of admission, besides screening there will be 6 scheduled visits, viz at 3 day, 12 h.1 week, 6 week & 12 week, sample will be collected in yellow vial during each visit and will be send to trauma pathology for magnesium investigation.

The above comment forwarded to PI was reviewed by PR.
Recommendation of PR:-
Approved
PGTSC Decision: Approval ratified

Ref. code: IX-PGTSC-IIA/P7

12- Clarification of research proposal entitled ***"Assessment of nutrition status and its effect on outcome in patient with limb injuries by subjective global assessment as a screening tool"*** submitted by Dr. Divya Bhanu, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no.2290/OS/22 dated 8th June, 2022.

Previous PGTSC Comment:	**PI response**
For biochemical investigations (biomarkers) methods are not given as also where these estimations will be carried out? Where will it be done?	*All investigations and biomarkers will be carried out in our institute KGMU as per treatment protocol of patient described in material and methods. Biochemical investigations/serum All investigations and biomarkers will be carried out in our institute KGMU as per treatment protocol of patient described in material and methods. Biochemical investigations / Serum Biomarkers such as* · *Albumin* · *CRP* *CBC will be carried out in admitted patients in our institute- KGMU department of orthopaedics during follow up/5* scheduled visits, viz at 1 week, at discharge, 3rd and 6 months. Blood sample will be collected from subjects in 3 different vials i.e. for CBC test will be done by automated count (3 part) and sample will be collected in EDTA vial . CRP test will be done by particle enhanced turbidimetric immunoassay method and it will be a qualitative test and sample will be collected in plain vial whereas for albumin Test it will be done by colorimetric bromocresol green (BCG) method and sample will be collected in plain vial and send to trauma pathology KGMU for further investigations.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to PI was reviewed by PR. *Recommendation of PR:-* Approved **PGTSC Decision:** Approval ratified ***Ref. code: IX-PGTSC-IIA/P8***
13-	Clarification of research proposal entitled ***"Retrospective and prospective outcome analysis of surgical management of spinal tuberculosis patient"*** submitted by Dr. Kishore Parihar, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no.2355/OS/22 dated 7th June, 2022.

Previous PGTSC Comment:	**PI response**
Sample size calculation has not been done.	Retrospective study - All operated cases of spinal tuberculosis admitted in Department of Orthopaedics, KGMU, Lucknow from register based data January 2017 to June 2020 with minimum follow up of one year. Prospective study- All operated cases of spinal tuberculosis admitted in Department of Orthopaedics, KGMU, Lucknow from OPD basis data July 2020 to June 2021.
Details of treatment/surgical protocol not mentioned.	All patients undergoing operative intervention were managed by debridement, decompression and posterior instrumentation.
Details of follow up not mentioned.	Patients with minimum follow up of one year will be included in our study. Patients will be followed initially at 6 weekly interval for three months than at 2 monthly interval for next 10 months. At every follow up patients will be evaluated clinically, neurologically,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		haematologically and radiologically. Clinical evaluation included presence of pain (VAS score), weight gain. Neurological evaluation will be done through FRANKEL grading, Haematological evaluation included CBC, CRP, LFT, KFT. Radiological evaluation included serial x-rays and MRI at final follow-up.
	Clinical end point mentioned.	Clinical end point will be defined as absence of pain, haematological subsidence of blood counts to baseline level and radiological healing of lesion evaluated through xrays and MRI (subsidence of edema and decrease in size of abscess).

The above comment forwarded to PI was reviewed by PR.
Recommendation of PR:-
Approved
PGTSC Decision: Approval ratified

Ref. code: IX-PGTSC-IIA/P9

14- Clarification of research proposal entitled "***Contribution of GHR, IGF1R and IGF2R in determining the craniofacial pattern and proportions- A genetic study***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Gulnaz Husain, JRII through her Mentor Prof. Amit Nagar, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 782/2022 dated 13th May, 2022.

Previous PGTSC Comment:	**PI response**
Age group of recruited subjects are between 14 to 24 years, therefore Child Assent form is needed which has not been submitted.	Child assent form attached.

The above comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: Approval ratified

Ref. code: IX-PGTSC-II B IMR-R/P3

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

15- Clarification of research proposal entitled ***"Amniotic membrane as a therapeutic agent for pulpotomy in permanent molars: A randomized controlled trial"*** submitted by Dr. Saumya Johri, SR, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 109/COMS & Endo/22 dated 15th June, 2022.

Previous PGTSC Comment:	PI response
Aims and objectives are stated in two different statements. These statements should be combined to make it "efficacy trial".	AIMS AND OBJECTIVES: To compare the clinical and radiographic efficacy of amniotic membrane (AM) and mineral trioxide aggregate (MTA) when used as a pulpotomy agent in carious permanent molars with irreversible pulpitis.
Research hypothesis should be defined in terms of properly identified parameters of the study.	For the study we have utilized equality hypothesis.(H_0: μ_t-μ_c = 0 where μ_t is the mean outcome response for test treatment and μ_c is the mean outcome response for control treatment). Therefore, the hypothesis was that amniotic membrane (Group 1) may have equal clinical and radiographic efficacy(parameters defined below) to Mineral trioxide aggregate (Group2). Parameters for defining a clinical success: 1-Absence of pain and sensitivity to hot and cold. 2-Absence of abscess/sinus 3- Absence of tooth mobility. 4- Absence of gingival/periodontal inflammation. Parameters for defining radiographic success: 1-Absence of periapical/furcal radiolucency 2-Pathological internal/external resorption 3-Intact lamina dura
The fundamentals of performing RCT are not completely specified: Clinical Trial Registry, method of randomization, blinding, follow-up, outcome event, efficacy or effectiveness trial, Statistical and methodological issues in RCT	**Clinical Trial registry:** CTRI registration has been applied for. Ref No: REF/2021/12/050056 (Date: 26/12/2021) **Method of Randomization:** The current study is a double blinded, parallel arm trial. The teeth will be randomly allocated to two groups(Group 1-AM) (Group 2-MTA).Randomization will be done using a variable block size, using nQuery Advisor

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		software. The sequence of randomization will be obtained from the statistician who is independent of the study. Allocation concealment will be done by sealed opaque envelopes kept at the reception of department's clinic and handed over to the operator at the time of treatment by an independent third person. **Blinding:** The study is a double blinded study where the participants and the outcome assessors are blinded to the particular intervention. Allocation concealment will be done by sealed opaque envelopes kept at the reception of department's clinic and handed over to the operator at the time of treatment by an independent person (department's non-clinical staff). Follow-up: Clinical procedure will be done by a single trained dentist and follow-up evaluations will be performed by two blinded evaluators. Follow-up at 1, 6 and 9 months following the procedure will be done to assess the clinical and radiographical success. Outcome event: The primary outcome of the study will be success of pulpotomy technique using AM at 9 months on examination. Clinical success will be defined by the absence of signs and symptoms such as pain, inflammation, abscess/sinus, mobility and gingival/periodontal inflammation. Radiographic success will be defined as the absence of (i) periapical/furcal radiolucency, (ii) pathological internal or external resorption, and (iii) integrity of lamina dura.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Any other adverse event(s) will be reported. **Efficacy or effectiveness trial:** The current trial is an Efficacy trial (explanatory trial) to determine whether the experiment agent, amniotic membrane (AM) produces pulpotomy success (expected result) under ideal circumstances. Statistical issues: Explained in further replies.
	Since, the research hypothesis is not defined, the sample size calculation is not clear	**Research hypothesis-** Amniotic membrane (Group1, experimental arm,) may have equal clinical and radiographic efficacy (parameters defined above) to Mineral trioxide aggregate (Group2 control arm). **Sample size calculation-** **On the basis of reference study,** Sample size is calculated on the basis of minimum success rate in clinical & radiological parameters of the two groups out of all the groups under study using the formula $n = \frac{(z_\alpha + z_\beta)^2}{[\ln(1-e)]^2}\left[\frac{1-p_1}{p_1} + \frac{1-p_2}{p_2}\right]$ Where p_1 = 0.52 (52%) proportion of minimum success rate in first group p_2 = 0.652 (100%) proportion of minimum success rate in second group (Prasad MG, Adiya P, Babu DN, RadhaKrishna AN. Amniotic Membrane versus Formocresol as Pulpotomy Agents in Human Primary Molars: An in vivo Study. 2017;9) $e = 0.5(p_1/p_2)$, the risk ratio considered to be clinically significant Type I error, α=5% Type II error β=10% for setting power of study 90% Loss to follow up = 10% The sample size is calculated to be **n = 14 each**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		group
	Statistical analysis section should be stated only after properly defining the research hypothesis.	The research hypothesis has been defined. **Statistical Analysis** Data will be tabulated in excel, and descriptive statistics will be performed using SPSS software 21.0. Frequency and percentages will be calculated. Chi-square test will be done in order to test for group difference among the variables. The p-value of <0.05 will be considered statistically significant. Inferential statistics (Mann-Whitney U test and Kruskal Wallis tests) will be used to assess the difference.
	The above comment forwarded to PI was reviewed by PR. ***Recommendation of PR:-*** Approved **PGTSC Decision:** Approval ratified	
		Ref. code: X-PGTSC-IIA/P4
16-	Clarification of research proposal entitled ***"Effect of platelet-rich fibrin and concentrated growth factor on the regenerative potential of human induced pluripotent stem cells (HIPSCS): A comparative analysis"*** submitted by Dr. Anisha, JRII, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 101/Cons dated 10th June, 2022. **Previous PGTSC Comment:** • Research hypothesis is missing. • The variables and parameters should be explicitly identified for the study. • Research hypothesis should be stated in terms of the parameters of the study. • Sample size calculation and statistical analysis section are missing. ***The above comment forwarded to PI was reviewed by PR.*** ***Recommendation of PR:-*** Approved **PGTSC Decision:** Approval ratified	
		Ref. code: X-PGTSC-IIA/P7
17	Clarification of research proposal entitled ***"Post operative residual corneal astigmatism in patients undergoing phacoemulsification with steep axis clear corneal incision, guided by android app"*** submitted by Dr. Shilpi Arya, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 451/OPH/22 dated 23rd June, 2022.	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous PGTSC Comment:	PI response
	Sample size is 81, why this number of subjects will be taken is not mentioned.	Sample size is 81, All subjects (cataract) cases approximately 500 per year. Calculated sample size is 81, Total 80 cases included in the study.

The above comment forwarded to PI was reviewed by PR.
Recommendation of PR:-
Approved
PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-IIA/P11

18- Clarification of research proposal entitled ***"Study of dysphagia-optimised intensity-modulated radiotherapy (Do-IMRT) versus standard in tensity-modulated radiotherapy (S-IMRT) in head and neck squamous cell cancer patients"*** submitted by Dr. Shally Batham, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 575/RT/22 dated 18th June, 2022.

Previous PGTSC Comment:	PI response
In each group 25 patients will be taken, why/on what basis this number of subjects will be taken is not mentioned.	

The above comment forwarded to PI was reviewed by PR.
Recommendation of PR:-
Approved
PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-IIA/P13

19- Clarification of research proposal entitled ***"Diagnostic accuracy of clinical evaluation and conditional imaging to detect urgent conditions in acute abdominal pain: A prospective cohort study"*** submitted by Dr. Ashi Verma, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1558/22 dated 26th June, 2022.

Previous PGTSC Comment:	PI response
ICF: Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindlyu follow the SOP	Attached separately

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

provided by IEC, available on website.	

Recommendation of Primary reviewer:
The above comment forwarded to PI was reviewed by PR:-
Second opinion of PR:

- ICF: Still the procedure is not explained to the patient in simple language.

The above comment forwarded to the PR.
Pending
PGTSC Comment:

- Re-write ICF in simple Hindi.

PGTSC Decision: Approval subject to modification

Ref. code: X-PGTSC-IIA/P18

20- Clarification of research proposal entitled ***"Evaluation of the outcome of video assisted thoracoscopic decortications in cases of early pleural empyema: A prospective observational study"*** submitted by Dr. Piyush, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1451 dated 13th June, 2022.

Previous PGTSC Comment:	PI response
ICF: different in Hindi and English	Attached separately
Explain the procedure of method for dividing the patients into A and B groups.	Study procedure-Randomization will be done in computer generated random number table.

The above comment forwarded to PI was reviewed by PR.
Recommendation of PR:-
Pending

Ref. code: X-PGTSC-IIA/P19

(Primary reviewer: Dr. Anita Rani Singh)

21- Clarification of research proposal entitled ***"Comparative evaluation of bone regeneration with L-PRF, amniotic membrane and simvastatin using CBCT after endodontic surgery: A randomized clinical trial"*** submitted by Dr. Niharika Singh, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1249/CONS & Endo/22 dated 29th June, 2022.

Previous PGTSC Comment	PI response

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Please provide the cost of treatment.	Routine endodontic surgery (receipt in favour of Department of Conservative Dentistry and Endodontics) : RS 1500 /- Study will be self – sponsored for any of the bone regenerative modality used : Amniotic membrane procured from TATA MEMORIAL HOSPITAL , Mumbai is for Rs 280/- per packet (single use) Simvastain 10 mg tablet (SIMVOTIN 10 , Sun pharmaceutical Ind.Ltd) – Rs 14.5 / tablet . Gelatin sponge (hemosponge) as carrier – Rs 310 / box of 32 sponges each of size 10 x 10 x 10 mm L-PRF - Autologus Blood Study will be done in collaboration with Department of oral medicine and radiology for CBCT analysis .
	Explain to the patient about 3 bone healing materials that may be used for his/her treatment in ICF and also that any of these 3 materials may be used in the ICF.	Revised Informed Consent Form attached in paper format Study procedures: •Use of L-PRF , amniotic membrane and simvastatin as bone regenerative modalities in peri apical surgery of endodontic origin. L – PRF will be prepared from patient's own blood (10 ml) in centrifuge machine. Amniotic Membrane will be procured from Tissue Bank, TATA Memorial Hospital, Mumbai, India for the study. Simvastatin 10 mg tablets (SIMVOTIN 10 , Sun pharmaceutical Ind. Ltd.) will be used with gelatin sponge as carrier . Any of the above mentioned modality may be used. The intervention to be given will be decided by allocation concealment method. For this purpose sequentially numbered, opaque, sealed envelopes (SNOSE) will be prepared and kept safely. Comparing radiographic changes in the size of the periapical defects after endodontic surgery by utilizing three bone regenerative modalities using CBCT.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The above comment forwarded to PI was reviewed by PR-

- The study procedure still is not properly explained.
- Patient must know for his benefit, why he has been selected for one of the three materials. Please explain him that as part of study, we may use any three of these, all of these are known materials and this will not affect the result of his treatment. So that he is convinced to take part in the research.
- If we do not explain, It is violation of Autonomy because only then he will be able to take appropriate decision for himself.
- In case , his treatment fails and he goes to court, only this properly written consent form can save the researcher.
- Procedure in the ICF means "what will be done with ***him***", should be explained to the patient.
- This is not the same as explained in the Proforma, which is a scientific document.

The above comment forwarded to PR:-

PGTSC Decision: Approved

Ref. code: X-PGTSC-IIA/P22

22- Clarification of proposal proposal entitled ***"Mechanical and chemical changes in root canal dentine by various chelating agents: An in-vitro study"*** submitted by Dr. Anvesha Kumar, JRII, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 102/Cons&Endo/22 dated 10th May, 2022.

Previous PGTSC Comment	PI response
Please specify where will scanning E.M. be done? Who will perform it?	Birbal Sahni Institute of Palaeo Sciences, Lucknow By Dr. Veeru Kant.

The above comment forwarded to PI was reviewed by PR-

Previous PGTSC Decision:

Approved

The above comment forwarded to PI was reviewed by PR-

Previous PGTSC Decision:

Approved

PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-IIA/P23

23- Clarification of proposal proposal entitled ***"Kinesiophobia in young adults after anterior crutiate ligament reconstruction in a tertiary care centre of northern India: A prospective study"*** submitted by Dr. Ankit Kumar, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2320/OS/22 dated 30th June, 2022.

Previous PGTSC Comment:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Sections of IEC form regarding consent/Advertising/Risk & benefits and not filled. ***The above comment forwarded to PI was reviewed by PR.*** ***Recommendation of PR:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: X-PGTSC-IIA/P26***
24-	Clarification of research proposal entitled ***"A study on patient waiting time in outpatient department in a tertiary care government Teaching Hospital"*** submitted by Dr. Swati Rai under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/197/22 dated 8th June, 2022. **Previous PGTSC Comment:** **Methodology:-** • **Study design-**Observational descriptive study. • **Variables-** • A- Patient arrival time in the queue for registration –Patient registration time. • B- To determine the patient waiting time for consultation with doctor-Time for consultation? • C- To identify the reasons which are responsible for increased waiting time? **Inclusion criteria:** • New patients on working days from OPD of-Endocrinology, Rheumatology, Surgical Oncology and Radiotherapy (Age/sex specificity not mentioned) ***The above comment forwarded to PI was reviewed by PR.*** ***Recommendation of PR:-*** Approved ***The above comment forwarded to PI was reviewed by PR-*** **Previous PGTSC Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: X PGTSC-II B-MHA/P1***
26.	Clarification of research proposal entitled ***"Comparison of HRCTV delineation in brachytherapy of carcinoma cervix using CT imaging with the gold standard MRI delineation"*** submitted by Dr. Mohammad Ahtesham Khan, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 741/RT/22 dated 18th July, 2022.

Previous PGTSC Comment	PI response

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Research hypothesis is missing.	MRI based Image-Guided Adaptive Brachytherapy(IGABT) is the current gold standard for brachytherapy in Carcinoma Cervix, But in a country like India, limited resources and other logistics issues are a road block to MRI based IGABT. So we tried to evaluate the dosimetric difference between HRCTV D90 and D_2CC of rectum, bladder and bowel in MRI based and CT based brachytherapy, to see if CT based brachytherapy in Carcinoma Cervix can become an upcoming practice.
	The variables and parameters should be explicitly identified for the study.	• HRCTV D90 • D_2CC of Rectum • D_2CC of Urinary bladder • D_2CC of Bowel
	In the absence of proper research hypothesis, the sample size calculation has no meaning.	Since it is a pilot study and due to logistic issues, sample size is taken to be 25.
	The statistical analysis section is missing.	Statistical Analysis will be done using SPSS software 22nd version, with considering the P-value to be significant below 0.05.
	The above comments forwarded to PI was reviewed by PI:- ***Recommendation of PR:-*** Approved ***The above comment forwarded to PI was reviewed by PR-*** **Previous PGTSC Decision:** Approved **PGTSC Decision:** Approval ratified ***Ref. code: X-PGTSC-IIA/P5***	
27.	Clarification of research proposal entitled ***"Evaluation of HIF-1ALPHA and CCND1 expression as a biomarker of treatment outcome in locally advanced Head and Neck cancer patients undergoing chemo-radiotherapy"*** submitted by Dr. Mansi Shukla, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 742/RT/22 dated 18th July, 2022.	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous PGTSC Comment	PI response
Start date of the project is given as June 2021 and the project is to be completed by June, 2022. Without IEC approval how was the project initiated? A clarification may be taken.	This study is one year, study start in after getting approval of ethical clearance.
Sample size is 100, why this number of subjects will be taken is not mentioned. If it is a pilot study then it may mentioned.	This is a prospective study, Sample size is taken to be 99. Using the formula $n=\frac{(z_{1-\alpha/2})^2 \times p \times q}{d^2}$ Where n= sample size, $z_{1-\alpha/2}$= value of normal deviate at 95 percent confidence interval, p= prevalence, q=1-prevalance, e= absolute error the sample size was calculated to be 98.9. Final sample size=99.

The above comment forwarded to PI was reviewed by PR-
Approved
PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-IIA/P10

28. Clarification of research proposal entitled ***"Mechanical and chemical changes in root canal dentine by various chelating agents: An in-vitro study"*** submitted by Dr. Nivedita, SR., Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 155/PCCM/22 dated 18th July, 2022.

Previous PGTSC Comment	PI response
Section on use of biological material does not mention biopsy specific harvesting.	Target biopsy sites are areas showing and endobronchial growth and/or abnormal appearing mucosa as seen by both WL & NBL.
There is no mention of how NBI bronchoscopy findings will be quantified/recorded/correlated with HPE results.	Based on consensus among the two bronchoscopists a particular NBI pattern to be labeled for each patients. In such patients were consensus could not be attained, opinion of 3rd bronchoscopists to be taken.
Ideally Co-PI cannot be a member of the	As per you discussion with HOD, PCCM,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	departmental Scientific Research Committee.	Co-PI being considered under special circumstances.

The above comment forwarded to PI was reviewed by PR.
Second opinion of PR:-

- Section on Biological material in IEC form was not filled.

Reply has given by PI.
Recommendation of Primary reviewer: Approved
PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-II A/P27

IB	**Expedited review**
1-	Expedited review of proposal entitled ***"Association of anthropometry with nerve conduction velocity of median nerve"*** for ICMR STS-2022 submitted by Ms. Rachna Singh, MBBS student 2nd Year under the guidance of Prof. Archana Ghildiyal, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.2540/PHY/2022 dated 27th May, 2022.. ***The above proposal forwarded to two Primary reviewers, reply has given by the both reviewers with following comments:*** ***Comment of First:*** • Who shall bear the cost of NCV test that is being administered to the volunteers? ***Comment of Secondary PR:*** • Kindly provide the budget ***The above comment forwarded to the PI was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XI PGTSC-I B /P1***
2.	Expedited review of proposal entitled ***"Comparison of soluble lectin-like oxidized low-density lipoprotein receptor-1, high-sensitive troponin-T and CK-MB as diagnostic biomarkers of acute coronary syndrome"*** for ICMR STS-2022 submitted by Mr. Vibhor Agrawal, MBBS Batch, 2019 under the guidance of Dr. Wahid Ali, Additional Professor, Department of Pathology, KGMU vide letter no.682 dated 23rd May, 2022. ***The above proposal forwarded to two Primary reviewers, reply has given by the both reviewers with following comments:*** ***Comment of First PR :*** • Sample size justification / calculation has not been provided • Who will be responsible for collecting data and validating data in the cardiology department, no investigator from cardiology. Ideally some faculty member should be recruited as co investigator.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• In inclusion criteria, no reference of CT angiography is given for selection in case or control group, whereas study group is mentioning it. Kindly clarify the role of CT angiography in selection of patients but not including it as inclusion criteria. • What will be the time for collecting blood sample for markers? • Are all these markers are routine investigations? • Who will bear the cost for additional investigations, if any? ***Comment of Secondary PR:*** • This is not a case-control study. The case-control study is retrospective study. • The objectives are mixed up. They are trying to compare the two groups. So it should be a comparative trial. • At the same time they are talking about finding sensitivity and specificity of some markers. This comes under "diagnostic test". • Sample size calculations are not given. This can be done only when proper research hypothesis is defined. • Statistical analysis is not clear. Actually it should be in coherence to proper research hypothesis. ***The above comments forwarded to the PI: Reply pending.*** **PGTSC Comment:** • Forwarded to both Primary reviewers ***Recommendation of PR*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XI PGTSC-I B /P2***
3-	Expedited review of proposal entitled ***"A study of association between hypertension and cognition in people over 60 years of age: A cross sectional study"*** for ICMR STS-2022 submitted by Ms. Nivedita Parandiyal, MBBS 2nd Year under the guidance of Dr. Shailendra Mohan Tripathi, Associate Professor, Department of G.M. H., KGMU vide letter no.1614/DGMH dated 27th May, 2022. ***The above proposal forwarded to two Primary reviewers, reply has given by the both reviewers with following comments:*** ***Comment of First PR*** • The title of the study mentions it is a Cross sectional study, however, it is actually a Case control study. The title may be suitably modified. • No justification for sample size of 40 cases and 40 controls has been given. Kindly explain. ***Comment of Secondary PR*** • Sample size calculation not done (Duration of study is not the criteria for

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	calculated sample size)-Please give sample size as it is not the Pilot study. • Kindly provide Semi structured Proforma on sociao-demographic data. • Kindly provide Approval letter from ICMR and budget. ***The above comments forwarded to the PI response has given by PI was forwarded to both PR.*** ***Second opinion of Secondary reviewer:*** Approved ***Second opinion of First PR:*** • The title mentions that is it 'A study of association between hypertension and cognition in people over 60 years of age'. The primary objective also mentions comparison with non-hypertensive individuals. However, she said **'association'** cannot be determined without a control group. The modified proforma does not mention a control group. If the study proposes to compare the findings with the already known data, the study must measure 'prevalence' as the primary objective. • A cross-sectional study can be used to measure of prevalence, a 'case control study can be used to measure' association'. • I will suggest either title modification to 'measure of prevalence of cognitive impairment in hypertensive patients' or changing the type of study to 'case control study'. I will also suggest modifying the primary objective. • The inclusion criteria do not mention hypertensive patients. • Justification for new sample size is well accepted. ***The above comments forwarded to the PI response have received by PI on 22nd July, 2022.*** **PGTSC Decision:** Approved ***Ref. code: XI PGTSC-I B /P3***
4.	Expedited review of proposal entitled ***"Impact of parenting styles and adverse childhood experiences on resilience in medical undergraduates"*** for ICMR STS-2022 submitted by Ms. Mridul Garg, MBBS Batch, 2018 under the guidance of Dr. Amit Singh, Assistant Profeesor, Department of Psychiatry, K.G's Medical University, U.P., Lucknow vide letter no.801/Psy dated 15th June, 2022. ***The above proposal forwarded to two Primary reviewers, reply has given by the both reviewers with following comments:*** ***Comment of First PR :*** • Pending ***Comment of Secondary PR:*** • Kindly provide Approval letter from ICMR and budget. ***The above comment forwarded to PI was reviewed by PR*** ***Recommendation PR:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Approved **PGTSC Decision:** As above ***Ref. code: XI PGTSC-I B /P4***
5.	Expedited review of proposal entitled ***"Adverse events after COVID-19 vaccination in Pediatric age group"*** for ICMR STS-2022 submitted by Mr. Khalid Ahmad Qidwai, MBBS Batch, 2018 under the guidance of Dr. Sanjeev Kumar Verma, Additional Professor, Department of Pediatrics, KGMU vide letter no.1833/Ped/2022 dated 15th June, 2022. ***The above proposal forwarded to two Primary reviewers, reply has given by the both reviewers with following comments:*** ***Comment of First PR :*** • In the Objective of the study point number one instead of "to estimate the incidence of…" may be replaced by "to assess the incidence of …" ***Comment of Secondary PR:*** • Do they want to find prevalence or incidence? It should be clarified. • The numerator and denominator are different for "incidence" and "prevalence". • These should be exclusively specified, which shall require target population, sampling frame etc. • The questionnaire is required. • The study is supposed to be across Uttar Pradesh. Do they really mean it? • The target population, sampling frame has to be explicitly defined in order to find proper rates. ***The above comments forwarded to the PI:*** was reviewed by PR ***Recommendation of PR*** Approved **PGTSC Decision:** As above ***Ref. code: XI PGTSC-I B /P5***
6-	Expedited review of proposal entitled ***"Interplay of Biotechnology and Bioengineering in enhancing standards of dentistry in India-A KAP study on undergraduate dental and engineering students (Proposal ID: 2022-06638)"*** for ICMR STS-2022 submitted by Ms. Anusha Agarwal, BDS 3rd year under the guidance of Dr. Deeksha Arya, Additional Professor, Department of Prosthodontics, Faculty of Dental Sciences, KGMU vide letter no.261/22 dated 8th July, 2022. ***The above proposal forwarded to two Primary reviewers, reply has given by the both reviewers with following comments:*** ***Recommendation of both reviewers*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XI PGTSC-I B /P6***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

IIA	New proposal
1.	Research proposal entitled ***"Efficacy of dexmedetomidine for prevention of postspinal anesthesia shivering in orthopaedic surgeries: randomized, controlled, double-blind, dose-finding study"*** submitted by Dr. Utkarsh Prasad, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/715/22 dated 5th May, 2022. ***Recommendation of Primary reviewer:*** • Aim and objectives are not clear. The aim states "evaluate the efficacy", whereas objectives states to find "incidence". • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.) (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary in the absence of proper research hypothesis. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Resubmit ***Ref. code: XI-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Long PFNA-II VS dynamic HIP screw for treatment of unstable intertrochanteric femur fracture-A prospective comparative study"*** submitted by Dr. Punit Agarwal, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 2079/OS/22 dated 2nd May, 2022. ***Recommendation of Primary reviewer:*** • Aim and objectives are not clear. • Research hypothesis should be formulated after identifying the study variables and population parameters. • It is prospective cohort study. The two cohorts, under comparison, should be properly defined. • Sample size calculation is arbitrary. The right formula can be used only after defining the proper research hypothesis. • Statistical analysis section is very genera. It should be specific to the aims and

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	objectives. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Resubmit ***Ref. code: XI-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Laparoscopic renal surgery: outcome analysis at a tertiary care center"*** submitted by Dr. Nitish Dev, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 258/Uro/22 dated 13th May, 2022. ***Recommendation of Primary reviewer:*** • Title should be: Assessment of outcomes of Laparoscopic renal surgery • Aims and objective should be expressed in the form of proper research hypothesis. • Study variables, primary and secondary outcome measures should be defined. • Study design is not clear. It is given as "Single centered observational retrospective and prospective study. • Sample size calculation and Statistical Analysis section are missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Resubmit ***Ref. code: XI-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Growth of urology in India as compared to other surgical branches"*** submitted by Dr. Sandeep Kumar Patel, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 259/Uro/22 dated 13th May, 2022. ***Recommendation of Primary reviewer:*** • Title should be "Growth of urology as compared to other surgical branches in India" • The attributes on which growth will be evaluated should be specified. • How the results will be presented? **PGTSC Comment:** • Data collection form must be enclosed. **PGTSC Decision:** Revise & Resubmit ***Ref. code: XI-PGTSC-IIA/P4***
5.	Research proposal entitled ***"A prospective study of grading the complexity of PCNL procedures using " GUY'S STONE SCORE"*** submitted by Dr. Ankush Sadotra, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 261/Uro/22 dated 14th May, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The sample size calculation is not given. • The detail for evaluating "reliability" and "validity" of "Guy's stone score" is missing. **PGTSC Comment:** • Has it been validated in Indian? • Include a Biostatistician as Co-guide **PGTSC Decision:** Revise & Re-submit ***Ref. code: XI-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Assessment of quality of urological care and services in a tertiary care centre"*** submitted by Dr. Jayant Maurya, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 260/Uro/22 dated 14th May, 2022. ***Recommendation of Primary reviewer:*** • Proposal seems to be O.K. • Would like to see "SWOPS" questionnaire. • Is this instrument applicable in Indian context? • Study period is "June 2021- October 2022" • Has the study already started? **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-IIA/P6***
7.	Research proposal entitled ***"To determine the basic and demographic, clinical and biochemical risk factors associated with pediatric tuberculosis (Pulmonary and extrapulmonary tuberculosis"*** submitted by Dr. T. Sudhakar, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1381/Ped/22 dated 10th May, 2022. ***Recommendation of Primary reviewer:*** • Research proposal is incomplete • They are proposing to find out the risk factors. • For doing, this experimental study is required. • The proposed design is: "prospective observational study". • Proper research hypothesis, study variables, outcome measures etc. are required. • Sample size calculation is arbitrary. • Statistical analysis section is also very general and not specific to the aim/objective of the study. **PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: XI-PGTSC-IIA/P7***
8.	Research proposal entitled ***"DIC scoring among newly diagnosed children with acute leukemia in a pediatric wardsor a north Indian teaching university: A prospective observational study"*** submitted by Dr. Karan Gond, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1380/Ped/22 dated 10th May, 2022. ***Recommendation of Primary reviewer:*** • This seems to be an incidence/prevalence study. • The title should mention it. • For finding incidence or prevalence, the theoretical population, target population, sampling frame, sampling methods should be clearly specified. • Sample size calculations are missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit ***Ref. code: XI-PGTSC-IIA/P8***
9.	Research proposal entitled ***"Effect of kinesiophobia on early functional outcome following total knee arthroplasty"*** submitted by Dr. Sripal Chaudhary, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 1686/OS/22 dated 2nd April, 2022. ***Recommendation of Primary reviewer:*** • There are total 8 Co-PIs and 7 from same department (including HOD) with almost same roles -Please justify or reduce the numbers of Co-PIs • In Undertaking document by PI the name of Prof. R N Srivastava has wrongly been mentioned as Co-PI – Please remove the name. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-IIA/P9***
10.	Research proposal entitled ***"To study thecomplications of percutaneous nephrolithotomy"*** submitted by Dr. Udham Singh, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. nil dated nil. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Study design in Protocol - Prospective observational study from June -21 to June -22 ? If study has already not started then how it is possible . In ICF the study design mentioned is Combined Retrospective and Prospective study • Sample size -All adult pts will be included , exact calculated sample size not given • In Exclusion criteria – it is mentioned that pt below 12 yrs of age not included (In methodology it has been mentioned that analysis of prospectively maintained data of more than 12 yrs of age)- – please Clarify the Age of the patients being included. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Complications associated with ureterorenoscopy (URS) related to treatment of urolithiasis: A prospective study"*** submitted by Dr. Jigardeep Singh, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. nil dated nil. ***Recommendation of Primary reviewer:*** • Sample size -not mentioned (All pts above 18 yrs of age Undergoing ureteroscopic stone removal) -Justify • It is a prospective observational study and PI mentioned that pts from June-2021 to June 2022 will be included - Is PI already started the study or pts will be taken retrospectively -Please specify **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-IIA/P11***
12.	Research proposal entitled ***"Comparative evaluation of depigmentation by locally injected Vitamin C versus surgical blade in the treatment of gingival hyperpigmentation"*** submitted by Dr. Aehad-ul-Haque, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2392/22 dated 28th May, 2022. ***Recommendation of Primary reviewer:*** • Study design not mentioned in protocol

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• No. of Co-PIs are 4 (including HOD) from same department with almost similar roles -Please justify • Please give details of clinical parameters to be seen –1. Gingival pigmentation index – how you will assess 2. How pts satisfaction analysis will be assessed -If any structured questionnaire are their then attach the same. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-IIA/P12***
13.	Research proposal entitled ***"Comparative evaluation of antimicrobial photodynamic therapy as an adjunct to periodontal surgery in intra-bony defects: A randomized controlled trial"*** submitted by Dr. Sheetal Sharma, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2394/P/22 dated 28th May, 2022. ***Recommendation of Primary reviewer:*** • Study design not mentioned in protocol • No. of Co-PIs are 4 (including HOD) from same department with almost similar roles –Please justify • Please give details of clinical parameters to be seen –1.Gingival pigmentation index – how you will assess 2. How pts satisfaction analysis will be assessed -If any structured questionnaire are their then attach the same. **PGTSC Comment:** • CTRI registration needed. **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-IIA/P13***
14.	Research proposal entitled ***"Association of polymorphisms in IGF-1, GHR and PAX-9 genes with tooth sixe"*** submitted by Dr. Varun Gupta, JRII, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 818/Ortho/22 dated 15th June, 2022. ***Recommendation of Primary reviewer:*** • As the inclusion criteria shows to take the patients between 13 to 25 yrs. of age, therefore Child Ascent Form should be submitted in addition to ICF.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-IIA/P14***
15.	Research proposal entitled ***"Comparative evaluation of periodontal health status and serum, saliva matrix metalloproteinases in patients with interstitial lung diseases (ILD): A case control study"*** submitted by Dr. Hirkane Prerna Santkumar, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2395/P/22 dated 28th May, 2022. ***Recommendation of Primary reviewer:*** • Total 5 Co-PIs in which 3 are from Periodontology with same roles-Please justify • Study design not mentioned separately in Protocol (mentioned in methodology) • In Inclusion criteria no mention of Healthy subjects which are to be taken as control. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Resubmit ***Ref. code: XI-PGTSC-IIA/P15***
16.	Research proposal entitled ***"Epidemiology of injured patients in paediatric age group admitted to department of orthopedics KGMU"*** submitted by Dr. Prajwal M C, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 2346/OS/22 dated 14th June, 2022. ***Recommendation of Primary reviewer:*** • Sample size-All pts –Specific and calculated sample size not mentioned • Guardian consent form E/H- not same –modification needed • As the pts of age group between 8 to 18 yrs. will be taken ,so Child Ascent Form should also be attached. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-IIA/P16***
17.	Research proposal entitled ***"Comparative analysis of injectable-platelet rich fibrin (I-PRF) and microneedling (MN) for gingival augmentation in thin gingival biotype patients: A randomized clinical trial"*** submitted by Dr. Masood Kamal, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	University, U.P., Lucknow vide letter no. 2390/P/22 dated 28th May, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-IIA/P17***
18.	Research proposal entitled ***"Sulfiredoxin levels in gingival crevicular fluid and its comparative evaluation in periodontal health and disease: A case control study"*** submitted by Dr. Disha Dixit, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2391/P/22 dated 28th May, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-IIA/P18***
19.	Research proposal entitled ***"Assessment of health related quality of life and patient reported outcome measures (PROM) in adolescent and young adult patients of malignant bone tumor treated surgically"*** submitted by Dr. Bhavesh Kumar, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 2369/OS/22 dated 21st June, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-IIA/P19***
20.	Research proposal entitled ***"A correlation between patient perceived functional outcome Vs clinical evaluation after primary arthroscopic ACL reconstruction"*** submitted by Dr. Sandeep Singh, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 2336/OS/22 dated 13th June, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-IIA/P20***
II-B	**MBBS Student**
1.	Research proposal entitled ***"Hypoalbuminemia as predictor of mortality in patients admitted to pediatric intensive care unit"*** submitted by Miss. Harshika Bhandari, MBBS, Batch 2020 through her Mentor Dr. Areesha Alam, Assistant Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1251/Ped/22 dated 2nd May, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-II B MBBS-S/P1***
3.	Research proposal entitled "***Association of ankle-brachial index with anthropometric parameters in young obese individuals***" sponsored by ICMR STS. New Delhi submitted by Mr. Vedansh Tyagi, MBBS, Batch of 2020 through his Mentor Prof. Nar Singh Verma, Head, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2529/PHY/22 dated 11th May, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-II B MBBS-S/P3***
4.	Research proposal entitled "***Determining Super-Specialty branch preferences and their covariatesd in general surgery residents: a multi-centric survey***" submitted by Mr. Atique Anwar, MBBS, Batch of 2018 through his Mentor Prof. Abhinav A. Sonkar, Head, Department of Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1206/22 dated 12th May, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-II B MBBS-S/P4***
5.	Research proposal entitled "***The study of cognition and impulsivity in patients of mild traumatic brain injury***" submitted by Mr. Mayank Singh, MBBS, Batch of 2018 through his Mentor Dr. Ankur Bajaj, Additional Professor Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/655/22 dated 11th May, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-II B MBBS-S/P5***
6.	Research proposal entitled "***Health related quality of life after traumatic basal ganglia Hemorrhage***" submitted by Mr. Anurag Yadav, MBBS, Batch of 2018 through his Mentor Dr. Awdhesh Yadav, Associate Professor Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/657/22 dated 12th May, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation has not been done. **PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-II B MBBS-S/P6***
7.	Research proposal entitled "***Attitude, perception and barriers of dental professionals towards artificial intelligence***" sponsored by ICMR STS submitted by Ms. Anushka Pandey, BDS through her Mentor Dr. Nishi Singh, Assistant Professor Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 663/22 dated 9th March, 2022. ***Recommendation of Primary reviewer:*** • Sample size required for questionnaire has not been mentioned. • Ethical waiver has been requested. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-II B BDS-S/P7***
8.	Research proposal entitled "***Title efficacy of dental caries telediagnosis using smartphone-an observational study in geriatric patients***" sponsored by STS ICMR submitted by Mr. Abhinav Kumar, BDS through his Mentor Dr. Pragya Pandey, Associate Professor Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 81/CONS&Endo/22 dated 21st May, 2022. ***Recommendation of Primary reviewer:*** • Approved. **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-II B BDS-S/P8***
9.	Research proposal entitled "***Barriers to breast cancer screening in a cohort of urban Indian Women***" sponsored by ICMR STS submitted by Mr. Vaibhav Singh, MBBS, through his Mentor Prof. Vinod Jain, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1264/22 dated 21st May, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-II B MBBS-S/P9***
10.	Research proposal entitled "***To evaluate a need for change in Indian dental curriculum: A student-centric, multi-centric questionnaire survey***" sponsored by ICMR STS submitted by Ms. Vaishnavi Parekh, BDS through her Mentor Dr. Rhythm, Professor Junior Grade, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	76/COM&Endo/22 dated 11th May, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-II B MBBS-S/P10***
11.	Research proposal entitled "***Effect of stress on menstrual cycle and its association with menstrual irregularities in young adult women: An observational study***" submitted by Ms. Chandrika Varshney, MBBS through her Mentor Prof. S.P. Jaiswar, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1147/22 dated 24th May, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-II B MBBS-S/P11***
12.	Research proposal entitled "***Evaluation of 'COVAXIN' COVIS-19 vaccine in Children of age 15-18 of Northern India***" submitted by Mr. Sujoy Bose, MBBS through his Mentor Dr. Arpita Bhriguvanshi, Associate Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1563/Ped/22 dated 24th May, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-II B MBBS-S/P12***
13.	Research proposal entitled "***A cross sectional study to correlate DMFS and stress on development of MPDS in medical students***" sponsored by ICMR STS submitted by Mr. Prakhar Mittal, MBBS through his Mentor Dr. Lakshya Kumar, Additional Professor, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 157 /22 dated 26th May, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation and proper justification needed. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-II B MBBS-S/P13***
14.	Research proposal entitled "***Prospective analysis of snakebite patients in a tertiary care referral centre in northern India***" sponsored by ICMR STS submitted by Mr. Akash Singh, MBBS through his Mentor Dr. D. Himanshu Reddy, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	no. 1108/MED /22 dated 28th May, 2022. ***Recommendation of Primary reviewer:*** • Sample size is 50, why this number of subjects will be taken is not mentioned. If it is a pilot study then it may be mentioned. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-II B MBBS-S/P14***
15.	Research proposal entitled "***Correlation of HbA1c with glycemic variability in diabetes management***" sponsored by ICMR STS submitted by Mr. Akash Kumar, MBBS through his Mentor Dr. Satyendra Kumar Sonkar, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1104/MED/22 dated 27th May, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation and proper justification needed. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-II B MBBS-S/P15***
16.	Research proposal entitled "***Effect of periodontal therapy on inflammatory biomarkers in patients with metabolic syndrome: a randomized controlled clinical trial***" sponsored by ICMR STS submitted by Mr. Pushpendra Singh, BDS through his Mentor Dr. Anjani Kumar Pathak, Additional Professor, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2409/P/22 dated 2nd June, 2022. ***Recommendation of Primary reviewer:*** • In the materials and Methods section instead of Patients as "Experimental Group" subjects shall be mentioned. • Sample size calculation and proper justification needed. • They are going to do biomarkers but no co-guide from any investigative department. • Similarly they are going to assess cardiovascular risk but no co-guide from Cardiology/Medicine is there. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-II B MBBS-S/P16***
17.	Research proposal entitled "***Elucidation of risk factors and impact of lifestyle on low***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	back pain among undergraduate students of medical university: A cross-sectional study" sponsored by ICMR STS submitted by Mr. Abhishek Singh, MBBS through his Mentor Prof. R. N. Srivastava, Head, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2250/OS/22 dated 31st May, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XI-PGTSC-II B MBBS-S/P17***
18.	Research proposal entitled ***"Psychological morbidity and quality of life in women undergoing hysterectomy"*** sponsored by ICMR STS submitted by Ms. Nikita Verma, MBBS through her Mentor Dr. Bandna Gupta, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 821/Psy/22 dated 16th June, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation and proper justification needed. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XI-PGTSC-II B MBBS-S/P18***
III	**Modification**
1.	Modification of research protocol entitled ***"Study of relationship between olfactory dysfunction and cognitive impairment in elderly patients with diabetes mellitus: A cross-sectional study"*** submitted by Dr. Porimita Chutia, SRI, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 1608/DGMH/2022 dated 24th May, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: V-PGTSC-IIA/P37***
2.	Modification of research protocol entitled ***"A study of phenomenology of major depressive disorder & its correlation with inflammatory markers among COVID-19 recovered elderly"*** submitted by Dr. Shashank Saurabh Sinha, SRII, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 1629/DGMH/2022 dated 7th June, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Approved **PGTSC Decision:** As above ***Ref. code: IV-PGTSC-IIA/P51***
IV	**Other Matter**
1-	Regarding request for change the Chief guide Prof. Monika Agarwal, in place of Prof. S.P. Patel entitled ***"Quality of life among elderly people living in Lucknow"*** submitted by Dr. Manoj Soni, JR-II, Department of Community Medicine and Public Health, KGMU UP, Lucknow vide letter no. 184/CM/Dr. Manoj/ Soni dated 20th May, 2022. **PGTSC Decision:** Approved ***Ref. code: V-PGTSC-IIA/P23***

The next EC Meeting will be held on 17th September, 2022(Saturday)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P.,
Institutional Ethics Committee

Office of the Institutional Ethics Committee
Lucknow - 226003 (UP) India

Prof. Alok Dhawan
Chairman, IEC

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

No. 1107 **Ethics/2022**

Dated: 06/09/2022

To,

Prof. Alok Dhawan,
Director,
Centre of Biomedical Research (CBMR),
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Raebarelli Road,
Lucknow, U.P. 226014

Sub.: Reg. Minutes of 117th Institutional Ethics Committee Meeting held on 30th July, 2022.

Dear Sir,

Please find enclosed herewith the Minutes of 117th Institutional Ethics Committee Meeting held on 30th July, 2022, for your kind signature.

Thanking you

With regards

Yours Sincerely,

Encl.: As above.

(Shally Awasthi)
Member Secretary, IEC

E-mail: ethics@kgmcindia.edu

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 118th ECM will be held on 17th September, 2022

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of 118th Institutional Ethics Committee Meeting *virtually* held on 17th September, 2022 from 10.30 AM.

The following Members were present in the Meeting:

1.	Dr. Alok Dhawan	-Chairman
2.	Dr. G.G. Agarwal	-Member
3.	Dr. K.K. Yadav	-Member
4.	Mr. Ujjawal Krishna	-Member
5.	Mrs. Akanksha Dubey	-Member
6.	Mrs. Vasundhara Kumari	-Member
7.	Dr.A.A. Mahdi	-Member
8.	Dr. Rajendra Nath	-Member
9.	Dr. Anita Rani	-Member
10.	Dr. Anupam Mishra	-Member
11.	Dr. Shally Awasthi	-Member-Secretary, IEC

The following Members were not present in the Meeting:

1.	Dr. Shubha R Phadke	-She has given her written comment
2.	Dr. D.N. Upadhayay	-He has given his written comment

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 118th ECM will be held on 17th September, 2022

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

<table>
<tr><th>IA</th><th>Action Taken</th></tr>
<tr><td>1-</td><td>Clarification of research proposal entitled "Measuring impact of COVID-19 pandemic at our Teaching Hospital in north India" submitted by Dr. Harish Gupta, Associate Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1211/MED/2022 dated 13th June, 2022.
Previous EC Comment:
• No sample size has been mentioned.
• If the study is using only anonymized patient data from OPD the PI may be encouraged to apply for IEC waiver.
• Very sketchy protocol
The above Comment forwarded to PI was reviewed by PR:-
Second opinion of PR:-
• The response is inadequate and does not answer the queries raised. Research proposal cannot be approved in its current form.
The above Second opinion was forwarded to PI –Reply is pending:-
Previous EC Decision:
• Dr. Harish Gupta to present his proposal in the Next EC Meeting.
EC Decision: Waiver approved for consent
Ref. code: 116th ECM IIA/P21</td></tr>
<tr><td>2-</td><td>Clarification of Additional document of research proposal entitled "Development of primary human microglial/astrocyte cell-based model for neurodegenerative diseases" sponsored by ICMR submitted by Prof. Shailendra Kumar Saxena, Head, Department of Centre for Advance Research, King George's Medical University, U.P., Lucknow vide letter no.615/CFAR/2022 dated 13th September, 2022.
<table>
<tr><th>Previous EC Comment</th><th>PI response</th></tr>
<tr><td>Patient information and ICF should include language/text compatible with the Patient understanding.</td><td>The patient information and ICF have been Modified as per the suggestions.</td></tr>
<tr><td>While annexure states that written consent will be obtained, the investigator has also Submitted reviewer waiver form.</td><td>The waiver form was attached mistakenly. Therefore, kindly ignore it.</td></tr>
<tr><td>What sorts of adverse event are anticipated in the study (as per the Annexure)?</td><td>There is no any adverse event expected related to the study (as per the annexure).</td></tr>
<tr><td>ICF should be renewed. For example, the compensation section should indicate Yes or No rather than irrelevant text. Moreover, the patient has right for his tissue to be included (or excluded) in the Study.</td><td>The ICF form has been renewed as per the Suggestions. The patient right has been Mentioned in annexure 7 section 5.</td></tr>
<tr><td>What are the criteria of sample size 100?</td><td>About 2-3 patients of traumatic brain injury undergo brain lobectomy per week</td></tr>
</table></td></tr>
</table>

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

		at the Department of Neurosurgery, KGMU. Hence on an average ~134 population size in a year. Therefore, n=100 (sample size) has been calculated with the confidence level of 95%.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:

- The right to participation is wrong and needs to be rectified.

EC Comment: As above

EC Decision: Approval subject to modification

Ref. code: 104th ECMIIA/P31

3- Clarification of research Protocol no. LRP/LUBT010/2016/008 entitled "***A global, phase-III, double blind, randomized controlled study to compare the efficacy, safety & immunogenicity of LUBT010 with lucentis® in patients with neovascular age-related macular degeneration***" sponsored by M/s Lupin Limited (Biotechnology Division) submitted by Prof. Sandeep Saxena, Department of Ophthalmology, K.G's Medical University, U.P., Lucknow vide letter no. 544/OPH/CT dated 11th July, 2022.

Previous EC Comment	PI response
ICF latest version 2.0 E/H and back	translation certificate not attached
DCGI cover letters and Notifications not attached	Response- DCGI cover letters and notifications were attached.
CTRI registration and draft CTA not attached	Response- These have been already shared and approved by EC as per EC approval letter (attached) dated 17Mar2021.
Insurance update certificate not attached	Response- As per the query, updated insurance attached for EC reference

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally Approved
The following documents were reviewed in the Meeting:-

1. Protocol LRP/LUBT010/2016/008 Version No.: 2.1, Dated 20 Apr 2021
2. SoC for Protocol No: LRP/LUBT010/2016/008; Version: 2.1, dated 20 Apr 2021
3. Investigator Brochure - Edition: 2.0, Dated 10 Jun 2021
4. Summary of Changes for Investigator's Brochure: Edition 2.0, 10 June 2021
5. Memorandum on Regulatory Submission and Approval of Protocol dated 12 Aug 2021

6a. Ranibizumab Protocol_LRPLUBT0102016008_V2.2_19May2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	6b. Ranibizumab_LRPLUBT0102016008_SoC_Protocol V2.2_19May2022 6c. Lupin_Protocol_LRPLUBT0102016008_V2.2_19May2022_Site 10523_Dr. Sandeep Saxena_PSP_29Jun2022 7a. Ranibizumab ICD SoC_V2.1_26May2022 7b. Main_V2.1IND(en)1.0_(23Jun2022) 7c. Main_V2.1IND(hi)1.0(23Jun2022) 7d. Translation Certificate for Hindi Dated 08Jul2022_Main_V2.1IND(hi)1.0(23Jun2022) 7e. Back Translation of Main_V2.1IND(hi)1.0(23Jun2022) 7f. Back Translation Certificate for Hindi Dated 08Jul2022_Back Translation of Main_V2.1IND(hi)1.0(23Jun2022) **EC Decision:** Approval subject to fulfillment of administrative formalities. ***Ref. code: 105th ECMIIC/P1***
4-	Clarification of research Protocol no.RLS/CNS/2020/01 Version 3.0 Dated 12 Nov,2020, entitled "***A prospective, multi-center, randomized, parallel group, two-arm, active control, open label, clinical study to evaluate efficacy and safety of Tenecteplasr/R-TPR-012(0.25mg/Kg) compared with acute ischemic stroke***" sponsored by Ahirubhai Ambani Life Sciences Centre submitted Dr. Imran Rizvi, Assistant Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no.379/Neuro/2022 dated 3rd August, 2022.

Previous EC Comment	PI response
The control arm also has the same drug (Tenectase). What is being tested, drug efficacy or dosage or new usage?	This trial compare two doses and two products for new indication. Presently RLS tenecteplase is approved for acute MI.
The study is supposed to be randomized but in the methodology the PI states that patients with up to 4.5hrs of ischemia time will be selected for both groups. This introduces bias. Please comment.	The comparator product chosen in this study is Tenectase which is to be administered within 3 hrs of onset of stroke. While RLS tenecteplase is proposed to be used within 4.5 hrs. In order to comply with randomization and also the time limit for dose administration we have designed randomization as follows: a) Randomization would be 2:1 (150 test , 75 reference) b) So there will be limit to maximum number of subjects that can get randomized to reference arm and subjects randomized to test arm would be more. It is likely

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

			that some of the patients would receive the drug at > 3 hrs to & it; 4.5 hrs c) Accordingly the following design will be followed and the bias would be prevented. So 150 subjects will be randomized exactly as per the randomization plan. Remaining 75 subjects would be those who receive the test product i9n 4.5 hrs. RANDOMIZATION PLAN IN TENECTEPLASE STUDY
		Tenecteplase is and established anti-thrombolytic agent. What is objective of study then? Is this a trial to find new usage of drug?	Yes
		Involvement of vulnerable participants is not mentioned. Please mention in IEC form.	RLS: Okay. (Vulnerable subjects will not be enrolled.)
		Numbers of subject in IEC form is given as 50 and in the methodology submitted to scientific review committee of department it is given as 225.	It's a typo error. Number of subject is 225.
		The parallel arm has the same drug (Tenectase) the justification for which has been asked from the PI.	This being a biological product and not a small molecule, it is appropriate to evaluate safety and efficacy of test and reference.
		Study is funded by private Indian pharmaceutical firm.	Yes, funded by Reliance life sciences pvt ltd.
		Informed consent mentions that there is only one study group- the one receiving the test drug. This has to be modified.	Please refer protocol page no. 76 of 106. "This is a two arm study. One arm will receive TenectaseTM (reference drug) which is approved in treatment of acute ischemic stroke. Other arm will receive study Drug {R-TPR-012, Tenecteplase (Tenecteplase manufactured by Reliance life sciences Pvt Ltd)} and your study doctor will know that you are receiving study Drug {R-TPR-012, Tenecteplase (Tenecteplase manufactured by Reliance life sciences Pvt Ltd)} or reference drug (TenectaseTM). Both the drugs contain active product called as

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	Tenecteplase."
Not given in consent form. Name and contact details of on- site PI/ Counselor must be mentioned in consent form.	Template has been provided in ICF which will be filled at site level.
Indirect identifiers/ coded in privacy & confidentiality.?	Confidentiality will be maintained. Each participant will be identified by unique subject ID.
Does the study involve a change in use of drug from Acute stroke? this has not been mentioned in IEC form.	No. As this drug will be used post regulatory approval only for acute ischaemic stroke (and for existing approved indication). Therefore such text has not been added.
The CTRI form does not have mentioned of KGMU site.	Will be added in new sites.
Roles of PI and Co.Inv's are overlapping.	Administrative point of view, PI can delegate his job to Co-I.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally Approved
The following documents were reviewed in Its Meeting:-

1. Clinical Trial Protocol (Protocol No.: RLS/CNS/2020/01 Version 3.0 Dated 12 Nov 2020)
2. Investigator's Brochure, Edition: 3.0, Release Date: 30 Mar 2020
3. Case Report Form for the study; Version 1.0 Dated 15 Mar 2021
4. DCG (I) Approval letter dated 04 Mar 2021
5. Draft Clinical Trial Agreement
6. Copy of Insurance Policy valid from 30 Aug 2020 to 29 Aug 2021
7. Patient Information Sheet and Informed Consent Form; Version 3.0, Dated 10 Mar 2021 in English
8. Patient Information Sheet and Informed Consent Form (PIS-ICF), Version 3.0, Dated 10 Mar 2021, translated from English to Hindi on 18 Mar 2021
9. Patient Information Sheet and Informed Consent Form (PIS-ICF), Version 3.0, Dated 10 Mar 2021, back translated from Hindi to English on 18 Mar 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	10. PIS-ICF - Translation Certificate – English to Hindi dated 18 Mar 2021 11. PIS-ICF Back Translation Certificate – Hindi to English dated 18 Mar 2021 12. Investigator Study Undertaking Dated: 20 Mar 2021 13. Investigator Consent Letter Dated: 20 Mar 2021 14. Investigator's Curriculum Vitae and Medical Registration Certificate 15. Other documents: STUDY QUESTIONNAIRES: a) Alberta stroke program early CT score (ASPECTS); Version 1.0, Dated 22 May 2020 b) Barthel Index of Activities of Daily Living; Version 1.0, Dated 22 May 2020 c) Modified Rankin scale (mRS); Version 1.0, Dated 22 May 2020 d) National Institutes of Health Stroke Scale; Version 1.0 Dated 22 May 2020 e) SF 36 Questionnaire; Version 1.0 Dated 22 May 2020 **EC Decision:** Approval subject to fulfillment of administrative formalities. ***Ref. code: 110th ECMIIC/P4***
5-	Clarification of research proposal entitled "***Mechanisms of autophagy-mediated cell survival in breast cancers and its implication in therapeutics and diagnostics***" submitted by Prof. M.L.B. Bhatt, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 944/RT/2022 dated 7th September, 2022. **Previous EC Comment:** • No patient information brochure. • The Hindi translation of title of the proposal is incorrect. ***The reply from PI to the above Comments were forwarded to PR:-*** ***Recommendation of PR:*** • Information about the project in English and Hindi should be simplified and to be written in an easy and understandable language. ***The above Comment forwarded to PI:- Reply pending*** ***Ref. code: 116th ECM IIA/P7***
6-	Clarification of research proposal entitled "***Evaluation of shear bond strength of composite resin, bonded to laser and bur prepared dentine surface using low level laser application before bonding***" sponsored by ICMR, New Delhi submitted by Dr. Vijay Kumar Shakya, Additional Professor, Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P.,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	Lucknow vide letter no. 229/Coms & Endo/2022 dated 23rd August 2022. **Previous EC Comment:** • Part 1 of the consent form has information. the second point - method of research/study in Hindi - the translation in not correct • दॉत - need to be written correctly. • स्वेच्छा - INCORRECTLY TYPED. • Hindi should be simple and of good quality. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Provisionally Approved **EC Decision:** Approved ***Ref. code: 116th ECM IIA/P8***
7-	Clarification of research proposal entitled "***Development of Indian TNBC patients-derived organoid (PDO) and xenograft (PDX) models to understand its therapeutic vulnerabilities***" sponsored by ICMR submitted by Prof. Dipak Datta, Head, Cancer Biology Division Central Drug Research, Co-PI Prof. Anand Kumar Mishra, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/279/2022 dated 30th August, 2022.

Previous EC Comment	PI response
No Informed Consent Form and Patient information sheet is attached for review	Informed consent form and patient information sheet attached for review please find the attached file.
Kindly provide required documents in local and English	Consent form in local and English attached. Please find the attached file.

The reply from PI to the above Comments were forwarded to PR:-
:-
Recommendation of PR:
- Again the Hindi and English consent forms are not similar, especially Procedure Part.

EC Comment: As above
EC Decision: Revise & resubmit

Ref. code: 116th ECM IIA/P16

8-	Clarification of research proposal entitled "***Management of ROCM: A clinico-radiological study- An institutional experience***" submitted by Dr. Rajat Jain, Assistant Professor, Department of Otorhinolaryngology, Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no.401/ENT/R/22 dated 22nd July, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

Previous EC Decision	PI response
The title has short form which is not explained. I do not know what is ROCM. On the page 11 of 13, the full form is mentioned. Rhino Oculo Cerbral Mucormycosis.	All the abbreviations used in this research proposal proforma have been explained under the heading "Abbreviation used'
5-vi-No answer about vulnerable subjects.	It is a retrospective study there will be no direct involvement of subject during the course of the study.
It is mentioned on point 8, that the written consent will be taken and patient information brochure is attached. But there is neither of them	Patients presented to us curing the epidemic of mucormycosis. All clinically and microbiologically confirmed cases were admitted and written informed consent was taken from each patient before surgery. Since the study is a retrospective analysis of data there is no requirement of consent forms. Hence not attached.
It is retrospective analysis of data. Please confirm if consent will be taken or not. If the answer is 'yes' provide appropriate document.	-----
It is mentioned that the patient will be directly benefited. How?	This is the first episode of mucormycosis epidemic all over India till date. No definitive management protocol has been established till date in the country. This is a single centre study. We have formulated management protocol which will benefit mucormycosis patients in for coming years.

The above comments forwarded to PI which was reviewed by Primary reviewer with following comments.

Second opinion of PR	PI response
Abbreviation should not be used in the title	The Title has been changed entitled *"Management of Rhino-orbito-cerebral mucormycosis (ROCM) : A clinic-radiological study- An institutional experience"*
Written consent for surgery is different from the written consent for participation of the study	Since this is the Retrospective study, consent for research purposes was taken alongwith consent for surgery. So, we are using the same consent for the study.
Management was done based on the protocol is helpful for the patient. But study is not benefitting the patient directly.	Mucormycosis epidemic happened during covid pandemic. Never before in the history of mankind such use mucormycosis patient have been dealt with. So no proper protocol was available in

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

		literature thus we have developed a protocol for management of patients of mucormycosis which will benefit forthcoming generations.
	The permission for the retrospective data analysis should be taken, Appropriate modifications in the application are needed.	The permission for data analysis was taken at the time of admission/ surgery.

The above reply from PI to the Comments was forwarded to PR:-

.

Recommendation of Primary reviewer:
Provisionally approved

EC Decision: Approved

Ref. code: 116th ECM IIA/P26

9- Clarification of research proposal entitled ***"Bone marrow metastasis in retinoblastoma: A retrospective study of hemato-morphological features"*** submitted by Dr. Geeta Yadav, Associate Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1123/22 dated 10th September, 2022.

Previous EC Comment:

- Sample size calculation missing.

The reply from PI to the above Comments were forwarded to PR:-
Recommendation of PR: Provisionally approved

EC Decision: Approved

Ref. code: 116th ECM IIA/P29

10- Clarification of research proposal entitled ***"Prevalence of Hepatitis B and Hepatitis C among IDUs of Lucknow"*** submitted by Prof. S.K. Singh, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 616/CM/22 dated 6th September, 2022.

Previous EC Comment	PI response
IDU- No full form given. Participants will be included from the hotspots.	Intravenous Drug Users Under syringe exchange program IDUs attend the target intervention sites (hotspots). Peer educators provide them with new needles and knowledge regarding safe Practices. With the help of these peer educators IDUs will be contacted and consent will be taken prior to sample collection.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

a) Why have I been chosen? b) What do I have to do?	1. Intravenous Drug Users (IDU) 2. IDUs age more than 18 years at the time of sample collection 3. IDUs taking drugs since at least 3 months 4. IDUs living in Lucknow for more than 3 months. Will have to give blood sample (5ml) for Hep B and Hep C testing. No other lifestyle or dietary restriction required by the study.
Dr Manish Manar	Working as Additional Professor (Junior grade) (B.Tech., M. Tech, PhD.) in Public Health Engineering in the Department of Community Medicine and Public Health, KGMU UP, Lucknow

The above Comment forwarded to PI reviewed by PR:-
Recommendation of PR:

- The replies are ok.
- But there were concerns about how the participants will be identified and selected. Whether the participants will give written consent? How the documentation of drug use will be done? Is it ok to go to the hot spots without police information?
- The participants will be included from the hotspots. They are not the ones who are coming to the hospitals. If the participant agrees to give written consent and give a sample then there are probably no issues. But the participants are drug addicts and I don't know if they will accept it and let it know to others unless they are into some reforms centre.
- **Will like others to give opinions.**

EC Decision: Approved if the study is from registered Deaddiction Centre.

Ref. code: 117th ECM IIA/P1

11- Clarification of research proposal entitled ***"Prevalence of iodine deficiency disorder among-6-12 years School Children of Uttar Pradesh"*** submitted by Prof. S.K. Singh, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 615/CM/22 dated 2nd August, 2022.

Previous EC Comment	PI response
How will the Parents be contacted? Why have I been chosen? What I have to do?	Information brochure explaining the objective of the study will be shared with the principal/head of the schools prior to the start of the study, to be given to the parents of the selected students for the consent. 1) Student enrolled in the selected school 2) Student fulfilling the age criteria. 3) Student who is present in the school at

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

		the day of sample collection. Will bring 1 Tsp (5gm) of salt from their respective home in the container provided to them. Will have to give urine sample (2ml) in the container provided to them on the sample collection day There are no other lifestyle restrictions or Dietary restriction related to this study.
	Dr Manish Manar	Working as Additional Professor (Junior grade) (B.Tech., M. Tech, PhD.) in Public Health Engineering in the Department of Community Medicine and Public Health, KGMU UP, Lucknow

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR: Provisionally approved
EC Decision: Approved

Ref. code: 117th ECM IIA/P2

12- Clarification of research proposal entitled ***"Evaluation of Her2Neu expression in periampullary carcinoma in tertiary care centre of northern India-A retrospective data analysis"*** submitted by Dr. Preeti Agarwal, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1095/22 dated 2nd September, 2022.

Previous EC Comment	PI response
Please clarify the budget	Zyto SPEC ERBB2/CEN 17 dual colour probe kit – (50ul) Pepsin Kit – Rs Buffer Total Rs 30,000 Rs 10,000 Rs 5000 Rs 45,000 The cost of the consumables will be borne by the investigators.
The secondary objective is to correlate the expression of Her2neu with survivals. Please give opinion if this can be considered as a part of retrospective study and suitability for waver of consent.	Secondary objective is deleted from the study.

The reply of the PI to the above Comments was forwarded to the PR:-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	Recommendation of PR: Provisionally Approved **EC Decision:** Approved ***Ref. code: 117th ECM IIA/P3***
13-	Clarification of research proposal entitled ***"Psychosocial analysis in patients with brachial plexus injury in a tertiary care Hospital of Northern India"*** submitted by Dr. Harsha Vardhan, Assistant Professor, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 859/22 dated 31st August, 2022. **Previous EC Comment:** • There are too many objectives. There should be one primary objective, and the rest can be covered in secondary objectives. Actual, other objectives would be side products of main objective. • The sample size calculation is missing. • How the items were generated for the questionnaire. Do they come from previous scales/ clinical observations/expert opinion/research findings/theory? • How the scale will be evaluated for internal consistency (reliability)? • Does the scale have face validity/ content validity/ construct validity? ***The reply of the PI to the above Comments was forwarded to the PR:-*** ***Recommendation of PR:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 117th ECM IIA/P9***
14-	Clarification of research proposal entitled ***"Randomized multi-center study to evaluate the efficacy of single versus double drains in breast cancer patients undergoing surgery"*** submitted by Dr. Pooja Ramakant, Professor Junior Grade, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/299/22 dated 9th September, 2022.

Previous EC Comment	Previous EC Decision
Title and primary objectives do not match. Title says: Randomized Multi-center study to evaluate the efficacy…..Primary objective says: To document the rate of seroma formation in both the groups.	Title: **'Randomized Multi-center study to evaluate the efficacy of single versus double drains in Breast Cancer Patients undergoing surgery'** Primary objectives have been modified to: **'To evaluate the efficacy of single versus double drains in Breast Cancer Patients undergoing surgery'** Secondary objectives - 1.To document the rate of seroma

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

		formation in both the groups. 2.To note down the number of days post surgery drain removal done in both the groups. 3.To document any surgical site infections in both groups. 4.To document hospital stays in both groups. 5.To compare the quality of life in both groups.	
	If it is really randomized multi-center study, all the pre-requisite should be mentioned properly. There are protocols for RCT. All those be properly defined	**RCT protocol has been attached along with this file** Once ethical approval is obtained, the project will also be registered in CTRI.	
	There are protocol/guidelines for Multi-center studies. All those should be mentioned.	An application for ethical approval has also been sent to the Institutional Ethics Committee of Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow.	
	Sample size calculation is arbitrary. It is ambiguous in the absence of proper research hypothesis.	Sample Size=79 Considering Prevalence of 36.4% as per study: *Ebrahimifard F. Effect of One versus Two Drain Insertion on Postoperative Seroma Formation after Modified Radical Mastectomy. Novel Biomed. 2016;4(2):45-50*, confidence level of 95% and margin of error of 5%. Formula used is- $n = \frac{z^2 \times \hat{p}(1-\hat{p})}{\varepsilon^2}$ $n' = \frac{n}{1+\frac{z^2 \times \hat{p}(1-\hat{p})}{\varepsilon^2 N}}$	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	where z is the z score ε is the margin of error N is the population size p̂ is the population proportion In this: z=1.96 (for confidence of 95%) ε=0.05 N=100 p=0.364 n= $(1.96^2 \times 0.364(1-0.364))/0.05^2$ = (3.8416 x 0.364 x 0.636)/0.0025 = 0.8893 /0.0025 =355.7383 n'= 355.7383/ (1+$(1.96^2$ x 0.364(1-0.364))/$(0.005^2$ x 100)) = 355.7383/ (1+(3.8416 x 0.364 x 0.636)/(0.0025 x 100) = 355.7383/ (1+ 0.8893/0.25) = 355.7383/ (1+ 3.5572) =355.7383/4.5572 =78.0607 So, sample size = 79
Statistical Analysis section is also very general, not specific to the study.	Data collected will be analyzed using SPSSv23 software. Student t-test will be used to compare two groups' weight, tumor weight, and number of lymph nodes involved, and Mann-Whitney test will be used to compare their cancer types. Comparison of volume of aspirated liquid during follow-up will be performed using Repeat Measure ANOVA. The significant level will be considered as less than 0.05.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:
Provisionally approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

EC Decision: Approved

Ref. code: 117th ECM IIA/P11

15- Clarification of research proposal entitled ***"Evaluation of efficacy of a paste of refined wheat flour and zinc oxide versus coloplast 2650 in skin care for pediatric patients who have undergone ileostomy or colostomy- A non-randomized controlled trial"*** submitted by Dr. Anand Pandey, Professor Junior Grade, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 641/PedSy/22 dated 29th August 2022.

Previous EC Comment	Previous EC Decision
The research is worth trying, because we need cost effective treatment modalities for our setups.	• Zinc oxide is a known agent which finds wide application in the cosmetic industry, which prevents and heals burns, is a non-irritant and is a skin healer and soother. Maida is another agent which is quite frequently used in cosmetic products, and is soft and inert. • Oral zinc supplementation may be beneficial in treating zinc-deficient leg ulcer patients. Topical administration of zinc appears to be superior to oral therapy due to its action in reducing superinfections and necrotic material via enhanced local defense systems and collagenolytic activity, and the sustained release of zinc ions that stimulates epithelialization of wounds in normozincemic individuals. Zinc oxide in paste bandages (Unna boot) protects and soothes inflamed peri-ulcer skin. (Ref: Lansdown, A.B.G., Mirastschijski, U., Stubbs, N., Scanlon, E. and Ågren, M.S. (2007), Zinc in wound healing: Theoretical, experimental, and clinical aspects. Wound Repair and Regeneration, 15: 2-16. https://doi.org/10.1111/j.1524-475X.2006.00179.x) • Zinc deficiency has been linked to delayed wound healing and low serum zinc levels have been reported in critically ill patients within Intensive Care Units. The benefits of supplemental zinc have been documented in critically ill patients, severe burn injury, subcutaneous abscess, minor surgery and pressure ulcers. The role zinc plays in wound healing can be viewed from two perspectives: first, the impact of zinc deficiency and second, the effect of zinc supplementation (topical/local or systemic) on wound repair. Treating zinc deficiency results in improved wound healing compared to those with zinc deficiency. For example, in patients considered to be at risk of refeeding syndrome, it may be appropriate to give a leading dose of 10-30 mg of Zn, followed by the daily maintenance dose of 2.5-5 mg. However, the impact of zinc supplementation on wound healing in patients without zine deficiency is less well known. There are very few well-done clinical studies on the topic and what little information currently available is inconsistent. For example, the Cochrane database reports 6 small studies on patients with arterial or Venous ulcers and found that oral zinc supplementation did not improve wound

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

			healing. Contrarily, another meta-analysis of topical zine therapy with zinc oxide paste-medicated dressing containing zinc concentration between 6-19% for chronic venous leg ulcers showed improved healing, though the authors point out that the studies were small and of sub-optimal quality Cereda and co-authors performed a randomized, prospective trial in malnourished patients with chronic pressure ulcers. They found a significant reduction in the size of the ulcers after 12 weeks of supplementation with a high calorie, high protein oral formula that was also supplemented with arginine, anti-oxidants and zinc (either orally or tube fed with 18-20 mg zinc daily). It is unknown how significant of a role the zinc supplementation played in this study. Attia and colleagues reported on 90 non-diabetic patients with uncomplicated wounds who were topically treated with one of two zine-containing fluids (regular crystalline insulin or aqueous zinc chloride solutions at 0.2 mg/100 ml. per 10 cm^3 wound) versus a control of 0.9% normal saline. The groups treated with the zinc-containing fluids had significantly improved healing. On the other hand, a study of 42 patients with pressure ulcers treated with oral L-camosine versus zinc containing polaprezine (at 34 mg per day) showed no difference in healing. It is clear that more studies utilizing more stringent controls will be necessary to fully understand the clinical potential of zinc supplementation. Due to the loss of zinc during injury, zine therapy has been used in wound care to enhance healing in zinc-deficient patients. Topical zinc sulphate (ZnSO4) application, usually at an optimal 3% concentration, has been widely used in wound healing for its antioxidant effect. Other forms of application include 1% ZnCl2 or the largely insoluble zinc oxide (ZnO) ZnO provides prolonged supply of zinc to wounds and enhance its healing ability. Additionally, ZnO increases collagen degradation in necrotic wounds. It has been shown that topical zinc application induces mRNA expression of metallothionein, which could account for its anti-UV photoprotective effect. A standard regimen for severe burn care includes regular daily dietary zinc supplementation equivalent or exceeding 22 mg. Moreover, recent advances in drug delivery with zinc oxide nanoparticle (ZnO-NPs) technology has received considerable attention for the treatment of wounds due to their effective cell penetration, immunomodulation and antimicrobial capacity. However, in-depth pharmacodynamics and toxicology studies are still needed prior to widespread applications. (Ref: Lin P-H, Sermersheim M, Li H, Lee PHU, Steinberg SM, Ma J. Zinc in Wound Healing Modulation. Nutrients. 2018; 10(1):16. https://doi.org/10.3390/nu10010016) • A combination of chitosan, polyvinyl alcohol (PVA) and Zinc oxide (ZnO) could be an effective option for faster healing of diabetic wounds due to the wound healing activities of chitosan-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

		PVA nanofibers and antibacterial properties of ZnO. The results revealed that chitosan/PVA/ZnO nanofibrous membranes possessed higher antibacterial potential against E. coli, P. aeruginosa, B. subtilis and S. aureus compared to chitosan/PVA nanofibrous membranes. Moreover, chitosan/PVA/ZnO nanofibrous membranes exhibited higher antioxidant potential compared to chitosan/PVA nanofibrous mats. The in vivo wound healing studies showed that chitosan/PVA/ZnO nanofibrous membranes resulted in accelerated wound healing as compared to chitosan/PVA nanofibers. The current study, revealed that chitosan/PVA/ZnO electrospun scaffolds could be effectively helpful in dressings for diabetic wounds. (Ref: Rashid Ahmed, Muhammad Tariq, Imran Ali, Rehana Asghar, P. Noorunnisa Khanam, Robin Augustine, Anwarul Hasan. Novel electrospun chitosan/polyvinyl alcohol/zinc oxide nanofibrous mats with antibacterial and antioxidant properties for diabetic wound healing. International Journal of Biological Macromolecules. 120(A);2018:385-393. https://doi.org/10.1016/j.ijbiomac.2018.08.057) There is significant biomedical potential of the effect of whole wheat flour solution as antioxidant wound coating for enhanced wound healing. The results show that the low concentration of whole wheat flour solutions have good biocompatibility and can scavenge radical and intracellular ROS in vitro, accelerating tissue remodeling in vivo to promote wound healing. This kind of whole wheat flour solution has great potential application for cutaneous wound repair. (Ref: Caihong Xian, Zhipeng Gu, Guiting Liu, Jun Wu. Whole wheat flour coating with antioxidant property accelerates tissue remodeling for enhanced wound healing. Chinese Chemical Letters. 31(6);2020:1612-1615.https://doi.org/10.1016/j.cclet.2019.09.011)
	Please provide adequate evidence to support success of application of Maida and ZnO combination, may be at any other area.	If the combination doesn't work, the patients will be then prescribed the expensive but proven treatment option Coloplast 2650. Although, no adverse effects are expected to happen due to the use of Maida and ZnO.
	If the combination does not work as expected, what would be the consequences?	We will do it as a pilot study, with 30 patients in each group.
	Sample size calculation must be given according to the known prevalence of cases of ILEOSTOMY or colostomy. Can be done as pilot study (30 in each group)	We will do it as a pilot study, with 30 patients in each group.
	Define outcome measures and include	**Wound Evaluation and Outcome Measurement:** Wound evaluation will

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	microbiological out comes.	include an examination and recording of wound characteristics, including wound size, as well as the results from microbiological wound culturing and standard wound imaging. We will apply transparent film dressing to the wound bed and outline the wound margin. The photographs of the films will be used to estimate the wound size d. At1 week, 1 month, 3 months and 6 months follow-up, percentage of wound size reduction will be calculated by the following formula: (baseline wound size- follow-up wound size)/baseline wound size × 100 (%). Wound healing is defined as complete epithelization of the wound by inspection. Wound evaluation and wound-healing outcomes will be examined and recorded at each visit. The skin complications will be graded as follows (to assess skin lesions, devised by Xavier ACM et al : Component / Score Active Excoriation / 0 to 10 Crust/ Bleeding / 0 to 10 Exulceration / 0 to 10 Linear Lesions / 0 to 10 Total Score / 0 to 40 Microbiological outcome measurement will not be a part of this study; rather it can be planned as a separate study. We also believe that not analyzing the microbiological outcome will make any difference to our study, as our goal is to study the excoriation due to the alkaline content of the gut, and not due to the microbiological flora of the gut, leading to the infection, which is actually secondary to the topic under discussion. Moreover, budget constraints are also binding to further expansion of the study.

The reply of the PI to the above Comments was forwarded to the PR:-

EC Comment:

- Provide QC of the proposed paste. Who will prepare it? Include Microbiology as a part of the study.

EC Decision: Approval subject to modification

Ref. code: 117th ECM IIA/P27

16-	Clarification of research proposal entitled ***"A multicentre prospective qualitative study on understanding the breast cancer and oral cancer patients"*** submitted by Dr. Pooja Ramakant, Additional Professor, Department of Endocrine Surgery, King George's

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

Medical University, U.P., Lucknow vide letter no. EndoSurg/270/22 dated 27th August, 2022.

Previous EC Comment	Previous EC Decision
Statistical methods to compare scores should be non parametric tests. Minor revision is needed.	I have made modifications accordingly in Methods section. "Non-parametric test will be used to test the difference in mean SRSSDL scores before and after the interactive session and between years of training.

EC Decision: Approved

Ref. code: 117th ECM IIA/P28

17- Clarification of research proposal entitled ***"A study to find the role of interactive session on self-directed learning in medical undergraduate and postgraduate students"*** submitted by Dr. Suyog Sindhu, Assistant Professor, Department of Pharmacology, King George's Medical University, U.P., Lucknow vide letter no. 544/Pharm/22 dated 20th August, 2022.

Previous PGTSC Comment	PI response
Statistical Methods to compare scores should be non parametric tests. Minor revision is needed.	I have made modification accordingly in methods section. "Non-parametric test will be used to test the difference in mean SRSSDL. Scores before and after the interactive session and between years of training"

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:
Provisionally Approved
EC Decision: Approved

Ref. code: 116th ECM IIA/P38

18- Clarification of research proposal entitled ***"Characterization and gene expression analysis of candida isolates from blood stream infection"*** submitted by Ms. Shivangi Tripathi, Ph.D Scholar 2020 under the guidance Prof. Gopa Banerjee, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 231/DST/CAND/22 dated 18th August, 2022.

Previous EC Comment	PI response
Budget column is crossed. It should be revised and give the detail of budget.	Self funded Research proposal. Amount: 85,000/-

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:
Provisionally Approved
EC Decision: Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

Ref. code: 117th ECM II B-Ph.D/P1

19- Clarification of research proposal entitled ***"Mechanistic analysis of host-protein crosstalks during JE neuropathogenesis and development of therapeutic and preventive interventions"*** submitted by Mr. Swatantra Kumar, Ph.D. Scholar under the guidance Prof. Shailendra Kumar Saxena, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/602/22 dated 29th August, 2022.

Previous EC Comment	PI response
1.Prof. Shailendra Kumar, Prof. A.K. Tripathi, and Prof. Rashmi Kushwaha are Co-PIs as well as doctoral committee members. This may involve conflict of interest. 2.The member secretary may take a call on this.	Prof. Shailendra K Saxena is my guide and Prof. AK Tripathi and Prof. Rashmi Kushwaha are Co-Guides (not the Co- PIs), hence they are the part of doctoral committee members (as per the KGMU). PhD programme Rules and regulations Section 3.3.4). Therefore, there would not be any conflict of interest.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 117th ECM II B-Ph.D/P8

20- Clarification of research proposal entitled ***"Pharmacological characterization of the neuroprotective properties of natural products against acute encephalitis syndrome"*** submitted by Mr. Vimal Kumar Maurya, Ph.D. Scholar under the guidance Prof. Shailendra Kumar Saxena, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/601/22 dated 29th August, 2022.

Previous EC Comment	PI response
Add in title in vitro neuroprotective	The title has been modified as "Pharmacological characterization (in vitro) neuroprotective properties of natural products against acute encephalitis syndrome"

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 117th ECM II B-Ph.D/P9

21- Clarification of research proposal entitled ***"Micro-RNAs and their target expression profiling in pregnancy miscarriage"*** sponsored by ICMR New Delhi submitted by Dr. Rajesh Kumar Jha, Associate Professor, Endocrinology Division CSIR-Central Drug

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

Research Institute, Lucknow Forwarded by Prof. Pushplata Sankhwar, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. 1942 dated 12th September, 2022.

Previous EC Comment	PI response
In SOP form PI ticked in the confidentiality column as NO –should be corrected.	In the SOP Form confidentiality column corrected and the files are attached for the further references.
In Inclusion criteria – Age matched women will be taken –Specific age group not mentioned.	The Inclusion criteria for this study are attached.
Exclusion criteria – not mentioned.	The Exclusion criteria for this study are attached.
Animal ethical clearance letter –if taken please attach (as Animals are also required in this study)	IAEC letter is attached.
Patient information sheet –Hindi translation missing –Please attach	Patient information sheets in Hindi and English are attached.
Technical approval letter for this fellowship study from ICMR, New Delhi not given– Please attach.	ICMR Technical approval letter for this fellowship are attached.
Budget for the project not mentioned.	MLP-2026

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:
Provisionally approved

EC Decision: Approved

Ref. code: 117th ECM II B-FS/P2

22- Clarification of research protocol entitled ***"A randomized, multicentre, double blind, placebo controlled, parallel-group, study to evaluate the efficacy and safety of linaclotide once daily of Dr. Reddy's laboratories limited in patients with chronic constipation"*** sponsored by Dr. Reddy's laboratories limited submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/24/2022 dated 24th August, 2022.

Previous EC Comment	PI response
PI has mentioned in point 10 that risks of doing this study are **not reasonable** compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed	As per your valuable comment please find enclosed the revised Annexure 07 copy after correction in section no. 10 for your kind perusal.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:

- Section 3 (ii) and 3(iv) are contradictory. If drug has not been approved elsewhere, it is an IND/ND.
- The total study duration needs to be mentioned.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

- Why use direct identifiers?

EC Comment:

- As above

EC Decision: Approval subject to modification and fulfillment of administrative formalities.

Ref. code: 117th ECMIIC/P2

23- Clarification of research protocol no. AKPL/FDC/AT/02/18 entitled ***"A phase III, multi-centre, double-blind, randomized, parallel-group, active-controlled trial to compare efficacy and safety of fixed dose combination of alfuzosin 10mg/10mg ER plus tadalafil 2.5mg/5mg tablets versus alfuzosin 10mg ER tablets in patients with lower urinary tract symptoms (LUTS) associated with benign prostatic Hyperplasia (BPH)"*** sponsored by Akums Drugs & Pharmaceuticals Limited submitted by Prof. Apul Goel, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. UR/CT/04/2022 dated 26th August, 2022.

Previous EC Comment	PI response
PI has mentioned In point 10 that risks of doing this study are not reasonable compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed.	As per your valuable comment please find enclosed the revised Annexure 07 copy after correction in section no.10 for your kind perusal.
Department Scientific Committee Head is Co-PI in one document, Senior Resident is Co-PI In another. Both conditions are not acceptable. Cannot be accepted for review.	As per your valuable comment please find enclosed the revised Scientific Committee Approval.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:

- Total study duration needs to be mentioned.
- Why use direct identifiers?
- Section 7 (ii) is incorrectly filled: blood and urine will be tested. Need to fill subsequent fields correctly.

EC Comment:

- As above

EC Decision: Approval subject to modification and fulfillment of administrative formalities.

Ref. code: 117th ECMIIC/P3

24- Clarification of research protocol no. QPT-ORE-006 entitled ***"A Phase 2, Double-blind, placebo-controlled, multicenter clinical trial comparing chemoimmunotherapy (Paclitaxel-carboplatin-oregovomab) versus chemotherapy (Paclitaxel-carboplatin-Placebo) as neoadjuvant therapy in patients with advanced epithelial ovarian, fallopian***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	tube or peritoneal carcinoma" sponsored by M/s Onco Quest Pharmaceuticals Inc submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/1464/2022 dated 31st August, 2022. ***The reply of the PI to the previous Comments was forwarded to the PR:-*** ***Recommendation of PR:*** • Need to have a clear policy statement on sending tissues out of the Country. The rest proposal is acceptable. **EC Comment:** • As above **EC Decision:** Approval is subject to modification and fulfillment of administrative formalities. ***Ref. code: 117th ECMIIC/P4***
25-	Clarification of research protocol entitled ***"A randomized, double blind, multicenter, parallel, placebo controlled clinical trial to assess the efficacy, safety and tolerability of antiviral drug umifenovir with standard care vs. standard care therapy in mild COVID-19 patients"*** sponsored by Midi Zest Pharmaceuticals Pvt. Ltd. submitted by Prof. V. Atam, Head, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/21/2022 dated 22nd August, 2022.

Previous EC Comment	PI response
PI has mentioned In point 10 that risks of doing this study are not reasonable compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed.	As per your valuable comment please find enclosed the revised Annexure 07 copy after correction in section no.10 for your kind perusal.
Department Scientific Committee Head is Co-PI in one document, Senior Resident is Co-PI In another. Both conditions are not acceptable. Cannot be accepted for review.	As per your valuable comment please find enclosed the revised Scientific Committee Approval

	The reply of the PI to the above Comments was forwarded to the PR:- ***Recommendation of PR:*** • Section 3 (ii) and 3 (iv) are contradictory. If the drug has not been approved elsewhere, it is IND/ND. **EC Comment:** • Mention study duration. **EC Decision:** Approval is subject to modification and fulfillment of administrative formalities. ***Ref. code: 117th ECMIIC/P5***
26-	Clarification of research protocol no. BRADPL/CT/FDC/AZM/03/30 entitled ***"A multi-center, double-blind, randomized, active-controlled, comparative, parallel-group, phase***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

III clinical study to evaluate the efficacy and safety of fixed dose combination of azelnidipine plus metoprolol succinate tablets in the treatment of subjects with stage 2 Hypertension" sponsored by M/s Akums Drugs & Pharmaceuticals Ltd. submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/23/2022 dated 22nd August, 2022.

Previous EC Comment	PI response
PI has mentioned In point 10 that risks of doing this study are not reasonable compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed.	As per your valuable comment please find enclosed the revised Annexure 07 copy after correction in section no.10 for your kind perusal.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:

- Statistician to comment on study design- extremely large number of arms. Statistical tests of significance for which arm/s versus which arm/s not specified.
- Information in Section 3 (iv) and DCGI certificate are contradictory.
- The total study duration needs to be mentioned.
- Why use direct identifiers?
- Section 7 (ii) is incorrectly filled: blood will be tested. Need to fill subsequent fields correctly.

EC Comment:

- As above

EC Decision: Approval subject to modification and fulfillment of administrative formalities.

Ref. code: 117th ECMIIC/P6

27- Clarification of research protocol entitled *"A pilot observation study to assess the role of centralized monitoring in general medicine wards"* sponsored by M/s Turtle Shell Technologies Pvt. Ltd. submitted by Dr. Ambuj Yadav, Assistant Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/22/2022 dated 22nd August, 2022.

Previous EC Comment	PI response
Will data be Anonimized	Undertaking is attached for the clarification.
How will you ensure that data will not be shared with third party.	Undertaking is attached for the clarification.
Get an Undertaking from the company.	Undertaking is attached for the clarification.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:
Approved
The following documents were reviewed in the Meeting:-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

Sl. No.	Document Type	Version	Date
1.	Proforma	-	30th June 2022
2.	Study Protocol	1	28th June 2022
3.	Case Record Forms	1	28th June 2022
4.	Patient Information Sheet (PIS) and Informed Consent Form (ICF) in English	1	25th June 2022
5.	Patient Information Sheet (PIS) and Informed Consent Form (ICF) in Hindi with the Certificate of Translation	1	27th June 2022
6.	Investigator's Brochure	1	28th June 2022
7.	Investigator's Undertaking	-	29th June 2022
8.	Investigator's Agreement with the Sponsor	-	30th June 2022
9.	Investigators' CVs	-	-
10	Medical Registration Certificate	-	-
11.	Trial Insurance Letter	-	30th June 2022
12.	Product Brochure	-	-
13	Product Manual (Instructions For Use)	-	-
14.	IEC 60601-1, 60601-1-11 Certificate	-	19th May 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	15.	CDSCO Registration Letter	-	3rd Nov 2021
	16.	ISO 13485 Certificate	-	20th May 2022
	17.	ISO 27001 Certificate	-	9th Dec 2021
	18.	List of Peer Reviewed Publications	-	30th Jun 2022
	19.	IEC Processing Fee Invoice	-	27th June 2022

EC Decision: Approval subject to fulfillment of administrative formalities.

Ref. code: 117th ECMIIC/P7

28- Clarification of research protocol no. LIB003-006 entitled ***"Randomized, double-blind, placebo-controlled, phase 3 study to evaluate the long-term efficacy and safety of LIB003 in patients with cardiovascular disease, or at high risk for cardiovascular disease, on stable lipid-lowering therapy requiring additional low-density lipoprotein cholesterol reduction (LIB Berate-HR)"*** sponsored by M/s LIB Therapeutics, LIC submitted by Dr. Akshayaya Pradhan, Additional Professor, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 281/Cardio/Res/2022 dated 2nd September, 2022.

Previous EC Comment	PI response
Section 3: Conflicting statements: If drug is approval for marketing worldwide, how come it's a IND/ND?	Ref. to annexure point 3 (ii)
DCGI approval not Attached	DCGI approval letter attached
Why use direct identifiers?	Ref. to annexure point 6
Section 7: Conflicting statements on biological material. Clearance letter to transport sample out of India not attached.	The approval for conduct of Clinical Trial released by CDSCO is sufficient for transportation of biological samples outside India. Please find enclosed Gazette notification No. 19 /2015-2020 S.O. 2612 (E) released by Directorate General of Foreign Trade dated 04.08.2016 for your perusal. We would like to quote the related regulation for your ready reference, "The import of human biological samples by the Indian diagnostic laboratories / Indian Clinical Research Centres for lab analysis / R & D testing or export of these materials to foreign laboratories should be permitted by Customs authorities at the port of entry / exit without prior approvals (import license / export permit) from any other Government agency." The study in reference is approved by CDSCO and will be conducted in compliance with laws and regulations applicable in

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

		India. As a process followed for all ongoing Clinical Trial an undertaking has to be submitted stating that we will follow all applicable procedures for safe transportation and disposal of biological samples. The Customs allow the transport of biological samples with the undertaking and CDSCO study approval is enclosed along with the undertaking. In addition to Gazette notification we are enclosing Annexure-A which is submitted to DCGI during online Regulatory application, it includes the justification for sample number & volume that will be exported to central laboratory. We would like to assure that the study will be conducted in compliance with laws and regulations applicable in India. Export NOC that was submitted to DCGI along with initial application for LIB006 study is attached herewith. The same was approved by DCGI on 11Nov2021 providing CT – NOC approval for study.
	Section 10: (ii) Is wrong.	Ref. to annexure point 10 (ii) No Risk.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:

- Reply to queries must be addressed directly, at least briefly, rather than redirecting to Annexure.
- Now that it is accepted that biological material is being transported, Section 7 (ii) is incorrectly filled.
- The Gazette Notification explicitly mentions "COMMERCIAL USE'. Is this a commercial activity or a research activity?
- There is no intervention which carries no discomfort.
- Again, IEC should make a clear policy statement on sending tissues out of the Country.

EC Comment:

- Transport of biological material out of the country will be after taking approval of competent National authorities.

EC Decision: Approval is subject to modification and fulfillment of administrative formalities.

Ref. code: 117th ECMIIC/P8

29- Clarification of research Protocol no. GLK-2101 entitled ***"A randomized, assessor-blind, placebo controlled, multi center, clinical endpoint bioequivalence study to compare the efficacy and safety of generic fluticasone propionate inhalation aerosol USP 44mcg (Glenmark Pharmaceuticals Ltd) to flovent HFA (Fluticasone propionate inhalation aerosol) 44mcg (GSK Group of Companies) in treatment of patients with bronchial asthma"*** sponsored by Glenmark Pharmaceuticals Ltd. B/2 Mahalaxmi Chamber submitted by Prof. R.A.S Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. RM/CT/05/2022 dated 25th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

August, 2022.

Previous EC Comment	PI response
PI has mentioned In point 10 that risks of doing this study are not reasonable compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed.	As per your valuable comment please find enclosed the revised Annexure 07 copy after correction in section no.10 for your kind perusal.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:

- Why use direct identifiers?
- Total study duration needs to be mentioned.
- Need to check if biological samples are being taken.

EC Comment:

- Kindly enumerate the direct identifiers being collected in the study.

EC Decision: Approval is subject to modification and fulfillment of administrative formalities.

Ref. code: 117th ECMIIC/P9

30- Clarification of research Protocol no. BSV-01-2021 entitled ***"A real world prospective study to evaluate the geographical distribution of prevalence, sensitization rate, and utilization of prophylactic treatment of Rh-negative women in India"*** sponsored by Bharat Serum and vaccine limited submitted by Prof. Rekha Sachan, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/CT/12/2022 dated 27th August, 2022.

Previous EC Comment	PI response
PI has mentioned In point 10 that risks of doing this study are not reasonable compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed.	As per your valuable comment please find enclosed the revised Annexure 07 copy after correction in section no.10 for your kind perusal.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR:

- Why use direct identifiers?

EC Comment:

- As above

EC Decision: Approval subject to modification and fulfillment of administrative formalities.

Ref. code: 117th ECMIIC/P10

31- Clarification of Modification of research protocol entitled ***"Multi-centric prospective cohort study of TB recurrence free cure among microbiologically confirmed new pulmonary tuberculosis patients treated under NTEP with the 4-Month moxifloxacin***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	containing daily regimen" submitted by Prof. Rajiv Garg, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. MOXI/2022/89 dated 7th September, 2022. **Previous EC Comment:** • Revised ICF to be submitted with earlier version tracking changes. ***A revised copy of ICF was submitted by the PI and was forwarded to the PR.*** ***Recommendation of PR:*** Provisionally Approved **EC Decision:** Approved ***Ref. code: 110th ECMIB/4***
32-	Research proposal entitled **"*Management of open fractures in tertiary care centre: an epidemiological, regional and comparative study of COVID-19 pandemic and non-pandemic phases*"** submitted by Dr. Ravindra Mohan, Assistant Professor, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 1931/OS/2022 dated 29th March, 2022.

Previous EC Comment	PI response
Submit ICF waiver form as it is a retrospective study	Attached Separately

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR: Provisionally Approved
EC Decision: Approved

Ref. code: 116th ECM IIA/P14

33- Research proposal entitled ***"Assessment of treatment outcomes for sebaceous cell carcinoma eyelid"*** submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1456/22 dated 30th August, 2022.

Previous EC Comment	PI response
1. Proper Research hypothesis should be defined after identifying the study variables and population parameters involved	This is an observational study on patients who have been already operated. We will study the treatment outcomes of our patients. Therefore, this study is not testing any hypothesis. The study variable and population parameters are described in the Case report form.
2.Study design is not clear. It says: single center, observation, retrospective case series study	We have used observational study design. There is no comparison group so it will be a descriptive study. It has retrospective time frame. Only patients from Surgical Oncology, KGMU will be studied.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	3: Sample size calculation is missing	This is a retrospective observational study, therefore formal sample size calculation was not done. The 30 patients which will be included in the study (from January 2017 to January 2022) are those which were treated in our department already.
	4: Statistical method section is very general, not specific to the study.	The descriptive statistic will be used to describe the data. Chi-square test will be used to see the association of categorical variables and t-test will be used for quantitative variables wherever necessary. Kaplan Meir statistics will be used to plot the survival curves.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR: Provisionally Approved
EC Decision: Approved

Ref. code: 117th ECM IIA/P15

34- Research proposal entitled ***"Assessment of treatment outcomes for carcinoma vulva"*** submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1455/22 dated 30th August, 2022.

Previous EC Comment	PI response
1.The status of vulnerable subjects need to be clarified	We apologize for the information which was missed previously submitted annexure 1. This has been clarified in the revised annexure 1 (point 5.VI)
2: What is the rationale of sample size of 65?	Proposed sample size of 65 is based upon the number of patients treated in the study period which is from January 2017 to January 2022.
3: This is labeled as a retrospective data analysis of 65 patients treated between 2017-2022 and requires estimation of survival (disease free and overall). Hence a Prospective arm of follow-up for 3-5 year need to be undertaken and patient examined for disease free status. Hence ethical approval may need a consent process to be incorporated as well.	The 65 patients which will be included in the study (from January 2017 to January 2022) are in the retrospective time frame. The analysis will be performed based upon the last follow up status as available in the departmental medical record till July 2022. This will make follow up ranging from 6 months to 65 months. And this will be sufficient for analyzing survival outcome of cancer patients. Our study has only retrospective arm (whatever follow up data available till July 2022) and there is no prospective collection of data. Therefore, we

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	requested for consent waiver.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR: Provisionally Approved
EC Decision: Approved

Ref. code: 117th ECM IIA/P16

35- Research proposal entitled ***"Assessment of treatment outcomes for esophageal cancer"*** submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1454/22 dated 30th August, 2022.

Previous EC Comment	PI response
The status of vulnerable subjects need to be clarified	We apologize for the information which was missed previously submitted annexure 1. This has been clarified in the revised annexure 1 (point 5.VI)
2: What is the rationale of sample size of 30?	Proposed sample size of 30 is based upon the number of patients treated in the study period which is from January 2017 to January 2022.
3: This is labeled as a retrospective data analysis of 30 patients treated between 2017-2022 and requires estimation of survival (disease free and overall). Hence a Prospective arm of follow-up for 3-5 year need to be undertaken and patient examined for disease free status. Hence ethical approval may need a consent process to be incorporated as well.	The 30 patients which will be included in the study (from January 2017 to January 2022) are in the retrospective time frame. The analysis will be performed based upon the last follow up status as available in the departmental medical record till July 2022. This will make follow up ranging from 6 months to 65 months. And this will be sufficient for analyzing survival outcome of cancer patients. Our study has only retrospective arm (whatever follow up data available till July 2022) and there is no prospective collection of data. Therefore we requested for consent waiver.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR: Provisionally Approved
EC Decision: Approved

Ref. code: 117th ECM IIA/P17

36 Minutes of the **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting held on 17th September, 2022 from 10:00 A.M. **(Non-DCGI)**

The following Members were present in the Meeting:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	1. Dr. Alok Dhawan -Chairman 2. Mr. Ujjawal Krishna -Member 3. Mrs. Akansha Dubey -Member 4. Mrs. Vasundhara Kumari -Member 5. Dr. Rajendra Nath -Member 6. Dr. Shally Awasthi -Member Secretary
	ADR of research protocol no. INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc. submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter nos.182/Cardio/Res/2022 dated 11th July, 2022. **Death** **Subject ID no. 010-0129** **Subject Initial:** A.K. **Gender:** F **Age:** 34 years **Patient starting date:** 27-10-2020 **Patient follow up under study:** **Randomization visit,** 1st Month, 6th Month, 12th Month, and every 6th Month till 5 year. **Weight:** 47 KG **Height:** 148 CM **Patient expired:** 6th April, 2022 **Patient History:** A letter was received in the office of the Ethics Committee on 12th July, 2022. The letter stated that SAE occurred on 6th April, 2022. Principal-Investigator telephonically called for a final follow up on 1st July, 2022 around 10.00 AM. LAR informed that **Subject expired on 6th April, 2022** around 12.30 PM at home. She developed breathlessness and chest pain. She was not hospitalized anywhere and they had called local physician for the evaluation. No Autopsy was done. **Death Certificate is attached.** ***Recommendation of Primary reviewer:*** • The SAE (death) doesn't appear to be related to the study. • The report mentions that no follow up was pending; whereas, the follow up

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	schedule mentions that follow up was planned till five years from the date of randomization. Please clarify. **ADR Sub-committee Comment:** As above **ADR Sub-committee Decision:** Approval subject to modification ***Ref. code: 83rd ECMIIC/P6***
37-	Minutes of the **"ADR Sub Committee"** of **"Institutional Ethics Committee"** Meeting held on 17th September, 2022 from 10:00 A.M. **(DCGI)** ***The following Members were present in the Meeting:*** 1. Dr. Alok Dhawan -Chairman 2. Mr. Ujjawal Krishna -Member 3. Mrs. Akansha Dubey -Member 4. Mrs. Vasundhara Kumari -Member 5. Dr. Rajendra Nath -Member 6. Dr. Shally Awasthi -Member Secretary
	Research Protocol no. CTQJ230A12301 entitled "***A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease***" sponsored by Novartis Health Care Pvt. Ltd. submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 224/Cardio/Res/22 dated 25th July, 2022. **Death** **Subject ID no. 1178-103** **Subject Initial:** R-M-V **Gender:** M **Age:** 58 years **Patient starting date:** 10-02-2022 **Patient follow up under study: Randomization visit,** 1st Month, 2nd Month, 3rd Month, 4th Month 5th, 6th Month, 9th Month, 12th Month, 15th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	Month, 18th Month, 21st Month, 24th Month, 27th Month and every three month Follow up till 4 year. **Weight:** 72 KG **Height:** 160 CM **Patient expired:** 25th May, 2022 **Patient History:** A letter was received in the office of the Ethics Committee on 26th July, 2022. The letter stated that SAE occurred on 25th May, 2022 around 06:00 AM. The letter mentioned that several times telephonic calls were made to remind the subject about the follow-up visit, but no reply was received. On 12th July, 2022, again a telephonic call was made by the principal investigator and the Subject's son received it. LAR (the son) informed that **Subject expired on 25th May, 2022 on the way to the hospital at around 06:00 AM.** Local practitioner declared him as dead. No Autopsy was done. **Death Certificate is attached.** ***Recommendation of ADR sub Committee:*** • SAE (Death) is likely due to disease outcome (Acute Coronary Syndrome / Non ST Elevation AWMI) as patient was enrolled in Treatment arm (given Intervention in the form of Pelacarsen-TQJ230 –A Lipoprotein lowering agent 80 mg monthly SC on 04th March, 2022 and 2 Months and 21 days has elapsed since taking the interventional drug. It has been told by LAR (subject's son) to PI that on 25th May, 2022, subject was not feeling well since morning, having breathlessness and was unable to move and expired on the way to hospital around 06:00 AM. • Causal relationship cannot be established as death occurs on the way to hospital and no autopsy was done. Death certificate is attached **ADR sub Committee Decision:** Noted ***Ref. code: 101st ECMIIC/P18***
IB	**Expedited review**
1-	Expedited review of research proposal entitled ***"Electronic capture and machine learning analysis of data pertaining to childhood tuberculosis form tertiary hospitals in India"*** submitted by Prof. Shally Awasthi, Head, Department of Pediatrics, K.G's Medical University, U.P., Lucknow vide letter no.2336/Ped/22 dated 5th August, 2022. ***The above proposal was forwarded to two reviewers:-*** Provisionally approved ***Recommendation of PR:*** • A scope of increasing the sample over 5000 (to enable training, testing and validation of machine learning) may consider if required in future but at the moment this seems fine as such.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	• Provisionally approved **EC Decision:** Approved ***Dr. Shally Awasthi did not take part in the discussion & making decision.*** ***Ref. code: 118th ECMIB/P1***
2-	ADE **(Hospitalization)** research protocol no. EGC002 entitled ***"A phase III, Randomized, multicenter, double-blind study to compare efficacy and safety of EG12014 (EirGenix-Trastuzumab) with Herceptin® as Neoadjuvant treatment in combination with anthracycline/Paclitaxel-based systemic therapy in patients with HER2-positive early breast cancer"*** sponsored by M/s Sun Pharma Laboratories Ltd. submitted by Prof. Anand Kumar Mishra, Department of Endocrine Surgery, K.G's Medical University, U.P., Lucknow vide letter no. ES/057/22 dated 7th September, 2022. **Patient ID: 910406** **Previous EC Comment:** • Please provide a follow-up report ***The reply of the PI to the above Comments was forwarded to the PR:-*** The SAE (Hospitalization) is possibly related to Investigational Product (EG 12014, Transuzumab or Herceptin as I.V. bolus every 3 weeks) or other Drug used in Cycle (Cyclophosphamide) for treating early breast cancer as told by PI in his initial and final reports. Subject developed severe abdominal pain for which she was hospitalized (SAE) on 25-10-2019 and given appropriate treatment and was discharged in stable condition on 27-10-2019 .Whether this SAE occurred due to intervention or not, has not been confirmed by doing any causality assessment test (e.g. Challenge and De-challenge test) and secondly almost one month has elapsed after getting Cycle 1 of interventional drugs (given on 25-09-2019) and occurrence of SAE. Causal relationship of SAE and drugs given (interventional and other drugs administered through Cycles as chemotherapy) cannot be established and moreover, patient at the time of event was given proper treatment and was discharged in stable condition, **therefore compensation may not be required in this SAE.** **(As this is an old SAE reported on 25th October, 2019 and details of ongoing Cycles to be given and follow-up reports are not available, therefore it is difficult to correlate the further events.)** **EC Decision**: Compensation may not be required in this SAE. ***Ref. code: 92nd ECM IIC/P3***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

IC	Brought forward from 117th ECM held on 30th July, 2022
	Action taken
1-	Clarification of research proposal entitled "***Randomized controlled trial to assess the feasibility of delivering psycho-social interventions and effectiveness in improving the common psychological problems of the non-clinical population: a multi-centric and multi-setting study from central India***" submitted by Dr. Amit Singh, Assistant Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 817/Psy/22 dated 16th June, 2022.

Previous EC Comment:	**PI response**
Calculation of sample size is not clear. It is mentioned that in total 173 cases will be recruited and in each group there will be 43 subjects. Why?	The estimated minimum sample size for the study is 170. Thus, in each of the 4 study settings (two general hospital settings and two community setting) around 43 participants will be required. Considering them to be divided equally into intervention arm and control arm we have proposed to recruit 22 participants in each arm.
In the setting of the study section it is mentioned that subjects will be recruited from Bhopal too. Which institution and who will be the Co-PI from there is not mentioned.	The details of the institution and Co-PI from Bhopal site are as follows:- **Name of the Institution:** All India Institute of Medical Sciences, Bhopal, Madhya Pradesh. **PI (Bhopal Site):** Dr. Snehil Gupta Assistant Professor, Department of Psychiatry, all India Institute of Medical Sciences, Bhopal (CV of the PI was submitted along with the study proposal)

The reply of the PI to the above Comments was forwarded to the PR:-
Second recommendation of PR:

- Kindly provide the consent of Dr. Snehil Gupta.
- Kindly provide the ethical clearance of AIIMS, Bhopal.

The reply of the PI to the above Comments was forwarded to the PR:-
Recommendation of PR: Pending

Previous EC Decision:

- Defer for the next Meeting because Primary reviewer was absent.

EC Decision: Approved

Ref. code: 116th ECM IIA/P28

2-	Expedited review of research proposal entitled ***"Evaluation of the urinary and serum biomarkers for acute kidney injury in patients admitted to the intensive care unit at the tertiary care centre"*** submitted by Dr. M.L. Patel, Professor,(Jr. Grade), Department of Medicine, K.G's Medical University, U.P., Lucknow vide letter no.1389/MED/2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	dated 15th July, 2022. **Previous EC Decision:** • Defer for the next Meeting because Primary reviewer was absent. ***The above research proposal forwarded to two reviewers.*** ***Recommendation of both Primary reviewers:*** Approved ***Ref. code: 117th ECM IB/P2***
3.	Research proposal entitled ***"To assess the clinical characteristics, inflammatory markers and co-morbidities of patients with obstructive sleep apnea with chronic obstructive pulmonary diseases"*** submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 757/22 dated 30th June, 2022. ***Recommendation of PR:*** • Sample size calculation not given. • Which inflammatory markers will be assessed is not mentioned in the methodology section. Moreover, where will they be assessed, and by which method? Although there are multiple Co-PIs none is from an investigating department • There are two Ph.D. scholars and one SR as Co-PI. Please check if they can be taken as Co-PIs. **EC Comment:** As above **EC Decision:** Revise & Re-submit with a tabular format ***Ref. code: 117th ECM IIA/P30***
4.	Research proposal entitled ***"Clinical course and outcome of electrical burn injury patients at tertiary care center. A single-center pilot study"*** submitted by Dr. Anshu Singh, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 617/22 dated 1st July, 2022. ***Recommendation of PR:*** • Objective No. 2 is not clear. • References missing **EC Comment:** As above **EC Decision:** Revise & Re-submit with tabular format. ***Ref. code: 117th ECM IIA/P31***
5.	Research proposal entitled ***"Buprenorphine transderma patch versus fentanyl transdermal patch for acute pain management in burn patients. A comparative study"*** submitted by Dr. Anshu Singh, Assistant Professor, Department of Plastic &

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 616/22 dated 1st July, 2022. ***Recommendation of PR:*** • References given in the text are not listed in the bibliography ((Jogdand et. al. & Arshad et. al.). **EC Comment:** As above **EC Decision:** Approval subject to modification with tabular format. ***Ref. code: 117th ECM IIA/P32***
6.	Research proposal entitled ***"Prospective study on Spectrum of Inhalation burn injury at a tertiary care center and role of prognostic factors and severity predictors in its management"*** submitted by Dr. Sandhya Pandey, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 613/22 dated 1st July, 2022. ***Recommendation of PR:*** • Which inflammatory markers will be assessed is not mentioned in the methodology section. Moreover, where will they be assessed, and by which method? Although there are multiple Co-PIs none is from an investigating department • Similarly where the biochemical parameters like carboxyhemoglobin and cyanide levels will be assessed and it methodology etc. is also not mentioned, **EC Comment:** As above **EC Decision:** Revise & Re-submit with tabular format. ***Ref. code: 117th ECM IIA/P33***
7.	Research proposal entitled ***"Use of HBOT for Limb salvageability and limiting the amputation level in electric burn injuries"*** submitted by Dr. Sandhya Pandey, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 615/22 dated 1st July, 2022. ***Recommendation of PR:*** • Sample size and study duration not clear. **EC Comment:** As above **EC Decision:** Revise & Re-submit with tabular format. ***Ref. code: 117th ECM IIA/P34***
8.	Research proposal entitled ***"Use of HBOT in improving outcome of electrical burn injuries-experience at a tertiary care burn center"*** submitted by Dr. Sandhya Pandey, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 614/22 dated 1st July, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	Recommendation of PR: • Approved **EC Decision:** As above ***Ref. code: 117th ECM IIA/P35***
9.	Research proposal entitled ***"Drug induce liver injury associated with treatment for COVID-19 (COVISILI): A nationwide study from India"*** submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1323/MED/22 dated 4th July, 2022. ***Recommendation of PR:*** • Approved **EC Decision:** As above ***Ref. code: 117th ECM IIA/P36***
II-A	**New Proposal**
1.	Research proposal entitled ***"Evaluation of changes in oral health profile, sensory acuity, emotional well-being and nutritional status of post-menopausal women: A pilot study"*** submitted by Dr. Vikram Khanna, Additional Professor, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 365/OMSR/2022 dated 18th July, 2022. ***Recommendation of Primary reviewer:*** • This is a prospective cohort comparative study. • Since this is a pilot study, sample size calculation is not required. • How the reliability and validity of the questionnaire shall be checked? • Statistical analysis section is very general. It should be specific to the study under consideration. **EC Comment:** • Consider using standardized questionnaires **EC Decision:** Approval subject to modification with tabular format ***Ref. code: 118th ECM IIA/P1***
2.	Research proposal entitled ***"To decipher the molecular role of IMP3 as a potential biomarker in chronic myeloid leukemia (CML) patients"*** submitted by Prof. Rashmi Kushwaha, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 896/2022 dated 18th July, 2022. ***Recommendation of Primary reviewer:*** • Aims and objectives are not specified. • Research hypothesis should be defined after properly identifying the study variables and parameters. • Study design is not clearly specified. It is simply written to be "prospective". • Sample size formula given is arbitrary.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	• In the absence of proper research hypothesis, everything (including sample size calculation, methodology and statistical analysis) is inappropriate. **EC Comment:** • As above **EC Decision:** Revise & Re-submit with tabular format ***Ref. code: 118th ECM IIA/P2***
3.	Research proposal entitled ***"Knowledge attitudes and practices in infection prevention and control at a tertiary care center"*** submitted by Prof. Rekha Sachan, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1547/22 dated 18th July, 2022. ***Recommendation of Primary reviewer:*** • There is no sample size calculation. • Please give the outline of evaluating reliability and validity of the questionnaire being used. • How the questionnaire will be assessed so as to be converted into a numerical score. • These numerical score can be used to judge the knowledge, attitude and practices among the different groups of participants. **EC Comment:** • As above **EC Decision:** Revise & Re-submit with tabular format ***Ref. code: 118th ECM IIA/P3***
4.	Research proposal entitled ***"Intelligent global surveillance of bacterial pathogens using whole genome sequencing through appropriate sampling and analysis in sentinel surveillance within strategically relevant countries (GHRU-NIHR)"*** submitted by Dr. Sheetal Verma, Associate Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 517/2022 dated 14th July, 2022. ***Recommendation of Primary reviewer:*** • The PI has applied for waiver since no patients/volunteers are being used. • The study is funded by Senger Institute; UK. No details of funding/original project details are attached. The foreign funding may kindly be discussed in the IEC meeting. • The MOU attached in the proforma is not signed. **EC Comment:** • Follow National guidelines for receiving International funding & provide evidence Indian samples cannot be used out of country without National consort or consort from KGMU. **EC Decision:** Revise & Re-submit with tabular format

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	Ref. code: 118th ECM IIA/P4
5.	Research proposal entitled ***"Retrospective study of effectiveness of hyper baric oxygen therapy (HBOT) in the management of COVID associated mucormycosis during COVID pandemic"*** submitted by Dr. Sandhya Pandey, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 682/2022 dated 21st July, 2022. ***Recommendation of Primary reviewer:*** • The project has one PI and four Co-PIs from the same department for a project which needs only retrospective data analysis. Please decrease the number of Co-PIs. • The sample size of 53 has not been statistically justified. • There is no comparison group/Control group to access the results of HBOT on the subject population. **EC Comment:** • As above **EC Decision:** Approval subject to modification with tabular format
	Ref. code: 118th ECM IIA/P5
6.	Research proposal entitled ***"Correlation of mitochondrial (mtDNA) DNA copy number with toxicity of heavy metals and pesticides in women with unexplained infertility"*** sponsored by ICMR, New Delhi submitted by Prof. Sujata Deo, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1631/2022 dated 26th July, 2022. ***Recommendation of Primary reviewer:*** • The sample size is mentioned differently at different place-150 in IEC form and 63/100+100 in the summary. **EC Comment:** • As above **EC Decision:** Approval subject to modification with tabular format
	Ref. code: 118th ECM IIA/P6
7.	Research proposal entitled ***"ICMR MYCONET inpatient clinical registry: establishment of an analytics platform"*** sponsored by ICMR, New Delhi submitted by Prof. Prashant Gupta, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 593/2022 dated 28th July, 2022. ***Recommendation of Primary reviewer:*** • The patient information sheet not related to the present research proposal should be revised.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	• PI ticked the written consent column in the IEC SOP form (HSRWF attached, as it is a data study) – Clarify or resubmit the IEC SOP form. • ICMR – acceptance letter and Budget not attached. **EC Comment:** • As above **EC Decision:** Approval subject to modification with tabular format ***Ref. code: 118th ECM IIA/P7***
8.	Research proposal entitled ***"Effect of natural protein powder on lean muscle mass and body fat with resistance training: A randomized controlled trial"*** sponsored by DHR, New Delhi submitted by Prof. Dileep Kumar Verma, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2622/PHY/2022 dated 28th July, 2022. ***Recommendation of Primary reviewer:*** • Study design –RCT- CONSORT guidelines not followed Method of randomization , blinding, sample size calculation not mentioned). • Sample size calculation not done. • From where PI will recruit the subjects (Which OPD/IPD etc.) –Please clarify. • Where and how resistance training will be done and monitored (assessed). • Scientific literature of Plant based powder (including Pumpkin seeds)-should be attached. If it is nutritional supplement, whether its FSSAI and GMP approved product? –please specify. • Who will assess the nutritional value of the powder by HPLC –Please clarify. • In Inclusion / Exclusion criteria- Pregnant and lactating mothers not mentioned (as PI will recruit the subjects of either sex). Control group details about Inclusion / exclusion criteria not given. Food frequency questionnaire – not attached. **EC Comment:** • As above **EC Decision:** Revise & Re-submit with tabular format. ***Ref. code: 118th ECM IIA/P8***
9.	Research proposal entitled ***"Effect of restriction of blue light exposure at night on anthropometric, biochemical and cognitive function: A randomized controlled trial"*** sponsored by DHR, New Delhi submitted by Prof. Narsing Verma, Head, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2621/PHY/2022 dated 28th July, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	• From where PI will recruit the subjects (Which OPD/IPD etc.) –Please clarify. • In Inclusion / Exclusion criteria- Control group details not given. • The patient information sheet is general (not research study related) – please revise. **EC Comment:** • As above **EC Decision:** Approval subject to modification with tabular format ***Ref. code: 118th ECM IIA/P9***
10.	Research proposal entitled ***"Frequency of campylobacter jejuni and coli in Children under five years with diarrhea/dysentery admitted in tertiary care Hospital"*** sponsored by DHR- ICMR, New Delhi submitted by Dr. Sunita Singh, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 598/2022 dated 28th July, 2022. ***Recommendation of Primary reviewer:*** • Hindi consent form not properly typed • The primary reviewer could not find the English version of the consent form. • The language of objectives needs minor corrections. **EC Comment:** • As above **EC Decision:** Revise & Re-submit with a tabular format. ***Ref. code: 118th ECM IIA/P10***
11.	Research proposal entitled ***"Development of 'app-based Cognitive Behavioural Intervention Program' for the management of problematic internet use among adults"*** sponsored by ICMR, New Delhi submitted by Dr. Shweta Singh, Professor Junior Grade, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1047/Psy/2022 dated 27th July, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approved ***Ref. code: 118th ECM IIA/P11***
12.	Research proposal entitled ***"A pilot study on therapeutic Hypothermia for inborn neonates with moderate to severe hypoxic ischemic encephalopathy in a tertiary care center of a lower middle income country"*** submitted by Prof. Mala Kumar, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2177/Ped/2022 dated 20th July, 2022. ***Recommendation of Primary reviewer:*** **EC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	• Consent forms need correction as consent will be taken from the parents/guardians of the neonates. **EC Decision:** Revise & Re-submit with a tabular format. ***Ref. code: 118th ECM IIA/P12***
13.	Research proposal entitled ***"Comparison of gut microbiota of Pediatric non-alcoholic fatty liver disease and non-alcoholic steatohepatitis cases to healthy children gut microbiota"*** sponsored by DHR-MRU submitted by Dr. Sanjeev Kumar Verma, Additional Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2205/Ped/2022 dated 23rd July, 2022. **EC Decision:** Approved ***Ref. code: 118th ECM IIA/P13***
14.	Research proposal entitled ***"Effect of circadian synchronization of metabolism on sign and symptoms associated with subjects of polycystic ovarian syndrome"*** sponsored by DHR submitted by Prof. Sandeep Bhattacharya, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2625/PHY/2022 dated 29th July, 2022. **EC Decision:** Approved ***Ref. code: 118th ECM IIA/P14***
15.	Research proposal entitled ***"Association of oral lichen planus with mental health status and role of behavior therapy on its management and relapse: A clinical comparative study"*** sponsored by DHR submitted by Dr. Vandana Singh, Additional Professor, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 408/OMSR/2022 dated 4th August, 2022. **EC Comment:** • What will be knowledge added by this work? **EC Decision:** Approved ***Ref. code: 118th ECM IIA/P15***
16.	Research proposal entitled ***"Efficacy and safety of intravitreal zybev (Biosimilar of Bevacizumab) in patients with macular edema due to retinal diseases"*** submitted by Prof. Sanjiv Gupta, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 545/OPH/2022 dated 12th July, 2022. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 118th ECM IIA/P16***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

17.	Research proposal entitled ***"Effectiveness of HBOT as an adjunct in the treatment of sensory neural hearing loss"*** submitted by Dr. Sandhya Pandey, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 763/2022 dated 5th August, 2022. ***Recommendation of Primary reviewer:*** • Most of the statements in the methodology section are phrased in past tense. It gives an impression that work has been done already. Kindly clarify or rectify. • Kindly provide details of all parameters to be studied. • Kindly provide sample size calculation. • ICF: procedure need to be explained in simple language. **EC Comment:** As above **EC Decision:** Revise & Re-submit with a tabular format. ***Ref. code: 118th ECM IIA/P17***
18.	Research proposal entitled ***"Practice pattern of aerosol therapy in critically ill patients (AERO-IN ICU)"*** submitted by Dr. Sai Saran, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/641/2022 dated 17th August, 2022. • Approved **EC Decision:** As above ***Ref. code: 118th ECM IIA/P18***
19.	Research proposal entitled ***"Laryngotracheal and upper airway symptoms due to mechanical ventilation after orotracheal intubation in critically ill patients- A prospective multi-centre cohort study"*** submitted by Dr. Saumitra Misra, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/615/2022 dated 8th August, 2022. ***Recommendation of Primary reviewer:*** • Kindly mention the names of other centers if this is a multi-centric study period. • Regarding the secondary objective of assessment of quality of life kindly justify the assessment of quality of life issue without using any quality of life assessment tool. • Kindly include sample size calculation formula if possible period. • In Annexure-1 it is stated that 'collection of banking or future research' will not be applicable but in consent section it is clear that the 'consent for future use of biological material' will be obtained: Kindly resolve the discrepancy period. • Kindly add a brief account on anticipated outcomes and statistical analysis process.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	EC Comment: • As above **EC Decision:** Approval subject to modification with a tabular format. ***Ref. code: 118th ECM IIA/P19***
20.	Research proposal entitled ***"Delineate molecular mechanism in development of chemo-resistance in non-Hodgkin's lymphoma"*** sponsored by Regional Centre for Biotechnology submitted by Prof. Seema Gupta, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 899/RT/2022 dated 24th August, 2022. ***Recommendation of Primary reviewer:*** Many facts need to be justified • The duration of study is three years in annexure 1 while in methodology section it is five years extendable for two more years. According to CDRI approval it is for one year- why this confusion? • In annexure 1 a. While "collection for banking future research' clause states "NO", the investigator further states that consent for future use of material biological will be obtained- Why this confusion? b. Information sheet needs to be attached both for patients and controls (which is missing) c. While data monitoring states that there is no plan for reporting adverse events, the IEC approval of CDRI states that the investigator should report serious adverse events within 24 hours- kindly clarify period. • Regarding the names of investigators: a. Kindly clarify/ rectify if they are collaborators or guides/ co-guides? b. Dr Sanjeev Kumar and Dr Sunil Kumar will perform surgery: Kindly clarify if Biopsy alone will be done or some other surgical procedure. c. Since immuno-histochemistry needs to be done it will be more appropriate to add a pathologist as a part of team. • The title pertains to non-Hodgkin's lymphoma while introduction, review and study. • Population focuses on mantle cell lymphoma (MCL). Kindly clarify if only MCL is the focus of study or non-Hodgkin's lymphoma as whole as reflected in inclusion criteria. In latter case the relevant review needs to be incorporated as well. • The aim states that pathways will be targeted. Is the word target reflects just identification or something more period. • Kindly justify sample size calculation. • Add consent form for Controls.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	• Regarding sample transportation where does SGPGI come in picture: kindly explain? • If clinic pathological features are to be recorded then enclose clinical observation Protocol. In addition, what is meant by 'rest of data': please clarify? • Mention potential risks and benefits. • Outcome measures should also be briefed. • Anticipated statistical analysis can also be briefed. • Also state if this is of any national significance. • The contact details of investigator are missing on first page of informed consent form. • How will the budget of 40 lakhs be utilized? Kindly clarify. **EC Comment:** • As above **EC Decision:** Revise & Re-submit with a tabular format. ***Ref. code: 118th ECM IIA/P20***
21.	Research proposal entitled ***"Identification of molecular therapeutic target leading to development of chemo-resistance in non-GC DLBCL patients in India"*** sponsored by American Society of Hematology submitted by Prof. Seema Gupta, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 912/RT/2022 dated 26th August, 2022. ***Recommendation of Primary reviewer:*** Many facts need to be justified: • The duration of study is three years in the annexure while further extendable for one year in the methodology section but only one-year approval in CDRI IEC – kindly make it more clear. • In annexure 1 a. While "collection for banking future research' clause states "NO", the investigator further states that consent for future use of material biological will be obtained- Why this confusion? b. Information sheet needs to be attached both for patients and controls (which is missing) c. While data monitoring states that there is no plan for reporting adverse events, the IEC approval of CDRI states that the investigator should report serious adverse events within 24 hours- kindly clarify the period. • Regarding the names of investigators: a. Kindly clarify/ rectify if they are collaborators or guides/ co-guides? b. Dr Sanjeev Kumar and Dr Sunil Kumar will perform surgery: Kindly clarify if biopsy alone will be done or some other surgical procedure.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	c. Since Immuno Histochemistry needs to be done it will be more appropriate to add a pathologist as a part of team. • Kindly clarify if only DLBCL will be included or all B-NHL as mentioned in inclusion criteria. • Kindly mention: a. What are the anticipated molecular features associated with clinical outcomes? b. What will be the source of healthy B-cells? Will it be from controls? Mention briefly about bioinformatic analysis/ approach if possible. c. Kindly quote full form of CRISPB approach • Kindly justify sample size calculation. • Add consent form for Controls (if applicable). • Regarding sample transportation where does SGPGI come in picture: kindly explain. • If clinicopathological features are to be recorded then enclose clinical observation Protocol. In addition what is meant by 'rest of data': please clarify? • Mention potential risks and benefits. • Outcome measures should also be briefed. • Anticipated statistical analysis can also be briefed. • Also state if this is of any national significance. • The contact details of investigator are missing on first page of informed consent form. • It is mentioned that US$150,000 will be the budget: so will some part of this budget be diverted for KGMU? kindly clarify **EC Comment:** • As above **EC Decision:** Revise & Re-submit with a tabular format. ***Ref. code: 118th ECM IIA/P21***
22.	Research proposal entitled ***"The Physical and psychological aspects of caregiving relatives in intensive critical units (ICUs)"*** submitted by Dr. Armin Ahmed, Associate Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/692/2022 dated 29th August, 2022. ***Recommendation of Primary reviewer:*** • This project can be approved. However the convenience sample of 50 may be extended if needed for a meaningful conclusion. **EC Decision:** Approved ***Ref. code: 118th ECM IIA/P22***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

23.	Research proposal entitled ***"Etiology of anemia among critically ill obstetric patients admitted to intensive care unit of a tertiary care center"*** submitted by Dr. Armin Ahmed, Associate Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/693/2022 dated 29th August, 2022. ***Recommendation of Primary reviewer:*** • Hindi translation of the title needs improvement to make it understandable easily. • The PID should be for guardian as well as some patients being very seriously ill may not be able to give the consent. **EC Comment:** • As above **EC Decision:** Approval subject to modification with a tabular format. ***Ref. code: 118th ECM IIA/P23***
24.	Research proposal entitled ***"Randomized comparison of I-gel, baska mask, ambu aurgain and laryngeal mask airway protector for airway management of patients with anticipated difficult airway"*** submitted by Dr. Rati Prabha, Assistant Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1107/2022 dated 31st August, 2022. ***Recommendation of Primary reviewer:*** • SADs comparison • Are these devices routinely used? Are there any situations about the specific use of each type? • What are the standard guidelines? What are the protocols in KGMU ICU? • Separate PID is not there. The information is in the consent form only. Is it ok? **EC Comment:** • As above **EC Decision:** Revise & Re-submit with a tabular format ***Ref. code: 118th ECM IIA/P24***
II-B	**Young Scientist**
1.	Research proposal entitled ***"To decipher the role of miRNAs and their potential mechanism of molecular targets in pregnancy associated with pre-eclampsia and its relation to clinicopathological variables"*** sponsored by DHR-ICMR submitted by Ms. Ummehani Siddiqui under the guidance Prof. S.P. Jaiswar, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1694/22 dated 2nd August, 2022. **EC Decision:** Approved ***Ref. code: 118th ECM II B-YS/P1***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

II-C	Review of New Drug Trial
1.	Research protocol no. AVT06-GL-C01 Version: Version 2.0,21 December 2021 entitled ***"A randomized, double-masked, parallel-group, multicenter clinical study to evaluate the efficacy and safety of AVT06 compared with EU-Eylea® in subjects with neovascular (Wet) age-related macular degeneration (ALCOEYE)"*** sponsored by M/s Alvotech Swiss AG Thurgauerstrasse submitted by Prof. Sandeep Saxena, Department of Ophthalmology, King George's Medical University, U.P., Lucknow, vide letter no. 651/OPh/2022 dated 29th July, 2022. ***Recommendation of Primary reviewer:*** • Two Co-PIs are SRs. Not acceptable according to University Guidelines. • PI has mentioned in point 10 that risks of doing this study are not reasonable compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed. **EC Comment:** • Remove SR as Co-PI. • In point 10, you have mentioned that risk of the study. **EC Decision:** Approval subject to modification & fulfillment Administrative formalities. ***Ref. code: 118th ECMIIC/P1***
III	**Modification**
1.	Modification of research protocol ***"Post COVID-19 sequelae registry (PCSR)"*** submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 850/Resmed/2022 dated 26th July, 2022. ***Recommendation of Primary reviewer:*** • List of changes in the amendment - seen. Does not seem to be any problem. **EC Decision:** Approved ***Ref. code: 117th ECM IIA/P6***
2.	Modification of research protocol no.GO42784 entitled ***"A phase III, randomized, open-label, multicenter study evaluating the efficacy and safety of adjuvant giredstrant compared with physician's choice of adjuvant endocrine monotherapy in patients with estrogen receptor-positive, HER2-negative early breast cancer"*** sponsored by M/s F. Hoffmann-La Roche Ltd. submitted by Prof. Anand Kumar Mishra, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ES/055/2022 dated 25th August, 2022. ***The following documents were reviewed in the Meeting:*** **Sr. No.** | **Document/Language** | **Version No. and Date**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	1.	Protocol Clarification Letter	02Feb2022
	2.	lidERA Study Patient Engagement Content_Onboarding survey_English_Hindi_	Version 1.0 27Dec2021 Translation Certificate Attached
	3.	lidERA Study Patient Engagement Content_ Device Labels_English	En-US_Version 1.0
	4.	lidERA Study Patient Engagement Content_ Device Labels_Hindi	Hi-IN_Version 1.0 04Nov2021 Translation Certificate Attached
	5.	lidERA Study Patient Engagement Content (Notifications, SPFQ, Quick Reference Guide, Announcements, Articles) _English	Version 1.0_27Oct2021
	6.	lidERA Study Study Core App Screenshots_English	Version 2.0_09Nov2021
	7.	lidERA Study Study Core App Screenshots_Hindi	Version 1.0_06Apr2022 Translation Certificate Attached
	8.	Protocol Clarification Letter	Dated 08Nov2021
	9.	Protocol Clarification Letter	Dated 23Dec2021
	10.	lidERA Study Study Core App Screenshots_English	Version 2.0_09Nov2021

EC Decision: Approval is subject to fulfillment of administrative formalities.

Ref. code: 115th ECM IIC/P2

IV **Other Matter**

1- Request to change the title & some modification submitted by Mr. Mukul Kumar Singh, Ph.D Scholar under the guidance of Prof. Vishwajeet Singh, Department of Urology, K.G's Medical University, U.P., Lucknow vide letter no.432/URO dated 11th August, 2022.

Previous title	Current title
Impact of BCG Failure on FGFR3, TP53 gene and blood metabolite alteration in non-muscle-invasive bladder cancer.	Role of FGFR3, TP53 genes and blood metabolites alteration in BCG failure Non-Muscle invasive bladder cancer.
Modification	
Exclusion criteria-Past or current smoking history.	Inclusion Criteria: Past or current smoking history.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	EC Decision: Approved
2-	Request to approve the research work on ***Channa punctatus, an edible fish*** of Ph.D. scholar Mr. Ramesh Mani Tripathi under the guidance of Prof. A.A. Mahdi, Head, Department of Biochemistry, KGMU UP, Lucknow without ethical approval as the edible fish is not an endangered species. **EC Decision:** This is out of the scope of the human Ethics Committee
V	**Brought to Ethics Committee after X-PGTSC held on 19th May, 2022**
	Minutes of XII **"PG Thesis sub Committee"** Meeting of "Institutional Ethics Committee" ***virtually*** held on 9th September, 2022 from 2.30 PM. ***The following Members were present in the Meeting:-*** 1. Dr. G.G. Agarwal -Member 2. Dr. Rajendra Nath -Member 3. Dr. A.A. Mahdi -Member 4. Dr. Shally Awasthi -Convener ***The following Members could not present in the Meeting:-*** 1. Dr. D.N. Upadhyaya -He has given his written comment 2. Dr. Anita Rani Singh -She has given her written comment
IA	**Action Taken**
1-	Clarification of research proposal entitled ***"Changing etiological profile of paediatric acute liver failure in the era of viral hepatitis immunization in northern India: A prospective observational study"*** submitted by Dr. Stuti Shukla, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2231/Ped/22 dated 25th May, 2022.

Previous PGTSC Comment	PI response
Lab. Methodology of all parameters has to given.	In response to the comment made by ethical committee, Table for methodology of all parameters is attached below.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: III PGTSC-IIA/P23

2-	Clarification of research proposal entitled ***"Expression pattern of MUC1 and MUC4 in (OPMD) oral premalignant disorders and oral squamous cell carcinoma (OSCC) and normal oral mucosa in an attempt to analyze its role played in oral carcinogenesis"***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Sharon John, JRI, Through her Mentor Prof. Shalini Gupta, Department of Oral Pathology & Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 840/OP/22 dated 24th August, 2022.

Previous PGTSC Comment	PI response
There are 6 Co-PIs -(2 from Oral Pathology & Microbiology apart from Chief Guide + 2 from Oral and Maxillofacial Surgery) with almost similar roles - please justify	The role of 4 Co-PIs is justified and to be included in the project further.
As all age gp patients will be recruited in the study therefore, Guardian and child Assent form is also needed apart from general ICF, which has not been submitted.	It has been attached here within
Study design not mentioned	Study design has been mentioned
SOP Form not filled completely -	should be revised

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: IX-PGTSC-II B IMR-R/P2

3- Clarification of research proposal entitled "***A comparative evaluation of efficacy of Different irrigants on smear layer in root canals of deciduous teeth with conventional irrigation Vs. passive ultrasonic irrigation: An in-vitro SEM study***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Alisha S. Jadhav, JRI, Through her Mentor Dr. Richa Khanna, Prof. Jr. Grade, Department of Paediatric and Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Ped/362/22 dated 10th August, 2022.

Previous PGTSC Comment	PI response
1) SEM in the title should be	A Comparative Evaluation of Efficacy of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	expanded/elaborated	Different Irrigants On Smear Layer In Root Canals of Deciduous Teeth with Conventional Irrigation Vs. Passive Ultrasonic Irrigation : An In-vitro Scanning Electron Microscopy Study
	2) Literature regarding use of Morinda citrifolia as irrigant should be submitted	1) Chandwani M, Mittal R, Chandak S, Pimpale J. Effectiveness of Morinda citrifolia juice as an intracanal irrigant in deciduous molars: An in vivo study. Dental Research Journal. 2017 Jul;14(4):246. 2) Murray PE, Farber RM, Namerow KN, Kuttler S, Garcia-Godoy F. Evaluation of Morinda citrifolia as an endodontic irrigant. Journal of endodontics. 2008 Jan 1;34(1):66-70. 3) Saghiri MA, García-Godoy F, Asgar K, Lotfi M. The effect of Morinda Citrifolia juice as an endodontic irrigant on smear layer and microhardness of root canal dentin. Oral Science International. 2013 May 1;10(2):53-7.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: IX-PGTSC-II B IMR-R/P4

4- Clarification of research proposal entitled ***"Comparative evaluation of the nasal cavity and pharyngeal airways in cleft LIP and palate individuals with normal subjects- A cone beam computed tomography study"*** submitted by Dr. Mehak Dobhal, JRII, Department of Orthodontics and Dentofacial Orthopaedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 890/22 dated 16th August, 2022.

Previous PGTSC Comment	PI response
Aims and objectives are stated in two different statements. These statements should be combined to make it "comparative study".	To evaluate Nasal cavity and Pharyngeal airway spaces in patients affected by Cleft lip and palate and compare them with normal subjects.
Research hypothesis is missing.	**RESEARCH HYPOTHESIS:** The purpose of this study is to evaluate Nasal cavity and Pharyngeal airway spaces in patients with cleft lip and Palate and compare them with

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

		Normal subjects. To study if there exists a difference in Nasal cavity and Pharyngeal airway spaces between unilateral ,bilateral Cleft patients and Normal subjects Since cleft Lip and Palate patients have a compromised Airway and Nasal Cavity and most commonly require Maxillary expansion and orthognathic Surgeries which might affect the airways and thus causing changes in breathing so a prior assessment of Nasal Cavity and Pharyngeal Airways might eventually be helpful in selection of best treatment option for patient .
	The variables and parameters should be explicitly identified for the study.	Depicted in Flow chart.
	Research hypothesis should be stated in terms of the parameters of the study.	3Vertical,6 linear, 3 volumetric and 3 cross-sectional parameters will be used for pharyngeal airway analysis. 1. **Hn [Nasopharyx height]** 2. **Hp [Palatopharyx height]** 3. **Hg [Glossopharynx height]** 4. **Ln [Length along PNS plane]** 5. **Wn [Width along PNS plane]** 6. **CSAn [Cross-sectional area along PNS plane]** 7. **Lp [Length along U plane]** 8. **Wp [Width along U plane]** 9. **CSAp [Cross-sectional area along U plane]** 10. **Lg [Length alone Ep plane]** 11. **Wg [Width along Ep plane]** 12. **CSAg [Cross-sectioal area along Ep plane]** 13. **Vn [Volume of Nasopharynx]- (Wang 2014)**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

		14. Vp [Volume of Palatopharynx]- (Wang 2014) 15. Vg [Volume of Glossopharyx]-(Wang 2014)
	The statistical analysis section is missing.	The final sample size calculated to be , n = 75 The mean, standard deviation and P value of each parameter will be calculated for different groups. The data will be collected, tabulated, and statistically analyzed using different test used in statistic science. The obtained data will be subjected to statistical evaluation. Any deviation, if required from the above mentioned method will be done in the best interest of the study.

Recommendation of Primary reviewer: Approved
PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-IIA/P6

5- Clarification of research proposal entitled ***"Evaluation of hypo-fractionated radiotherapy versus conventionally fractionated radiotherapy for the adjuvant management of resected Head and Neck squamous cell cancers"*** submitted by Dr. Aman Verma, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 828/RT/22 dated 5th August, 2022.

Previous PGTSC Comment	PI response
Aims & objectives section is not clear. It has the definition of primary and secondary end points, which should be in methodology section.	1. To analyze the safety of the hypo-fractionated adjuvant radiotherapy regimen (50 Gy in 20 fractions 5 fractions per week, total time 4 weeks)compared with conventional adjuvant radiotherapy regimen (60 Gy in 30 fractions 5 fractions per week, total time 6 weeks). 2. Patients from low- and middle-income countries (LMIC) have limited resources for Radiotherapy and face long waiting times to be treated . Consequently, in addition to the radiobiological and clinical benefits of accelerated Radiotherapy, hypofractionation regimes can also be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

		an important strategy to shorten treatment times and thus improve access to Radiotherapy. 3. Additionally, a short Radiotherapy schedule (4 weeks vs 6 weeks) is associated with better patient compliance.
	The variables and parameters should be explicitly identified for the study. Research hypothesis should be stated in terms of the parameters of the study.	Primary end point-Acute toxicity Secondary end point – progression free survival, overall survival and quality of life
	In the absence of proper research hypothesis, the sample size calculation has no meaning.	As the research hypothesis properly conveyed this time so sample size calculation attached separately (methods section)
	The statistical analysis section is missing	Statistical Analysis will be done using SPSS software 22nd version, with considering the P- value to be significant below 0.05.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-IIA/P8

6- Clarification of research proposal entitled ***"Diagnostic accuracy of clinical evaluation and conditional imaging to detect urgent conditions in acute abdominal pain: A prospective cohort study"*** submitted by Dr. Ashi Verma, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1911/22 dated 5th August, 2022.

Previous PGTSC Comment	PI response
ICF: Kindly explain the study procedure to the patient in simple language instead of writing study design. Kindly follow the SOP provided by IEC, available on website.	Modified and written in a simple language the ICF and enclosing the same for the needful.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-IIA/P18

7- Clarification of research proposal entitled ***"Endobronchial ultrasound elastography in the evaluation of mediastinal and hilar lymph nodes"*** submitted by Dr. Maqsumi Reza, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

University, U.P., Lucknow vide letter no.153/PCCM/22 dated 18th July, 2022.

Previous PGTSC Comment	PI response
No mention of tissue sample collection in the section on 'Use of Biological Material'	EBUS-TBNA to be carried out on targetlymph nodes. Smears stained by hematoxylin and eosin and examined.
Sample size in mentioned as 60 at one place and 30 at another.	Sample size is 30
Ideally Co-PI cannot be member of the departmental Scientific Research Committee.	As per your discussion with HOD PCCM, Co-PI being part of research committee to be considered under special circumstances.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-IIA/P28

8- Clarification of research proposal entitled ***"Clinical and etiological study of hyponatremia in patients admitted in respiratory intensive care unit in a Tertiary Care Hospital"*** submitted by Dr. Shivam Gupta, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.151/PCCM/22 dated 18th July, 2022.

Previous PGTSC Comment	PI response
Sample size in mentioned as 70 at one place and 100 at another.	No vulnerable subjects used in the study
Involvement of vulnerable subjects has to be mentioned.	Sample size is 100.
Ideally Co-PI cannot be part of the committee approving the proposal.	As per your discussion with HOD PCCM, CO-PI being part of research committee to be considered under special circumstances

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-IIA/P30

9- Clarification of research proposal entitled ***"Role of ultrasound guided IVC-CI versus central venous pressure in assessing fluid status in critically ill patients"*** submitted by Dr. Shubham Jain, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.152/PCCM/22 dated 18th July, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	Previous PGTSC Comment / **PI response**
	Study uses seriously ill patients as subject but the IEC proforma does not mention use of vulnerable subjects modify. / No vulnerable subjects used in the study.
	Sample size is mentioned as 70 at one place and 100 at another. / Correct sample size is 70
	Ideally Co-PI cannot be part of committee approving the proposal. / As per your discussion with HOD PCCM, Co-PI being part of research committee to be considered under special circumstances.
	The above Comment forwarded to PI was reviewed by PR:-
	Recommendation of PR: Approved
	PGTSC Decision: Approval ratified
	Ref. code: X-PGTSC-IIA/P31
10-	Clarification of research proposal entitled ***"Validation of cancer ratio (Serum pleural fluid ADA ratio) for malignant pleural effusion"*** submitted by Dr. Jitendra Agarwal, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no.154/PCCM/22 dated 26th July, 2022.
	Previous PGTSC Comment / **PI response**
	Sample size calculation has not been done. / Attached separately
	Co-PI cannot be part of committee approving the proposal. / As per your discussion with HOD PCCM, Co-PI being part of research committee to be considered under special circumstances.
	The above Comment forwarded to PI was reviewed by PR:-
	Recommendation of PR: Approved
	PGTSC Decision: Approval ratified
	Ref. code: X-PGTSC-IIA/P33
11-	Clarification of research proposal entitled ***"Long PFNA-II VS dynamic HIP screw for treatment of unstable intertrochanteric femur fracture-A prospective comparative study"*** submitted by Dr. Punit Agarwal, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 2585/OS/22 dated 20th August, 2022.
	Previous PGTSC Comment / **PI response**
	Aim and objectives are not clear. / ***AIM*** *To compare the results of long proximal femoral nail (PFNA- II) vs Dynamic hip screw (DHS) in treatment of unstable intertrochanteric femur fracture using Harris Hip score.* ***OBJECTIVES*** *PRIMARY OBJECTIVE: To evaluate the functional*

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

		outcome in terms of HARIS HIP SCORE of unstable intertrochanteric femur fracture treated by long proximal femoral nail (PFNA- II) vs Dynamic hip screw (DHS). *SECONDARY OBJECTIVE: To evaluate the Surgical time, Blood loss and union time in unstable intertrochanteric femur fracture treated by long proximal femoral nail (PFNA- II) vs Dynamic hip screw (DHS).*
	Research hypothesis should be formulated after identifying the study variables and population parameters.	*There will be a significant difference between Surgical time, Blood loss, union time and functional outcomes in unstable intertrochanteric femur fracture treated by long proximal femoral nail (PFNA- II) vs Dynamic hip screw (DHS).*
	Sample size calculation is arbitrary. The right formula can be used only after defining the proper research hypothesis	• ***Group p:*** *Patients managed with closed /open reduction internal fixation of unstable intertrochanteric femoral fracture by PFN-A II* • ***Group d:*** *Patients managed with closed /open reduction internal fixation of unstable intertrochanteric femoral fracture by DHS.* *Both groups will be compared with surgical time, blood loss, fracture union time.* *The follow ups will be done at 6th Week, 12th weeks, 6 months and 1 year of after the procedure to compare the functional outcome of the fracture using Harris Hip Score.*
	Statistical analysis section is very genera. It should be specific to aims and objectives.	• *Data will be collected in Microsoft Excel sheet and will be evaluated using Statistical Package for Social Sciences, version 23 (SPSS Inc., Chicago, IL).* • *Results for continuous variables are shown as mean±standard deviation (SD), whereas results for categorical variables are shown as number (percentage).* • *For comparison of categorical variables, chi-square ($\chi 2$) / Fisher's test will be used.* • *Independent sample 't' test was used to compare the mean values between groups.*

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

		• *The level P < 0.05 was considered as the cutoff value or significance.* *sample size was calculated with 95% confidence in interval estimation and 10% absolute error of margin by using formula:*[1] $n = Z2\pi (1-\pi)/d2$ *Where,* *Z = Table Value of alpha error from Standard Normal Distribution table (1.96 for 95% confidence interval)* π *= anticipated range* *d = the absolute precision required on either side of true value of the population proportion* π *Population proportion =* π *= 20% = 0.2.* *Level of significance (alpha error) = 5%* *Margin of error = d = 0.1* *Confidence interval = 95%* *n = (1.96)2X 0.2 X 0.8 / (0.1)2= 60.4* • *Hence a sample size of 60 will be considered adequate for our study.*

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-IIA/P2

12- Clarification of research proposal entitled ***"Effect of kinesiophobia on early functional outcome following total knee arthroplasty"*** submitted by Dr. Sripal Chaudhary, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 2583/OS/22 dated 18th August, 2022.

Previous PGTSC Comment	PI response
There are total 8 Co-PIs and 7 from same department (including HOD) with almost same roles -Please justify or reduce the numbers of Co-PIs.	Reduce the the no of Co-PIs to 5 (from two department.) Removal of three Co-PIs done.
In Undertaking document by PI the name of Prof. R N Srivastava has wrongly been mentioned as Co-PI – Please remove the name.	Removal of name of Prof.R N Srivastava done.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-IIA/P9

13- Clarification of research proposal entitled ***"Comparative evaluation of depigmentation by locally injected Vitamin C versus surgical blade in the treatment of gingival hyperpigmentation"*** submitted by Dr. Aehad ul Haque, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2508/P/22 dated 25th August, 2022.

Previous PGTSC Comment	PI response
Study design not	mentioned in protocol
No. of Co-Pis are 4	(including HOD) from
Please give details of Clinical parameters to be seen- 1. Gingival pigmentation index – how will you assess 2. How pts. satisfaction analysis will be assessed- If any structured questionnaire are there then attach the	□ Gingival Pigmentation Index by Kumar et al., 2012,It will be recorded by the principal investigator at baseline, 1 month follow up and 6 months follow up. It is based on the visual appearance of the patient's gingiva. Only routine dental diagnostic instruments, that is mouth mirrors will be used to retract the lips of the patient to visualize the gingiva. The distribution of hyperpigmentation, will be assessed in the regions of labial gingiva corresponding to maxillary and mandibular incisors and canines (aesthetic zone). Based on the observations, an individual index score will be assigned to the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	same	patient by the principal investigator as follows: Score 0: Absence of pigmentation Score 1: Spots of brown to black colour or pigments. Score 2: Brown to black patches but not diffuse pigmentation Score 3: Diffuse brown to black pigmentation, marginal, and attached Reference: Kumar S, Bhat SG, Bhat MK. Development in techniques for gingival depigmentation-An update. Indian J Dent.2012;3:213–21 □ Patient Satisfaction Analysis (by Visual Analogue Scale) It will be done by providing the patients a printed 10 cm long line Visual Analogue scale (VAS), with the words "Not satisfied" (0% satisfaction) anchored to the extreme left and the word "Satisfied" (100% satisfaction) anchored to the extreme right. Each patient will be asked to make a handwritten mark on the line, in order to reflect how satisfied he/she is by the treatment provided. Each centimetre measured on the line

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

		starting from the extreme left and up to the extreme right will denote 10% satisfaction. For example, a mark made by the patient which lies 2cm away from the extreme left of the line will denote 20% satisfaction. A prototype of VAS to be used: Reference: Voutilainen A, Pitkäaho T, Kvist T, Vehviläinen-Julkunen K. How to ask about patient satisfaction? The visual analogue scale is less vulnerable to confounding factors and ceiling effect than a symmetric Likert scale. J Adv Nurs. 2016 Apr;72(4):946-57.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-II B/P12

14- Clarification of research proposal entitled ***"Association of polymorphisms in IGF-1, GHR and PAX-9 genes with tooth sixe"*** submitted by Dr. Varun Gupta, JRII, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 889/Ortho/22 dated 16th August, 2022.

Previous PGTSC Comment	PI response
As the inclusion criteria shows to take the patients between 13 to 25 yrs. of age, therefore Child Ascent Form should be submitted in addition to ICF.	Child Assent form attached (Hindi and English)

Recommendation of Primary reviewer: Approved
PGTSC Decision: Approval ratified

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

Ref. code: XI-PGTSC-IIA/P14

15- Clarification of research proposal entitled ***"Association of polymorphisms in IGF-1, GHR and PAX-9 genes with tooth sixe"*** submitted by Dr. Varun Gupta, JRII, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 889/Ortho/22 dated 16th August, 2022.

Previous PGTSC Comment	PI response
As the inclusion criteria shows to take the patients between 13 to 25 yrs. of age, therefore Child Ascent Form should be submitted in addition to ICF.	Child Assent form attached (Hindi and English)

Recommendation of Primary reviewer: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-IIA/P14

16- Clarification of research proposal entitled ***"Epidemiology of injured patients in paediatric age group admitted to department of orthopedics KGMU"*** submitted by Dr. Prajwal M C, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2610/OS/22 dated 23rd August, 2022.

Previous PGTSC Comment	PI response
Sample Size & Sample Technique • Sample size-All patients-specific and calculated sample size not mention.	**Now the sample size has been** calculated (n=166) and has been incorporated in the revised performa.
Annexure • Guardians consent form E/H-not same-modification needed. • As the patients of age group between 8 to 18 years will be taken, so Child Ascent form should also be attached.	Now, As per suggestion, • The Guardian consent form has been incorporated in the revised performa. • The Child Ascent form has been incorporated in the revised performa.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-II B/P16

17- Clarification of research proposal entitled **"*Health related quality of life after traumatic basal ganglia Hemorrhage*"** submitted by Mr. Anurag Yadav, MBBS, Batch-2018 Through his Mentor Dr. Awdhesh Yadav, Associate Professor Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

NS/1162/22 dated 8th August, 2022.

Previous PGTSC Comment	PI response
Sample size calculation has not been done.	This is an exploratory study, and not a hypothesis-testing work. Therefore no hypothesis based sample size calculation is performed. Study is expected to generate testable hypothesis for future research. Hence sample size was determined based on logistical and budgetary consideration, which a preliminary review indicate are more than 200.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-II B MBBS-S/P6

18- Clarification of research proposal entitled "***Attitude, perception and barriers of dental professionals towards artificial intelligence***" sponsored by ICMR STS submitted by Ms. Anushka Pandey, BDS through her Mentor Dr. Nishi Singh, Assistant Professor Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 221/Coms&Endo/22 dated 18th August, 2022.

Previous PGTSC Comment	PI response
Sample size required for questionnaire has not been mentioned	The sample size required comes out to be 200. The method used to calculate the sample size is explained below.
Ethical waiver has been requested	Ethical waiver form has been filled and attached below.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-II B BDS-S/P7

19- Clarification of research proposal entitled "***A cross sectional study to correlate DMFS and stress on development of MPDS in medical students***" sponsored by ICMR STS submitted by Mr. Prakhar Mittal, BDS through his Mentor Dr. Lakshya Kumar, Additional Professor, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 364 /22 dated 22nd August, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-II B BDS-S/P13

20- Clarification of research proposal entitled "***Prospective analysis of snakebite patients in a tertiary care referral centre in northern India***" sponsored by ICMR STS submitted by Mr. Akash Singh, MBBS through his Mentor Dr. D. Himanshu Reddy, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1606/MED /22 dated 17th August, 2022.

Previous PGTSC Comment	PI response
Sample size is 50, why this number of subjects will be taken is not mentioned. If it is a pilot study then it may be mentioned.	It is a pilot study.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-II B MBBS-S/P14

21- Clarification of research proposal entitled "***Correlation of HbA1c with glycemic variability in diabetes management***" sponsored by ICMR STS submitted by Mr. Akash Kumar, MBBS through his Mentor Dr. Satyendra Kumar Sonkar, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1593/Med/22 dated 13th August, 2022.

Previous PGTSC Comment	PI response
Sample size calculation and proper justification needed.	The required sample size calculation and its proper justification is attached.

Recommendation of Primary reviewer: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-II B MBBS-S/P15

22- Clarification of research proposal entitled "***Effect of periodontal therapy on inflammatory biomarkers in patients with metabolic syndrome: a randomized controlled clinical trial***" sponsored by ICMR STS submitted by Mr. Pushpendra Singh, BDS through his Mentor Dr. Anjani Kumar Pathak, Additional Professor, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2500/P/22 dated 18th August, 2022.

Previous PGTSC Comment	PI response

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	In the materials and Methods section instead of Patients as "Experimental Group" subjects shall be mentioned.	Mentioned "Experimental group as subject group in Method sections".
	Sample size calculation and proper justification needed.	Sample size mentioned in methodologies section.
	They are going to do biomarkers but no co-guide from any investigative department.	Dr. Wahid Ali (Co-guide) Additional Professor, Department of Pathology.
	Similarly they are going to assess cardiovascular risk but no co-guide from Cardiology/Medicine is there.	Dr. Akhil Sharma (Co-guide) Additional Professor, Department of Cardiology.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-II B MBBS-S/P16

23- Clarification of research proposal entitled "***Psychological morbidity and quality of life in women undergoing hysterectomy***" sponsored by ICMR STS submitted by Ms. Nikita Verma, MBBS through her Mentor Dr. Bandna Gupta, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1185/Psy/22 dated 22nd August, 2022.

Previous PGTSC Comment	PI response
Sample size calculation and proper justification needed.	Attached

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision Approval ratified

Ref. code: XI-PGTSC-II B MBBS-S/P18

IB **Expedited review**

1- Research proposal entitled ***"Neurotrauma among pedestrians in India: A retrospective comparison of pedestrians walking along and against the direction of traffic"*** submitted by Mr. Vinay Suresh, MBBS under the guidance of Prof. Chhitij Srivastava, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/1207/22 dated 20th August, 2022.
The above proposal was forwarded to two reviewers.
Recommendation of both reviewers: Approved
PGTSC Decision: Approval ratified

Ref. code: XII-PGTSC-I B /P1

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

2-	Research proposal entitled ***"An explorative study of cognitive deficits, sleep disturbance, quality of life and activity of daily living in patients with mild cognitive impairment"*** submitted by Ms. Hansita Yadav, MBBS under the guidance of Dr. Pooja Mahour, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1122/Psy dated 8th August, 2022. ***The above proposal was forwarded to two reviewers.*** ***Recommendation of both reviewers:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XII-PGTSC-I B /P2***
IIA	**New Thesis-Resident**
1.	Research proposal entitled ***"Efficacy of nasolabial flap in post mucor infrastructure maxillectomy defects"*** submitted by Dr. Ravi Katrolia, SR, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 577/OMSD/22 dated 6th July, 2022. ***Recommendation of Primary reviewer:*** • This is a before and after treatment study. • Study variables and parameters should be properly defined for the study. • Research hypothesis should be formulated in terms of the parameters. • Sample size calculation is required. • Statistical analysis section is required. **PGTSC Comment:** As above **PGTSC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Clinical & biochemical evaluation of herbal preparation in early stages of sub mucous fibrosis- A randomized control trial"*** submitted by Dr. Richa, JRII, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 584/OMSD/22 dated 7th July, 2022. ***Recommendation of Primary reviewer:*** • There is no proposal attached. • Only "Undertaking by investigator" and "consent forms" are attached. • There is an external member" Vaidya Abhaiy Narayan Tiwari". • What is his role? Is any kind of permission required for his inclusion. • Is this for approval of "Thesis topic" only? **PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	As above **PGTSC Decision:** Re-submit with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Modified baumann's angle: A comparative study between dominant and non-dominant upper limb in paediatric age group attending KGMU"*** submitted by Dr. Mohammad Zohaib Abbas, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 202/Ortho/22 dated 10th June, 2022. ***Recommendation of Primary reviewer:*** • This is a prospective cohort study, not "cross sectional study". • This is a comparative study. The two groups, under comparison" should be exclusively identified. • Research hypothesis should be formulated after properly identifying study variables and parameters. • Sample size calculation is arbitrary. It should be appropriate to the research hypothesis. • Statistical analysis section is also very general. It should be in accordance with the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Epidemiological assessment of acetabular fracture in trauma center, King Georges Medical University, Lucknow"*** submitted by Dr. Faisal Ahmad, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 204/Ortho/22 dated 10th June, 2022. ***Recommendation of Primary reviewer:*** • Study design mentioned is "retrospective and prospective". • It should be one of these. Here, it seems to be prospective study. • There are too many objectives. • One primary objective should be identified. Research hypothesis should be formulated for this objective in terms of properly identified parameters of the study. • Other objectives could be the side products of main hypothesis. • Sample size calculation is inadequate. It should be specific to the research hypothesis. • Statistical analysis section is very general. It should be specific to the research hypothesis. **PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	As above **PGTSC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P4***
5.	Research proposal entitled ***"Development and validation of age estimation formula based on OLZE's methodin North Indian population using orthopantograms and CBCTs"*** submitted by Dr. Ayushi Jain, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 813/OP/22 dated 20th July, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XII-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Immunohistochemical expression of minichromosome maintenance complex 3 (MCM3) and transport and GOLGI organization protein 1 (TANGO1) in different grades of oral squamous cell carcinoma"*** submitted by Dr. Saloni Verma, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 815/OP/22 dated 21st July, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XII-PGTSC-IIA/P6***
7.	Research proposal entitled ***"Myofibroblast expression in oral squamous cell carcinoma and oral potentially malignant disorders using H1 calponin and integrin α II; A comparative study"*** submitted by Dr. Roshna Sankar N S, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 812/OP/22 dated 20th July, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XII-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Exploration of three proteins panel to predict prognosis in oral squamous cell carcinoma"*** submitted by Dr. Priya Devi, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 811/OP/22 dated 20th July, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XII-PGTSC-IIA/P8***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

9.	Research proposal entitled ***"Anatomical variation of posterior tibial slope in North Indian population: A Hospital based study"*** submitted by Dr. Anmol Chaurasia, JRI, Department of Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 210/Orth/22 dated 10th June, 2022. ***Recommendation of Primary reviewer:*** • Sample size is mentioned 200 in the IEC form and 100 in the synopsis. • Drs Devarshi and Ravindra Mohan are Co-PIs as well as part of Scientific Review Committee. This is conflict of interest. • No Co-PI from department of Radiology has been taken when the study is mainly on radiographs. **PGTSC Comment:** As above **PGTSC Decision:** Approval after modification with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Comparative analysis of TNF-α and THF-β in serum and saliva of oral lichen planus patients"*** submitted by Dr. Rajlaxmi Mitra, JRI, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 394/OM&R/22 dated 26th July, 2022. ***Recommendation of Primary reviewer:*** • There are 6 Co-PIs of which 5 are from the same department. Please justify those rules. • Sample size in mentioned as 25 at one place and 39 at another. • Two aims of the study are given which are identical • Control group consists of healthy individuals but no mention has been made of using volunteers for the study • Who will bear the cost of blood biochemistry examination for TGF? **PGTSC Comment:** As above **PGTSC Decision:** Approval after modification with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Evaluating the efficacy of intralesional autologous platelet rich plasma (PRP) therapy in patients with oral lichen planus"*** submitted by Dr. Praveen. S, JRI, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 395/OM&R/22 dated 26th July, 2022. ***Recommendation of Primary reviewer:*** • There are six Co-PIs in the study of which 5 are from the same department. Please justify those rules. • The calculated sample size is 39 for statistical significance. However, the PI is splitting this into two groups which decreases the sample size in each group. I will suggest that the sample size of 39 be maintained in each group for the study to be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	valid. • Who will bear the cost of PRP preparation and blood biochemistry examination for TGF? **PGTSC Comment:** As above **PGTSC Decision:** Approval after modification with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P11***
12.	Research proposal entitled ***"Comparison of biomarkers in breast cancer by manual assessment and digital image analysis"*** submitted by Dr. Damini Singh, SR, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 998/22 dated 5th August, 2022. ***Recommendation of Primary reviewer:*** • There are four Co-PIs in the project with overlapping roles. • Waiver has been applied for as it is a retrospective observational study. The same may be granted to the PI. **PGTSC Comment:** As above **PGTSC Decision:** Waiver of taking Ethical granted. ***Ref. code: XII-PGTSC-IIA/P12***
13.	Research proposal entitled ***"Effect of periodontal therapy on acute phase response proteins in chronic periodontitis patients with metabolic syndrome- A randomized clinical trial"*** submitted by Dr. Vikas Jayant, JR, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2393/P/22 dated 28th May, 2022. ***Recommendation of Primary reviewer:*** • There are 6 Co-PIs in the project of which 4 are from the same department. Please justify. • The sample size is not mentioned anywhere in the proposal • Patients in control arm are not being offered oral antibiotics will this not be sub-optimal/sub-standard treatment exposing the patients to the risk of failure of treatment of the condition for which they are consulting the institution. • Who will bear the cost of the biochemical tests being offered to the patients? **PGTSC Comment:** As above **PGTSC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P13***
14.	Research proposal entitled ***"Impact of intense smartphone application based versus routine follow-up on short term clinical outcomes in acute decompensated Heart failure (ADHF)"*** submitted by Dr. Ajit Pratap Singh, SRII, Department of Cardiology,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	King George's Medical University, U.P., Lucknow vide letter no. 529/Cardio/22 dated 29th July, 2022. ***Recommendation of Primary reviewer:*** • In Scientific Review Committee no faculty of Cardiology or Medicine has taken part? Review from faculty of Medicine be also done. • Study design not mentioned in Protocol • In Exclusion criteria the PI did not mentioned about inclusion /exclusion of pregnant women lactating • women patients of ADHF • Why PI mentioned in Title as short term clinical outcomes (In Introduction the PI has mentioned to explore long term patient care by this study) –Please justify • Sample size calculation not done (only mentioned that sample size will be according to Cochrane's formula-please justified. **PGTSC Comment:** As above **PGTSC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P14***
15.	Research proposal entitled ***"COLOUR DOPPLER evaluation of photobiomodulation as a therapeutic adjunct in non-surgical management of periapical bone defects: A randomized controlled trial"*** submitted by Dr. Jagruti Mutalikdesai, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 212/Coms&Endo/22 dated 10th August, 2022. ***Recommendation of Primary reviewer:*** • Study design as RCT should be justified as CONSORT guidelines has not been followed (Randomization method, blinding, sample size calculation not mentioned and total sample size is 24 pts). • Flow chart of methodology not mentioned. • Sample size calculation not done. (Only formula is given) **PGTSC Comment:** As above **PGTSC Decision:** Modify and re-submit with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P15***
16.	Research proposal entitled ***"Utility of video-oculography in parkinsonian syndromes- A prospective exploratory study"*** submitted by Dr. Saurabh Kumar, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 426/Neuro/22 dated 23rd August, 2022. ***Recommendation of Primary reviewer:*** • It is mentioned that patients from SGPGIMS and RMLIMS will be recruited, but

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	no co-guide from the institutions has been included. • It is mentioned that patients from SGPGIMS and RMLIMS will be recruited, but no co-guide from the institutions has been included. **PGTSC Comment:** As above **PGTSC Decision:** Approval after modification with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P16***
17.	Research proposal entitled ***"Predictors of response to botulinum treatment in patient with hemifacial spasm: A prospective study"*** submitted by Dr. Sneh Jain, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 427/Neuro/22 dated 23rd August, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XII-PGTSC-IIA/P17***
18.	Research proposal entitled ***"Myelitis in patients with tuberculous meningitis-predictors and outcomes-prospective study"*** submitted by Dr. Prem Singh, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 428/Neuro/22 dated 23rd August, 2022. ***Recommendation of Primary reviewer:*** • Although a co-guide has been taken from the Department of Radio diagnosis, it is not mentioned in the Materials & Methods section that work will be carried out in collaboration with the Department of Radio diagnosis, apart from the Department of Microbiology. **PGTSC Comment:** As above **PGTSC Decision:** Approval after modification with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P18***
19.	Research proposal entitled ***"Clinical, radiological and laboratory predictors of post ventriculoperitoneal shunt outcome in adult tuberculous meningitis patient-A prospective observational study"*** submitted by Dr. Saddam Ahmad Hasib, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 294/Neuro/22 dated 24th August, 2022. ***Recommendation of Primary reviewer:*** • There are many typographical errors and language problems which need to be corrected. • In the Objectives of the study it is mentioned that "To assess the 6 months outcome of these patients". Please mention the disease, (Tuberculous meningitis patients).

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	PGTSC Comment: As above **PGTSC Decision:** Revise and re-submit with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P19***
20.	Research proposal entitled ***"Quantitative assessment of cysticercosis on whole body MRI in patients with disseminated cysticercosis treated with albendazole with steroids v/s steroids alone and outcome assessment at 3 months-a randomized controlled trial"*** submitted by Dr. Jadhav Padmajeet Ranjeetsinh, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 293/Neuro/22 dated 24th August, 2022. ***Recommendation of Primary reviewer:*** • Hindi consent Performa not typed properly. **PGTSC Comment:** As above **PGTSC Decision:** Approval after modification with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P20***
21.	Research proposal entitled ***"Assessment of various lung function parameters of impulse oscillometry in chronic obstructive pulmonary disease patients at a tertiary care centre"*** submitted by Dr. Aneekrt Rastogi, JRIII, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 909/22 dated 8th August, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XII-PGTSC-IIA/P21***
22.	Research proposal entitled ***"Renal dysfunction in tuberculous meningitis and its correlation with outcomes"*** submitted by Dr. Arjun Bal K.P, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 434/Neuro/22 dated 24th August, 2022. ***Recommendation of Primary reviewer:*** • Age specificity in inclusion criteria is not mentioned (if all pts will be taken then Guardian and Child Assent form should also be submitted) • English ICF mentioning different disease (Neurocysticercosis instead of Tuberculous meningitis) **PGTSC Comment:** As above **PGTSC Decision:** Approval after modification with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P22***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

23.	Research proposal entitled ***"Clinico-radiological characteristics of degenerating and calcified solitary neurocysticercosis with persistent seizure: prospective comparative study"*** submitted by Dr. Aditya Kumar, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 435/Neuro/22 dated 24th August, 2022. ***Recommendation of Primary reviewer:*** • Study design mentioned as Prospective comparative study, whether it is observational or analytical –Please clarify. • Sample size calculation not done (total no. of pts in Protocol-100 pts and in SOP form -108 pts • –Please justify the discrepancy in total number of pts to be included). • As in Inclusion criteria, patients of more than 12 yrs. of age will be taken, therefore Child Assent form should also be submitted in addition to regular ICF. **PGTSC Comment:** As above **PGTSC Decision:** Approval after modification with tabular format in word file. ***Ref. code: XII-PGTSC-IIA/P23***
24.	Research proposal entitled ***"Clinical characteristics and response to treatment among patients having migraine and calcified NCC with and without perilesional edema: A prospective study"*** submitted by Dr. Vishwesh Vishnu Naik, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 463/Neuro/22 dated 24th August, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XII-PGTSC-IIA/P24***
IIB	**M. Phil Course**
1.	Research proposal entitled ***"A study of object relations, narrative identity and neuropsychological functions in borderline personality disorder"*** submitted by Ms. Manjistha Datta, II Year under the guidance Dr. Shweta Singh, Additional Professor, Department of Psychiatry King George's Medical University, U.P., Lucknow vide letter no. 697/Psy/22 dated 23rd May, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XII-PGTSC-II B M.Phil/P1***
II-B	**MBBS Student**
1.	Research proposal entitled ***"A case control study on impact of screen time on language development of children between 2-5 years of age"*** submitted by Ms. Gunjan Parasher &

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

	Mr. Shikhar Gupta, MBBS, Batch 2019 through their Mentor Prof Shally Awasthi, Head, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1805/Ped/22 dated 15th June, 2022. ***Recommendation of Primary reviewer:*** • Role of PI given, but role of chief guide and Co-PIs not given • ICF –English & Hindi –not similar (Hindi ICF-is incomplete)–PI should submit Guardian consent form instead of regular ICF, as subjects to be taken are between age group of 2-5 years. **PGTSC Decision:** Revise and re-submit with tabular format in word file. ***Ref. code: XII-PGTSC-II B MBBS-S/P1***
III	**Additional Document**
1.	Additional of research protocol entitled "***Infection profile of patients and utility of neutrophil CD64 expression, presepsin, procalcitonin, neutrophil to lymphocyte ratio and CRP in differentiating infections from flares in systemic lupus erythematosus***" submitted by Dr. Mukesh Kumar Maurya, SR, Department of Clinical Immunology and Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/544//22 dated 3rd August, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: VII-PGTSC-IIA/P18***

The next Meeting will be scheduled on 22nd October, 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman

King George's Medical University U.P.,
Institutional Ethics Committee

Lucknow - 226003 (UP) India

Prof. Shally Awasthi
Member Secretary, IEC

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

No. 1392 **/Ethics/2022**

Dated: 20/10/2022

To,

Dr. Alok Dhawan,
Director,
Centre of Biomedical Research (CBMR),
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Raebareli Road,
Lucknow, U.P. 226014

Sub.: Reg. Minutes of 118th Institutional Ethics Committee Meeting held on 17th September, 2022.

Dear Sir,

Please find enclosed herewith the Minutes of 118th Institutional Ethics Committee Meeting held on 17th September, 2022, for your kind signature..

Thanking you
With regards

Encl.: As above

Yours Sincerely

(Shally Awasthi)
Member Secretary, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 119th ECM held on 22nd October, 2022

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of 119th Institutional Ethics Committee Meeting virtually held on **22nd October, 2022** from 10.30 A.M.

The following Members were present in the Meeting:-

1. Dr. Alok Dhawan -Chairman
2. Dr. G.G. Agarwal -Member
3. Mrs. Akansha Dubey -Member
4. Mrs. Vasundhara Kumari -Member
5. Mr. Ujjawal Krishna -Member
6. Dr. Akash Agarwal -Member
7. Dr. K.K. Yadav -Member
8. Dr. Rajendra Nath -Member
9. Dr. A.A. Mahdi -Member
10. Dr. Anupam Mishra -Member
11. Dr. D.N. Upadhyaya -Member
12. Dr. Shally Awasthi -Member-Secretary, IEC

The following Members were not present in the Meeting:-

1. Dr. Shubha R. Phadke -She has given her written comment
2. Dr. Anita Rani -She has given her written comment

IA	Action Taken
1-	Clarification of research proposal entitled "***Missed injury associated with maxillofacial trauma: An observational study***" submitted by Dr. Arunesh Kumar Tiwari, Associate Professor, Department of Oral and Maxillofacial Surgery, FODS, King George's Medical University, U.P., Lucknow vide letter no.762/OMSD/2021 dated 9th September, 2022. **Previous EC Comment:** • The protocol appears to be a part of the manuscript prepared for publication. Kindly

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

resend the proposal in a proper format.

- Apply as the fresh proposal for a waiver

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
EC Decision: As above

Ref. code: 111th ECM IIA/P14

2- Clarification of research proposal entitled "***Identification and characterization of novel molecular biomarkers with prospects of targeted drug therapy development in pediatric B-Cell acute lymphoblastic leukemia (ALL) with diverse genetic subgroups***" submitted by Dr. Nishant Verma, Additional Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no.2551/Ped/22 dated 13th October, 2022.

Previous EC Comment	PI response
1.Summary mentions : No funding. However patient information sheet mentions: funding will be applied from Govt organizations or NGOs.	The funding will be applied to Govt organizations, NGOs and intramural fund from IIT Hyderabad. The application for the same is in process. There will be no financial implications for the patient or for KGMU, Lucknow.
2.Study setting: Other participating institutions.... which are these?	The samples would be obtained from KGMU Lucknow and processed at IIT Hyderabad.
3.Study design: multicentric: which all	The samples would be obtained from KGMU Lucknow and processed at IIT Hyderabad
4.Sample size: last sentence: to achieve statistical significance.... What and how, which test?	As there are no data available on genomic and transcriptomic profile of Indian Pediatric B lymphoblastic leukemia patients, we will be conducting this study as a 'Pilot' project. We will follow the convenience sampling (non-probability sampling) method, wherein 100 consecutive children satisfying the inclusion and exclusion criteria will be enrolled. In the paediatric B cell ALL, 70 to 75% of the cases can be classified as per the WHO. classification of tumors of hematopoietic and lymphoid tissue, while 25 to 30% remain unclassified and constitute the novel subgroup. The subgroups are heterogeneous, with most common subgroup accounting for not more than 15% of B cell ALL cases as per the available literature. With our initial study with 100 cases, we expect to pick up the common subgroups. We should also be able to pick up novel subgroups as well, though it is 5 Outcome measures: Do you think this sample size is good enough to identity subgroups with in this mixed bag and also find actionable solutions, despite the fact that WHO has been unable to do so, with possibly much
5.Outcome measures: Do you think this sample size is good enough to identity subgroups with in this mixed bag and also find actionable solutions, despite the fact that WHO has been unable to do so, with possibly much larger sample size and genetic data etc?	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		larger sample size and genetic data etc? possible that the novel subgroups with low incidence might be missed. However, we envision to be able to generate RNA and DNA profiling data for Indian B-ALL patients.
	6. Statistical analysis Statistical analysis 7.categorical data in 2 groups: which two groups 8. continuous data in 2 groups: which two groups 9. Means between more than 2 sub groups: specify groups.	For statistical analysis, SPSS software Version 22 will be used. Case related data will be entered in the Microsoft Excel Sheet. Incidence of various sub groups thus identified would be calculated as a percentage. Normally distributed data would be summarised by using mean and standard deviation and data which are not normally distributed would be summarised by median and interquartile range. Analysis of RNA-seq data obtained from patients to identify various differentially expressed genes between the B ALL patients and normal population will be performed. RNA-seq analysis methods have been classified into four categories based on the type of statistical methods used for differential analysis: (i) t-test analogical methods (Cuffdiff and Cuffdiff2), (ii) Poisson or negative binomial model-based methods (edgeR, DESeq, DESeq2, baySeq, EBSeq), (iii) non- parametric methods (SAMseq and NOIseq), and (iv) linear models (voom and sleuth). All the above methods will be applied on the obtained datasets to obtain statistically relevant results. Categorical variables like gender or age predilections of subgroups would be compared using the Chi-square test.
	Ethical consideration: delinked?? Really?	Samples would be collected from patients voluntarily enrolling for the study, post approval of the proposal by the ethical committee of KGMU. Informed written consent would be obtained from the patient and patients confidentiality would be maintained. As the study is purely observational in nature, there is no risk to the patient due to this study.
	Transcriptomic and genomic data analysis needs specialized tests.	Transcriptome and genome will be analyzed using simple PCR and FISH based approach as well as by using high throughput technologies NGS.
	Flowchart: what is yellow painted testing?	The information presented in the flowchart has now been incorporated in the proposal text. The yellow colored part of the flowchart submitted earlier represented the tests that are routinely done as a part of workup in a case of B cell ALL, indicating that the the cost would be borne by the patient.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Dr. Anurag Gupta: He appears to be a student. Can he be co- investigator? He can be student investigator.	Dr. Anurag is MD in Pathology with more than a decade of experience in cytogenetics and molecular hematopathology. As his interest lies in molecular genetics of haematolymphoid neoplasm, he was an integral part of this study since its conceptualization as a part of his PhD. However, as suggested by the ethical committee, his name has been designated as student investigator.
	Who will fund the study?	The study requires analysis of RNA and DNA for achieving the aim, for which the funding will be applied by us to Govt organizations, NGOs and IIT Hyderabad. The application for the same is in process. There will not be any financial implications for the patient nor for KGMU, Lucknow.
	Sponsor information needed.	The study requires analysis of RNA and DNA for achieving the aim, for which the funding will be applied by us to Govt organizations, NGOs and IITH as well. The application for the same is in process. There will not be any financial implications for the patient nor for KGMU, Lucknow.
	Bio banking will be done: who holds	Dept of Biotechnology, Indian Institute of technology, Hyderabad
	Reason for reframing the & #39;Title' of the study	To make the aim more clearer. All cases of B ALL irrespective of the subgroups will being collected for 4 the study. The data thus generated will provide us the details of the differentially expressed genes in B ALL. The data will be interpreted for the presence of any potential marker of significance in B ALL.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:

- Bio-banking will be done. This has not been mentioned in the Consent form.

EC Comment:

- Where the consent form is also that bio-banking will be kindly follow Institutional I.P.R. policy for out cases of bio banking, if any.

EC Decision: Approval subject to modification

Ref. code: 114th ECM IIC/P19

3-	Clarification of research protocol no.082-20, Version no:1.0 & Protocol amendment no.01 dated 14.01.2021 entitled ***"A prospective, open-label, multi-centered, non-randomized, non-comparative active post-marketing surveillance to test the safety and efficacy of diperoxochloric acid (DPOCL) topical solution in subjects with diabeticneuropathic ulcers of skin and subcutaneous tissue"*** sponsored by M/s

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Centaur House, Opp. Grand Hyatt, Vakola, Santacruz-East, Mumbai submitted by Dr. Kushagra Gaurav, Assistant Professor, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3259/2022 dated 28th September, 2022.

Previous EC Comment	PI response
No reasoning for Sample size of at least 200 participants given.	This is an Active PMS Study of CDSCO-approved drug i.e. Diperoxochloric Acid [DPOCL] topical solution. In compliance with NDCT Rules, 2019 and the conditions stated in the form 46, active PMS study should be carried out in diabetic foot ulcer patients, hence this trial is planned. Since the purpose of the study is to generate data as part of post- marketing surveillance and such studies are non-comparative, usually sample size estimations are not required. For your record, this trial is planned to be carried out in at least 20 centers in India, with number of DFU patients not less than 200 and not more than 500.
A payment clause is there in point number 19. How much amount and why the payment would be charged is not provided.	There is no payment clause is mentioned in point number 19 in any of the document submitted in dossier of EC submission.
Insurance policy has expired.	We had already submitted the renewed insurance policy on 01/04/2022 vide Insurance Policy No. OG-22-1919-3306-00000039 having period of insurance 15-Mar-2022 To 14-Mar-2023. We are herewith resubmitting the insurance policy (Policy No. OG-22- 1919-3306-00000039) with acknowledgement copy dated 01.04.2022 for your reference [Enclosure 1 is Enclosed].
Duration of the Study is incorrect, Subject participation is not mentioned.	This is an Active PMS Study of CDSCO approved drug i.e. Diperoxochloric Acid [DPOCL] topical solution, therefore DSMB is not applicable. Section 11 of Ethical Clearance Form is modified. Resubmitting Ethical Clearance Form as Annexure 1-RV- 01/2019.
Ethical clearance form section 5 incomplete.	Section 5 is modified in Ethical Clearance Form. Resubmitting Ethical Clearance Form as Annexure 1-RV- 01/2019

The following documents were reviewed in the Meeting:-

Sl. no.	Documents
1-	Annexure 1: Submission Form from Principal investigator to IEC
2-	Letter from Sponsor to IEC
3-	Permission from DCGI to conduct Active PMS Study

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	4-	Letter of Acknowledgement against permission to conduct Active PMS study and Protocol amendment.
	5-	Form 46- WOXHEAL (Diperoxochloric Acid Topical solution)
	6-	Protocol
	7-	Protocol Amendment dated 14-01-2021
	8-	Study synopsis
	9-	Investigators Brochure
	10-	Insurance policy acknowledgement copy
	11-	Insurance Policy- L0178082
	12-	CTRI acknowledgement copy
	13-	CTRI Registration details
	14-	. CTA draft
	15-	Patient Information Sheet and Inform Consent Form (PIS-ICF)- English
	15-1	PIS-ICF Hindi translation
	15-2	PIS-ICF Certificate of translation-Hindi
	15-3	PIS-ICF Back translation Hindi to English
	15-4	PIS-ICF Certificate of back translation-Hindi to English
	16	Case Report Form (CRF)
	17	Undertaking by the investigator-KGMU format
	18	Undertaking by the investigator as per NDCT rule 2019
	19	Medical Registration Certificate
	20	Curriculum Vit
	21	Other IEC Approvals
	22	DPOCL-Presentation
	EC Decision: Approved ***Ref. code: 115th ECM IIC/P1***	
4-	Clarification of research protocol no. CA-170-302 entitled ***"A phase IIB/III, randomised, double-blind, placebo-controlled, study title: A multicentre, study of CA-170 in combination with chemotherapy in patients with stage IV non-squamous non-small cell lung cancer (ASIAD-3)"*** sponsored by M/s Aurigene Discovery Technologies Limited submitted by Dr. Sudhir Singh, Associate Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 969/RT/2022 dated 19th September, 2022.	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comment	PI response
Fresh IEC form has not been filled.	Attached
A lot of information is present in the Investigator brochure. It's the PI's duty to fill it in the IEC form, not that of IEC to search for it in 100s of pages of documents.	Reviewed and attached
The fact that it's a new drug doesn't justify use of Direct Identifiers.	New Drug & use for Fresh subject
PI should ensure that all the sections are filled properly.	Ensured

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:

- PI needs to know the difference between Study duration and the duration of subject participation and specify accordingly.
- PI is rigid on the use of direct identifiers, despite being advised against it. PI to kindly furnish document by DCGI/ justification that states that Direct Identifiers should be used.
- Why use vulnerable subjects like pregnant women?

EC Comment:

- As above

EC Decision: Approval subject to modification, Give a table of revisions done.

Ref. code: 116th ECM IIC/P4

5- Clarification of research proposal entitled ***"Mucormycosis: A comparative study between endoscopic and radiological features"*** submitted by Dr. Manish Chandra, Associate Professor, Department of Otorhinolaryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 607/ENT/MC/22 dated 13th September, 2022.

Previous EC Comment	PI response
Proper research hypothesis should be defined after identifying the study variables and population parameters involved.	Records of all patients diagnosed with mucormycosis between May 2021 and September 2021 will be retrieved and analysed. Details such as age, history of chronic illness, associated co-morbidities will be collected. Radiological findings only on Magnetic Resonance Imaging (MRI) and nasal endoscopic findings will be recorded. A comparison will be made between the above to find out a better and more effective diagnostic tool.
Study design seems to be case-control study	Our study is not a case-control study since all the patients diagnosed with mucormycosis and fulfilling the inclusion and exclusion criteria will be included in the study. All such patients should have undergone radiological and endoscopic investigations. Hence this is a retrospective

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	cohort observational study.
All the fundamentals for case-control study should be clearly outlined.	The study design is not a case-control study. Rather it is a retrospective cohort study.
Sample size calculation and statistical analysis are missing.	The study design of our research proposal is a retrospective observational study and hence all patients fulfilling the inclusion and exclusion criteria will be included in the study. The statistical analysis will be done using SPSS software 22.

The reply from PI to the above Comments was forwarded to PR:-

:-

Recommendation of PR: Provisionally Approved

EC Decision: Approved

Ref. code: 117th ECM IIA/P13

6- Clarification of research proposal entitled ***"Evaluation of blood group in patients of congenital malformation"*** submitted by Dr. Piyush Kumar, Assistant Professor, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 722/Ped Sy/22 dated 1st October, 2022.

Previous EC Comment	PI response
To include sample size(and its calculation)	Sample Size Estimation: The required sample size for the Study is calculated based on the standard formula for one-point sample estimation: Z 2 1-∞/2 P (1-P) Sample Size= d 2 To ensure coverage of minimum required sample size for estimating various outcome indicators of the study the value of 'P' (congenital anomaly) is taken as 1.7%. With the above assumption the required sample size at 95 percent level of confidence with 2 percent of permissible error in the estimates, is worked out as: n =1.96 2 * 0.017 * 0.983 / 0.02 2 = 160.49 Hence minimum sample size will be161.
ICF to be detailed in a simple way to make the patient understand the contents	Information added- File attached**
Give a brief account of the anticipated statistical analysis	Statistical analysis: The data will be entered in MSExcel, critically analyze and tabulate using SPSS- 28.0 version software. Statistical tests of significance Chi square test will be applied to test and validate the findings of the study. Adjusted and unadjusted odds ratios (OR) and their 95% confidence intervals (Cis) will be used as indicators of the strength of the association. A p-value of 0.05 or less will be used as cut off level for statistical significance.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	What major types of congenital anomalies are likely to be targeted?	Pediatric surgical condition- Anorectal malformation, Tracheoesophafea l fistula, Hypospadias, Hirschsprung's disease, intestinal atresia, meconium ileus/meconium plug syndrome, hydrocephalus, meningomyelocele / encephalocele, Posteri or urethral valve.

The reply from PI to the above Comments was forwarded to PR:-
:-
Recommendation of PR: Provisionally Approved
EC Decision: Approved

Ref. code: 117th ECM IIA/P21

7- Clarification of research proposal entitled ***"Palato-lingual direct-cross wire maxilla-mandibular fixation: A comparative study"*** submitted by Dr. Amiya Agrawal, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 810/OMSD/22 dated 3rd September, 2022.

Previous EC Comment	PI response
No review of literature to support the rationale of the study.	Review of Literature has been attached alongwith

The reply from PI to the above Comments was forwarded to PR:-
:-
Recommendation of PR: Approved
EC Decision: As above

Ref. code: 117th ECM IIA/P40

8- Clarification of research proposal entitled ***"Evaluation of dental implants with platelet rich in growth factor (PRGF) in smokers: A split mouth randomized controlled clinical trial"*** submitted by Dr. Aastha Singh, Ph.D. Scholar under the guidance Prof. Uma Shanker Pal, Department of Oral & Maxillofacial Surgery, FODS, King George's Medical University, U.P., Lucknow vide letter no. 787/OMSD/22 dated 22nd September, 2022.

Previous EC Comment	PI response
Sample size justification/calculation has not been done.	In reference to the EC comments, I am attaching the sample size calculation for the proposed research proposal entitled "Evaluation of dental implants with Platelet rich in growth Factor (PRGF) in smokers: A split mouth randomized controlled clinical trial." □ We will be taking 20 smoker patients who fulfillthe criteria of the study for bilateral replacement of missing teeth with implants and will be followed for 1 year after implant placement. □ As it is a split mouth study, we will consider 20 experimental and 20 control group sites i.e., 1 site will be randomly allocated for experimental

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		group and its bilateral site will be the control group in each smoker patient. ☐ The minimal sample calculated will be 19 (sample size at power 80%) or 23 (sample size at power 90%).
	Patient information sheet in Hindi has not been attached.	I am also attaching a copy of Hindi consent form as per the EC Comments.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Provisionally Approved
EC Decision: Approved

Ref. code: 117th ECM IIB/P6

9- Clarification of research proposal entitled ***"Association of apoptotic pathway genes polymorphism with newly diagnosed chronic phase-chronic myeloid leukemia"*** submitted by Ms. Kaynat Fatima, Ph.D Scholar under the guidance Prof. Syed Tasleem Raza & Co Guidance Dr. Shailendra Prasad Verma, Associate Professor, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. 545/CH/22 dated 17th October, 2022.

Previous EC Comment	PI response
Section on vulenerable subject	No vulnerable subjects included
Patient information sheet	Patient information sheet has now been attached with the proposal
Letter of scientific review committee	Dr. Shailendra Verma being the Co-PI is now not being considered as member of scientific review committee and there is no conflict of interest

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
EC Decision: As above

Ref. code: 117th ECM II B-Ph.D/P7

10- Clarification of research Protocol no. ODM-203-201 entitled ***"A phase II open-label trial evaluating the efficacy and safety of once daily Oral ODM-203 in patients with unresectable transitional cell urothelial carcinoma with FGFR3 mutation (TEJAS-1)"*** sponsored by Aurigene Discovery Technologies Ltd. submitted by Dr. Sudhir Singh, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 968/RT/2022 dated 19th September, 2022.

Previous EC Comment	PI response
Fresh IEC form has not been filled.	Attached
A lot of information is present in the Investigator brochure. It's the PI's duty to fill it in the IEC form, not that of IEC to search for it in 100s of pages of documents.	Reviewed and attached
The fact that it's a new drug doesn't justify use of	New Drug & use for Fresh subject

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Direct Identifiers.	
	PI should ensure that all the sections are filled properly.	Ensured
	PI should make some effort and put in all the information in the IEC form mentioning that it's a revised protocol.	Reviewed

The reply from PI to the above Comments was forwarded to PR:-

EC Comment:

- Mention the duration of study in Section III.
- Mention that there could be minimum discomfort on eating the tablet.
- Do not use the direct identifier.

EC Decision: Approval subject to modification

Ref. code: 117th ECM IIC/P1

11- Clarification of research protocol no. AKPL/FDC/AT/02/18 entitled ***"A phase III, multi-centre, double-blind, randomized, parallel-group, active-controlled trial to compare efficacy and safety of fixed dose combination of alfuzosin 10mg/10mg ER plus tadalafil 2.5mg/5mg tablets versus alfuzosin 10mg ER tablets in patients with lower urinary tract symptoms (LUTS) associated with benign prostatic Hyperplasia (BPH)"*** sponsored by Akums Drugs & Pharmaceuticals Limited submitted by Prof. Apul Goel, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. UR/CT/05/2022 dated 13th October, 2022.

Previous EC Comment	PI response
PI has mentioned In point 10 that risks of doing this study are not reasonable compared to anticipated benefits. Thus, conducting such a study will be completely unethical. Rest of the proposal has not been reviewed.	As per your valuable comment please find enclosed the revised Annexure 07 copy after correction in section no.10 for your kind perusal.
Department Scientific Committee Head is Co-PI in one document, Senior Resident is Co-PI In another. Both conditions are not acceptable. Cannot be accepted for review.	As per your valuable comment please find enclosed the revised Scientific Committee Approval .

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of PR:

- PI needs to know the difference between study duration and duration of subject participation.
- Does the PI doesn't consider that blood and urine as body fluids?
- Corrected and updated form not submitted.

EC Comment:

- Kindly correct your statement of Blood where are body fluids.
- Kindly submit document in which DCGI says direct identifiers are to be used.

EC Decision: Approval subject to modification

Ref. code: 117th ECM IIC/P3

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

12- Clarification of research protocol no. QPT-ORE-006 entitled ***"A Phase 2, Double-blind, placebo-controlled, multicenter clinical trial comparing chemoimmunotherapy (Paclitaxel-carboplatin-oregovomab) versus chemotherapy (Paclitaxel-carboplatin-Placebo) as neoadjuvant therapy in patients with advanced epithelial ovarian, fallopian tube or peritoneal carcinoma"*** sponsored by M/s Onco Quest Pharmaceuticals Inc submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/1656/2022 dated 14th October, 2022.

Previous EC Comment	PI response
Need to have a clear policy statement on sending tissues out of the Country. The rest proposal is acceptable	This is to clarify that The Director General of Foreign Trade (DGFT) has notified that the human biological samples imported into India for commercial purposes should be permitted by the customs authorities without prior approvals from any government agency, therefore it would no longer require import or export licenses for human biological samples. The importer of the human biological samples has to comply with the norms set for the save transfer and disposal of the biological samples. Earlier, the importer had to submit an application to the Indian Council of Medical Research (ICMR) for the import of human biological samples and the ICMR has been advised to set up a committee consisting of experts from relevant fields for deciding each proposal on a case-by-case basis and to furnish their views to the Government for consideration. For this purpose, the DGFT has inserted import and export policy for the transfer of human biological samples for commercial purposes under general notes 17 to schedule 1 import policy of Indian Trade Classification (Harmonised System) [ITC (HS)] 2012 and general notes 4 to schedule - 2 Export policy of ITC (HS) 2012. In the notification the DGFT said that the import of human biological samples by the Indian diagnostic laboratories or Indian clinical research centres for lab analysis or R&D testing or export of these material to foreign laboratories should be permitted by customs authorities at the port of entry or exit without prior approvals from any government agency, provided the concerned Indian company or agency submits an undertaking that they are following and will follow all the applicable rules, regulations and procedures for safe transfer and disposal of the biological samples being imported or exported as per the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		related norms or regulations set by WHO/DGFT or ministry of environment, forest and climate change, government of India, to the customs Authorities at the port of entry or exit along with the details of such sample. *https://main.icmr.nic.in/content/transfer-biological-material * Supporting notification has been attached with the letter.

The following documents were reviewed in the Meeting:

Sr. No.	Documents	Version	Date
1	DCGI Approval Letter For Protocol Version 1.0 dated 14 April 2022	NA	17 June 2022
2	Protocol	Version 1.0	14 April 2022
3	Investigator Brochure	Edition Number OVA-IB-Q8	18 May 2022
4	Patient Information Sheet And Informed Consent Form - in English	Version 01	24 May 2022
5	Patient Information Sheet And Informed Consent Form - in Hindi (Translated from English to Hindi) with its translation certificate	Version 01	20 June 2022
6	Patient Information Sheet And Informed Consent Form – Back Translated from Hindi to English with its translation certificate	Version 01	22 June 2022
7	Audio Video Recording Consent Form – in English	Version 00	27 April 2022
8	Audio Video Recording Consent Form – Hindi -Translated from English to Hindi with its translation certificate	Version 00	13 June 2022
9	Audio Video Recording Consent Form – Back Translated from Hindi to English with its translation certificate	Version 00	15 June 2022
10	Draft CRF	NA	25 April 2022
11	Insurance Certificate (Policy Number - 2022-L0208031-CLT	NA	8 June 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	with validity period from 01 Jun 2022 to 1 Dec 2025		
12	Partially Executive Clinical Trial Agreement	NA	NA
13	Principal Investigator CV & MRC	NA	NA
14	Protocol Signature Page For Protocol Version 1.0	NA	NA
15	Investigator Undertaking For Protocol Version 1.0	NA	NA
16	GCP Certificate of Principal Investigator dated 20-Apr-2022	NA	NA

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:

- Member-Secretary to decide if information and documentation for biological samples to be sent abroad is acceptable.

EC Decision: Approval is subject to fulfillment & Administrative formalities

Ref. code: 117th ECM IIC/P4

13- Clarification of research protocol no. BRADPL/CT/FDC/AZM/03/30 entitled ***"A multi-center, double-blind, randomized, active-controlled, comparative, parallel-group, phase III clinical study to evaluate the efficacy and safety of fixed dose combination of azelnidipine plus metoprolol succinate tablets in the treatment of subjects with stage 2 Hypertension"*** sponsored by M/s Akums Drugs & Pharmaceuticals Ltd. submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/26/2022 dated 13th October, 2022.

Previous EC Comment	PI response
Statistician to comment on study design-extremely large number of arms. Statistical tests significance for which arm/s versus which arm/s not specified.	The above mentioned study design is six arm, double-blind and parallel group study. In this study, each test drug arm will be compared with each reference arm. Comparison of each test arm vs reference arm is to prove superior efficacy of FDC versus the Monotherapy. Note that detailed statistical analysis will be mentioned in the Statistical Analysis Plan. Also, this Protocol is already approved by the SEC.
Information in section 3 (IV) and DCGI certificate are contradictory.	In section 3 (IV) this is New drug. It is inadvertently tick as NO. Kindly consider as YES and DCGI Permission and IB are attached in the Study Dossier.
he total study duration needs to be mentioned.	As per your valuable comment the total study Duration are already mention in the Annexure 07 section no 05 sub section (b) and in the Study Protocol also. (Total Study Duration is 12 weeks

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		per enrolled subject, Study treatment period is 12 weeks per subject)
	Why use direct identifiers.	Direct Identifiers is recommended by the DCGI.
	Section 7 (ii) is incorrectly filled: blood will be tested. need to fill subsequent fields correctly.	As per the section 07 use of fetal tissue, organs or body fluids are not collected. Only blood and urine will be tested for safety parameters.

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of PR:

- Section 3 (iii) not filled.
- Duration of study not mentioned.
- Direct identifiers: Why?
- Eating a tablet is physical discomfort. Why ticked no?

EC Comment:

- Statement expert to comment in sample size.
- Give study duration.

EC Decision: Approval subject to modification

Ref. code: 117th ECM IIC/P6

14- Clarification of research Protocol no. GLK-2101 entitled ***"A randomized, assessor-blind, placebo controlled, multi center, clinical endpoint bioequivalence study to compare the efficacy and safety of generic fluticasone propionate inhalation aerosol USP 44mcg (Glenmark Pharmaceuticals Ltd) to flovent HFA (Fluticasone propionate inhalation aerosol) 44mcg (GSK Group of Companies) in treatment of patients with bronchial asthma"*** sponsored by Glenmark Pharmaceuticals Ltd. B/2 Mahalaxmi Chamber submitted by Prof. R.A.S Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. RM/CT/06/2022 dated 18th October, 2022.

Previous EC Comment	PI response
Why use direct identifiers?	Direct Identifiers is recommended by the DCGI.
Total study duration needs to be mentioned.	As per your valuable comment the total study Duration are already mention in the Annexure 07 section no 05 sub section (b) and in the Study Protocol also. (Total Study Duration is 28 days per enrolled subject, Study treatment period is 28 days per subject)As per your valuable comment the total study Duration are already mention in the Annexure 07 section no 05 sub section (b) and in the Study Protocol also. (Total Study Duration is 28 days per enrolled subject, Study treatment period is 28 days per subject)
Need to check if biological samples are being taken.	As per the section 07 use of fetal tissue, organs or body fluids are not collected. Only blood and urine will be tested for safety parameters.
Kindly enumerate the direct identifiers being collected in the study.	Direct Identifiers is DCGI Recommendation.

The reply from PI to the above Comments was forwarded to PR:-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Recommendation of PR:

- PI needs to know the difference between study duration and duration of subject participation.
- PI to kindly furnish document by DCGI that states that Direct Identifiers should be used.
- Does the PI doesn't consider that blood and urine as body fluids?
- Corrected and updated form not submitted.

EC Comment:
As above

EC Decision: Revise and Resubmit, Give a table of revisions done.

Ref. code: 117th ECM IIC/P9

15- Clarification of research proposal entitled ***"ICMR MYCONET inpatient clinical registry: establishment of an analytics platform"*** sponsored by ICMR, New Delhi submitted by Prof. Prashant Gupta, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 958/2022 dated 13th October, 2022.

Previous EC Comment	PI response
The patient information sheet not related to the present research proposal should be revised.	Revised and eCRF attached.
PI ticked the written consent column in the IEC SOP form (HSR WF attached, as it is a data study) – Clarify or resubmit the IEC SOP form.	Written consent is not required as waiver has been asked for. No direct patient contact will be there in the study. ICMR has also provided approval from Central Ethics Committee on Human Research (CECHR) (Copy attached)
ICMR - acceptance letter and Budget not attached.	Add on project under AMDRC ICMR project attached letter and ICMR acceptance letter attached. Therefore, no extra budget is required.

The reply from PI to the above Comments was forwarded to PR:-

EC comment: Approved

EC Decision: As above

Ref. code: 118th ECM IIA/P7

16- Clarification of research proposal entitled ***"Delineate molecular mechanism in development of chemo-resistance in non-Hodgkin's lymphoma"*** sponsored by Regional Centre for Biotechnology submitted by Prof. Seema Gupta, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 1126/RT/2022 dated 15th October, 2022.

Previous EC Comment	PI response
The duration study is three years in annexure 1 while in methodology section it is 5 years Extendable for two more years. According to CDRI approval it is for one year- why this confusion?	Duration of this project according to department of Biotechnology and CSIR- CDRI document is total 5 years (7th August 2019 to 6th August 2024).
In annexure 1 a. While collection for banking future research' clause States NO, the investigator further states that consent for future	a. Collection for banking and future research will be done. b. Attached

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	use of material biological will be obtained- why this confusion? b. Information sheet needs to be attached both for patients and controls (which is missing) c. While data monitoring states that there is no plan for reporting adverse events, the IEC approval of CDRI states that the investigator should report serious adverse events within 24 hours- kindly clarify period.	c. Adverse events have to be reported within 24 hrs in KGMU only. This is not required at CDRI.
	Regarding the names of investigators: a. Kindly clarify/ rectify if the collaborators or guides/ co-guides? b. Dr Sanjeev Kumar and Dr Sunil Kumar will perform surgery: kindly clarify if biopsy alone will be done or some other surgical procedure. c. Since immuno- histochemistry needs to be done more appropriate to add a pathologist as a part of team.	a. Collaborators b. Biopsy alone will be done by Dr Sanjeev Kumar and Dr. Sunil Kumar c. Pathologist has been added (Prof. Rashmi Kushwaha, Pathology Department)
	The title pertains to non-Hodgkin's lymphoma while introduction, review and study population focuses on mantle cell lymphoma (MCL). Kindly clarify if only MCL is the focuses of study or non- Hodgkin's lymphoma as whole as reflected in inclusion criteria. In latter case the relevant review needs to be incorporated as well.	This study will enroll and include only mantle cell lymphoma (MCL).
	The aim states that pathways will be targeted. Is the word target reflects just identification or something more period.	New therapeutic avenues can be added to target these initiating cells specific gene and that would help to overcome development of chemo resistance in MCL Patients. We have mentioned in AIM "I will identify and target the de-regulated pathways associated to cancer stem cells and causing chemo- resistance development Mantle cell lymphoma that the chemoresistance pathway". This means using clinical MCL samples, we will isolate the cancer stem population by FACS sorting and followed by RNA sequencing. Once we will have the knowledge of differentially regulated genes in primary samples, we will use this knowledge to modify our MCL cell lines such as Z138, MINO, MAVER, and G519 to further investigate the mechanism of chemoresistance. Once we know which pathway are involved using MCL lymphoma cell lines, we will use specific inhibitor to test the efficacy to eliminate the chemoresistance again using MCL cell lines only described above. Please note, no such inhibitor will be used either on patient's samples or patients itself.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Kindly justify sample size calculation.	This is the pilot study (first time we are performing) therefore we are using n=50 at least to define the cancer stem cells signatures.
Add consent form for controls.	Consent form for control group is attached.
Regarding sample transportation where does SGPGI come and picture: kindly explain?	Samples will be collected by Dr. Neeraj Jain and his lab staff whenever the samples at KGMU will be available.
If clinical pathological features are to be recorded then enclose clinical observation protocol. In addition, what is meant by rest of data please Clarify?	Included in material document. Rest of the data means all the data obtained using mantle cell lymphoma cell lines (in vitro assays) will be statistically test using Student's-test or ANOVA.
Mention potential risks and benefits.	Included in material document.
Outcome measures should also be briefed.	Included in material document.
Anticipated statistical analysis can also be briefed.	Included in material document.
Also state if this is of any national significance.	This project has both national and global impact by providing a potential knowledge about chemo-resistant mantle cell lymphoma associated to cancer stem cells. The deregulated pathway in cancer stem cells can be further characterized by other researchers in this field and may possibly be helpful to utilized as therapeutic molecule for targeted therapy, and will be beneficial for those Mantle cell lymphoma patients who are relapsed/refractory to chemotherapy.
The contact details of investigator are missing on first page of informed consent form.	has been added
How will the budget of 40 lakhs be utilized? Kindly clarify.	Budget of 40 lakh will be utilized for consumables and sequencing services only (attached project sanction report).

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of PR: Approved

EC Decision: As above

Ref. code: 118th ECM IIA/P20

17- Clarification of research proposal entitled ***"Identification of molecular therapeutic target leading to development of chemo-resistance in non-GC DLBCL patients in India"*** sponsored by American Society of Hematology submitted by Prof. Seema Gupta, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 1125/RT/2022 dated 15th October, 2022.

Previous EC Comment	PI response
The duration of study is three years in the annexure while further extendable for one year in the methodology section but only one-year approval in CDRI IEC - kindly make it clear.	IEC has provided approval to investigator Dr. Neeraj Jain for one year but this extendable as mentioned in the approval letter. The IEC ethical is still active at CDRI (till 12/12/2022) and Dr. Jain has already submitted the extension request to CDRI.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The CDRI IEC approval letter will be submitted to KGMU once this will be available. Please also note; this project is ending on 31st March 2024 and also this is extendable at no cost (mentioned in the terms and condition of this grant attached)
In annexure 1 a. While collection for banking future research clause States NO, the investigator further states that consent for future use of material biological will be obtained- why this confusion? b. Information sheet needs to be attached both for patients and controls (which is missing) c. While data monitoring states that there is no plan for reporting adverse events, the IEC approval of CDRI states that the investigator should report serious adverse events within 24 hours- kindly clarify period.	a. Collection for banking and future research will be done. b. Attached c. Adverse events have to be reported within 24hrs.This isnot required at CDRI.
Regarding the names of investigators: a. Kindly clarify/ rectify if the collaborators or guides/ co-guides? b. Dr Sanjeev Kumar and Dr Sunil Kumar will perform surgery: kindly clarify if biopsy alone will be done or some other surgical procedure. c. Since immuno- histochemistry needs to be done more appropriate to add a pathologist as a part of team.	a. Collaborators b. Biopsy alone will be done by Dr Sanjeev Kumar and Dr Sunil Kumar c. Pathologist has been added (Prof. Rashmi Kushwaha, Pathology Department)
Kindly clarify if only DLBCL will be included or all B-NHL patient in inclusion criteria.	This study will enroll and include only DLBCL.
Kindly mention: a. What are the anticipated molecular features associated with clinical outcomes? b. What will be the source of healthy B-cells? Will it be from controls? Mention briefly about bioinformatics analysis/ approach if possible. c. Kindly quote full form of CRISPR approach.	a. Chemo resistance cells have expression of differential cell surface receptors or unique cell surface proteins. Identification of these unique cell surface proteins in relapse and refractory Non-GC DLBCL tumors and targeting these unique receptors would help to overcome treatment resistance in Non-GC DLBCL. b. Healthy person of similar age group as of majority of DLBCL patients will be considered as control group. 5 ml blood in EDTA tube will be collected to isolate B cells from them. These samples will be utilized for next generation sequencing including RNA or proteomics. c. Clustered regularly interspaced short palindromic repeats
Kindly justify sample size calculation.	This is the pilot study (first time we are performing) therefore we are using n=50 total DLBCL patients samples.
Add consent form for controls (if applicable)	Attached

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Regarding sample transportation where does SGPGI come in picture: kindly explain	Samples will be collected by Dr. Neeraj Jain and his lab staff whenever the samples at KGMU will be available.
	If clinical pathological features are to be recorded then enclose clinical observation protocol. In addition, what is meant by ' rest of data': please clarify?	Included in material document. Rest of the data means all the data obtained using mantle cell lymphoma cell lines (in vitro assays) will be statistically test using Student's-test or ANOVA.
	Mention potential risks and benefits.	Included in material document.
	Outcome measures should also be briefed.	Included in material document.
	Anticipated statistical analysis can also be briefed.	Included in material document.
	Also state if this is of any national significance.	This project has both national and global impact by providing a potential knowledge about chemo-resistant diffuse large B cells lymphoma associated to changes in cell surface proteins. These cell surface proteins can be further characterized by other researchers in this field and may possibly be helpful to utilized as therapeutic molecule for targeted therapy and will be beneficial for those DLBCL patients who are relapsed/refractory to chemotherapy.
	The contact details of investigator are missing on first page of informed consent form.	has been added
	It is mentioned that US$150,000 will be the budget: so will some part of this budget be diverted for KGMU? Kindly clarify	Budget of US$150,000 will be utilized for consumables, one manpower, computer purchase and conference attend, and publication charges payment and sequencing services only (attached project sanction report). No fund will be transferred to KGMU, any consumable required for sample collection can be provided from this fund through CDRI.

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of PR: Approved

EC Decision: As above

Ref. code: 118th ECM IIA/P21

18- Clarification of research protocol no. AVT06-GL-C01 Version: Version 2.0,21 December 2021 entitled ***"A randomized, double-masked, parallel-group, multicenter clinical study to evaluate the efficacy and safety of AVT06 compared with EU-Eylea® in subjects with neovascular (Wet) age-related macular degeneration (ALCOEYE)"*** sponsored by M/s Alvotech Swiss AG Thurgauerstrasse submitted by Prof. Sandeep Saxena, Department of Ophthalmology, King George's Medical University, U.P., Lucknow, vide letter no. 1096/OPh/2022 dated 17th October, 2022.

Previous EC Comment	PI response
Two Co-PIs are SRs Not acceptable according to University Guidelines.	As per the instruction, both SR's have been removed and the updated Investigator Undertaking form is attached for your kind

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		review and reference
	PI has mentioned in Point 10 that risks of doing this study are not reasonable compared to anticipated benefits. Thus, conducting such a study will be completely unethical.	In this study, the study drug is developed as a bio similar to the approved medication, 'EYLEA'. Due to this fact that this study involves with no placebo or sham arm treatment, the risk of the study drug are expected to be similar to the risks of the market available, approved EYLEA. Hence, the risk category was not selected. However, as 2 mentioned in the protocol and in the subject informed consent form, the most common side effect / risk in subjects receiving EYLEA are conjunctive hemorrhage, eye pain, clouding of the lens, moving spots in vision etc., During the consenting process, prior to the signatures, the Investigators will explain the side effects to the participants as mentioned in detail in page no 8 of the informed consent form. According to the above mentioned details, we have also updated the Annexure and attaching the document as an enclosure for your kind review and reference.
	Remove SR as Co-PI	As per the instruction, both SR's have been removed and the updated Investigator Undertaking form is attached for your kind review and reference
	In point 10, you have mentioned that risk of the study.	Described in 2nd point of this table.

The above comment forwarded to PI was reviewed by PR:-

Recommendation of PR:

- The sponsor information in form and DCGI documents is different.
- What investigations will be done locally?
- What tests and imaging will be done for this study and how will data be transferred securely for central imaging review?
- PI needs to know the difference between study duration and duration of subject participation.
- Confidentiality and privacy section: not filled.

EC Comment:

- As above

EC Decision: Revise and Resubmit, Give a table of revisions done

Ref. code: 118th ECM IIC/P1

19- A letter was received in the office of the Ethics Committee vide letter no. 1577/Psy dated 19th October 2022 under the research proposal entitled ***"A study of Activity of daily living, Behavioral & psychologist symptoms and cognition in Alzheimer's disease vis a vis their association with structural MRI brain changes"*** in respect of Dr. G.Prasad Rao, Ph.D. Scholar received from Prof. Vivek Agarwal, Head, Department of Psychiatry, K.G's Medical University, U.P., Lucknow.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: • Whether ASHA Hospital Ethics Committee is registered with ICMR? • Submit the number of Registration also. **EC Decision:** Approval subject to modification
20	**ADR sub Committee (DCGI & Non DCGI)**
IA-	Minutes of the **"ADR Sub Committee"** Meeting of **"Institutional Ethics Committee"** virtually held on 22nd October, 2022 from 10:00 A.M. **(DCGI)** ***The following Members were present in the Meeting:*** 1. Dr. Alok Dhawan -Chairman 2. Mrs. Akanksha Dubey -Member 3. Mrs.Vasundhara Kumari -Member 4. Dr. Rajendra Nath -Member 5. Dr. D.N.Upadhyaya -Member 6. Mr. Ujjawal Krishna -Member 7. Dr. Shally Awasthi -Member-Secretary, IEC
	Hospitalization
1.	ADR of research protocol entitled ***"A multicenter, open label, long-term extension study to assess the safety and efficacy of filotinib in subjects with Rheumatoid Arthritis"*** sponsored by M/s KlinEra Corporation India, Mumbaiby Dr. Puneet Kumar, Department of Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/331 dated 30th May, 2022. **Subject ID no. C-D/15876-43979** **Subject Initial:** F **Gender:** F **Age:** 56 yrs, 08 months **Weight:** 45 KG **Height:** 152 CM **Hospitalized:** 26-08-2019 **Discharge Date:** 31-08-2019 **Patient History:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	A letter was received in the office of the Ethics Committee on 30/05/2022. The patient has visited the site for wk 24 visit on 26th August, 2019 and informed that she has mild pain in her abdomen since 19th August, 2019. Pentofer 40 was advised for pain in abdomen. She has completed the visit procedure. On 28th August, 2019, PI has received an alert for the subject with high S Amylase and S Lipase level G4 toxicity. PI has called the patient to visit the site immediately. Patient visited the site on 29th August, 2019. A retest sample was sent for S Amylase and S Lipase and the patient was hospitalized for close monitoring, further evaluation and management of the event. USG abdomen was performed on 30th August, 2019. Patient was discharged on 31/08/2019 as serum Amylase and S Lipase levels reduced and the patient was clinically stable and asymptomatic. Patient was advised to visit the site after one week for a repeat test. A repeat blood sample was sent to the central lab for Amylase and Lipase tests on 09th September, 2019. Reports were received on 16th September, 2019 and were within normal range. Patient was informed to restart IP on 21st September, 2019. ***Recommendation of PR:-*** The SAE (Hospitalization) is likely due to disease outcome (Rheumatoid arthritis) and not due to the Interventional product (Filgotinib) as Subject was taking IP from 13th March, 2019 (Starting date) and event reported to PI on 26th August-2019 i.e. more than 5 months has elapsed after starting the interventional drug. A causality relationship cannot be established. Moreover, as the subject was immediately hospitalized and given proper management which resolved the SAE (hospitalization due to pancreatitis); thus, no compensation is required. **ADR sub Committee Comment:** ▪ The Committee is of the opinion that this information should have been given immediately as per protocol. **ADR sub-Committee Decision:** Noted ***Ref. code: 86th ECM II E/P1***
2.	ADR of research protocol entitled ***"A multicenter, open label, long-term extension study to assess the safety and efficacy of filotinib in subjects with Rheumatoid Arthritis"*** sponsored by M/s KlinEra Corporation India, Mumbai, by Dr. Puneet Kumar, Department of Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/40/2022, dated 24th September, 2022. **Subject ID no. K/15876-44017** **Subject Initial:** R-K **Gender:** F **Age:** 41 yrs, 08 months, **Weight:** 50 KG

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Height: 145 CM **Hospitalized:** 29/08/2019 **Discharge Date:** 09/09/2019 **Patient History:** A letter was received in the office of the Ethics Committee on 24/09/2022. The patient had visited for wk 24 visit and informed that she had a gland in Neck with fever since 14th August 2019. Ultrasound was performed and findings were suggestive of left supraclavicular Lymphadenopathy (infective/inflammatory). Patient was hospitalized for further evaluation and management. Patient also had C/o decreased appetite, Nausea, Vomiting, mild Dysphagia, Fever with Chills. FNAC was done on 30th August, 2019. Cytomorphology was consistent with Reactive Lymph Node Hyperplasia. No Granuloma or atypical cells were seen. Patient was treated with Inj. Emset 8mg IV TDS, Tab Calcium 500mg 1BD, Cap. Sompraz-D 1OD BBF, Tab Dolo 650mg SOS, Inj Pantocid 40mg IV OD, Inj Ceftriaxone iG IV BD, Tab Cloze 0.5 mg 1OD HS. Treatment advice on 9.9.2019: Tab Dolo 650 mg SOS, Tab Cefixime 200mg 1BD X 5 days, Tab Cloze 0.5mg 1 OD HS, Tab Adirab DSR 1 OD BBF. ***Recommendation of PR:-*** The SAE (Hospitalization) is likely due to disease outcome (Rheumatoid arthritis) and not due to the Interventional product (Filgotinib) as the subject was taking IP from 13th March, 2019 (Starting date) and event reported to PI on 14th August-2019 i.e. 5 months has elapsed after starting the interventional drug. Therefore, causality relationship of SAE with the IP drug is difficult to assess and cannot be established as the subject was managed and treated properly in the hospital and was discharged safely after recovery; thus, no compensation is needed. (Follow-up after discharge of the subjects after the occurrence of SAE may be submitted by PI for further monitoring and for signaling of post marketing cases in this clinical trial for both of the above SAEs). **ADR sub Committee Comment:** ▪ The Committee is of the opinion that this information should have been given immediately as per protocol. **ADR sub Committee Decision:** Noted ***Ref. code: 86 ECM-IIE/P1***
3-	ADR of research protocol entitled ***"Evaluate the effectiveness, safety and tolerability of various doses of Linezolid in combination with Bedaquillne and pretomanid in Adults with Pre-Extensively Drug-Resistant (Pre-XDR) or Treatment Intolerant /Non-responsive Multidrug-Resistant ($MDR_{TI/NR}$) Pulmonary Tuberculosis in India"*** sponsored by ICMR-NIRT, New Delhi submitted by Prof. Surya Kant, Head,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1067/Res. Med./22 dated 22nd September, 2022. **Death** **Subject ID no. L010** **Subject Initial:** P-G **Gender:** F **Age:** 35 years **Weight:** 35 KG **Height:** 152 CM **Hospitalized:** 01-09-2022 **Discharge Date:** 04-09-2022 **Patient History:** A letter was received in the office of the Ethics Committee on 06/09/2022. The letter stated that subject hospitalized on 26/08/2022. Subject came into the hospital OPD on 26/08/2022 with the complaint of Atypical symptoms, pain in shoulder and Dyspnea on exertion from last 7 days; hence yesterday he got admitted for the stabilization, his Coronary Angiography done 27/08/2022. All stent patent LCX/RCA distal small vessel disease. Distal to LAD stent 50% disease. FFR to LAD: 0.92. ***Recommendation of Primary reviewer:-*** • SAE (Hospitalization) due to severe anaemia is likely due to chronic disease i.e. PRE-XDR-TB, although it may be due to chronic intervention (Linezolid) but as the patient was randomized to Arm-1 on 02-05-2022 & patent had completed 15 week follow-up safely. Therefore, it was unlikely due to intervention. • No compensation is required as patient was treated in hospital well & SAE (hospitalization due to anaemia) was resolved. • (Weekly Follow up from the beginning and after discharge from hospital has not been given by PI which would be helpful for further monitoring of the subject) **EC Comment:** • Give information on follow-up of the patient. **EC Decision:** Noted ***Ref. code: 102nd /ECMIIA/P24***
IB	Minutes of the **"ADR Sub Committee"** Meeting of **"Institutional Ethics Committee"** virtually held on 22nd October, 2022 from 10:00 A.M. **(Non-DCGI)** ***The following Members were present in the Meeting:*** 1. Dr. Alok Dhawan -Chairman 2. Mrs. Akanksha Dubey -Member

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	3. Mrs.Vasundhara Kumari -Member 4. Dr. Rajendra Nath -Member 5. Dr. D.N.Upadhyaya -Member 6. Dr. Shally Awasthi -Member-Secretary, IEC
	SAEs
	Hospitalization
1-	ADR of research protocol entitled ***"Tuxedo-2 Study "Ultra-Thin strut versus XiencE in a Diabetic population with Multi-Vessel Disease-2-India Study"*** M/s Batara Hospital and research centre, submitted by Prof. Sharad Chandra, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 287/Cardio/Res/2022 dated 6th September, 2022, preliminary information was received by email on 27th August, 2022 at 4.36 AM. **Death** **Subject ID no. 105024** **Subject Initial:** M **Gender:** M **Age:** 50 years **Patient follow up under study:** **Randomization visit:** 1st Month, 6th Month, 12th Month, 24th Month, 36th Month, 48th Month, 60th Month **Weight:** 72 KG **Height:** 165 CM **Hospitalized:** 26/08/2022 **Discharge Date:** 28/08/2022 **Patient History:** A letter was received in the office of the Ethics Committee on 06/09/2022. The letter stated that the subject was hospitalized on 26/08/2022. The subject came to the hospital OPD on 26/08/2022 with the complaint of Atypical symptoms, pain in the shoulder, and Dyspnea on exertion from last 7 days; hence he got admitted for stabilization, his Coronary Angiography was done on 27/08/2022. All stents were patent LCX/RCA distal small vessel disease. Distal to LAD stent 50% disease showed. ***Recommendation of Primary reviewer:*** • The subject was enrolled on 19th May, 2022. 1 month follow up was completed. Awaiting 6 month follow up. • SAE was detected on 26.08.2022. Hospitalization from 26th August 2022 to 28th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	August, 2022. Conservative management was done. Patient improved. • SAE appears to be an outcome of the disease process and not related to the drug. Angiography shows patent stent with distal small vessel disease. **ADR sub Committee Comment:** • As above **ADR sub Committee Decision:** Noted ***Ref. code: 101/ECMIIC/P11***
	Death
1-	ADR of research protocol entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trail"*** M/s Gilead Sciences Inc. submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 288/Cardio/2022 dated 7th September,/2022 preliminary information was received by email on 25th August, 2022 at 11.02 AM. **Death** **Subject ID no. 009** **Subject Initial:** M **Gender:** M **Age:** 53 years (According to Death Certificate) **Patient follow up under study:** **Randomization visit,** 6th Month, 12th Month, 18th Month, 24th Month, 30 Month, 36th Month **Weight:** 50 KG **Height:** 166 CM **Patient expired:** 13/05/2022 **Patient History:** A letter was received in the office of the Ethics Committee on 07/09/2022. The letter stated that the subject expired on 13/05/2022. Principal Investigator telephonically called for a final follow-up on 24th August, 2022 around 11:30 A.M. LAR informed that **Subject expired on 13/05/2022** around 11:30 A.M at home. He suddenly collapsed at home. He was not hospitalized anywhere and they had called a local physician for an evaluation. No Autopsy was done. The subject developed some uneasiness 30 minutes prior and suddenly collapsed at home. He could not be hospitalized anywhere and the local practitioner visited his place and confirmed the subject's death. PI revealed that he does not has the exact records to ascertain the cause of death. No Autopsy was done. Hence, a causality assessment cannot be done. **Death Certificate is attached.** ***Recommendation of Primary reviewer:*** • The subject was enrolled on 29th April, 2022. Enrolment and Baseline follow-up completed. Waiting for 6 month follow up. • SAE occurred on 13th May, 2022, which was detected on 24th August, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• SAE doesn't appear to be related to the study international product and appears to be related to disease outcome. **ADR sub Committee Comment:** • As above **ADR sub Committee Decision:** Noted ***Ref. code: 102 /ECMIIA/P24***
II-A	**New Proposal**
1.	Research proposal entitled "***Self-directed learning readiness among medical, dental, and nursing students: a cross-sectional study***" submitted by Prof. Apjit Kaur, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 785/2022 dated 23rd August, 2022. ***Recommendation of Primary reviewer:-*** • Approved **EC Decision:** As above ***Ref. code: 119th ECM IIA/P1***
2.	Research proposal entitled "***Determinants of readmission to the intensive care unit: A Hospital data based approach***" submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 227/CCU/2022 dated 5th September, 2022. ***Recommendation of Primary reviewer:-*** • There are different annexures including patient consent form, but the proposal details are missing. **EC Comment:** • As above **EC Decision:** Approval after modification ***Ref. code: 119th ECM IIA/P2***
3.	Research proposal entitled "***Effect of dopamine as VEGF antagonist on progression of sepsis to septic shock, ALI (acute lung injury) and AKI (acute kidney injury)***" submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 225/CCU/2022 dated 5th September, 2022. ***Recommendation of Primary reviewer:-*** • To mention the incidence of septic shock ALI/ AKI in severe sepsis and how much reduction is anticipated? Sample size to be mentioned accordingly. • Proper patient information sheet needs to be attached both in English and Hindi. • The aim indicates estimation of VEGF levels, while no biological samples will

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	be collected as per the submission- How will assess of VEGF levels be made. As there is no co-investigator other than Department of anaesthesiology where will this VEGF be estimated and how? Also all relevant lab work on such patients may be mentioned in methodology section. • How will the third aim be assessed i.e. survival benefit? Whether it would be a short-term survival benefit or long-term survival outcomes? What data will be collected in this regard? • Apart from describing the methodology in detail also attach the data collecting sheet/ protocol to support the aims and objectives. • If no biological specimen is to be obtained then what is the role of cytogenetic lab? • What will be the dosing schedule of dopamine? Will it be over and above of routine clinical requirement- if yes, then what will be the anticipated adverse effects that further needs to be mentioned in informed consent form? • The project needs to be re-written with the literature, review, methodology, anticipated data, outcomes and statistical analysis according to all the three aims and objectives. **EC Comment:** • As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: 119th ECM IIA/P3***
4.	Research proposal entitled ***"The diagnostic and prognostic role of vascular endothelial growth factor- A in patients with early sepsis"*** submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 228/CCU/2022 dated 5th September, 2022. ***Recommendation of Primary reviewer:-*** • Proper patient information sheet needs to be enclosed both in English and Hindi. • Sample size justification is to be included. • Methodology is grossly incomplete. • There is No indication of VEGF estimation as has been mentioned in the title. • How will the diagnostic role of VEGF be established? • How will the prognostic role of VEGF be established? • Anticipated outcome variables need to be mentioned. • Anticipated statistical analysis need to be mentioned. • A co-investigator other than Anesthesiologist need to be included who can do VEGF estimation assessment. • The review of literature should also mention the diagnostic and prognostic status of VEGF in sepsis. • Overall the project needs to be rewritten and all the above points to be clarified. **EC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: 119th ECM IIA/P4***
5.	Research proposal entitled ***"Analyzing tympanic membrane central perforation using AI protocol: a pilot study"*** sponsored by Joint Collaboration by KGMU, AKTU submitted by Prof. Anupam Mishra, Department of Otorhinolaryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 602/ENT/AM/2022 dated 8th September, 2022. ***Recommendation of Primary reviewer:-*** Pending • Approved. A consent waiver is applied for and may be granted. **EC Decision:** As above ***Dr. Anupam Mishra did not take part in the discussion & making decision.*** ***Ref. code: 119th ECM IIA/P5***
6.	Research proposal entitled ***"Randomized controlled trial of herbal product (HF-Gel) for treating vulvovaginal candidiasis with clotrimazole gel as control"*** sponsored by CSIR-National Botanical Research Institute Lucknow submitted by Dr. Manju Lata Verma, Associate Professor Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1924/2022 dated 8th September, 2022. ***Recommendation of Primary reviewer:-*** Pending • Sample size justification has not been given. • The IEC form mentions the study as a 'Clinical Trial' but denies that it is a Investigational New Drug (section 3 iv of IEC form) • Response to the question 'Is the risk reasonable' has been ticked a 'No'. • The proforma mentions that DCGI clearance is not application. • No mention of a trial registry in the proforma. **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 119th ECM IIA/P6***
7.	Research proposal entitled ***"A study on assessing the role of circulating tumor DNA/circulating free DNA (ctDNA/CfDNA) ratio in oral squamous cell carcinoma progression through RNA sequencing meta-analysis and subsequent real-time PCR"*** submitted by Prof. Shaleen Chandra, Head, Department of Oral Pathology & Microbiology FODS, King George's Medical University, U.P., Lucknow vide letter no. 865/OP/2022 dated 31st August, 2022. ***Recommendation of Primary reviewer:-*** • Principal-Investigator has stated that the project is an ICMR multi-centric project; however no communication regarding the same from ICMR has been attached to the proforma.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Budget approximation is presented but the approval from ICMR is not attached. • Answer to the question 'is the risk reasonable' has been mentioned as 'No'. **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 119th ECM IIA/P7***
8.	Research proposal entitled "***Role of peer assessment in modifying professional behavior and self-assessment among phase I medical undergraduates: A prospective interventional study***" submitted by Prof. Jyoti Chopra, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 295/Anat/2022 dated 13th September, 2022. **EC Decision:** Approved ***Ref. code: 119th ECM IIA/P8***
9.	Research proposal entitled "***Clinical profile of young rectal cancers in India, A retrospective audit***" submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1457/2022 dated 30th August, 2022. **EC Decision:** Approved ***Ref. code: 119th ECM IIA/P9***
10.	Research proposal entitled "***FOXTROT 2 India: pilot randomised trial evaluating neoadjuvant chemotherapy in older and/or frail patients with locally advanced but operable colon cancer***" submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1453/2022 dated 30th August, 2022. ***Recommendation of Primary reviewer:-*** • Multicentric drug trial. • IEC approval of other centers should be provided. At least the main coordinating centre. • The drug trial is on old and frail patients but under subject selection – the Vulnerable subject Is ticked as 'NO' . They will be enrolling old and frail patients. • Need to address this issue. • See pages 28 and 29 for frailty score. It also includes cognitive domain. Of course the inclusion criteria mentions. Patient able and willing to provide written informed consent for the study'. • PLEASE TAKE OPINION FROM SOME EXPERT ABOUT THE DRUGS IN TRIAL. • The safety and efficacy of NAC in the fit colon cancer population has been established in the FoXTROT 1 study. However, benefits have not been proven

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	in frail or older patients, not significantly represented in that trial. Two important findings suggest that this group should be studied. Firstly, major postoperative complications were reduced in patients who had received NAC, and secondly that subgroup analysis shows evidence of a comparable benefit in older and frail patients. We hypothesise that this population may gain most from a NAC approach. These benefits may be enhanced in the Indian subcontinent, where more patients present with locally advanced disease. • Patient information brochure is comprehensive but too big. Need to be reduced, otherwise no-one will read. **EC Comment:** • Optional video/audio may be needed. • Kindly provide Patient information sheet. **EC Decision:** Approval subject to modification & fulfillment administrative formalities. ***Ref. code: 119th ECM IIA/P10***
11.	Research proposal entitled "***Anorectal melanoma: clinicopathological features and correlation with survival-prognostic model***" submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1458/2022 dated 30th August, 2022. ***Recommendation of Primary reviewer:-*** • Retrospective study and waver of consent has been asked. It is a multicentric study. There is no information about the other centers and what is the approval of their IECs. • To explore the molecular and biomarker profile of the anorectal melanomas especially for BRAF, cKit, RAS and PDLL – This is one of the aims and the researcher says that if previously this testing had not been done then the testing for the same will be performed using the formalin fixed paraffin embedded tissue by sequencing for BRAF, cKit and RAS and by IHC for PDL1 as per the established protocols in the pathology department. • The committee should see if this is eligible for the waver of consent. • The follow up data will be included as available in the records. Please confirm whether the patients will be recon acted for the follow up. **EC Comment:** • When initial samples were collected was approval taken for future use? • Waiver of informed consent approved it patients are not re-contacted. **EC Decision:** Approval subject to modification ***Ref. code: 119th ECM IIA/P11***
12.	Research proposal entitled "***Intra ocular pressure changes with reading on a smart phone (Digital Print) compared to conventional printed text among healthy***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	volunteers and medically controlled primary open angle glaucoma patients" submitted by Dr. Rajat Mohan Srivastava, Associate Professor, Department of Ophthalmology King George's Medical University, U.P., Lucknow vide letter no. 926/2022 dated 13th September, 2022. ***Recommendation of Primary reviewer:-*** Approved **EC Decision:** As above ***Ref. code: 119th ECM IIA/P12***
13.	Research proposal entitled ***"Developing an artificial intelligence (AI) based mobile application for cataract detection in Uttar Pradesh"*** submitted by Prof. Apjit Kaur, Head, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 937/OPH/2022 dated 16th September, 2022. ***Recommendation of Primary reviewer:-*** Approved **EC Decision:** As above ***Ref. code: 119th ECM IIA/P13***
14.	Research proposal entitled ***"A comparative study on orientation to adult learning of facilitators of King George's Medical University Lucknow between teaching of undergraduate and postgraduate students"*** submitted by Dr. Dilutpal Sharma, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. 321/DME/2022 dated 15th September, 2022. ***Recommendation of Primary reviewer:-*** • Patient information sheet to change subject information sheet. **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 119th ECM IIA/P14***
15.	Research proposal entitled ***"Comparison of JAK2/STAT3 signaling pathway and its expression in placental tissue of GDM versus non-GDM pregnant women"*** submitted by Dr. Kalpana Singh, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/520/2022 dated 22nd September, 2022. ***Recommendation of Primary reviewer:-*** Approved **EC Decision:** As above ***Ref. code: 119th ECM IIA/P15***
16.	Research proposal entitled ***"Incidence of congenital anomalies in a tertiary care hospital and the need to establish a birth defect registry for pediatric surgical conditions"*** submitted by Prof. Jiledar Rawat, Head, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 701/PedSy/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:-*** Approved **EC Decision:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 119th ECM IIA/P16
17.	Research proposal entitled ***"Heel pain and calcaneal enthesophytes: A radiological evaluation"*** submitted by Prof. Archana Rani, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 329/ANAT/2022 dated 28th September, 2022. ***Recommendation of Primary reviewer:-*** • The PI has said that the risks involved are not reasonable. Thus, doing this study will be unethical. **EC Comment:** • As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. *Ref. code: 119th ECM IIA/P17*
18.	Research proposal entitled ***"Evaluation of lignocaine HCI as a therapeutic and diagnostic tool in myofascial pain dysfunction syndrome (MPDS0 and internal derangement"*** submitted by Prof. U.S Pal, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. OMSD/809/2022 dated 29th September, 2022. ***Recommendation of Primary reviewer:-*** • The PI has said that the risks involved are not reasonable. Thus, doing this study will be unethical. **EC Comment:** • As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. *Ref. code: 119th ECM IIA/P18*
II-B	**New Ph. D Proposal**
1.	Research proposal entitled ***"COVID-19 testing in two districts of Uttar Pradesh: access utilization, and associated factors during the second epidemic wave"*** submitted by Mr. Raghukul Ratan Pandey, Ph.D Scholar 2021 under the guidance Prof. Amita Jain, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 800/22 dated 9th September, 2022. ***Recommendation of Primary reviewer:-*** • In Inclusion criteria there is no mention of Pregnant /Lactating women, but in SOP form Pregnant women column is ticked yes–please clarify. • Two Co-PIs from abroad University have been taken in the study –whether there is any collaboration between KGMU & John Hopkins University, Baltimore , Maryland USA for this study (Matter for discussion in EC) **EC Comment:** • As above **EC Decision:** Approval subject to modification

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 119th ECM II B-Ph.D/P1
II-C	**Review of New Drug Trial**
1.	Research protocol no.LIB003-007 entitled ***"Open-label extension phase 3 study to evaluate the long-term efficacy and safety of LIB003 in patients with homozygous and heterozygous familial hypercholesterolemia, cardiovascular disease, or at high risk for cardiovascular disease, on stable lipid-lowering therapy requiring additional low-density lipoprotein cholesterol reduction (LIBerate-OLE)"*** sponsored by M/s LIB Tharapestics, LLC Ltd. submitted by Dr. Akshyaya Pradhan, Additional Professor, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no. 278/Cardio/Res/2022 dated 29th August, 2022.

The following documents were reviewed in the Meeting:

Sr. No	Document	Version	Version/Document Date
1	Study Protocol	1.1	27July2021
2	Investigator Brochure (IB)	6.0	25June2021
3	Principal Investigator Undertaking	N/A	23April2021
4	Principal Investigator CV	N/A	4March2021
5	Principal Investigator GCP Certificate	N/A	N/A
6	Principal Investigator Medical Registration Certificate	N/A	N/A
7	Principal Investigator -Protocol Signature Page	1.1	
8	Participant Infor mation Sheet and Informed Consent Form-OLE (Main ICF) in English	Master : 1.1 India: 1.1 Site-specific: 1.0	Master: 24Sep2021 India: 06Oct2021 Site specific:19Oct2021
9	Participant Information Sheet and Informed Consent Form OLE (Main ICF) in Hindi with translation certificate	Master : 1.1 India: 1.1 Site-specific: 1.0	Master: 24Sep2021 India: 06Oct2021 Site specific:19Oct2021
10	Participant Information Sheet and Informed Consent Form OLE (Main ICF) : Back translation from Hindi to English with translation certificate	Master : 1.1 India: 1.1 Site-specific: 1.0	Master: 24Sep2021 India: 06Oct2021 Site specific:19Oct2021
11	Participant Information Sheet	Master : 1.0	Master: 15Sep2020

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	and Informed Consent Form (Home nursing) in English	India: 1.0 Site-specific: 1.0	India: 02April2021 Site specific:19Oct2021
12	Participant Information Sheet and Informed Consent Form (Home nursing) in Hindi with translation certificate	Master : 1.0 India: 1.0 Site-specific: 1.0	Master: 15Sep2020 India: 02April2021 Site specific:19Oct2021
13	Participant Information Sheet and Informed Consent Form (Home nursing): Back translation from Hindi to English with translation certificate	Master : 1.0 India: 1.0 Site-specific: 1.0	Master: 15Sep2020 India: 02April2021 Site specific:19Oct2021
14	Pregnant Partner Release of Information Consent Form in English	Master : 1.1 India: 1.1 Site-specific: 1.0	Master: 29Sep2021 India: 06Oct2021 Site specific:19Oct2021
15	Pregnant Partner Release of Information Consent Form in Hindi with translation certificate	Master : 1.0 India: 1.0 Site-specific: 1.0	Master: 29Sep2021 India: 06Oct2021 Site specific:19Oct2021
16	Pregnant Partner Release of Information Consent Form: Back translation from Hindi to English with translation certificate	Master : 1.0 India: 1.0 Site-specific: 1.0	Master: 29Sep2021 India: 06Oct2021 Site specific:19Oct2021
17	Informed Consent Form For Audio-Video Recording of Informed Consent Process in English	India: 1.0 Site-specific: 1.0	India: 06April2021 Site specific: 19Oct2021
18	Informed Consent Form For Audio-Video Recording of Informed Consent Process in Hindi with translation certificate	India: 1.0 Site-specific: 1.0	India: 06April2021 Site specific: 19Oct2021
19	Informed Consent Form For Audio-Video Recording of Informed Consent Process:	India: 1.0 Site-specific: 1.0	India: 06April2021 Site specific:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Back translation from Hindi to English with translation certificate		19Oct2021
20	Patient Emergency Card in English	2.0	15March2021
21	Patient Emergency Card in Hindi with translation certificate	2.0	15March2021
22	Patient Emergency Card : Back translation from Hindi to English with translation certificate	2.0	15March2021
23	Patient Instructions card in English	1.0	19Oct2020
24	Patient Instructions card in Hindi	1.0	19Oct2020
25	Patient Instructions card : Back translation from Hindi to English with translation certificate	1.0	19Oct2020
26	RA approval letter	NA	22July2021
27	eCRF	1.0	18Jan2021
28	Insurance certificate	NA	17May2021
29	Draft CTA	NA	NA
30	CTRI ack number (REF/2021/09/046932)	NA	NA
31	Self -Administration of Study Medication Information Sheet Addendum – Main ICF (English)	Master : 1.0 India: 1.0 Site-specific: 1.0	Master: 25Jan2022 India: 03Mar2022 Site specific:08Apr2022
32	Self -Administration of Study Medication Information Sheet Addendum- Main ICF (Hindi with translation certificate)	Master : 1.0 India: 1.0 Site-specific: 1.0	Master: 25Jan2022 India: 03Mar2022 Site specific:08Apr2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	33	Self -Administration of Study Medication Information Sheet Addendum – Main ICF (Back translation from Hindi to English with translation certificate)	Master : 1.0 India: 1.0 Site-specific: 1.0	Master: 25Jan2022 India: 03Mar2022 Site specific:08Apr2022
	34	Self -Administration of Study Medication Information Sheet Addendum and Assent Form of a Minor (Aged 12 – 17) (English)	Master : 1.0 India: 1.0 Site-specific: 1.0	Master: 07Feb2022 India: 03Mar2022 Site specific:08Apr2022
	35	Self -Administration of Study Medication Information Sheet Addendum and Assent Form of a Minor (Aged 12 – 17) (Hindi with translation certificate)	Master : 1.0 India: 1.0 Site-specific: 1.0	Master: 07Feb2022 India: 03Mar2022 Site specific:08Apr2022
	36	Self -Administration of Study Medication Information Sheet Addendum and Assent Form of a Minor (Aged 12 – 17) (Back translation from Hindi to English with translation certificate)	Master : 1.0 India: 1.0 Site-specific: 1.0	Master: 07Feb2022 India: 03Mar2022 Site specific:08Apr2022
	37	Self -Administration of Study Medication Assent Form of a Minor (Aged 10 – 11) (English)	Master : 1.0 India: 1.0 Site-specific: 1.0	Master: 01Feb2022 India: 03Mar2022 Site specific:08Apr2022
	38	Self -Administration of Study Medication Assent Form of a	Master : 1.0	Master: 01Feb2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Minor (Aged 10 – 11) (Hindi with translation certificate)	India: 1.0 Site-specific: 1.0	India: 03Mar2022 Site specific:08Apr2022
	39	Self -Administration of Study Medication Assent Form of a Minor (Aged 10 – 11) (Back translation from Hindi to English with translation certificate)	Master : 1.0 India: 1.0 Site-specific: 1.0	Master: 01Feb2022 India: 03Mar2022 Site specific:08Apr2022
	40	Patient item for self-administration of study medication (Sharps container replacement)	NA	Version 1.0_23Mar2022
	41	Patient item for self-administration of study medication – (Patient Items Sheet)	NA	Version 2.0_23Mar2022
	42	LIB003-007 - Instructions for Self-Administration of LIB003	NA	Version 1.0_03Sep2021
	43	LIB003-007 - Self-Administration Log	NA	Version 3.1_26Nov2018

Recommendation of Primary reviewer:-

- Approved

EC Decision: Approval is subject to fulfillment of administrative formalities.

Ref. code: 119th ECMIIC/P1

III — Modification

1. Modification of research protocol no. LTE15174 entitled "***ATLAs-OLE: An open label long term safety and efficacy study of fitusiran in patients with hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX***" submitted by Dr. S.P. Verma, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no.CH/CT/15/2022 dated 31st August, 2022.

The following documents were reviewed in the Meeting:-

Sl. No.	Document/Language	Document Details/Versions
1	Investigators Brochure	Investigator's brochure Edition 10 dated 16 Mar 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		(Controlled Copy No: PPD/LTE15174/ Investigator's Brochure/Edition 10/Dated 16 Mar 2022/ 001-004) Clean Copy
2	Investigators Brochure (Track change copy)	Investigator's brochure Edition 10 dated 16 Mar 2022
3	Investigators Brochure (Summary of changes)	Investigator's brochure Edition 10 dated 16 Mar 2022
4	DCGI Acknowledgment for Submission_ IB Ed 10 dtd 16 Mar 2022 and ICFs v 5.1_dtd 25 May 2022 and 2.1 dtd 25 May 2022	Cover Letter Dated 19 May 2022 E-Mail Acknowledgement dated 20 May 2022
5	English Patient Instructions for Use for Fitusiran (SAR439774) Pre-filled Pen (50mg) Clean Copy	Version 3.0, Dated 03 Dec 2021
6	Hindi Patient Instructions for Use for Fitusiran (SAR439774) Pre-filled Pen (50mg) along with COT	Version 3.0, Dated 03 Dec 2021
7	Hindi to English_Patient Instructions for Use for Fitusiran (SAR439774) Pre-filled Pen (50mg) along with COT	Version 3.0, Dated 03 Dec 2021
8	English Participant/ Parental ICF (Clean copy):	India English Main ICF v5.1_25May2022_Site #: 3560005_Dr Verma
9	English Participant/ Parental ICF (Track Change copy):	India English Main ICF v5.1_25May2022_Site #: 3560005_Dr Verma
10	Hindi Participant/ Parental ICF along with COT	India Hindi Main ICF v5.1_25May2022_ Site #: 3560005_Dr Verma
11	Hindi to English Participant/ Parental ICF along with COT	India English Back Translated from Hindi Main ICF v.1_25May2022_ Site #: 3560005_Dr Verma

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

12	English Assent ICF (Clean Copy)	ATLAS-OLE (LTE15174) ASSENT STATEMENT FOR CHILDREN 12 - 17 YEARS OF AGE India_V5.1 dated 25May2022_Site #: 3560005_Dr Verma
13	English Assent ICF (Track change Copy)	ATLAS-OLE (LTE15174) ASSENT STATEMENT FOR CHILDREN 12 - 17 YEARS OF AGE India_V5.1 dated 25May2022_Site #: 3560005_Dr Verma
14	Hindi Assent ICF along with COT	ATLAS-OLE (LTE15174) ASSENT STATEMENT FOR CHILDREN 12 - 17 YEARS OF AGE India Hindi_V5.1 dated 25May2022_ Site #: 3560005_Dr Verma
15	Hindi to English Assent ICF along with COT	ATLAS-OLE (LTE15174) ASSENT STATEMENT FOR CHILDREN 12 - 17 YEARS OF AGE India English Back Translated from Hindi_V5.1 dated 25May2022_ Site #: 3560005_Dr Verma
16	English Pregnant Partner ICF (Clean Copy)	India English Pregnant Partner ICF v2.1_25May2022_Site #: 3560005_Dr Verma
17	English Pregnant Partner ICF (Track change Copy)	India English Pregnant Partner ICF v2.1_25May2022_Site #: 3560005_Dr Verma
18	Hindi Pregnant Partner ICF along with COT	India Hindi Pregnant Partner ICF v2.1_25May2022_ Site #: 3560005_Dr Verma
19	Hindi to English Pregnant Partner ICF along with COT	India English Back Translated from Hindi Pregnant Partner ICF v2.1_25May2022_ Site #: 3560005_Dr Verma
20	Updated Insurance Certificate	-Policy No. 4067/130926568/05/000 Policy Period: 01-May-22 To 30-Apr-23

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer:- • Approved **EC Decision:** As above ***Ref.code:90th ECMIIC/P1***
IV	**Brought to Ethics Committee after XIII-PGTSC held on October, 2022**
	Minutes of **XIII-PG Thesis sub Committee"** Meeting of "Institutional Ethics Committee" ***virtually*** held on 18th October, 2022 from 3.00 P.M. ***The following members were present in the Meeting:-*** 1. Dr. G.G. Agarwal -Member 2. Dr. A.A. Mahdi -Member 3. Dr. Rajendra Nath -Member 4. Dr. Shally Awasthi -Convener ***The following member was present in the Meeting:-*** 1. Dr. Anita Rani -She has given her written comment.
IA	**Action Taken**
1-	Clarification of research proposal entitled ***"Molecular mechanisms of the preventable causes of Oral cancer and precancer in through polymorphism in DNA base excision repair genes in patients with tobacco products habits"*** submitted by Dr. S. Ezhilarasi, JRI, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. OMSD/789/22 dated 21st September, 2022.

Previous PGTSC Comment	PI response
The study design is not mentioned	Study design has been mentioned A hospital based case-control study.
The sample size calculation uses formula for two groups. What are the two groups? What are the different quantities (parameters) used in the formula	Sample size calculation and two different groups has been mentioned
There is no statistical analysis section	Statistical analysis section has been included
The statistical analysis section should be more specific	Statistical analysis section made more specific

	The above Comment forwarded to PI was reviewed by PR:- ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IX-PGTSC-IIA/P3***
2-	Clarification of research proposal entitled ***"An evaluation of lingual split vs buccal guttering technique in extraction of lingually placed impacted mandibular third***

(Shally Awasthi)
Member-Secretary, IEC

(Alpk Dhawan)
Chairman, IEC

molars- A randomized control trial" submitted by Dr. Reading Well Kharmawlong, JRII, Department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.801/OMSD/22 dated 30th September, 2022.

Previous PGTSC Comment	PI response
Suggesting changing randomized controlled trial to a comparative study	After approval from my thesis guide I hereby changing my study design to a comparative study.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: IX-PGTSC-IIA/P11

3- Clarification of research proposal entitled ***"Evaluation of the outcome of video assisted thoracoscopic decortications in cases of early pleural empyema: A prospective observational study"*** submitted by Dr. Piyush, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 813/Surg/22 dated 20th September, 2022.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-IIA/P19

4- Clarification of research proposal entitled ***"Clinical findings and lab parameters in cases of acute lymphoblastic leukemia with thrombocytosis at initial diagnosis"*** submitted by Dr. Anurag Singh, SR, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no.1122 dated 10th September, 2022.

Previous PGTSC Comment	PI response
Sample size justification has not been done.	Attached Separately
Sections on use of Biological material are not properly filled.	Attached Separately

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-IIA/P34

5- Clarification of research proposal entitled ***"Antibiotic prescription practice in febrile children: a hospital based ovservational study"*** submitted by Ms. Raghda Mateen, MBBS, 2020 through his Mentor Dr. Sarika Gupta, Prof. Jr. Grade, Department of Paediatics, King George's Medical University, U.P., Lucknow vide letter no.2270/Ped/22 dated 10th September, 2022.

PGTSC Comment	Name & Qualification	Details
Role of PI	Ms. Raghda Mateen (Student	Role-Data Collection

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	of MBBS Batch 2020)	through Questionnaire
Role of Co-PI	Dr. Sarika Gupta (Professor (J. Gr.) MD, PhD)	Role-Guide

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: X-PGTSC-II B MBBS-S/P5

6- Clarification of research proposal entitled ***"Efficacy of dexmedetomidine for prevention of postspinal anesthesia shivering in orthopaedic surgeries: randomized, controlled, double-blind, dose-finding study"*** submitted by Dr. Utkarsh Prasad, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1224/22 dated 21st September, 2022.

Previous PGTSC Comment	PI response
Aim and objectives are not clear. The aim states & quot; evaluate the efficacy & quote;, whereas objectives states to find & quote; incidence & quote;.	Now the objectives have been changed as per our aim of the study.
If it is really, RCT, all the fundamentals are missing. For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequences, including details of any restrictions (blocking, stratification etc.) (v) How double blinding is done, (vi) how the success of masking assessed.	i) Formulation of the research hypothesis has been done. ii) Study variables have now been mentioned in the revised protocol. iii) Outcome variables have been mentioned. iv) Now randomization has been mentioned in detail. v) As per suggestion, the success of the masking assessing method has been mentioned in the revised protocol.
The sample size calculation is arbitrary in the absence of proper research hypothesis.	Now the research hypothesis is mentioned in the revised protocol, and the sample size calculation is based on the study hypothesis.
The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses.	As per suggestion, now the statistical analysis has been re-written and incorporated in to the revised protocol.
How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc.	Now as per suggestion, way of result presentation will be mentioned in the revised protocol.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-II A/P1

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

7- Clarification of research proposal entitled ***"Comparative evaluation of antimicrobial photodynamic therapy as an adjunct to periodontal surgery in intra-bony defects: A randomized controlled trial"*** submitted by Dr. Sheetal Sharma, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2586/P/22 dated 4th October, 2022.

Previous PGTSC Comment	PI response
Study design not mentioned in protocol	Study design is already mentioned in the protocol and a copy of study design is attached herewith
No of Co-PIs are 4 (including HOD) from partment with almost similar roles- Please Justify.	A copy of detailed roles of each Co-PI is attached herewith.
Please give details of.Clinical parameters to.be seen- 1. Gingival.pigmentation..will you assess 2. How pts. satisfaction analysis will be assessed- If any structured questionnaire are there then attach the same.	Gingival pigmentation index is not a part of my thesis topic. 2. □ Patient Satisfaction Analysis (by Visual Analogue Scale) It will be done by providing the patients a printed 10 cm long line Visual Analogue scale (VAS), with the words "Not satisfied" (0% satisfaction) anchored to the extreme left and the word "Satisfied" (100% satisfaction) anchored to the extreme right. Each patient will be asked to make a handwritten mark on the line, in order to reflect how satisfied he/she is by the treatment provided. Each centimetre measured on the line starting from the extreme left and up to the extreme right will denote 10% satisfaction. For example, a mark made by the patient which lies 2cm away from the extreme left of the line will denote 20% satisfaction. A prototype of VAS to be used: Reference: Voutilainen A, Pitkäaho T, Kvist T, Vehviläinen-Julkunen K. How to ask about patient satisfaction?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		The visual analogue scale is less vulnerable to confounding factors and ceiling effect than a symmetric Likert scale. J Adv Nurs. 2016 Apr;72(4):946-57.
	CTRI registration needed	The CTRI registration requires the ethical approval. hence, attaching the copy of the same.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XI-PGTSC-II A/P13

8- Clarification of research proposal entitled ***"Clinical & biochemical evaluation of herbal preparation in early stages of sub mucous fibrosis- A randomized control trial"*** submitted by Dr. Richa, JRII, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 802/OMSD/22 dated 30th September, 2022.

Previous PGTSC Comment	PI response
There is no proposal attached	Proposal has been attached along with.
Only undertaking by investigator and consent forms are attached	Proposal has been attached along with.
There is an external member, Vidya Abhaya Narayan Tiwari	Providing Ayurvedic (herbal) extract for patients
What is his role? Is any kind of permission required for his inclusion?	Providing Ayurvedic (herbal) extract for patients. No permission is required to include any non-KMGU guide. Reference has been attached alongwith
Is this for approval of Thesis topic only?	This is for approval of thesis

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XII-PGTSC-II A/P2

9- Clarification of research proposal entitled ***"Utility of video-oculography in parkinsonian syndromes- A prospective exploratory study"*** submitted by Dr. Saurabh Kumar, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 364/Neuro/22 dated 29th September, 2022.

Previous PGTSC Comment	PI response
It is mentioned that patients from SGPGIMS and RMLIMS will be	Consultants from SGPGI and RMLIMS have been included as the Co-guides.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	recruited, but no co-guide from the institutions has been included | I accept the mistake and correction has been made.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XII-PGTSC-II A/P16

10- Clarification of research proposal entitled ***"Myelitis in patients with tuberculous meningitis-predictors and outcomes-prospective study"*** submitted by Dr. Prem Singh, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 360/Neuro/22 dated 27th September, 2022.

Previous PGTSC Comment	PI response
Although a co-guide has been taken from the Department of Radio diagnosis, it is not mentioned in the Materials & Methods section that work will be carried out in collaboration with the Department of Radio diagnosis, apart from the Department of Microbiology.	The study will be conducted in Department of Neurology, KGMU, Lucknow in Collaboration with Department of Microbiology and Radiodiagnosis, KGMU, Lucknow.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XII-PGTSC-II A/P18

11- Clarification of research proposal entitled ***"Clinical, radiological and laboratory predictors of post ventriculoperitoneal shunt outcome in adult tuberculous meningitis patient-A prospective observational study"*** submitted by Dr. Saddam Ahmad Hasib, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 359/Neuro/22 dated 26th September, 2022

Previous PGTSC Comment	PI response
There are many typographical errors and language problems which need to be corrected.	Improved and corrected
In The objectives of the study it is mentioned that "To assess the 6 months outcome of these patients". Please mention the disease. (Tuberculous meningitis patients)	Improved

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XII-PGTSC-II A/P19

12- Clarification of research proposal entitled ***"Renal dysfunction in tuberculous meningitis and its correlation with outcomes"*** submitted by Dr. Arjun Bal K.P, SRI,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 362/Neuro/22 dated 29th September, 2022.

Previous PGTSC Comment	PI response
Age specificity in inclusion criteria is not mentioned(If all patients are taken then Guardian and child assent form should also be submitted)	Will include patients of age 18 years and above. Changes have been made in inclusion criteria.
English ICF mentioning different disease(Neurocysticercosis instead of tuberculous meningitis)	I accept the mistake, changes has been made in the English ICF form as advised. English ICF form mentioning tuberculous meningitis has been attatched.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XIII-PGTSC-II A/P22

13- Clarification of research proposal entitled ***"Clinico-radiological characteristics of degenerating and calcified solitary neurocysticercosis with persistent seizure: prospective comparative study"*** submitted by Dr. Aditya Kumar, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 361/Neuro/22 dated 29th September, 2022.

Previous PGTSC Comment	PI response
Study design mentioned as study, whether it is observational or analytical-please clarify.	Prospective observational study.
Sample size calculation not done(total number of pts in protocol-100 pts and in SOP form-108 pts	Sample size calculated, it is 128 patients in total (64 patients in both group).Details have been added to methods section. I accept the mistake; the correction has been done as per sample size calculation.
Please justify the discrepancy in the total number of patients to be included.	Sample size calculated and now there is no discrepancy in the total number of patients to be included.
As in inclusion criteria, patients of more than 12 yrs. of age will be taken, therefore child assent form should also be submitted in addition to regular ICF.	We will include patients of age more than 18 years Change has been done in inclusion criteria.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

<table>
<tr><td></td><td>Ref. code: XIII-PGTSC-II A/P23</td></tr>
<tr><td>14-</td><td>Clarification of research proposal entitled "A case control study on impact of screen time on language development of children between 2-5 years of age" submitted by Ms. Gunjan Parasher & Mr. Shikhar Gupta, MBBS, Batch 2019 through her Mentor Prof Shally Awasthi, Head, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2465/Ped/22 dated 1st October, 2022.
<table>
<tr><th>Previous PGTSC Comment</th><th>PI response</th></tr>
<tr><td>Role of PI given, but role of chief guide and Co- PIs not given.</td><td>Roles of Guides, PI, Co-PI have been added and
henceforth attached.</td></tr>
<tr><td>PI should submit Guardian consent form instead of regular ICF, as subjects to be taken are between age group of 2-5 years.</td><td>Guardian consent form is attached herewith.</td></tr>
</table>
The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified
Dr. Shally Awasthi did not take part in the discussion and making decision.
Ref. code: XII-PGTSC-II B MBBS-S/P1</td></tr>
<tr><td>15-</td><td>Clarification of modification under the research protocol entitled "Study the effect of melatonin on psychological and physical outcome in older adults with acute ischemic stroke" submitted by Dr. Prerak Kumar, SRI, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 1792/DGMH/2022 dated 8th October, 2022.
<table>
<tr><th>Previous PGTSC Comment</th><th>PI response</th></tr>
<tr><td>Methodology steps

After ethical clearance from the institute ethical committee, the subjects GMU trauma emergency center or department of Neurology indoor wards with diagnosis of ischemic stroke. Sample.</td><td>Methodology steps (Page 17) Summary of assessments (Page 20)
1. After ethical clearance from the institute ethical committee, the subjects will be recruited either from KGMU trauma emergency center or department of Neurology indoor wards or Neurology OPD as specified days with diagnosis of ischemic stroke.
2. Summary of assessments - two rows added to the table to clarify the assessment procedure.</td></tr>
</table>
Recommendation of Primary reviewer:- Approved
PGTSC Decision: Approval ratified
Ref. code: VII-PGTSC-II A/P32</td></tr>
<tr><td>I-B</td><td>Expedited review</td></tr>
</table>

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

1	Expedited review of research proposal entitled ***"A comparative study of the effects of emotion regulation, attachment and coping styles on treatment motivation in alcohol and Opioid use disorder patients"*** submitted by Ms. Chancheri Singh, M.Phil student under the guidance of Dr. Pooja Mahour, Additional Professor (Clinical Psychology), Department of Psychiatry, K.G's Medical University, U.P., Lucknow vide letter no. 1339/Psy dated 8th September, 2022. ***The above research proposal was forwarded to both reviewers:-*** ***First reviewer -Reply was pending.*** ***Secondary reviewer*** -recommendation is Approved. **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IB/P1***
2	Expedited review of research proposal entitled ***"An exploratory study of expressed emotion, rejection sensitivity, cognitive flexibility & working memory among children with specific learning disability"*** submitted by Ms. Pratibha Mishra, M.Phil student under the guidance of Dr. Pooja Mahour, Additional Professor (Clinical Psychology), Department of Psychiatry, K.G's Medical University, U.P., Lucknow vide letter no. 1473/Psy/22 dated 9th September, 2022. ***The above research proposal was forwarded to two reviewers.*** ***Both reviewers have Approved.*** **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IB/P2***
3	Expedited review of research proposal entitled ***"A study on illness-related perception, needs and behavior among breast survivors"*** submitted by Ms. Anunka Mondal, M.Phil student under the guidance of Dr.Shweta Singh, Prof. Jr. Grade, Department of Psychiatry, K.G's Medical University, U.P., Lucknow vide letter no. 1338/Psy/22 dated 8th September, 2022. ***The above research proposal was forwarded to two reviewers -*** ***First Primary reviewer has given his reply & Approved.*** ***Secondary reviewer has given his following recommendation:-*** • There are too many objectives. • There should be one "primary objective", which should be converted into a proper "research hypothesis. This can be done after identifying study variables and parameters. • The sample size calculation and "statistical analysis" will be specific to the research hypothesis. • The present sample size calculation and "statistical analysis" section is arbitrary. • Why "purposive sampling" is being used? • The study design is also not clear. • How the "reliability" and "validity" of the questionnaire (under use) will be checked? ***The above comment forwarded to PI but reply has pending.***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: As above **PGTSC Decision:** Awaiting reply ***Ref. code: XIII-PGTSC-IB/P3***
4	Expedited review of research proposal entitled ***"A study of childhood stress and trauma, neuropsychological functioning and reflective functioning in adolescents with dissociative disorder presented"*** submitted by Ms. Saakshi, M.Phil student under the guidance of Dr. Shweta Singh, Prof. Jr. Grade, Department of Psychiatry, K.G's Medical University, U.P., Lucknow vide letter no. 1300/Psy/22 dated 1st September, 2022. ***The above research proposal was forwarded to two reviewers:-*** ***Both reviewers have approved.*** **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IB/P4***
5	Expedited review of research proposal entitled ***"A study of Bayesian learning and decision making in adult patients with obsessive-compulsive disorder and their first degree relatives"*** submitted by Ms. Tanya Mathur, M.Phil student under the guidance of Dr. Shweta Singh, Prof. Jr. Grade, Department of Psychiatry, K.G's Medical University, U.P., Lucknow vide letter no. 1299/Psy/22 dated 1st September, 2022. ***The above research proposal was forwarded to two reviewers:-*** ***Both reviewers have approved.*** **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IB/P5***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"A study to estimate prevalence of ASTHMA-COPD overlap (ACO) among patients of obstructive airway disease at a tertiary care center"*** submitted by Dr. Santost Kumar Mishra, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 917/22 dated 10th August, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Efficacy of laser and ultrasonic activated root canal irrigants in biofilm eradication"*** submitted by Dr. Vineet Gupta, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 148/Coms7Endo/22 dated 15th July, 2022. ***Recommendation of Primary reviewer:*** • This is a comparative study. • The control group should be exclusively defined. • There seems to be more than one treatment groups.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The research hypothesis should be stated for comparing more than two groups. • Study design is not mentioned. • Sample size calculation should be modified according to the appropriate research hypothesis. At present, it is for comparing two groups only. • Statistical analysis section is missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: XIII-PGTSC-IIA/P2***
3.	Research proposal entitled ***"A study to estimate the prevalence of pulmonary hypertension in patients of chronic obstructive pulmonary disease at a tertiary care centre"*** submitted by Dr. Neha Kumari, JR, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 918/22 dated 10th August, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation is missing. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIII-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Psychological distress and health related quality of life in lung cancer patients"*** submitted by Dr. Arun Kumar, JR, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 992/22 dated 6th September, 2022. ***Recommendation of Primary reviewer:*** • Is it really a health-related quality of life (HRQL) measurement study? • If so, then DASS-21 is not the appropriate instrument to measure HRQL. • Two basic approaches to quality-of-life measurements are available: generic instruments that provide a summary of HRQL; and specific instruments that focus on problems associated with single disease states, patient groups, or areas of function. • Depending on the goal of the study, the proper HRQL instrument should be constructed and administered. • All the prerequisites of measurement scales should be followed. **PGTSC Comment:** As above **PGTSC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: XIII-PGTSC-IIA/P4***
5.	Research proposal entitled ***"A study of lung function parameters by impulse oscillometry and spirometry in COVID-19 survivor patients attending a tertiary care centre"*** submitted by Dr. Ankit Kumar, JRIII, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1017/22 dated 9th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	September, 2022. ***Recommendation of Primary reviewer:*** • Research hypothesis, sample size calculation and statistical analysis section are missing. • The sample size is by convenience. • It seems to be a fit case for "PILOT study". **PGTSC Comment:** As above **PGTSC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: XIII-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Effect of percutaneous supracondylar femoral osteotomy on body image & gait parameters in adolescents with genu valgum deformity at a tertiary care Hospital- A prospective study"*** submitted by Dr. Kunwar Utkarsh Yadav, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 4817/22 dated 13th September, 2022. ***Recommendation of Primary reviewer:*** • This is "One-group pretest-posttest design". • The research hypothesis should be accordingly stated after identifying the study variables and parameters. • Sample size calculation is missing. • Statistical analysis section should be properly discussed. **PGTSC Comment:** As above **PGTSC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: XIII-PGTSC-IIA/P6***
7.	Research proposal entitled ***"Co-incidence of liver fibrosis with OSMF in areca nut habituals-An observational study"*** submitted by Dr. Karina Hyanki, JRI, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 494/OM&R/22 dated 13th September, 2022. ***Recommendation of Primary reviewer:*** • There are four sections: Research question, research hypothesis, aims and objectives. They do not syndromes. • The statements under these sections are contradictory and confusing. • There should be one primary research hypothesis clearly stated. Everything thing else should be subjected to secondary objectives. • The study design, methodology, sample size calculation, statistical analysis section etc. should be properly discussed (according to Step 3). **PGTSC Comment:** As above **PGTSC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: XIII-PGTSC-IIA/P7***
8.	Research proposal entitled ***"The effect of concentrated growth factor (SGF) and***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	platelet rich fibrin (PRF) on post endodontic surgery healing: A randomized clinical trial" submitted by Dr. Supriya Choudhary, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 269/Coms&Endo/22 dated 14th September, 2022. ***Recommendation of Primary reviewer:*** • If it is really, RCT, all the fundamentals are missing. • Clinical trial registry is required. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary in the absence of proper research hypothesis. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **PGTSC Comment:** As above **PGTSC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: XIII-PGTSC-IIA/P8***
9.	Research proposal entitled ***"Clinicophysiological outcome after peroral endoscopic myotomy (POEM) vs heller's cardiomyotomy for achalasia cardia"*** submitted by Dr. Sanjay Kumar Tripathi, SR, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SGE/539/22 dated 16th September, 2022. ***Recommendation of Primary reviewer:*** • Research hypothesis should be stated after properly identifying the study variables and parameters. • Sample size calculation is missing. • Statistical analysis section is arbitrary. It should be specific to the research hypothesis in question. **PGTSC Comment:** As above **PGTSC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: XIII-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Prospective analysis of pre-operative assessment of duodenal involvement in gallbladder cancer"*** submitted by Dr. Rohit Jain, SR, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SGE/538/22 dated 16th September, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Sample size calculation and proper justification needed. • In the inclusion criteria, it is not clear what the sentence "All patients suspected to have GBC will undergo an ultrasound examination of the abdomen" means. • Exclusion criteria are also not proper. • In the consent form, it is mentioned that complications will be none, although in the above line it is mentioned that it is major surgery. Surgery-related complications shall be given. **PGTSC Comment:** As above **PGTSC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: XIII-PGTSC-IIA/P10***
14-	Clarification of research proposal entitled ***"A case control study on impact of screen time on language development of children between 2-5 years of age"*** submitted by Ms. Gunjan Parasher & Mr. Shikhar Gupta, MBBS, Batch 2019 through her Mentor Prof Shally Awasthi, Head, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2465/Ped/22 dated 1st October, 2022.

Previous PGTSC Comment	PI response
Role of PI given, but role of chief guide and Co- PIs not given.	Roles of Guides, PI, Co-PI have been added and henceforth attached.
PI should submit Guardian consent form instead of regular ICF, as subjects to be taken are between age group of 2-5 years.	Guardian consent form is attached herewith.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified
Dr. Shally Awasthi did not take part in the discussion and making decision.
Ref. code: XII-PGTSC-II B MBBS-S/P1

15- Clarification of modification under the research protocol entitled ***"Study the effect of melatonin on psychological and physical outcome in older adults with acute ischemic stroke"*** submitted by Dr. Prerak Kumar, SRI, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 1792/DGMH/2022 dated 8th October, 2022.

Previous PGTSC Comment	PI response
Methodology steps After ethical clearance from the institute ethical committee, the subjects GMU trauma emergency center or department of Neurology indoor wards with diagnosis of ischemic stroke. Sample.	Methodology steps (Page 17) Summary of assessments (Page 20) 1. After ethical clearance from the institute ethical committee, the subjects will be recruited either from KGMU trauma emergency center or department of Neurology indoor wards or Neurology

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		OPD as specified days with diagnosis of ischemic stroke. 2. Summary of assessments - two rows added to the table to clarify the assessment procedure.

Recommendation of Primary reviewer:- Approved
PGTSC Decision: Approval ratified

Ref. code: VII-PGTSC-II A/P32

16. Research proposal entitled ***"Role of diaphragm excursion time index for predicting fast track extubation in cardiac surgical patients"*** submitted by Dr. Shreya Rastogi, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1160/22 dated 7th September, 2022.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P16

17. Research proposal entitled ***"Comparison between landmark method and real time ultrasound technique to determine the correct depth of inscrtion of central venous catheter in right internal jugular vein in pediatric neurosurgical patients: A prospective randomized controlled trial"*** submitted by Dr. Shagun Paliwal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1161/22 dated 7th September, 2022.

Recommendation of Primary reviewer:

- Kindly confirm the number of cases (100 or 126) 2. Mention the process for Randomization of Patients.

PGTSC Comment: As above
PGTSC Decision: Approval subject to modification

Ref. code: XIII-PGTSC-IIA/P17

18. Research proposal entitled ***"Molecular cytogenetic study of CYP1B1 gene variants in patients of glaucoma at a Tertiary Health Care Centre"*** submitted by Dr. Sehra Jabeen, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. ANAT/312/22 dated 20th September, 2022.

Recommendation of Primary reviewer:

- Approved

PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P18

19. Research proposal entitled ***"Morphometric and morphological analysis of the optic strut and optic tubercle: A computed tomography study"*** submitted by Dr. Ajay Kumar Verma, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. ANAT/313/22 dated 20th September, 2022.

Recommendation of Primary reviewer:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P19***
20.	Research proposal entitled ***"Expression of interferon-γ and inducible protein (IP)-10 in oral squamous cell carcinoma (OSCC), oral premalignant lesions and its prognostic significance-A study"*** submitted by Dr. Nirmal Kumar Chourasia, JRIII, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 781/OMSD/22 dated 19th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P20***
21.	Research proposal entitled ***"Epidemiology of heart disease in critically ill obstetric patients admitted to intensive care unit of a tertiary care centre"*** submitted by Dr. Prachi Jain, SR, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 739/Cardio/Res/22 dated 19th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P21***
22.	Research proposal entitled ***"A study of extended lipid profile in patients with acute coronary syndrome"*** submitted by Dr. Pardeep Kumar, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 681/Cardio/Res/22 dated 6th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P22***
23.	Research proposal entitled ***"Assessment of quality of life in patients with knee osteoarthritis"*** submitted by Dr. Jay Vardhan Kumar, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 4841/22 dated 20th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P23***
24.	Research proposal entitled ***"A cross sectional study on prevalence and factors associated with work-related musculoskeletal disorders and quality of life affected among health care health centre in North India"*** submitted by Dr. Joe Antony, JRI,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 4843/22 dated 20th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P24***
25.	Research proposal entitled ***"The effect of dexmedetomidine addition to levobupivacaine-epinephrine in ultrasound guided bilateral superficial cervical plexus block on ost operative analgesia in patients undergoing thyroid surgery under general anaesthesia: A randomized controlled study"*** submitted by Dr. Manas Omer, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaea/1163/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P25***
26.	Research proposal entitled ***"A study of predictive factors for unfavourable outcome of tubercular cervical lymphadenitis"*** submitted by Dr. Nagendra Kumar, JRIII, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1039/22 dated 16th September, 2022. ***Recommendation of Primary reviewer:*** • In IEC-SOP form, Privacy & Confidentiality Column Ticked by PI as –No (should be changed in revised SOP form) • In Inclusion criteria -Age specificity not mentioned , • In Exclusion criteria, other co-morbities ,pregnancy and lactation and TB of other organs not mentioned • Patient information sheet attached is not related to disease –should be rewritten. **PGTSC Comment:** As above **PGTSC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: XIII-PGTSC-IIA/P26***
27.	Research proposal entitled ***"Effect of face masks on six minute walk test in apparently healthy individuals"*** submitted by Dr. Md. Tanveer, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2689/PHY/22 dated 17th September, 2022. ***Recommendation of Primary reviewer:*** • IEC-SOP form not ticked properly many details left vacant-should be revised. • In Inclusion criteria–PI written that apparently healthy individuals will be taken, but in SOP form PI mentioned that Patients will be taken- please clarify. • In role of Investigators-The name of PI and Chief Investigator written are same (Dr. Md. Tanveer). The name and role of Prof. Shraddha Singh has not been

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	given- Please correct. • From where the Healthy individuals will be recruited-please clarify. • Inform Consent Forms–English / Hindi not similar–should be revised. **PGTSC Comment:** As above **PGTSC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: XIII-PGTSC-IIA/P27***
28.	Research proposal entitled ***"Effect of smartphone usage on neck muscle and hand grip strength"*** submitted by Dr. Keerti, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2696/PHY/22 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • IEC Form in incorrectly and incompletely filled. Please fill the form properly and resubmit for approval. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIII-PGTSC-IIA/P28***
29.	Research proposal entitled ***"Relationship of triglyceride glucose index with body fat percentage and various anthropometric parameters in apparently healthy adults"*** submitted by Dr. Shivani Verma, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2708/PHY/22 dated 24th September, 2022. ***Recommendation of Primary reviewer:*** • IEC Form in incorrectly and incompletely filled. Please fill the form properly and resubmit for approval. • Where will the hematological investigations be done? • Who will bear the cost of these? **PGTSC Comment:** As above **PGTSC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: XIII-PGTSC-IIA/P29***
30.	Research proposal entitled ***"Comparison of efficacy transforaminal epidural injection of autologous platelet rich plasma vs triamcinolone in patient of lumbar disc herniation with radicular pain: A prospective randomized control study"*** submitted by Dr. Amit Kumar, JR, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anae/1159/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • IEC form is incompletely filled. • CTRI registration will be required. • Inclusion criteria must include patients. • Who have been recommended non-operative management by clinician/Neurosurgeon/orthopedic surgeon?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• A neurosurgeon/orthopedic surgeon must be included as a co-supervisor who can help in management of patient's problems. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIII-PGTSC-IIA/P30***
31.	Research proposal entitled ***"Survey of family satisfaction and decision making in polytrauma patients in intensive care unit"*** submitted by Dr. Ahmad Azin, JR, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anae/1156/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P31***
32.	Research proposal entitled ***"Long term outcomes of tubercular bacterial meningitis in children: a prospective observational study"*** submitted by Dr. Neha Kumari, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2370/Ped/22 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P32***
33.	Research proposal entitled ***"Comparative evaluation of implant stability in welded immediate implant with and without bicortical anchorage: A randomized controlled trial"*** submitted by Dr. Akshi, JRI, Department of Prosthodontics Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 334/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • Time duration of follow up not given. • How will post-intervention radiology be correlated to implant stability? • Suggest changing the term 'Randomized Controlled Trial" in the title of the study to 'Randomized Controlled study'. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIII-PGTSC-IIA/P33***
34.	Research proposal entitled ***"Antifungal efficacy of herbal extracts against candida albicans biofilm established on heat cure denture base as compared to commercially available antifungal agent: an in-vitro study"*** submitted by Dr. Apurva Verma, JRI, Department of Prosthodontics Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 335/22 dated 7th September, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 22nd October 2022

	Recommendation of Primary reviewer: • Approved. In vitro study on models. Human subjects review waiver may be granted. **PGTSC Decision:** Approved for waiver of consent. ***Ref. code: XIII-PGTSC-IIA/P34***
35.	Research proposal entitled ***"A prospective, randomized study to compare the effect of neutral and extended head position during awake orotracheal intubation using fiberoptic bronchoscope in adult patients"*** submitted by Dr. Shalu Yadav, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1157/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P35***
36.	Research proposal entitled ***"Comparision of effects of intratracheal with intravenous dexmedetomidine on recovery from general anaesthesia after laparoscopic surgeries: A randomized controlled double blind study"*** submitted by Dr. Esha Batra, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1133/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • Too many Co-PIs from the same department. • No Co-PI from the department of general surgery from where the patients will be recruited. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIII-PGTSC-IIA/P36***
II-B	**Nursing KGMU Institute**
1.	Research proposal entitled ***"Effectiveness of educational package on knowledge and practice regarding care of child with seizure disorder among care givers of children admitted in pediatric units"*** submitted by Ms. Kirti Lal, through her Guide Mr. Subin S Mishra, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIB/P1***
2.	Research proposal entitled ***"Effectiveness of helfer skin tap technique in pain reduction among infants undergoing intramuscular vaccination at Pediatric outdoor at tertiary care center"*** submitted by Ms. Priya Kamari, through her Guide Mr. Subin Sudarsanan, Assistant Professor, Department of KGMU College of Nursing, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Tools: 1. Demographic data questionnaire 2. FLACC Pain Score chart • Inform Consent Form English form is incomplete, but PI should submit Guardian consent form instead of Adult general consent form (As recruited subjects are children between1 month to 1 year of age. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIII-PGTSC-IIB/P2***
3.	Research proposal entitled ***"Effectiveness of CAUTI bundle approach to reduce urinary catheter associated infection rate among Children admitted in Pediatric unit"*** submitted by Ms. Anju Shukla, through her Guide Mr. Subin Sudarsanan, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Tools: 1. Demographic data form (E/H) 2. Assessment of infection form (pre test / post test) (E/H) 3. CAUTI maintenance checklist (E/H) -attached • Methodology details regarding experimental and control grouping in study design is missing –Flow chart of the study is needed. • Review literature (background of study) regarding CAUTI Bundle approach with references is missing. • ICF-Guardian consent and Child Assent form instead of Adult ICF is needed as Pts below 15 yrs. of age will be recruited in the study. **PGTSC Comment:** As above **PGTSC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: XIII-PGTSC-IIB/P3***
4.	Research proposal entitled ***"Effectiveness of demonstration on knowledge and practice regarding surgical site care among primary care giver of post-operative Children admitted in Pediatrics Surgery"*** submitted by Ms. Rambha Yadav, Through her Guide Mr. Subin Sudarsanan, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIB/P4***
5.	Research proposal entitled ***"Suicide risk, perceived stress and coping among adult patients***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	with dissociative disorder" submitted by Miss. Sushmita, through her Guide Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Tools: 1. Socio-demographic and clinical variables form (E/H) 2. Columbia-Suicide Severity Rating Scale (E/H) 3. Perceived Stress Scale 4. Coping Scale with permission (E/H)-Attached • In SOP form against type of subjects -PI ticked –Volunteer column instead of Patients (should be revised) • Study design details not given –whether descriptive observation / cross-sectional etc.- please clarify • Why ICD-10 classification for diagnosis has been chosen when latest ICD-11 is available –please clarify. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIII-PGTSC-IIB/P5***
6.	Research proposal entitled ***"Effectiveness of coconut oil massage therapy on weight gain among preterm neonate admitted in neonatal unit Queen Mary Hospital, KGMU, Lucknow, U.P."*** submitted by Mr. Arun Singh, through his Guide Mr. Subin Sudarsanan, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Tools: 1. Interview/ Observation schedule on weight gain –i) Background data of the mother ii) Background data of Neonates iii) Observation schedule on weight gain (E/H) –attached. • Experimental and control grouping not discussed in methodology and in ample size section of Protocol – please give details. • Adult ICF attached but as Neonates will be recruited in this study therefore Guardian consent form is needed –ICF should be revised. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIII-PGTSC-IIB/P6***
7.	Research proposal entitled ***"Assess demoralization, religious belief and emotional regulation among patient with obsessive compulsive disorder (OCD)"*** submitted by Mr. Aditya Gautam, Through his Guide Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Tools: 1. Socio-demographic & Clinical variable form (E/H) 2. Demoralization Scale (E/H) 3. Religious Attitude Scale (E/H) 4. Emotional Regulation Scale

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	(E/H) -attached • Why ICD-10 classification for diagnosis has been chosen when latest ICD-11 is available –please clarify. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIII-PGTSC-IIB/P7***
8.	Research proposal entitled ***"Early identification of diabetes mellitus and risk factors among relatives of patient admitted with coronary artery disease in Tertiary Care Hospital"*** submitted by Ms. Aparna Pandey, through her Guide Dr. Suchana Roy Bhowmik, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Tools: 1. Pre Diabetes Risk Score (E/H) 2. Fasting Blood glucose level chart (E/H) • Give details about study design (whether Observational / Cross-sectional etc.) **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIII-PGTSC-IIB/P8***

The next IEC Meeting **offline** will be held on 21st December, 2022 from 10.30 A.M.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University U.P.,
Institutional Ethics Committee
Lucknow - 226003 (UP) India

Prof. Shally Awasthi
Member Secretary, IEC

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

No. 1592 **/Ethics/2022**

Dated: 06/12/2022

To,

Dr. Alok Dhawan,
Director,
Centre of Biomedical Research (CBMR),
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Raebareli Road,
Lucknow, U.P. 226014

Sub.: Reg. Minutes of 119th Institutional Ethics Committee Meeting held on 22nd October, 2022.

Dear Sir,

Please find enclosed herewith the Minutes of 119th Institutional Ethics Committee Meeting held on 22nd October, 2022, for your kind signature..

Thanking you
With regards

Encl.: As above

Yours Sincerely

(Shally Awasthi)
Member Secretary, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 120th ECM held on 21st December, 2022

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of 120th Institutional Ethics Committee Meeting held on **21st December, 2022 from 3:00 PM.** in the Board Room, Administrative Block, K.G's Medical University, U.P., Lucknow in ***virtual & Physical mode both.***

The following Members were present in the Meeting:-

1. Dr. Alok Dhawan -Chairman
2. Dr. G.G. Agarwal -Member
3. Dr. Akash Agarwal -Member
4. Dr. K.K. Yadav -Member
5. Mrs. Vasundhara Kumari -Member
6. Mr. Ujjawal Krishna -Member
7. Dr. Anita Rani -Member
8. Dr. A.A. Mahdi -Member
9. Dr. Anupam Mishra -Member
10. Dr. Rajendra Nath -Member
11. Dr. Shally Awasthi -Member

The following members were not present in the Meeting:-

1. Dr. Shubha Phadke -Member
2. Mrs.Akansha Dubey -Member
3. Dr. D.N. Upadhyaya -Member

IA	Action Taken
1-	Clarification of research proposal entitled ***"Development of primary human microglial/astrocyte cell-based model for neurodegenerative diseases"*** sponsored by ICMR, New Delhi submitted by Prof. Shailendra Kumar Saxena, Head, Department of Centre for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/651/2022 dated 20th October, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comment	PI response
The rights to the participation are wrong and needs to be rectified.	The rights to the participation have been modified as per the suggestions.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Provisionally Approved
EC Decision: Approved

Ref. code: 104thECMIIA/P31

2- Clarification of research proposal entitled "***Effect of vocational rehabilitation in myocardial infaraction patients and returning back to their work after myocardial infarction***" submitted by Ms. Meenakshi Mishra, Ph.D. Scholar 2019 under the guidance of Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.434/Cardio/Res/2022 dated 24th November, 2022.

Previous EC Comment	PI response
Spelling and syntax errors in covering letter.	It was perhaps the typo error which got overlooked for which I tender my humblest of apologies.
Can PHD Student be PI?	Yes , PI is PhD student
If this is revised review, details of comments of first review.	This is the first review.
Sec. 5 Which employees (special group) will be included and why?	Employed group refers to salaried persons involved in any kind of job to earn their livelihood. We wish to evaluate the role of Vocational Rehabilitation of MI patients who resume their work (Specified in Sec. 5)
Risk is not reasonable …. Why do the study?	Yes, there is a reasonable amount of risk component involved and hence the harvested data will be compared to the anticipated benefits to subjects as updated in Sec. 10.
How will the patient benefit?	This is an attempt to demonstrate that Vocational Training during post-MI phase improves the proportion of patients returning to their work similar to what has been reported earlier too.
Details of DSMB	No DSMB is there as has been updated in Sec. 11
PhD student should write much better review of literature.	The review of literature has been thoroughly redone per attachment.
Hypothesis	The extensively revised review may kindly be looked into.
When there is consensus that vocational rehabilitation should be done, not providing	It is proposed that structured Vocational Rehabilitation by dedicated Para- medical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

VR to control is. It is proposed that structured Vocational Rehabilitation by dedicated Para- medical person will be compared versus routine, minimal Vocational Rehabilitation suggested by unethical	person will be compared versus routine, minimal Vocational Rehabilitation suggested by treating physician during a follow up visit in OPD.
App tracking activities is violation of patient privacy.	There is absolutely no compromising of patient privacy. More, there is no App tracking activity involvement whatsoever under any circumstances. We will simply collect, collate and analyze patients vital such as: daily step count and calorie count through this App. We will further transmit the data through Whatsapp or messages over the phone - a common practice. Currently, these applications are employed on a daily basis since the people's awareness; knowledge has tremendously improved for health issues. It basically is an Indian App. which harvests minimal data.
Exclusion Criteria: define high risk patients.	High risk patients refers to those with LVEF & lt; 30% or NYHA class III/IV or uncontrolled arrhythmia.
What type of randomization takes place? Please specify elements of RCT.	Computer- generated Random Table method will be employed.
Sample size calculation is not for RCT	Calculation is corrected by using G*Power3.1.9
What is appropriate statistical test?	F-test, ANOVA (t- tests) would be used to compare variance of two different sets of values.
Are the questionnaire is self designed or old?	The questionnaire has not been self-designed but derived from WHO-QOLBREF questionnaire format. It's Hard-copy will be provided to the patient in both Hindi/ English language as per need.
Keep activity data as hard copy.	Yes, we will mandatorily retain activity data in Hard-copy format.
Use of a private app is not permitted.	The App that we will employ is an Indian product. It is simply to facilitate collection of vitals, Daily Step Count and Calorie Count only.

The reply from PI to the Comments was forwarded and reviewed by PR:-
Recommendation of PR:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• This appears to be a PhD Thesis of 2019 enrollment. It's at least 3 years from enrollment time and research work has not yet been approved. Institute to decide if this is alright. • Can a PhD candidate be called PI? • The PI mentions in section 10 that the risks are unreasonable, when compared to benefits, to conduct this study. Thus, the research is unethical and cannot be approved. **EC Comment:** As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: 113th ECM II B- Ph.D /P3***
3-	Clarification of research proposal entitled "***Development of Indian TNBC patients-derived organoid (PDO) and xenograft (PDX) models to understand its therapeutic vulnerabilities***" sponsored by ICMR submitted by Prof. Dipak Datta, Co-PI & Head, Cancer Biology Division Central Drug Research Institute through Prof. Anand Kumar Mishra, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/377/2022 dated 3rd November, 2022. **Previous EC Comment:** • ICF: study procedure has to be explained to the patient properly. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Provisionally Approved **EC Decision:** Provisionally approved. Please submit approval of CDRI. ***Ref. code: 116th ECM IIA/P16***
4-	Clarification of research protocol no. EX6018-4758 Study Phase: 3 a entitled "**ZEUS** - ***Effects of ziltivekimab versus placebo on cardiovascular outcomes in participants with established atherosclerotic cardiovascular disease, chronic kidney disease and systemic inflammation***" sponsored by Novo Nordisk India Private Ltd. submitted by Prof. Rishi Sethi, Department of Cardiology King George's Medical University, U.P., Lucknow, vide letter no. 421/Cardio/Res/2022 dated 17th November, 2022.

Previous EC Comment	PI response
Approval attached. approval, for export of biological samples: not there is a process and certificate for as attached with proposal 720.	As per Gazette of India part 2 section 3 subsection 2 dated 4 Aug 2016; notification number 19/2015-2020, the import of human biological samples by the Indian diagnostic laboratories/Indian Clinical Research Centers for lab analysis D testing or export of these materials to foreign laboratories is permitted by Customs authorities at the port

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		of entry/ exit without prior approvals (import/ export license) from any Government agency provided the concerned Indian company submits an undertaking that they are following and will follow all applicable rules, regulations and procedures for safe transfer and disposal of biological samples being imported or exported as per related norms/ regulations set by WHO/ DGFT/ Ministry of Environment, Forest, climate change, Government of India, to the Customs authorities at port of entry/ exit along with details of such samples. Hence, no approval for export of biological samples required. Novo Nordisk confirms that all above stated norms related to safe transfer and disposal of biological samples are bring Followed.
	Can samples send, if CDSCO Approves.	CDSCO does not provide approvals for sending samples. As per Gazette of India part 2 section 3 subsection 2 dated 4 Aug 2016; notification number 19/2015-2020, no approval from any.

The reply from PI to the above Comments was forwarded to PR:-

Second opinion of PR:

- Direct identifiers will be used: Why?
- KGMU Policy for biological material sharing to decide on biological sample transport.

The reply from PR to the above Comments was forwarded to PI:- Response received from PI.

EC Decision: Defer to the next Meeting because Quorum was incomplete.

Ref. code: 116thECM IIC/P1

5- Clarification of research proposal entitled ***"Effectiveness of kinesio taping in management of low back pain"*** submitted by Dr. Narendra Singh Kushwaha, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3054/OS/22 dated 14th November, 2022.

Previous EC Comment	PI response
In ICF study procedures and benefits of study are written in past tense and therefore ICF needs to be revised.	Attached separately
Sample size calculation need to be mentioned.	Attached separately
The page where role of PI is mentioned it has to be clarified if investigators is form pulmonary medicine also or only from orthopaedics.	Only from Department of Orthopaedics.

The reply from PI to the above Comments was forwarded to PR:-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Recommendation of PR:

- PI information sheet is still not submitted.
- The Hindi version of IEC is acceptable while the past tense used in English version needs to be corrected.

The reply from PR to the above Comments was forwarded to PI:- Pending

EC Decision: Pending by PI

Ref. code: 117th ECM IIA/P18

6- Clarification of research proposal entitled ***"Local vs systemic tranexamic acid in total hip arthroplasty"*** submitted by Dr. Narendra Singh Kushwaha, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3055/OS/22 dated 14th November, 2022.

Previous EC Comment	PI response
In ICF study procedures and benefits of study are written in past tense and therefore ICF needs to be revised.	Attached separately
Sample size calculation need to be mentioned.	Attached separately
The page where role of PI is mentioned it has to be clarified if investigator is from pulmonary medicine also or only from orthopaedics.	Only from Department of Orthopaedics.
To add subheadings of outcome variables and statistic analysis so as to make methodology section more explanatory.	Attached separately

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of PR:

- PI information sheet is still not submitted.
- The Hindi version of IEC is acceptable while the past tense used in English version needs to be corrected.

The reply from PR to the above Comments was forwarded to PI:- Pending

EC Decision: Pending by PI

Ref. code: 117th ECM IIA/P19

7- Clarification of research proposal entitled ***"Effect of LAABH (Lined-up Antenatal Approach to better health) on knowledge attitude and practice regarding perinatal care among pregnant women attending antenatal clinic)"*** submitted by Mrs. Sarita Dubey, Ph.D. Scholar 2019 under the guidance Prof. Sujata Deo, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3088/22 dated 19th October, 2022.

Previous EC Comment:-

- Several sections of the IEC forms like Consent, Privacy and Confidentiality, Compensation and Conflict of interest have not been filled.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Provisionally Approved
EC Decision: Approved

Ref. code: 117th ECM II B-Ph.D/P5

8- Clarification of proposal entitled ***"A randomized, multicentre, double blind, placebo controlled, parallel-group, study to evaluate the efficacy and safety of linaclotide once daily of Dr. Reddy's laboratories limited in patients with chronic constipation"*** sponsored by Dr. Reddy;s laboratories limited submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/28/2022 dated 9th November, 2022.

Previous EC Comment	PI response
Section 3(ii) ad 3(iv) is contradictory if Drug has not been approved else were. It is a IND/ND.	Section 3(ii) was inadvertently mentioned "None", I would like to clarify that Study drug (Linaclotide) has been approved in US, Canada, Japan, China and EMA region, however Linaclotide have not been marketed in India yet. Sponsor (Dr. Reddy's Laboratories Limited) is planning to market the product in India. As per Regulatory requirement, sponsor has decided to conduct phase III clinical trial in India. Section 3(iv) The investigational drug has been already approved in other countries however study drug (Linaclotide) has not been approved in India yet. Investigator Brochure copy and DCGI Approval letter had been submitted along with EC dossier. After the Correction Annexure 7 copy attached for the reference.
The total study duration needs to be mentioned.	Total study duration around 16 weeks (4 weeks screening including pre-treatment period, 12 weeks treatment period). We had captured this information in Annexure 07.
Why use direct identifiers?	We would like to clarify that patient confidentiality would be maintained strictly as per guideline through-out the study and we are capturing only subject initials and subject number in the source note. We will not share any subject related confidential information except for Regulatory Authority requirements.

The reply to above Comments was forwarded and reviewed by PR:-
Second opinion of PR:
- Using direct identifiers is not acceptable.

The reply from PR to the above Comments was forwarded to PI:- Response received from PI which was forwarded to the PR vide this office letter no. 1627/Ethics/2022 dated 19th December, 2022.
Recommendation of PR:- Pending

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

EC Decision: Defer to the next Meeting because quorum was incomplete.

Ref. code: 117th ECM IIC/P2

9- Clarification of research protocol no. BRADPL/CT/FDC/AZM/03/30 entitled ***"A multi-center, double-blind, randomized, active-controlled, comparative, parallel-group, phase III clinical study to evaluate the efficacy and safety of fixed dose combination of azelnidipine plus metoprolol succinate tablets in the treatment of subjects with stage 2 Hypertension"*** sponsored by M/s Akums Drugs & Pharmaceuticals Ltd. submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/31/2022 dated 21st November, 2022.

Previous EC Comment	PI response
Section 3(iii) not filled.	Annexure 07 Copy attached with updated Section 3(iii).
Duration of the study not mentioned.	As per the sponsor study completion is expected March 2023. The study duration for our KGMU site will start once EC issues the approval letter for the study.
Direct Identifiers: Why?	Direct Identifiers marked as NO in updated Annexure 07. As per your valuable comment we would like to clarify that patient confidentiality would be maintain strictly as per guideline through-out the study and we are capturing only subject initials and subject number in the source note and subject file. We will not share any subject related confidential information except for Regulatory Authority requirement. As per your valuable comment we would like to clarify that patient confidentiality would be maintain strictly as per guideline through-out the study and we are capturing only subject initials and subject number in the source note and subject file. We will not share any subject related confidential information except for Regulatory Authority requirement.
Eating a tablet is physical discomfort. Why ticked no?	After the correction updated form submitted for your reference. There is minimal or no risk for eating a tablet.
Statement expert to comment in sample size.	Sample size supporting document attached for your reference.
Give study duration.	The study duration is started after the EC approval for KGMU site and Study completion date is March 2023 for all over sites including KGMU.

The above Comment forwarded to PI was reviewed by PR:-

Second opinion of PR:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Duration of subject participation has not been mentioned.
- Prof. G.G. Agarwal to comment on Sample size estimation. It seems to be extremely small with too many arms to reach a reasonable conclusion.

The above Comment forwarded to PI:-

- The PI has informed this office that **this protocol is over.**

EC Decision: Trial has closed.

Ref. code: 117th ECM IIC/P6

10- Clarification of research Protocol no. GLK-2101 entitled ***"A randomized, assessor-blind, placebo controlled, multi center, clinical endpoint bioequivalence study to compare the efficacy and safety of generic fluticasone propionate inhalation aerosol USP 44mcg (Glenmark Pharmaceuticals Ltd) to flovent HFA (Fluticasone propionate inhalation aerosol) 44mcg (GSK Group of Companies) in treatment of patients with bronchial asthma"*** sponsored by M/s Glenmark Pharmaceuticals Ltd. B/2 Mahalaxmi Chamber submitted by Prof. R.A.S Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. RM/CT/07/2022 dated 21st November, 2022.

Previous EC Comment	PI response
PI needs to know the difference between study duration and duration of subject participation.	As per the sponsor study completion date is expected Dec 2023 the study duration is started after the EC approval for KGMU site. Total Study Duration is 04 week per enrolled subject, as per the study design total 07 days is screening period and 14 days is a Run in period and 04 weeks is a treatment period for each enrolled subject in the study.
PI to kindly furnish document by DCGI that states that Direct Identifiers should be used.	As per your valuable comment we would like to clarify that patient confidentiality would be maintain strictly as per guideline through-out the study and we are capturing only subject initials and subject number in the source note and subject file. We will not share any subject related confidential information except for Regulatory Authority requirement.
Does the PI doesn't consider that blood and urine as body fluids.	As per the section 07 HbA1c, Hematology, Blood Chemistry and urine pregnancy test (for Female subject only) will be tested for safety parameters.
Correct and updated form not submitted.	After the correction updated form submitted for your reference.

The reply to above Comments was forwarded and was reviewed by PR:-
Recommendation of PR: Provisionally Approved

EC Decision: Defer to the next Meeting because quorum was incomplete.

Ref. code: 117th ECM IIC/P9

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

11- proposal entitled ***"Evaluation of changes in oral health profile, sensory acuity, emotional well-being and nutritional status of post-menopausal women: A pilot study"*** submitted by Dr. Vikram Khanna, Additional Professor, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 587/OMSR/2022 dated 19th November, 2022.

Previous EC Comment	PI response
This is prospective cohort Comparative study.	Changes made in the proposal according to the Suggestion.
Since this is pilot study, sample size calculation is not required.	Changes made in the proposal according to the Suggestion.
How the reliability and validity of the questionnaire shall be checked?	The questionnaire used for the evaluation is a group of many standardized questionnaires used for different parameters. We want to assess four parameters (oral health status, sensory activity, emotional well-being and nutritional status) collectively and assess their relationship intra- and Inter group.
Statistical analysis section is very general. It should be specific to the study under consideration.	Demographic and treatment details from patients would be recorded the data would be entered into an Excel worksheet. The analysis would be performed using the commercially available Statistical Package for Social Sciences–20 statistical software (SPSS -20). Assessment of reliability and validity of the data would be performed Reliability: Internal consistency would be measured using Cronbach's alpha coefficient. Validity: Construct validity would be assessed for The structured questionnaire by correlating the constructs with existing tools. Content or face validity would be evaluated for the original content by common consensus process in a multidisciplinary team setting, which consisted of Experts and patients. In order to validate the structure of the questionnaire confirmatory factor Analysis shall be performed. Significance level shall be computed at p & lt; 0.05 (2-tailed).
Consider using standardized questionnaire.	We have used standardized questionnaire used for different parameters and made a collection of standardized questionnaires for intra-and intergroup evaluation.

The above reply to Comments of the PI was forwarded and reviewed by PR:-
Recommendation of PR: Provisionally Approved

EC Decision: Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: 118th ECM IIA/P1

12. Clarification of proposal entitled ***"Effect of natural protein powder on lean muscle mass and body fat with resistance training: A randomized controlled trial"*** sponsored by DHR, New Delhi submitted by Prof. Dileep Kumar Verma, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2758/PHY/2022 dated 7th November, 2022.

Previous EC Comment	PI response
Study design-RCT-CONSORT guidelines not followed – Method of randomization, blinding, sample size calculation not mentioned.	▪ **Study Design-** Simple random sampling will be followed in the study. ▪ **Method of randomization-**Random number table method ▪ **Blinding-** There is no blinding in the study. Therefore, it is mentioned in the project proposal that the study is unblinded or open label (Both researcher and the enrolled patients will be aware of the treatment(s). **Sample Size-**It is mentioned below.
Sample size calculation not done.	**Sample Size:** Sample size is calculated by using following Daniel's formula (1999) with the help of online sample size calculator (https://www.calculator.net/sample-size-calculator.html?type=1&cl=95&ci=5&pp=79.5&ps=10000&x=89&y=16) $Sample\ Size\ (n) = \frac{z^2 \times \hat{p}(1-\hat{p})}{s^2}$ Where, n is the sample size z is the z score s is the margin of error $\hat{p}$ is the population proportion Now, $z = 1.96$ $\hat{p} = 14\% = 0.14$

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		$(1-p) = 1-0.14$ s= 5% = 0.05 Thus the value of *n* comes out to be 182 for each group i.e., in case and control group. Assuming dropouts we make this figure 182 to be 190 for each group. Thus, Total number of subjects for both the groups i.e. case and control = **190+ 190 = 380** Therefore, 380 will be the total sample size of the study.
	From where PI will recruit the subjects (which OPD/IPD etc.)	▪ Resistance training is a strength training involving the performance of physical exercises that are designed to improve strength and endurance. ▪ The subjects not taking any supplement and already on resistance training (doing same type of resistance for the same period of time) will be enrolled in the study from gym in various localities of Lucknow city. ▪ The subjects will be enrolled as per the study's inclusion criterion.
	Where and how resistance training will be done and monitored assessed)	▪ With the collaboration of the gym, the Field Staff of the project will monitor the subjects performing resistance training in gym. ▪ The PI &Field Staff will recruit only those subjects who perform the same type of resistance training for the same period of time and not taking any supplement. Only the dietary intervention (plant based protein powder) will be given from our side.
	Scientific literature of plant based powder should be attached. If it is nutritional supplement, whether its FSSAI and GMP approved product?	**Attached** Yes it is FSSAI and GMP approved plant based protein powder manufactured by Herbalveda Pharmacy.
	Who will assess the	Herbal Valley plant based protein powder manufactured by Herbalveda

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

nutritional value of the powder by HPLC.	Pharmacy which is already HPLC tested for the assessment of the nutritional value. Details of Nutritional Information- **Attached**
In Inclusion/Exclusion criteria pregnant and lactating mothers not mentioned (as PI will recruit the subjects of either sex), Control group details about Inclusion/Exclusion criteria not given. Food frequency questionnaire – not attached.	**Inclusion and Exclusion Criteria** *Note: The inclusion and exclusion criteria will remain same for the case and control group, only the change is in the intervention i.e., intervention will be given to the case group and not to the control group.* **Inclusion Criteria** ▪ Resistance exercise doing individuals aged between 18-35 years. ▪ Subjects of either sex i.e., both male and female ▪ Subjects willing to consent in writing ▪ Subjects not taking any Protein supplement powder. **Exclusion Criteria:** ▪ Subjects not willing to participate in the study ▪ Aged <18 and >35 years ▪ Subject taking Whey and Casein Protein supplement powder. ▪ **Pregnant, nursing, or planning for pregnancy** ▪ Active medical condition- a known allergy or intolerance. ▪ History of head injury, seizures, or stroke ▪ Subjects having any medical or surgical illness requiring priority management ▪ Subjects having any medical condition like chronic illness, metabolic diseases, endocrinal diseases, congenital disorder, neurological and psychiatric disorder. ➢ Food frequency questionnaire – **Attached**

The reply of the PI was forwarded and reviewed by PR:-
Recommendation of PR: Provisionally Approved

EC Decision: Approved

Ref. code: 118th ECM IIA/P8

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

13- Clarification of research proposal entitled ***"Effect of restriction of blue light exposure at night on anthropometric, biochemical and cognitive function: A randomized controlled trial"*** sponsored by DHR, New Delhi submitted by Prof. Narsing Verma, Head, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2754/PHY/2022 dated 5th November, 2022.

Previous EC Comment	PI response
From where PI will recruit the subjects (Which OPD/IPD etc.)- Please clarify.	The subjects will be the attendants of the patient, coming along with the patient to the OPD of King George's Medical College, Lucknow. Subject enrolment will be done in the registration area of New OPD Building, King George's Medical College where patients register themselves and book appointments to see a doctor in the OPD.
In Inclusion/ Exclusion Criteria-Control group details not given.	Inclusion and Exclusion Criteria: Note: The inclusion and exclusion criteria will remain same for the case and control group, only the change is in the intervention i.e., intervention will be given to the case group and not to the control group. Inclusion Criteria: □ Subjects of either sex i.e. both male & female. □ Subjects aged 18-35 years □ Subjects with screen time more than 2 hours in continuity at night after 8:00 p.m. □ Subjects willing to consent in writing. Exclusion Criteria: □ Pregnant, nursing, or planning to become pregnant during the study □ History of head injury, seizures, or stroke □ Patients having any medical or surgical illness requiring priority management □ Participation of subject in any other clinical trial within the last 30 days. □ Known Alcoholics □ Subjects not willing to participate in the study □ Patient having history of any cardiomyopathy, retinopathy or nephropathy. □ Non-volunteers □ Presence of any other disease; cancer, chronic diarrhea or significant gastrointestinal issues or surgery that impacts nutrition.
The patient information sheet is general (not research	Revised and enclosed.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	study related)- Please revise.

The above reply of the PI to the Comments was forwarded and reviewed by PR:-
Recommendation of PR: Provisionally Approved

EC Decision: Approved

Ref. code: 118th ECM IIA/P9

14- Clarification of research proposal entitled ***"A pilot study on therapeutic Hypothermia for inborn neonates with moderate to severe hypoxic ischemic encephalopathy in a tertiary care center of a lower middle income country"*** submitted by Prof. Mala Kumar, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2621/Ped/2022 dated 20th October, 2022.

Previous EC Comment:

- Consent forms need correction as consent will be taken from the parents/guardians of the neonates.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Provisionally Approved

EC Decision: Approved

Ref. code: 118th ECM IIA/P12

15- Clarification of research proposal entitled ***"Laryngotracheal and upper airway symptoms due to mechanical ventilation after orotracheal intubation in critically ill patients- A prospective multi-centre cohort study"*** submitted by Dr. Saumitra Misra, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1001/2022 dated 17th November, 2022.

Previous EC Comment	PI response
Kindly mention the name of other centers if this is a multi-centric study.	This study is proposed to be done across the following 10 centres in India – 1. Critical care medicine, St John's Medical College Hospital, Bengaluru, Karnataka 2. Surgical intensive care unit, Christian Medical College, Vellore, Tamil Nadu 3. Sanjay Gandhi Postgraduate Institute (SGPGI), Lucknow, Uttar Pradesh 4. Rajendra institute of medical sciences (RIMS), Ranchi, Jharkhand 5. All India Institute of Medical Sciences (AIIMS), Jodhpur, Rajasthan 6. Institute of Medical Sciences, Banaras

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Hindu University, Varanasi, Uttar Pradesh 7. King George Medical University, Lucknow, Uttar Pradesh 8. Manipal Hospital, Yeswanthpur, Bengaluru, Karnataka 9. PSG medical college hospital, Coimbatore, Tamil Nadu 10. Bharati Hospital and Research Centre, Vidyapeeth, Pune, Maharashtra.
	Regarding the secondary objective of assessment of quality of life kindly justify the assessment of quality of life without issuing any quality of life tool.	We are assessing quality of life (QOL) with respect to voice and swallowing in patients post-extubation in ICU. We are not studying the general QOL. EAT-10 and VHI-10 are validated, easy-to-use and reproducible questionnaires to assess the quality of life due to swallowing and voice problems.
	Kindly include sample size calculation formula.	The prevalence of stridor is the least among all other upper airway symptoms so anticipating the prevalence of combined laryngotracheal and upper airway symptoms will be close to the prevalence of stridor. Taking 7% prevalence from literature (6.7% combined prevalence from existing data) a sample size of 278 was calculated considering 3% absolute precision, 95% confidence limits. Software used : https://statulator.com/SampleSize/ss1P.htm l Reference: Dhand, N. K., & Khatkar, M. S. (2014). Statulator: An online statistical calculator. Sample Size Calculator for Estimating a Single Proportion. Considering the average extubation rate in our unit is around 20 per month, amounting to some exclusions, loss to follow up, consent denial, covid pandemic, and inclusion of other centers (which may have variable extubation rates) anticipating 6-12 months to achieve the necessary sample size. As factors associated with this complication are common and predictive modelling with factors

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		may help prevent these, a higher sample is desirable. So, patients will be screened and all potentially eligible patients we come across during the study period will be enrolled with a minimum of 280 patients. i.e., all patients (as many as eligible) during the study period will be enrolled in the study. Since the study is being done at 10 centres, each study centre will contribute 30 patients for the proposed study.
	In Annexure-I it is stated that 'collection of banking or future research' will not be applicable but in consent section it is clear that the 'consent for future use of biological material' will be obtained: Kindly resolve the discrepancy period.	Correction done.
	Kindly add a brief account on anticipated outcomes and statistical analysis process.	Anticipated outcomes: The anticipated prevalence of LTUAS will be around 6-10%. The individual prevalence of each will vary. The factors that may affect these symptoms will be the type of intubation, duration of mechanical ventilation, trauma to airways, sedation practices, agitation during ICU stay, etc will be analysed using multiple logistic regression. Statistical analysis plan: Demographic, clinical and disease-related variables will be presented as frequency (Percentage) and mean (S.D), median as appropriate. Categorical variables will be analysed using Chi-square test or Fisher's exact test (for binary variable). Multiple logistic regression will be performed to find factors associated with the laryngotracheal and upper airway symptoms. p value < 0.05 will be considered statistically significant.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Provisionally Approved

EC Decision: Approved

Ref. code: 118th ECM IIA/P19

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

16- Clarification of research proposal entitled ***"Randomized comparison of I-gel, baska mask, ambu aurgain and laryngeal mask airway protector for airway management of patients with anticipated difficult airway"*** submitted by Dr. Rati Prabha, Assistant Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1380/2022 dated 14th November, 2022.

Previous EC Comment	PI response
SADs comparison.	I-gel: It is anatomically preshaped, with the cuff made of gel-like soft thermoplastic elastomer. [1,2] The cuff is non-inflating type and anatomically fits the laryngeal, peri-laryngeal,and pharyngeal structures. It is available in 7 sizes. [2] It has an integrated gastric channel through which a gastric tube can be inserted. It has integrated a bite-block. A wide-diameter airway tube allows the insertion of an endotracheal tube through it. Major advantages are high oropharyngeal seal pressure(OLP) and fast device insertion. [1-4] 2. Baska mask: Unique feature is self- expanding membranous cuff- that inflates and deflates with inspiration and expiration. [1,5] The airway tube is oval-shaped and has an integrated bite block. [1,5,6] There are two gastric drains through which gastric drain can be inserted and active suction applied. [1] It is available in four sizes. An inbuilt hand-tab is used to increase the angulation and ease the device insertion. [1,5,6] 3. Ambu Auragain: It is an anatomically curved single-use SAD with an inflatable cuff. [7,8] It has an integrated gastric port. [7] For aiding endotracheal intubation through its airway lumen, it has a wide airway lumen and has no aperture bars. [7-9] 4. Laryngeal mask airway protector: It is a supraglottic airway device with cuff made of silicone. [10-12] It has two gastric access channels. [10] It has an integrated cuff pressure indicator. [10] It has integrated bite block. [10-12]
Are these devices routinely used? Are there any situations about the specific use of each type?	Yes, these devices are routinely used. There are no specific differences in indications/situations for use of each of these devices. These are used for patients with normal or difficult airways.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Another common indication is when endotracheal intubation is expected/anticipated to be difficult or endotracheal intubation has failed.
	What are standard guidelines? What are the protocols in KGMU ICU?	The '2022 American Society of Anesthesiologists Practice Guidelines for Management of the Difficult Airway' recommend the use of second-generation guidelines for management of difficult airway. [13] All the SADs used in the trial suitable this as all the four SADs are second generation devices. Currently, there no written protocol for use of SAD in KGMU ICU. The trial is to be conducted in operation theaters. There is no written KGMU protocol for management of airway and use of SAD/other devices in KGMU operation theater.
	Separate PID is not there. The information is in the consent form only. Is it ok?	Yes.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:

- There is no PATIETN INFORMATION BROCHURE
- The information is consent mentions that THE ALTERATIVE TOPARTICIPATION IS THAT THEY WILL BE PROVIDED USUALCARE AS PER STANDARD GUIDELINES AND PROTOCOLS but what is the standard protocol is not mentioned.
- Routinely, do the anesthetists use any one of these?
- Which one of them? If any of these are used what are the reasons of choosing one of them. The methodology is not clear.
- To the questions asked, what is the current protocol, the answer provided is that there is no protocol at present.
- This needs clarification in the methodology so that the patient information brochure should include correct information about alternative to refusal to participate.
- Also standard care provided currently should be clearly mentioned.

The reply from PR to the above Comments was forwarded to PI:- Pending

EC Decision: Reply pending by PI.

Ref. code: 118th ECM IIA/P24

17-	Clarification of research proposal entitled AVT06-GL-C01 Version: Version 2.0,21 December 2021 entitled ***"A randomized, double-masked, parallel-group, multicenter***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

clinical study to evaluate the efficacy and safety of AVT06 compared with EU-Eylea® in subjects with neovascular (Wet) age-related macular degeneration (ALCOEYE)" sponsored by M/s Alvotech Swiss AG Thurgauerstrasse submitted by Prof. Sandeep Saxena, Department of Ophthalmology, King George's Medical University, U.P., Lucknow, vide letter no. 1567/OPh/2022 dated 18th November, 2022.

Previous EC Comment	PI response
The Sponsor information in form and DCGI documents is different.	As mentioned in the DCGI Submission letter dated 17 May 2022, duly submitted to the Ethics Committee dated .....Kindly note that IQVIA is the CRO applicant and submitted the study details to the DCGI on behalf of the sponsor(ALVOTECH). A Letter of Authorization has been submitted to DCGI. Hence in the DCGI. Approval letter it was addressed to IQVIA. the sponsor name is not mentioned in DCGI letter as CRO IQVIA has submitted the application to DCGI to conduct the CT in India. The sponsor 2 name mentioned in form is correct and same is mentioned in Protocol and DCGI Submission Letter. The Sponsor name and Address is Alvotech Swiss AG Thurgauerstrasse 54 8050 Zurich Switzerland.
What investigations will be done locally?	Below investigations will be done locally- 1. Informed Consent 2. Demographics 3. Medical History 4. Complete physical examination including height and weight 5. Vital Signs 6. 12 Lead ECG 7. Examinations of Eyes (BCVA, IOP, Slit lamp, Indirect Ophthalmoscopy, SD-OCT, Fundus Angiography, Fundus Photography) 8. Urine Pregnancy test 9.Blood Sampling (Hematology, Clinical Chemistry and Urinalyses) Blood will be withdrawn at site i.e locally and processed and will be sent to central laboratory for the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		results. Local laboratory results are only required in the event that the central laboratory results are not available in time for either study treatment administration and/or response evaluation. If a local sample is required, it is important that the sample for central analysis is obtained at the same time. Additionally, if the local laboratory results are used to make either a study treatment decision or response evaluation, the results must be entered into the eCRF.
	What tests and imaging will be done for this study and how will data be transferred securely for central imaging review?	SD-OCT, Fundus Fluoresceine Angiography and Fundus Photography will be performed by using subject ID given by sponsor maintaining confidentiality and securely from certified device the images will be transferred to pendrive and then will be uploaded in imaging portal of central imaging center.
	PI Needs to know difference between study duration and duration of subject Participation.	As mentioned in the protocol the total study Duration is 56 weeks for each subject participation. The duration of study depends on the (competitive) enrollment period and the number of subjects enrolled at the site level.
	Confidentiality and privacy section not filled.	Confidentiality and privacy section updated in enclosed form.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:

- Despite pointing out, PI is unable to address the difference between study duration and duration of subject participation needs to be clarified. Subject recruitment cannot go on or ever.

The reply from PR to the above Comments was forwarded to PI:- Response received from PI which was forwarded to PR:-
Recommendation of PR: Pending

EC Decision: Defer to the next Meeting because quorum was incomplete.

Ref. code: 118th ECM IIC/P1

18- Clarification of research proposal entitled "***A study on assessing the role of circulating***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

tumor DNA/circulating free DNA (ctDNA/CfDNA) ratio in oral squamous cell carcinoma progression through RNA sequencing meta-analysis and subsequent real-time PCR" submitted by Prof. Shaleen Chandra, Head, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 984/OralPatho/2022 dated 30th November, 2022.

Previous EC Comment	PI response
Principal-Investigator has stated that the project is an ICMR multi-centric project: however no communication regarding the same from ICMR has been attached to the proforma.	The research project co-investigator is from AIIMS, New Delhi and the research project has been submitted to ICMR and it is in review process.
Budget approximation is presented but the approval from ICMR is not attached.	The research project has been submitted to ICMR and it is in review process and the budget has not been sanctioned yet.
Answer to the question "is the risk reasonable" has been mentioned as "No".	Now Corrected as "Yes".

The reply from PI to the above Comments was forwarded to PR:-
Second opinion of PR:

- Approval of the multi-centric project from ICMR with inclusion of KGMU as one of the sited and the proposer as one of the CO-PIs.
- Budget approval from ICMR for expenses related to the study so that the expenses are not passed on to the subjects participating in the study.

The reply from PR to the above Comments was forwarded to PI:- Pending

EC Decision: Reply pending by PI

Ref. code: 119th ECM IIA/P7

19- Clarification of research proposal entitled ***"Heel pain and calcaneal enthesophytes: A radiological evaluation"*** submitted by Prof. Archana Rani, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 428/ANAT/2022 dated 29th November, 2022.

Previous EC Comment	PI response
Risks & benefits i. Is the risk reasonable compared to the anticipated benefits to subjects/community country?- No	**Risks &benefits:** i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?- Yes (As the study is an observational study which will only utilize routine parameters and variables collected for management of a patient).

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:-Approved
EC Decision: Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: 119th ECM IIA/P17

20- Clarification of research proposal entitled ***"Evaluation of lignocaine HCI as a therapeutic and diagnostic tool in myofascial pain dysfunction syndrome (MPDS0 and internal derangement"*** submitted by Prof. U.S Pal, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. OMSD/924/2022 dated 25th November, 2022.

Previous EC Comment	PI response
The PI has said that the risks involved are not reasonable. Thus, doing this study will be unethical.	The risks involved in this study are reasonable. No new drug trail is being conducted and the lignocaine HCl is considered a safe drug in humans. Corrections have been done accordingly in the proforma and copy attached.

The reply from PI to the above Comments was forwarded to PR:-

- What is the need for direct identifiers?
- Efficacy measures are not mentioned.
- Sample size calculation is not correct.
- Case record format is not attached.
- As this is an intervention study, and adverse effects can happen, needs to be reported, compensation should be accounted for.

EC Comment:

- As above

EC Decision: Revise and Resubmit, Give a table of revisions done.

Ref. code: 119th ECM IIA/P18

21- Clarification of research proposal entitled ***"COVID-19 testing in two districts of Uttar Pradesh: access utilization, and associated factors during the second epidemic wave"*** submitted by Mr. Raghukul Ratan Pandey, Ph.D Scholar 2021 under the guidance Prof. Amita Jain, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1186/22 dated 8th December, 2022.

Previous EC Comment	PI response
In Inclusion criteria there is no mention of Pregnant/Lactating women, but in SOP form Pregnant women column is ticked yes-Please clarify	Inclusion criteria revised as per the comment and Pregnant women column in SOP form ticked-NO
Two Co-PIs from abroad University have been taken in the study-whether there is any collaboration between KGMU & Johns Hopkins University, Baltimore, Maryland USA for this study (matter for	Both Co-PIs from Johns Hopkins University have been included as subject expert and consented to provide guidance for this study.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	discussion in EC) |
	The above Comment forwarded to PI was reviewed by PR:- *Recommendation of PR:* Provisionally Approved **EC Decision:** Approved ***Ref. code: 119th ECM II B-Ph.D/P1***
22-	Clarification of research protocol no. ODM-203-201 entitled ***"A phase II open-label trial evaluating the efficacy and safety of once daily Oral ODM-203 in patients with unresectable transitional cell urothelial carcinoma with FGFR3 mutation (TEJAS-1)"*** sponsored by Aurigene Discovery Technologies Ltd. submitted by Dr. Sudhir Singh, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 278/RT/2022 dated 18th June, 2022.

S.no.	Previous EC Comment	Response by PI
1-	Mention the duration of study in section III	Study duration-02 years
2-	Mention that there could be minimum discomfort on eating the tablet.	Minimum discomfort while consuming tablet size is not large.
3-	Do not use the direct identifier	We are not using the direct identifiers; details of patients will be in coded format.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Pending
EC Decision: Defer to the next Meeting because quorum was incomplete.
Ref. code: 117th ECM II C/P1

23-	**ADR sub Committee** Defer to the next Meeting because quorum was incomplete.
IIA	**New Proposal**
1.	Research proposal entitled ***"Fetomaternal outcome in IVF versus spontaneously conceived twin pregnancy at tertiary care Hospital in Northern India"*** submitted by Dr. Vandana Solanki, Associate Professor, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/2078/2022 dated 3rd October, 2022. *Recommendation of Primary reviewer:* • Proposal is incomplete. • Only "Aims & Objectives" are given. • Study design, methodology, sample size calculation are missing. • Statistical Analysis section is very general. It should be in conformity to the research hypothesis.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Patient consent form is also missing. **EC Comment:** As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: 120th ECM IIA/P1***
2.	Research proposal entitled "***Study of virological profile in Hepatitis B virus infected women of reproductive age***" sponsored by CST-UP submitted by Dr. Sumit Rungta, Head, Additional Professor, Department of Medicine Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. 1723/MedGastro/2022 dated 6th October, 2022. ***Recommendation of Primary reviewer:*** • Proposal is incomplete. • "Aims & Objectives" are not given. • Study design, methodology, sample size calculation, statistical analysis sections are missing. **EC Comment:** As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: 120th ECM IIA/P2***
3.	Research proposal entitled "***Comprehensive metabolic fingerprinting of cancer patients: An attempt towards the development of partially non-invasive tool for diagnostic, therapeutic and disease progression***" submitted by Dr. Teerthraj Verma, Additional Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 1070/RT/2022 dated 6th October, 2022. ***Recommendation of Primary reviewer:*** • Proposal is incomplete. • "Aims & Objectives" are not given. • Study design, methodology, sample size calculation, statistical analysis sections are missing. **EC Comment:** As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: 120th ECM IIA/P3***
4.	Research proposal entitled "***24 hour glucose profile and beta cell function in women with early gestational diabetes mellitus***" submitted by Prof. Amita Pandey, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3012/2022 dated 8th October, 2022. ***Recommendation of Primary reviewer:*** • There are too many primary objectives. There should be one primary objective. The rest should be included into secondary objectives. • After identifying the study variables and study parameters, the objective should be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	converted into research hypothesis in terms of the study parameters. • Study design is mentioned as prospective case control study. Case control study is retrospective. • Sample size calculations are missing. • Statistical analysis section is very general. It should be specific to the research hypothesis. **EC Comment:** As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: 120th ECM IIA/P4***
5.	Research proposal entitled "***To assess immunoexpression of glucocorticoid receptor alpha (GRα) isoform in oral squamous cell carcinoma (OSCC) and exploration of three protein panel (OCLN, PIK3CB, & SCRIB) to predict prognosis in oral squamous cell careinoma***" sponsored by ICMR submitted by Prof. Shalini Gupta, Department of Oral Pathology & Microbiology Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 909/OP/2022 dated 11th October, 2022. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 120th ECM IIA/P5***
6.	Research proposal entitled "***Expression of minichromosome maintenance complex 3 (MCM3), transport and golgi organization protein 1 (TANGO1), and myofibroblast expression using III calponin and integrin α2 in oral squamous cell carcinoma and oral potentially malignant disorders by immunohistochemistry and its validation by RTPCR***" sponsored by ICMR submitted by Prof. Shaleen Chandra, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 908/OP/2022 dated 11th October, 2022. ***Recommendation of Primary reviewer:*** • Approved. **EC Decision:** As above ***Ref. code: 120th ECM IIA/P6***
7.	Research proposal entitled "***Clinical manifestation of different dengue virus serotypes and its association with disease severity and outcome***" submitted by Prof. Avinash Agrawal, Head, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/808/2022 dated 29th September, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 120th ECM IIA/P7***
8.	Research proposal entitled "***To asses patient satisfaction of hearing outcome following frequency specific sound amplification through smartphone based application: a pilot study***" submitted by Prof. Anupam Mishra, Head, Department of Otorhinolaryngology &

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 688/ENT/2022 dated 12th October, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Dr. Anupam Mishra did not take part in the discussion and making decision.*** ***Ref. code: 120th ECM IIA/P8***
9.	Research proposal entitled "***Maternal near miss review (MNM-R) and corrective measures at selected tertiary hospitals in India***" sponsored by ICMR submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3035/2022 dated 12th October, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 120th ECM IIA/P9***
10.	Research proposal entitled "***Acceptability and usability of hepatitis-C self-Testing and its distribution models among the general population, and people who inject drugs and their partners in India***" sponsored by Program for Appropriate Technology in Health (PATH) submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1979/MED/2022 dated 12th October, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 120th ECM IIA/P10***
11.	Research proposal entitled "***A case-control observational study to determine relation between indoor air pollution and lung cancer***" sponsored by ICMR submitted by Dr. Ankit Kumar, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1105/2022 dated 17th October, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 120th ECM IIA/P11***
12.	Research proposal entitled "***Importance of chromatogram interpretation while estimating HbA1c using ion-exchange high performance liquid chromatography (HPLC) method***" submitted by Dr. Kalpana Singh, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/589/2022 dated 17th October, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** Approval for waiver of consent ***Ref. code: 120th ECM IIA/P12***
13.	Research proposal entitled "***Mutational landscape of signaling pathways, transcription factor, epigenetic regulator, tumor suppressor, and spliceosome genes in newly diagnosed chronic phase-chronic myeloid leukemia cases in North India***" sponsored by ICMR submitted by Prof. Syed Tasleem Raza, Department of Biochemistry, Era

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	University, Lucknow Co-PI & Dr. Shailendra Prasad Verma, Additional Professor, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. Bio/589/2022 dated 17th October, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 120th ECM IIA/P13***
14.	Research proposal entitled "***A study on the behavioral and neuropsychological correlates of problematic internet use among adolescents***" submitted by Dr. Shweta Singh, Professor Jr. Grade, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1589/Psy/2022 dated 20th October, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 120th ECM IIA/P14***
15.	Research proposal entitled "***Mechanisms of autophagy-mediated cell survival in TNBC: implications in therapeutics and diagnostics***" submitted by Dr. Navin Singh, Additional Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 1157/RT/2022 dated 18th October, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 120th ECM IIA/P15***
16.	Research proposal entitled "***Artificial intelligence to predict pulmonary tuberculosis using chest X-ray of symptomatic population***" submitted by Prof. Anit Parihar, Head, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 920/RD/2022 dated 29th October, 2022. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 120th ECM IIA/P16***
17.	Research proposal entitled "***Study to establish validity of rubric based assessment tool for evaluation of analytical cognitive skills in neuroanatomy module in first phase MBBS course***" submitted by Prof. Anita Rani, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 344/ANAT/2022-23 dated 6th October, 2022. ***Recommendation of Primary reviewer:*** • References not attached **EC Decision:** Revise & Re-submit ***Dr. Anita Rani did not take part in the discussion & making decision.*** ***Ref. code: 120th ECM IIA/P17***
18.	Research proposal entitled "***Growth and development outcomes in severe acute malnutrition (SAM) children discharged from Nutrition rehabilitation centre (NRC): A community based follow up study***" submitted by Mr. Rohitash Kumar, Assistant Professor, KGMU College of Nursing under the guidance of Prof. Monica Agarwal, Department of Community Medicine & Public Health, King George's Medical University,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 21st December, 2022

	U.P., Lucknow vide letter no. 1492/PF/22 dated 7th October, 2022. ***Recommendation of Primary reviewer:*** • Revise consent Form as it is being given by the legal Guardian. **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 120th ECM II A/P18***
19.	Research proposal entitled "***Development of patient derived organoid/xenograft (PDO/PDX) tumor models in immune-compromised mice and assessment of tumor associated changed in breast cancer***" submitted by Prof. Seema Gupta, Department of Radiotherapy,King George's Medical University, U.P., Lucknow vide letter no. 1151/RT/22 dated 18th October, 2022. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 120th ECM II A/P19***
20.	Research proposal entitled "***Elucidate the role of miR-384-5p as promising biomarker in predicting the severity of acute spinal cord injury a case-control study***" sponsored by UPCST-, Lucknow submitted by Dr. Shah Waliulla, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2941/OS/22 dated 18th October, 2022. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 120th ECM II A/P20***
21.	Research proposal entitled "***Sustainable laboratory network for monitoring of viral hemorrhagic fever viruses in India and enhancing bio-risk mitigation for high-risk group pathogens***" sponsored by ICMR submitted by Prof Amita Jain, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1089/22 dated 12th November, 2022. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 120th ECM II A/P21***
22.	Research proposal entitled "***An Indo-German approach to identify universal and specific molecular targets in breast cancer prevention: impact of environmental disruptors, diet and lifestyle on sex hormone levels and cellular consequences thereof in human breast tissues***" sponsored by ICMR-DFG submitted by Prof Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1745/22 dated 2nd November, 2022. ***Recommendation of Primary reviewer:*** • Kindly rectify the Hindi version of ICF. It should be same as in English.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: As above **EC Decision:** Approval subject to modification ***Ref. code: 120th ECM II A/P22***
23.	Research proposal entitled "***Distribution of nutrient foramina in scaphoid: A bone study***" submitted by Dr. Arvind Kumar Pankaj, Additional Professor, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 401/ANAT/22 dated 16th November, 2022. ***Recommendation of Primary reviewer:*** • Approved for waiver **EC Comment:** As above ***Ref. code: 120th ECM II A/P23***
24.	Research proposal entitled "***Study of biochemical parameters and socio-economic determinants of hepatitis-B infection in North Indian population: A public Health issue***" submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2167/Med/22 dated 17th November, 2022. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 120th ECM II A/P24***
25.	Research proposal entitled "***Obesity and its impact on public Health: An epidemiological study on Uttar Pradesh population***" submitted by Dr. Suchit Swaroop, Associate Professor, Department of Zoology, Co-PI Prof. Satyendra Kumar Sonkar, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2166/Med/22 dated 17th November, 2022. ***Recommendation of Primary reviewer:*** • The decision of scientific review committee has not been made but it can be taken as approved. • The PI is a zoologist from Lucknow University. Kindly mention his role in this project dealing with obesity and public health or noncommunicable diseases? What will be the biochemical tests that will be carried out? Would it not be appropriate to add a pathologist / microbiologist and public health faculty as a co-investigator? • What are the other Hospitals that have been enrolled for this study and have given ethical clearance? Kindly attach the relevant documents. • Since this requires clinical data and investigation-details of the patient prospectively, the ICF needs to be included. • While at one point it is mentioned that duration the study is one year (from November 22 to November 23); at another place it is three years. Why is this confusion? kindly clarify. • Will privacy and confidentiality be not maintained? While it is indicated as NA in annexure 1, it is indicated otherwise in informed consent form. kindly clarify.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• What are the plans of reporting adverse effects? • As stated this is a "randomized- study". Kindly clarify as how randomization will be carried out? • The anticipated statistical analysis of outcome parameters is to be included. • The patient information sheet is not attached. Kindly attach both English and Hindi versions. **EC Comment:** As above **EC Decision:** Approval subject to modification, Give a table of revisions done. ***Ref. code: 120th ECM II A/P25***
26.	Research proposal entitled ***"Evaluation of Hyperbric oxygen therapy in OSMF"*** submitted by Prof. U.S. Pal, Department of Oral & Maxillofacial Surgery Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 914/OMSD/22 dated 18th November, 2022. ***Recommendation of Primary reviewer:*** • Annexure needs to be filled up completely such as the section of clinical trials, vulnerable subject types, data monitoring and list of attached documents. • The patient. Information sheet is not attached as per the standard operating procedure (Both English and Hindi version) contrary to data indicated in annexure 1. • Brief description under required headings (eg. point 4) is missing. • The review of literature in terms of rationale of using hyperbaric oxygen is not supported by references. The side-effects of hyperbaric oxygen also need to be mentioned. • Recent histories of ear surgery, along with evidence of chronic lung disease also need to be added in exclusion criteria. • If cases with dysplasia/ malignant changes in OSMF are to be excluded, then biopsy need to be considered in material method section. If biopsy is to be undertaken in every case of OSMF, then this needs to be mentioned before hand. • The study procedure in consent form need to be elaborated in terms of ruling out lung disease, apart from dysplasia/ malignant changes etc. There are well-known other complications of hyperbaric oxygen such as changes and vision and so close monitoring mission to be done for vision and lung condition or changing middle ear fluid/ function. Hence these remote complications need to be explained to the patient. • The methodology needs to be elaborated: a-What are the inclusion criteria specially age. b-What Pre -therapy investigations will be carried out? c- How will the improvement in mouth opening be judged? d-What will be the criteria of declaring significant subjective improvement in spicy food tolerance? e-What would be the duration of follow-up period?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: 120th ECM II A/P26***
27.	Research proposal entitled "***Right ventricular dysfunction in critically ill: prognostic impact on short and long term mortality***" submitted by Dr. Nitin Rai, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1018/22 dated 19th November, 2022. *Recommendation of Primary reviewer:* • Scientific review committee report is missing. • While duration of study in annexure 1 is mentioned as six months, it is quoted as one year elsewhere. Kindly clarify the duration of the data collection and duration of follow-up. • Sample size and it's calculation is missing. Kindly submit it. • Kindly fill in the gaps which are left over in annexure 1. • The patient information sheet in Hindi is incomplete with respect to its English version. Kindly make necessary corrections. **EC Comment:** As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: 120th ECM II A/P27***
28.	Research proposal entitled "***A multicenter cross-sectional study to evaluate the clinical, immunological, and radiological profile of allergic bronchopulmonary aspergillosis (ABPA registry)***" submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1231/22 dated 16th November, 2022. *Recommendation of Primary reviewer:* • The sponsor information and budget need to be clarified further. • The patient information sheet needs to be attached both in English and Hindi versions. • To fill in the gap and make some required trivial corrections in annexure 1. • What are the various centers in India that are collaborating? • Which are the various countries participating in this research? • Which is the lead and coordinating centre in India and abroad? • To submit the relevant document of this multinational multicentric Research study proposal. • To also submit the information regarding the IRB approval of the various centers and status of centralized ethics committee approval as stated in the protocol. • Kindly define the position in the status of Dr Ritesh Agarwal and Dr Sundeep Salvi. Are they the leaders across all the global centres? In that case is the study originating in India? If yes, then kindly quote the lead centre and its communication with KGMU. **EC Comment:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Revise and Resubmit, Give a table of revisions done. ***Ref. code: 120th ECM II A/P28***
29.	Research proposal entitled "***To study the validation of cut off threshold of mangled extremity severity score >7 in decision making of lower limb open injuries in our population***" submitted by Dr. Devarshi Rastogi, Additional Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3093/OS/22 dated 21st November, 2022. *Recommendation of Primary reviewer:* • Fill in the blanks in annexure 1 to submit patient information sheet as per the IRB protocol. • The purpose of study in ICF should be listed point wise as in its English version and care needs to be taken that both are replica of one another. **EC Comment:** As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: 120th ECM II A/P29***
30.	Research proposal entitled "***A retrospective case-note review of subjects with compulsions and obsessions presenting to Geriatric Medicine Health***" submitted by Prof. Shrikant Srivastava, Head, Department of Geriatric Medicine Health, King George's Medical University, U.P., Lucknow vide letter no. 1849/DGMH/22 dated 23rd November, 2022. *Recommendation of Primary reviewer:* • This is a well-planned retrospective review of the de-identified records of patients of obsessive compulsive disorders and can be approved. • However following information needs to be provided by the PI: • To fill in the left out gaps in annexure 1. • The anticipated sample size, duration of project/ analysis may be mentioned **EC Comment:** As above **EC Decision:** Approval subject to modification, Give a table of revisions done. ***Ref. code: 120th ECM II A/P30***
31.	Research proposal entitled "***Efficacy of grid-based dental rubrics as an effective assessment tool when compared to traditional assessment methods for undergraduate students managing a class II carious defect***" submitted by Dr. Rhythm, Professor Jr Grade, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 358/Coms&Endo/22 dated 26th November, 2022. *Recommendation of Primary reviewer:* • Kindly fill the checklist **EC Comment:** As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: 120th ECM II A/P31***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

IIB	New Ph. D Proposal
1.	Research proposal entitled "***Role of DNA methylation and autophagy regulator genes in prognosis of non-muscle invasive bladder cancer***" sponsored by CST-UP submitted by Mr. Anil Kumar, Ph.D Scholar under the guidance Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 492/URO/22 dated 6th September, 2022. ***Recommendation of Primary reviewer:*** • This appears to be a PhD Thesis of 2019 enrollment. It's at least 3 years from enrollment time and research work has not yet been approved. Institute to decide if this is alright. • Can a PhD candidate be called PI? • The PI mentions in section 10 that the risks are unreasonable, when compared to benefits, to conduct this study. Thus, the research is unethical and cannot be approved. **EC Comment:** As above **EC Decision:** Revise and Resubmit, Give a table of revisions done. ***Ref. code: 120th ECM II B/P1***
IIC	**Review of New Drug Trial**
1.	Research protocol no. 22-07 entitled "***An active post-marketing surveillance study to evaluate the safety of measles & rubella vaccine (Live) I.P. (Freeze Dried) of M/s Zydus Lifesciences Limited in healthy subjects aged 9-12 months***" sponsored by M/s Zydus Lifesiences Limited submitted by Dr. Nishant Verma, Additional Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow, vide letter no. 2500/Ped/2022 dated 6th October, 2022. ***Recommendation of Primary reviewer:*** • Attached documents -1. Subject diary card (E/H) 2. Investigator brochure and Undertaking by investigator 3. DCGI permission letter 4. CTA document (but not signed by PI) 5. Budget-Rs. 11,000/per subject 6. Insurance- till 19-03-2023 7. CTRI –missing and according to PI will be given to EC before screening of 1st subject. • IP –Measles and Rubella combined vaccine (live) I.P. (freeze dried) at 9 months of age. • Co-investigator, Dr. Neeraj Anand's details are missing • Sample size detail is not given (only total subjects number-1900 is given) • Details of different other centers in the country where study is going on are missing • Separate summary of Synopsis/ Protocol by PI is not given • PI to submit CTRI document to EC before screening of 1st subject as told by him • Insurance must be renewed after 19-03-2023 **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 120th ECMIIC/P1***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

2.	Research protocol no. CP/03/22; NV-05-1387-2022 entitled "***A randomized, double blind, placebo-controlled, prospective, multicentre, phase2, dose-finding study of itraconazole administered as a dry powder for inhalation (PUR 1900) in adult subjects with asthma and allergic bronchopulmonary aspergillosis (ABPA)***" sponsored by M/s Cipla Ltd. submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow, vide letter no. Res/CT/26/2022 dated 1st October, 2022. ***Recommendation of Primary reviewer:*** • Documents attached- 1. Investigator brochure and Undertaking 2. Subject diary (E/H) + translation certificates 3. eCRF (Case record form) 4. CT NOC from DCGI 5. CTA with budget –Rs 55,050/ per pt 6. Insurance-up to 31st March ,2023 7. Questionnaire for Asthma control 8. Pt information sheet (E/H) • -IP- Itraconazole (PUR1900) powder for inhalation in two doses ,20 mg and 40 mg • -Total duration of study -23 wks (including treatment period of 16 wks) • PI did not submitted summary of Protocol • Details of centers to be involved in the study trial across India not given • CTA document with budget is attached but PI mentioned in summary as not applicable-please specify • CTRI document not attached? –Whether after approval from EC/ after start of trial –please specify • Insurance is going to expire on 31st March ,2023 –should be renewed **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 120thECMIIC/P2***
3.	Research protocol no. MC/PLX/22-002 version 1.0/05 May, 2022 entitled "***An open label, randomized, prospective, multicentric clinical trial to evaluate the efficacy and safety of parenteral placentrex with oral Azitjromycin ve oral asithromycin alone in chronic and recurrent pelvic inflammatory disease"*** sponsored by M/s Albert David Limited, Kolkata, India submitted by Prof. Amita Pandey, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow, vide letter no. OG/1972/22 dated 16th September, 2022. ***Recommendation of Primary reviewer:*** • Documents attached -1. Investigator brochure and Undertaking by PI 2. Subject diary (E/H) with translation certificates 3. CRF 4. CTA- with budget-Rs. 17000/ per pt. 5. State directorate of drugs control –West Bengal NOC for Inj. Placentrex extract manufacturing. 6. Insurance document-valid up to 27th May ,2023. • IP- test arm- Placentrex inj 2 ml IM X14 days + Tab Azithromycin 1 gm OD orally X 7days , Reference arm –Tab AZT 1gm OD orally x 7 days. • Can SR be taken as Co-PI in clinical trials –please justify (open discussion in EC) • PI did not submitted summary of Protocol • Details of other sites involved in this trial –please mention

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• CTA –Document not signed • ICF- not attached (but given in summary of documents) • CTRI document missing (Whether after approval from EC/ after start of trial)– please specify. **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 120th ECMIIC/P3***
4.	Research protocol no. LYT-100-2022-204 entitled ***"A randomized double-blind, four-arm active and placebo-controlled dose-finding trial to evaluate the efficacy, tolerability, safety and dose response of LYT-100 in patients with idiopathic pulmonary fibrosis (IPF)"*** sponsored by M/s Pure Tech LYT 100 Inc.6 Tide street, Suite 400 Boston MA 02210 submitted by Prof. Santosh Kumar, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1236/22 dated 17th November, 2022. *Recommendation of Primary reviewer:* • Documents attached -1. Pt ID Card (E/H) 2. Pt INFO reminder (E/H) 3. Pt TIP Sheet (For APP information) 4. EQ –Questionnaire + Pt source base line satisfaction quest. +SGRQ quest. + Kings brief Interstitial Lung disease quest. + Pt notification quest. + Pt report assessment document +Side effect questionnaire 5. PGI-C-Cough + PGI-C -IPF-severity +PGI-Side effects 6. Koneksa screen report guide + K participant guide etc. 7. Insurance document valid up to 15th December ,2024 8. Draft CTA +Case record form. • In Scientific review committee no Faculty from Respiratory Medicine or Medicine Deptt. has taken part (All members are from Deptt. of Surgical Oncology) -Please revise or justify • PI did not submitted summary of Protocol • DCGI submission letter and acknowledgment letter –attached but permission letter is missing • CTRI document –missing ((Whether after approval from EC/ after start of trial)– please specify. **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 120th ECMIIC/P4***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

IIIA-	Additional Document
1.	Additional of research protocol no. EX9536-4388 SELECT entitled ***"Semaglutide effects on cardiovascular outcomes in people with overweight or obesity"*** submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 361/Cardio/Res/22 dated 19th October, 2022. ***Recommendation of Primary reviewer:*** • The trial is near its completion. • Attachments approved & noted **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 92nd ECM IIC/P1***
III-B	**Modification**
1.	Modification of research protocol entitled ***"A hybrid type-2 study of next generation pulse oximeters to support the integrated management of childhood illness in primary care settings"*** submitted by Prof. Shally Awasthi, Head, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 381/PATH/10/2022 dated 10th October, 2022. ***Recommendation of Primary reviewer:*** • Project has already been approved during a previous meeting of the IEC. Proposed modifications to the Protocol/ICF may be approved. **EC Decision:** Approved ***Dr. Shally Awasthi did not take part in the discussion & making decision.*** ***Ref: code: 117th ECM IIA/P5***
2.	Modification of research protocol entitled ***"Tools for the integrated management of childhood illness evaluation of pulse oximetry and clinical decision support algorithms in primary care pragmatic cluster randomized controlled trial, with embedded mixed methods, cost and cost-effectiveness studies in India and tanzania"*** submitted by Prof. Shally Awasthi, Head, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 380/PATH/10/2022 dated 10th October, 2022. ***Recommendation of Primary reviewer:*** • Project has already been approved during a previous meeting of the IEC. Proposed modifications to the Protocol/ICF may be approved. **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Dr. Shally Awasthi did not take part in the discussion & making decision.*** ***Ref: code: 103rd ECM IIC/P2***
3.	Modification of research protocol no. EX9536-4388 SELECT entitled ***"Semaglutide effects on cardiovascular outcomes in people with overweight or obesity"*** submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 344/Cardio/Res/2022 dated 11th October, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Project has already been approved during a previous meeting of the IEC. Proposed modifications to the Protocol/ICF may be approved. **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref: code: 92nd ECM IIC/P1***
4.	Modification of research protocol entitled ***"Indian trial of tranexamic acid in spontaneous intracerebral haemorrhage (Intrinsic Trial)"*** sponsored by ICMR, New Delhi submitted by Dr. Praveen Kumar Sharma, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 587/Neuro/2022 dated 30th November, 2022. *Recommendation of Primary reviewer:* • Project has already been approved during a previous meeting of the IEC. Proposed modifications to the Protocol/ICF may be approved. **EC Decision:** Approved ***Ref: code: 115th ECM IIA/P5***
IV	**Brought to Ethics Committee after XIII-PGTSC held on October, 2022**
	Minutes of XIV-PG Thesis sub Committee" of "Institutional Ethics Committee" Meeting ***virtually*** held on 14th December, 2022 from 3.00 PM. ***The following members were present in the Meeting:-*** 1. Dr. G.G. Agarwal -Member 2. Dr. Rajendra Nath -Member 3. Dr. D.N. Upadhyaya -Member 4. Dr. Shally Awasthi -Convener ***The following members were not present in the Meeting:-*** 1. Dr. Anita Rani -She has given her written comment. 2. Dr. A.A. Mahdi -He has given his written comment
I-A	**Action taken**
1-	Clarification of research proposal entitled "***A comparative study to evaluate masticatory performance and satisfaction level of the patient with conventional and three appointment complete denture***" sponsored by Research Cell, KGMU UP, Lucknow submitted by Dr. Deep Shikha Tripathi, JRI, Through her Mentor Prof. Niraj Mishra, Department of Prosthodintics and Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 536/22 dated 2nd November, 2022.

Previous PGTSC Comment	PI response
Study design should be blinded Randomized Controlled Study instead of Trial	Outcome assessor blinded randomized controlled study

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Sample size calculation details not mentioned	Sample Size Sample size is calculated on the basis of variation in OHIP –EDENT score in two study groups using the formula Where □ 1 = 10.1, The SD of OHIP- EDENT in traditional group □ 2 = 14.5, The SD of OHIP-EDENT in simplified group (Ref. Kawat et. al.) d = mean(□ 1 , □ 2) the minimum mean difference consider to be clinically significant type I error α = 5% corresponding to 95% confidence level type II error β = 10% for detecting results with 90% power of study. data loss factor = 10% So the required sample size n = 30 each group.
	ICF –Hindi / English not similar –should be revised	Kindly find the attached document
	The reply from PI to the above Comments was forwarded to PR:- **Recommendation of PR:** Approved **PGTSC Decision:** As above ***Ref. code: IX-PGTSC-II B IMR-R/P1***	
2-	Clarification of research proposal entitled ***"Evaluation of non-endoscopic and endoscopic assisted platysma flap- A randomized control trial"*** submitted by Dr.	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Sandeep Kumar, JRII, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 938/OMFS/22 dated 3rd December, 2022.

Previous PGTSC Comment	PI response
The study design is not mentioned	The study design has been mentioned. A hospital-based randomized control trial. corrections done in proforma and attached in Annexure I
The hypothesis is not stated	No significant difference between the two groups in terms of ease of operation & post operative function.
It is actually RCT, it should be properly planned	Attached in Annexure I
The fundamentals of performing RCT are not completely specified: 1- Clinical Trial Registry, method of randomization, 2- blinding , 3- follow-up, 4- outcome event, 5- efficacy or effectiveness trial, 6- statistical and methodological issues in RCT	1-Clinical trial registration will be done only after ethical approval. 2-Single blinded 3- day of operation, 3 rd day ,1week ,15 day, 1 months, 3 month, 6 months. 4- Outcome event: □ Time taken (using stopwatch, time starts from incision to flap reaches in oral cavity) □ Viability of the Flap (pin-prick test bleeding (yes/no)) □ Congestion of neck & oral cavity

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 21st December, 2022

		☐ Neurological assessment o Motor(marginal mandibular nerve lips) o Senory (two point discrimination test) ☐ Measurement of pain 5- Through this randomized control trail. We would like to assess the efficacy of endoscopic assisted platysma flap over non-endoscopic plastysma flap. 6-Attached in Annexure II
	The sample size calculation, statistical analysis section, etc, are missing.	Sample size calculation and statistical analysis calculation is attached in Annexure II

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: X-PGTSC-IIA/P2

3- Clarification of research proposal entitled ***"A comparative study on lung function of post tuberculosis obstructive pulmonary disease (TOPD) versus chronic obstructive pulmonary disease patient"*** submitted by Dr. Bishal Debbarma, JR, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1316/22 dated 8th December, 2022.

Previous PGTSC Comment	PI response
The objectives should be very specific. The first objective is to find out prevalence, whereas the	I have changed my first objective to :

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	other objectives are pointing toward "Comparative study"	• To compare lung function in TOPD patient versus COPD patient using impulse oscillometry. • Comparative spirometric assessment of TOPD patient versus COPD patients. • Lung volume assessment with diffusion capacity of lung for carbon monoxide (DLCO) of TOPD patients versus COPD patients Finding out prevalence won't be included in the study.	
	Research hypothesis should be properly defined after identifying the parameters of the study.	My research hypothesis – Although extensive parenchymal destruction due to TB and following airflow limitation is clinically common, the degree of airflow obstruction and bronchodilator esponsiveness have not been evaluated objectively; moreover, treatment guidelines for those with secondary airflow obstruction due to post tubercular sequelae may be confused with those of COPD. Thus, we compared pulmonary function and bronchodilator responsiveness in Post TB OAD and COPD patients, and also examined whether	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	differences exist in lung functions.
The sample size calculation is inadequate. It Should be for "Comparative study" not for prevalence.	My sample size will be for comparative study between COPD and TOPD Patients Sample size. On the basis of previous study, the changes in the Baseline Post-bronchodilator FVC% in TOPD (47.29) and COPD (60.81) was 13.52 and the population variance (σ2) was 21.42 (Swain et al., 2021). The sample size (n) = 2 (Zα/ 2 + Z [1- β]) 2 × σ 2 /(μ1−μ2) 2 , assuming 0.05 level significance (Z α/2 =1.96), and 80% power (Z [1-β])=0.84) was 39.36 in each group. In this study we will enroll 40 patients in each group. 2 (Zα/ 2 + Z [1- β]) 2 × σ 2 n= (μ1−μ2) 2 2 (1.96 + 0.84) 2 × 21.42 2 n= (60.81-47.29) 2 n=39.36 Swain S, Pothal S, Behera A, Manjhi R, Dutta P, Pradhan G. Treatment outcome among Post TB obstructive airways diseases and COPD: A prospective cohort study. J Family Med Prim Care. 2021; 10(9):3411-3416.
Statistical analysis section is missing	All data are expressed means and standard deviations or

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			frequencies. Statistical analysis is performed using SPSS-PC non-parametrically. The Wilcoxon signed rank test is used to compare data in paired samples, the McNemar test to analyze categorical variables in paired samples, the Wilcoxon rank sum test to compare data in two independent groups, and the χ 2 test to analyze categorical variables in two independent groups. Statistical significance was accepted for P values less than 0.05.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: X-PGTSC-IIA/P3

4- Clarification of research proposal entitled ***"Modified baumann's angle: A comparative study between dominant and non-dominant upper limb in paediatric age group attending KGMU"*** submitted by Dr. Mohammad Zohaib Abbas, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3036/OS/22 dated 12nd November, 2022.

Previous PGTSC Comment	PI response
This is a prospective cohort study, not "cross sectional study".	As per suggestion, now the study design has been modified
This is a comparative study. The two groups,	As per suggestion, now we

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	under comparison" should be exclusively identified.	had mentioned in the revised protocol
	Research hypothesis should be formulated after properly identifying study variables and parameters.	Now the research hypothesis has been formulated
	Sample size calculation is arbitrary. It should be appropriate to the research hypothesis.	The sample size has been recalculated (n=148).
	Statistical analysis section is also very general. It should be in accordance with the research hypothesis.	Now the statistical analysis section has been revised

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XII-PGTSC-IIA/P3

5- Clarification of research proposal entitled ***"Epidemiological assessment of acetabular fracture in trauma center, King Georges Medical University, Lucknow"*** submitted by Dr. Faisal Ahmad, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2324/Ortho/22 dated 1st November, 2022.

Previous PGTSC Comment	PI response
Study design mentioned is "Retrospective and Prospective"	This study prospective and Retrospective (Register based data in departmental register after 2018-2021)
There are too many objectives.	Primary objective "To study the demographic characteristics of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		patients presenting with acetabulum fractures"	
	Sample size calculation is inadequate. It should be specific to the research hypothesis.	This is a prospective study, Sample size is taken to be 99. Using the formula n= Where n= sample size, = value of normal deviate at 95 percent confidence interval, p= prevalence, q=1-prevalance, e= absolute error the sample size was calculated to be 120. Final sample size=120. (Trikha V, V G, Cabrera D, Bansal H, Mittal S, Sharma V. Epidemiological assessment of acetabular fractures in a level one trauma centre: A 7-Year observational study. J Clin Orthop Trauma. 2020 Nov-Dec;11(6):1104- 109)	
	Statistical analysis section is very general. It should be specific to the research Hypothesis.	Demographic data such as age, sex, mechanism of injury, other associated injuries, and days of stay	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		in the hospital will be noted. MS. Excel 2016 and the statistical software SPSS 22 nd version will be used for the descriptive data analysis, applying the Chi-Square Test and Fischer's Exact Test. P- value to be significant below 0.05.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XII-PGTSC-IIA/P4

6- Clarification of research proposal entitled ***"Anatomical variation of posterior tibial slope in North Indian population: A Hospital based study"*** submitted by Dr. Anmol Chaurasia, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2314/Orth/22 dated 16th November, 2022.

Previous PGTSC Comment	PI response
Sample size is mentioned 200 in the IEC form and 100 in the synopsis.	Corrected sample size is 200.
Drs Devarshi and Ravindra Mohan are Co-PIs as well as part of Scientific Review Committee. This is conflict of interest.	Kindly remove Dr. Devarshi Rastogi and Dr. Ravindra Mohan from scientific review committee page no conflict of interest.
No Co-PI from department of Radiology has been taken when the study is mainly on radiographs.	As per your advice in co-PI added in Department of Radiodiagnosis Dr. Nitin Arun Dikshit (MD) Assistant Professor, Department of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Radiodiagnosis, KGMU, Lucknow.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XII-PGTSC-IIA/P9

7- Clarification of research proposal entitled ***"Effect of periodontal therapy on acute phase response proteins in chronic periodontitis patients with metabolic syndrome- A randomized clinical trial"*** submitted by Dr. Vikas Jayant, JR, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2603/P/22 dated 22nd October, 2022.

	Previous PGTSC Comment	PI response
1.	There are 6 Co-PIsin the project of which 4 are from the same department. Please justify.	There are only 5 Co-PIs of which 3 are from the same department including HOD sir. Their names along with specific roles are hereby attached
2.	The sample size is not mentioned anywhere in the proposal	A copy of Sample size has been herewith attached.
3.	Patients in control arm are not being offered oral antibiotics will this not be sub optimal/ sub standard treatment exposing the patients to the risk of failure of treatment of the condition for which they are consulting the institution.	Patients in the control group would be given B-complex as placebo. Since its a clinical trial, control group cannot be administered with any therapeutic drug. But, the patients of chronic periodontitis under inclusion criteria in control group would also be treated with non surgical periodontal therapy.
4.	Who will bear the cost of the biochemical tests being offered to the patients?	The cost of all the biomedical tests would be my own responsibility and

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			will not be asked from the patients

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XII-PGTSC-IIA/P13

8- Clarification of research proposal entitled ***"Impact of intense smartphone application based versus routine follow-up on short term clinical outcomes in acute decompensated Heart failure (ADHF)"*** submitted by Dr. Ajit Pratap Singh, SRII, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 961/Cardio/22 dated 9th November, 2022.

Previous PGTSC Comment	PI response
In scientific review committee no faculty of cardiology or medicine has taken part? Review from faculty of Medicine be also done.	Repeat review done by medicine faculty. Please find attached annexure.
Study design not mentioned in protocol.	Prospective open label randomised study.
In exclusion criteria the PI did not mentioned about inclusion/exclusion of pregnant women/lactating Women patients of ADHF.	Patient irrespective of gender, pregnancy and lactation status will be considered for the study.
Why PI mentioned in the title as short term clinical outcomes (in introduction the PI has mentioned to explore long term patient care by this study)- please justify.	It's a short term study to explore the possibility of long term online follow up.
Sample size calculation not done (only mentioned that sample size will be according to Cochran's formula)- please justify.	Cochran formula used is n = z 2 x p (1-p) e 2 n = Sample size z = it is the abscissa of the normal curve that cuts off an area α at the tails p= estimated proportion

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		of an attribute that is present in the population. Its value is 1.96 for 95% Confidence interval e = desired level of precision n = 1.96 2 x 0.35 (1-0.65) 0.05 2 n = 350

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XII-PGTSC-IIA/P14

9- Clarification of research proposal entitled ***"COLOUR DOPPLER evaluation of photobiomodulation as a therapeutic adjunct in non-surgical management of periapical bone defects: A randomized controlled trial"*** submitted by Dr. Jagruti Mutalikdesai, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 369/Coms&Endo/22 dated 15th November, 2022.

Previous PGTSC Comment	PI response
Study design as RCT should be justified as CONSORT guidelines has not been followed (Randomization method, blinding, sample size calculation not mentioned and total sample size is 24 pts).	Enclosure-1
Flow chart of methodology not mentioned.	Enclosure-2
Sample size calculation not done. (Only formula is given)	Enclosure-3

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XII-PGTSC-IIA/P15

10- Clarification of research proposal entitled ***"Quantitative assessment of cysticercosis on whole body MRI in patients with disseminated cysticercosis treated with albendazole with steroids v/s steroids alone and outcome assessment at 3 months-a randomized***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	controlled trial" submitted by Dr. Jadhav Padmajeet Ranjeetsinh, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 387/Neuro/22 dated 28th October, 2022. ***The reply from PI to the above Comments was forwarded to PR:-*** **Recommendation of PR:** Approved **PGTSC Decision:** As above ***Ref. code: XII-PGTSC-IIA/P20***
11-	Clarification of expedited review of research proposal entitled ***"A study on illness-related perception, needs and behavior among breast survivors"*** submitted by Ms. Anunka Mondal, M. Phil student under the guidance of Dr. Shweta Singh, Prof. Jr. Grade Department of Psychiatry, K.G's Medical University, U.P., Lucknow vide letter no. 1699/Psy/22 dated 14th November, 2022.

Previous PGTSC Comment	PI response
There are too many objectives.	To study Illness perception, Fear of Cancer Recurrence, Psychosocial needs (physical, emotional, psychological, spiritual, informational, social and practical needs), Health Behaviour and Body Image among Breast Cancer Survivors. 2. To study associations among the study variables with each other. 3. To study association among Socio-demographic characteristics (Age, socio-economic status, onset of Cancer, type of treatment) and Clinical Variables (Depression, Anxiety, Stress) and Study variables (Illness perception, Fear of Recurrence, Psychosocial needs, Health Behaviour and Body Image).
Sample size calculation and "statistical analysis" specific to research hypothesis.	Sample Size Estimation: 36 Statistical Test: Correlation: Bivariate Normal Model. Analysis: A prior: Computed required Sample size. Input: □ Correlation p H: 0.45 Output:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		□ Critical t = 1.6698042 □ Actual Power=0.8065550
	Why "Purposive Sampling" is being used?	Purposive sampling refers to a non-probability sampling technique in which units are selected because they are characteristics that are needed in the sample. 4. Study Design- Cross Sectional Research Design.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIII-PGTSC-IB/P3

12- Clarification of research proposal entitled ***"Efficacy of laser and ultrasonic activated root canal irrigants in biofilm eradication"*** submitted by Dr. Vineet Gupta, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 399/Coms7Endo/22 dated 6th December, 2022.

Previous PGTSC Comment	PI response
This is a comparative study	Yes,this is a comparative study
The Control Group should be exclusively defined.	2. The Control group(Group 1) is a No Treatment group. No intervention was given after the culture of biofilm in this group. Biofilm was cultured in Extracted tooth Roots. Group 2: Treated wih Hypochlorite & EDTA Group 3: Treated with Hypochlorite, EDTA and Ultrasonic Activation Group 4: Treated with Hypochlorite, EDTA and LASER Activated . Group 5: Treated with Hypochlorite, EDTA Alexidine dihydrochloride & Ultrasonic activated. Group 6: Treated with Hypochlorite, EDTA Alexidine dihydrochloride & LASER Activated. Group 7: Treated with Hypochlorite, EDTA Octenidine dihydrochloride &

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ultrasonic Activated. Group 8: Treated with Hypochlorite, EDTA Octenidine dihydrochloride & LASER Activated.
There seems to be more than one treatment group	Yes there are more than one (seven) treatment groups.
The research hypothesis should be stated for comparing more than two groups.	The study is to compare the efficacy of LASER and Ultasonic Activated Root Canal Irrigants in Eradication of Biofilm. The control group(n=20) in which No Treatment was given and Ultrasonic and LASER activated irrigants were used in other 7 treatment groups(n=140) by evaluate the reduction in mean microbial viability by Colony Forming Units(CFU) per ml.
Study design is not mentioned.	The design of the study is Concurent Randomized-Controlled Trials(RCT)
Sample size calculation should be modified according to the appropriate research hypothesis. At present, it is comparing two groups only.	Sample size calculation method: Sample size will be calculated on the basis of bacterial viability of the control group and seven other experimental groups with minimum variation using the formula $n = \frac{(z_\alpha + z_\beta)^2(\sigma_1^2 + \sigma_2^2)}{d^2}$ Where σ_1 = 9893.85, bacterial viability of the control group σ_2 = 106.39 bacterial viability of the experimental group with minimum variation (according to the reference paper "J. Race et al.") d =15% of mean viability (=48892.85), the difference considered to be clinically significant type I error α = 5% corresponding to 95% confidence level type II error β = 20% for

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	detecting results with 80% power of study. So the required sample size is calculated to be $n = 20$ each group
Statistical analysis section is missing.	**Statistical Analysis:** Statistical Analysis is done by calculating the Mean Cell Viat by determining the Colony Forming nits(CFU/ml) amongst all the Groups and the difference was stated using comparison tests. One way ANOVA was applied on quantitative variable to test the hypothesis. Post Hoc Tukeys was applied to note the difference between the respective group at confidence interval of 95% and level of significance at $p<0.05$.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P2

13- Clarification of research proposal entitled ***"A study to estimate the prevalence of pulmonary hypertension in patients of chronic obstructive pulmonary disease at a tertiary care centre"*** submitted by Dr. Neha Kumari, JR, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1269/Res/22 dated 29th November, 2022.

Previous PGTSC Comment	PI response
Sample size calculation is missing	Sample Size: The sample size was calculated based on a previous study that reported that the Prevalence of chronic obstructive pulmonary disease in India was 7.4 (Daniel et al. 2021), 95% level of confidence and Error rate, usually set at 0.05 level is 4. Total 100 patients will be included in this study. n=Z 2 P(1-P)/d 2 Where,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		• n = sample size, • Z = Z statistic for a level of confidence, for the level of confidence of 95%, which is conventional, Z value is 1.96. • P = expected prevalence or proportion (in proportion of one; if 7.4%, P = 0.07), • d = precision (in proportion of one; if 5%, d = 0.05). n=1.96x1.96x0.07x0.93/0.05 2 n=100.04 Ref - Daniel RA, Aggarwal P, Kalaivani M, Gupta SK. Prevalence of chronic obstructive pulmonary disease in India: A systematic review and meta-analysis. Lung India. 2021 Nov-Dec;38(6):506-513.

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of PR: Approved

PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P3

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

14- Clarification of research proposal entitled ***"A study of lung function parameters by impulse oscillometry and spirometry in COVID-19 survivor patients attending a tertiary care centre"*** submitted by Dr. Ankit Kumar, JRIII, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1306/22 dated 5th December, 2022.

Previous PGTSC Comment	PI response
Research hypothesis, sample size calculation and statistical analysis section are missing.	This study hypothesizes that patients affected by the COVID-19 infection develop lung function impairment in the post covid period. Sample size was taken as of convenience as it's a Pilot study.
Sample size is by convenience	Due to the scarcity of patients due to the ongoing governmental restrictions for public safety during the data collection period, sampling by convenience seemed a better option. Also it's a pilot study so we incorporated the maximum available subjects during that period.
It seems to be a fit case for PILOT study	It indeed is a pilot study to evaluate the lung parameters of COVID survivor patients in this novel disease entity.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P5

15- Clarification of research proposal entitled ***"Morphometric study of anatomic landmarks of skull base using 64 slice multidetector computed tomography: A surgical perspective"*** submitted by Dr. Savita Kanaujea, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 419/ANAT/22 dated 24th Movember, 2022.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P11

I-B **Expedited review**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

1- Expedited review of the research proposal entitled ***"A study of interoception, self-regulation, self-awareness, mind-body connection & trauma in dissociative disorder"*** submitted by Mr. Amandeep Singh Garaya, M.Phil student under the guidance of Dr. Pooja Mahour, Additional Professor (Clinical Psychology), Department of Psychiatry, K.G's Medical University, U.P., Lucknow vide letter no. 1675/Psy dated 10th November, 2022 & 1832/Psy dated 10th December, 2022.

The above proposal forwarded to reviwers, reply has given both reviewers with following comments:-

First Primary reviewer-

Previous PGTSC Comment	PI response
There should be one primary objective and the rest should be designated as secondary objectives.	The Aim and Objectives of the study have been re-defined. Primary and Secondary Objectives have been included. Please refer Page No. 5
The study variable and parameters should be defined.	Study Variables and Clinical Variables have been identified. Please refer Page No. 5
The primary objective should be converted into a research hypothesis in terms of the study variables and parameters.	Research Hypotheses have been mentioned in terms of Study Variables. Please refer Page No. 6
Sample size calculation is arbitrary. It can only be done after properly defining the research hypothesis.	Sample Size based upon the re-defined Primary Objective and hypothesis has been calculated and mentioned. Please refer Page No. 12
Are the instruments used in the study "Gold	Yes, most instruments are gold standards and widely

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Standards"	used in research. The rationale for selecting the Instruments has been mentioned alongside each instrument. Please refer Pages 7 – 10
Were their validity and reliability checked?	Yes, the reliability and validity of all the instruments were checked, and they were found to have good reliability and validity. Please find the details mentioned on pages 7 – 10
How these tools would be scored to convert into an "aggregate score.	The scoring procedure, including the calculation of Aggregate Score has been mentioned for each instrument. Please refer Page No. 7 – 10.
Statistical section should include the method of scoring these instruments.	The statistical section has been edited and the method of scoring has been added to the description of the tests.

Secondary reviewer-

Previous PGTSC Comment	PI response
In inclusion criteria all adult patients above 18 years with dissociative disorder will be taken	The Inclusion & Exclusion Criteria have been edited accordingly.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	but PI did not mention above serial no. 1-4 tools not attached	Please find attached
	In Tools mentioned above, serial no. 1-4 tools not attached:- 1- Hamilton Depression Rating Scale (HDRS), 2 - Hamilton Anxiety Rating Scale (HAM – A) 3 - PGI – Battery for Brain Dysfunction's 4 - General Health Questionnaire (GHQ)	Please find the tools attached.
	PGTSC Decision: Approved ***Ref. code: XIV-PGTSC-IB/P1***	
II-A	**New Thesis-Resident**	
1.	Research proposal entitled ***"Compliance of pediatric patients during ocular prosthesis fabrication with and without midazolam conscious sedation: a pilot randomized control"*** submitted by Dr. Anshu Baid, JRI, Department of Prosthodontics Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.342/22 dated 8th September, 2022. ***Recommendation of Primary reviewer:*** There is nothing like pilot RCT. • It should be simply a pilot study. • There are too many primary objectives. There should be one primary objective. The rest should be included into secondary objectives. • After identifying the study variables and study parameters, the objective should be converted into research hypothesis in terms of the study parameters. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P1***	
2.	Research proposal entitled ***"Sustained virological response to direct acting antiviral therapy in chronic hepatitis C patients with compensated and Decompensated liver cirrhosis-A pilot study"*** submitted by Dr. Shailja, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.920/22 dated 6th October, 2022. ***Recommendation of Primary reviewer:*** • After identifying the study variables and study parameters, the objective should be converted into research hypothesis in terms of the study parameters • This is comparative study. The study design should be properly defined. Here it is mentioned simply as observational study. • Statistical analysis section should be more specific. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P2***	
3.	Research proposal entitled ***"Ultrasound guided caudal block versus supra inguinal fascia block for pain management in Paediatric hip surger-Arandomized comparative study"*** submitted by Dr. Anuj Verma, JR-I, Department ofAnaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes / 1158 / 22 dated	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	7th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Determinants of re-admission in ICU survivors"*** submitted by Dr. Ratnesh Kumar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1149/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • The study variables and study parameters should be identified. • The research hypothesis should be properly formulated in terms of study parameters. • The sample size calculation is arbitrary. It can be done only after defining the research hypothesis. Statistical Analysis section is missing. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P4***
5	Research proposal entitled ***"Sentinel lymph node biopsy in post NACT breast cancer patients using low cost dual dye technique with carbon 12 nano particles and methylene blue dye-a pilot study"*** submitted by Dr. Anirudh Gupta, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3319/22 dated 6th October, 2022. ***Recommendation of Primary reviewer:*** • The study variables and study parameters should be identified. • The research hypothesis should be properly formulated in terms of study parameters. • This is a pilot study; the sample size calculation is not required. • The study design is not mentioned. It simply says "prospective study". **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Assessment of midterm estimated GFR(EGFR) by different formula (24HRS CREATININE CLEARANCE, MDRD, CKD-EPI & NANRA) in patients of hypertensive disorders of pregnancy and its association with fetomaternal outcomes"*** submitted by Dr. Priya Agarwal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	OG/2082/22 dated 3rd October, 2022. ***Recommendation of Primary reviewer:*** • The study variables and study parameters should be identified. • The research hypothesis should be properly formulated in terms of study parameters. • The sample size calculation is arbitrary. It can be done only after defining the research hypothesis. Statistical Analysis section is missing. • The study design is mentioned as "prospective case control study". • It should be properly mentioned as case-control study is retrospective study. • Statistical analysis section is missing. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P6***
6.	Research proposal entitled ***"Assessment of midterm estimated GFR(EGFR) by different formula (24HRS CREATININE CLEARANCE, MDRD, CKD-EPI & NANRA) in patients of hypertensive disorders of pregnancy and its association with fetomaternal outcomes"*** submitted by Dr. Priya Agarwal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/2082/22 dated 3rd October, 2022. ***Recommendation of Primary reviewer:*** • The study variables and study parameters should be identified. • The research hypothesis should be properly formulated in terms of study parameters. • The sample size calculation is arbitrary. It can be done only after defining the research hypothesis. Statistical Analysis section is missing. • The study design is mentioned as "prospective case control study". • It should be properly mentioned as case-control study is retrospective study. • Statistical analysis section is missing. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving point wise response to comments. ***Ref. code: XIV-PGTSC-IIA/P6***
7.	Research proposal entitled ***"Clinical audit of critically ill obstetric patients in intensive care unit: A retrospective & prospective study"*** submitted by Dr. Rashi Rastogi, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/2079/22 dated 3rd October, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The type of study is mentioned as "retrospective and prospective observational study" • The study can not be prospective and retrospective at the same time. • The research hypotheses, sample size calculations etc. would be different for two types of studies. • The proposal should be very specific clearly defining the objectives, research hypotheses etc. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Measurement of changes in blood flow across coronary sinus using transoesophageal echocardiography post coronary artery bypass grafting: A single center observational study"*** submitted by Dr. Himanshu Sharma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1147/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • This seems to be one-group pretest-posttest design. • So everything should be planned according to this. • The study variables and study parameters should be identified. • The research hypothesis should be properly formulated in terms of study parameters. • The sample size calculation is arbitrary. It should be specific to research hypothesis. • Statistical analysis section is very general. It should be also specific to research hypothesis. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P8***
9.	Research proposal entitled ***"A randomized control trial to determine effect of dopamine as vegf (Vascular endothelial growth factor) antagonist on development of acute lung injury in sepsis"*** submitted by Dr. Shivam Agarwal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1132/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 21st December, 2022

	(iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is not given. It simply says 40 subjects in each group. • The clinical trial registry is required. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P9***
10.	Research proposal entitled ***"A comparative evaluation of effect of osseodensification on bone density around dental implants: A randomized control trial"*** submitted by Dr. Bhujbal Rushikesh Bhau, JRI, Department of Prosthodontics Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 344/22 dated 8th September, 2022. ***Recommendation of Primary reviewer:*** • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary. It should be specific to the research hypothesis. • The clinical trial registry is required. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants outcomes and estimation, (iv) adverse events, etc. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P10***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

11.	Research proposal entitled ***"Evaluating the effect of osseodensification technique versus conventional technique of implant placement on bone marker (BMP-9) and clinical implant parameters: A randomized controlled trial"*** submitted by Dr. Husbana Bakrolwala, JRI, Department of Prosthodontics Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 343/22 dated 8th September, 2022. ***Recommendation of Primary reviewer:*** • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary. It should be specific to the research hypothesis. • The clinical trial registry is required. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P11***
12.	Research proposal entitled ***"A clinical comparison of efficacy of BASKA mask and LMA blockbuster for patients undergoing laparoscopic cholecystectomy: A prospective randomized comparative clinical study"*** submitted by Dr. Seema Reyaz, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1162/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • The study variables and study parameters should be identified. • The research hypothesis should be properly formulated in terms of study parameters. • The sample size calculation is not given. It can be done only after defining the research hypothesis. • Statistical Analysis section is very general. It should be done according to the research hypothesis. **PGTSC Comment:** • As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 21st December, 2022

	PGTSC Decision: Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P12***
13.	Research proposal entitled ***"Comparison of modified thoracolumbar interfascial plane block with erector spinae plane block for postoperative analgesia fillowing lumbar spine surgeries"*** submitted by Dr. Vaishali Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1150/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • After identifying the study variables and study parameters, the objective should be converted into research hypothesis in terms of the study parameters • This is comparative study. The study design is not mentioned. • Sample size calculation is not given. • Statistical analysis section should be more specific. It should be planned after defining the proper research hypothesis. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P13***
14.	Research proposal entitled ***"Arterial lactate as independent predictor of in-hospital mortality in trauma patient admitted in intensive care unit: A prospective observational study"*** submitted by Dr. Sarvesh Kumar Vishwakarma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1146/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • After identifying the study variables and study parameters, the objective should be converted into research hypothesis in terms of the study parameters • The study design is not defined. • The sample size calculation is not given. • Statistical analysis section is very general. It should be specific the research hypothesis. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P14***
15.	Research proposal entitled ***"A study of Cardiometabolic risk factors in non alcoholic steatohepatitis patients"*** submitted by Dr. Shalini Suri, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2736/PHY/22 dated

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	12th October, 2022. ***Recommendation of Primary reviewer:*** • The "Study hypothesis" and "Aims & Objectives" do not match. • After identifying the study variables and study parameters, the objective should be converted into research hypothesis in terms of the study parameters • The sample size calculation is arbitrary. It should be specific to the research hypothesis. • Statistical analysis section is missing. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P15***
16.	Research proposal entitled ***"Computed tomography versus ultrasound guided cricoids cartilage diameter measurement as a tool to determine the size of double lumen tube in thoracic surgery-a prospective randomized comparative study"*** submitted by Dr. Roshni Mariam Mathew, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1165/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • After identifying the study variables and study parameters, the objective should be converted into research hypothesis in terms of the study parameters • This is comparative study. The study design should be properly defined. • The sample size calculation is arbitrary. It can be properly done only after defining the proper research hypothesis. • Statistical analysis section is missing. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P16***
17.	Research proposal entitled ***"Short term outcome of premature ejaculation: A clinic based naturalistic observational study"*** submitted by Dr. Vaibhav Singh, JRI, Department of Phychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1568/Psy/22 dated 19th October, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P17***
18.	Research proposal entitled ***"Apnoeic oxygenation with low-flow oxygen cannula during intubation in Paediatric patients with hydrocephalus: A randomized-controlled trial"***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	submitted by Dr. Kartikey Vaish, JR1, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1135/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary. It should be specific to the research hypothesis. • The clinical trial registry is required. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P18***
19.	Research proposal entitled ***"Clinical audit of acute kidney injury in critically ill obstetric patients and association with maternal outcome"*** submitted by Dr. Himani Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3059/22 dated 14th October, 2022. ***Recommendation of Primary reviewer:*** • The type of study is mentioned as "retrospective and prospective observational study" • The study can not be prospective and retrospective at the same time. • The research hypotheses, sample size calculations etc. would be different for two types of studies. • The proposal should be very specific clearly defining the objectives, research hypotheses etc. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P19***
20.	Research proposal entitled ***"Study of endometrial scratching in infertile couples***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	undergoing ovulation induction and intrauterine insemination" submitted by Dr. Vertika, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3060/22 dated 14th October, 2022. ***Recommendation of Primary reviewer:*** • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary. It should be specific to the research hypothesis. • The clinical trial registry is required. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P20***
21.	Research proposal entitled ***"Analysis of treatment and survival outcome of vulval carcinoma over a period of 10 years"*** submitted by Dr. Akanksha Jaiswal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3013/22 dated 10th October, 2022. ***Recommendation of Primary reviewer:*** • Title says: "Analysis of treatment and survival outcome of vulval carcinoma over a period of 10 years" • The duration of study is supposed to be one year. • The study variables and study parameters should be identified. • The research hypothesis should be properly formulated in terms of study parameters. • The study design is mentioned as "prospective and retrospective analytic study". It can not be both. • The sample size calculation is arbitrary. It should be done after properly formulating the research hypothesis. • Statistical analysis section is also very general. It should be planned according to the research hypothesis. **PGTSC Comment:** • As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P21***
22.	Research proposal entitled ***"A study of cardiovascular hemodynamic assessment in normotensive vs pre-eclamptic pregnancies and its association with maternal outcomes"*** submitted by Dr. Sneha Agarwal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3030/22 dated 11th October, 2022. ***Recommendation of Primary reviewer:*** • The study variables and study parameters should be identified. • The aim and objectives should be converted into proper research hypothesis in terms of study parameters. • The study design is mentioned as "prospective case control study". Case-control study is retrospective. • The sample size calculation is arbitrary. It should be done after properly formulating the research hypothesis. • Statistical analysis section is also very general. It should be planned according to the research hypothesis. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P22***
23.	Research proposal entitled ***"To study the ultrasound and histopathological scoring system to predict prognosis of placenta accrete syndrome and its correlation with surgical and neonatal outcome"*** submitted by Dr. Akansha, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3062/22 dated 15th October, 2022. ***Recommendation of Primary reviewer:*** • The study variables and study parameters should be identified. • The aim and objectives should be converted into proper research hypothesis in terms of study parameters. • The study design is mentioned as "prospective comparative study". The two groups are not exclusively defined. Whether it would be prospective cohort study or Randomized control study for comparing groups. • The sample size calculation is arbitrary. It should be done after properly formulating the research hypothesis. • Statistical analysis section is also very general. It should be planned according to the research hypothesis. **PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P23***
24.	Research proposal entitled ***"Experience of repairing genitourinary fistula-retrospective and prospective study"*** submitted by Dr. Krishna Kumar Bhandari, SRI, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 601/URO/22 dated 19th October, 2022. ***Recommendation of Primary reviewer:*** • The type of study is mentioned as "retrospective and prospective study" • The study can not be prospective and retrospective at the same time. • The research hypotheses, sample size calculations etc. would be different for two types of studies. • The proposal should be very specific clearly defining the objectives, research hypotheses etc. • The "patient consent form" is missing (English & Hindi both) **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P24***
25.	Research proposal entitled ***"Comparison of ultrasound guided continuous erector spinae plane block and epidural block for postoperative analgesia in laparoscopic nephrectomy: A prospective randomized study"*** submitted by Dr. Amita Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1159/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • The study variables and study parameters should be identified. • Research hypothesis should be defined in terms of study parameters. • Sample size calculation is arbitrary. It should be specific to the research hypothesis. • Statistical analysis section is also very genera. It should be specific to the research hypothesis. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P25***
26.	Research proposal entitled ***"Randomised, single blind, control trial of transcranial direct current stimulation in adults with obsessive compulsive disorder as early***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	augmentation" submitted by Dr. Lokesh Kumar, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1476/Psy/22 dated 29th September, 2022. ***Recommendation of Primary reviewer:*** • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary. It should be specific to the research hypothesis. • The clinical trial registry is required. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P26***
27.	Research proposal entitled ***"Pilot study on levels of brain derived neurotrophic factor in the cerebrospinal fluid of children with acute encephalitis syndrome"*** submitted by Dr. Shiv Kant Prakratyansh, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2357/Ped/22 dated 21st October, 2022. ***Recommendation of Primary reviewer:*** • The study variables and study parameters should be identified. • Research hypothesis should be defined in terms of study parameters. • Study design is not mentioned. It simply says "pilot study". • Statistical analysis section is very general. It should be specific to the research hypothesis. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P27***
28.	Research proposal entitled ***"Efficacy and safety of carbetocin versus oxytocin in prevention of postpartum hemorrhage in highrisk women-an open label randomized control trial"*** submitted by Dr.Smriti Bag, JRI, Department of Obstetrics & Gynecology,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	King George's Medical University, U.P., Lucknow vide letter no. OG/3102/22 dated 21st October, 2022. ***Recommendation of Primary reviewer:-*** • Sample size discrepancy in SOP form, Protocol and flow chart –Please correct • Inclusion criteria –Age specificity of recruiting pts not mentioned (only gestational Age is given) – Please mention. • Patient Information sheet not related to study – please submit revised PIS **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P28***
29.	Research proposal entitled ***"Effect of red blood cell storage duration on cerebral blood oxygenation in elective cranial surgery: A prospective randomized controlled study"*** submitted by Dr. Anjali Kumari, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1137/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • In Scientific Review Committee –one Co-guide's (Dr. Hemlata) name is there- please justify. • Departmental names against two Co-guides (Prof. B K Ojha and Prof. Tulika Chandra) are wrongly mentioned in Investigator detail page- please corrects. • As this is Randomized Controlled study, therefore Flow chart of methodology should be included. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P29***
30.	Research proposal entitled ***"Comparision between video laryngoscopy and direct laryngoscopy for tracheal intubation in Pediatrics patients with hydrocephalus: A randomized control study"*** submitted by Dr. Mona Nayak, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1138/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • PI sheet not related to study –should be revised • As this is Randomized control study ,PI should submit Flow chart of methodology • ICF – Guardian consent form is needed instead of regular ICF (Attached ICF E/H-are not similar)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Assessment scales not attached **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P30***
31.	Research proposal entitled ***"A study to determine the prevalence of congenital cmv infection in neonates admitted in the NICU of a tertiary care center"*** submitted by Dr. Sujata Kumari, JRI, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2359/Ped/22 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Sample size–Total number disparity (SOP Form-105 and Protocol -110) –Please specify. • Guardian consent form is needed instead of regular ICF- Please submit. **PGTSC Comment:** • As above **PGTSC Decision:** Modifiy & Re-submit with table giving point wise response to comments ***Ref. code: XIV-PGTSC-IIA/P31***
32.	Research proposal entitled ***"Role of point of care lung ultrasound in ventilator associated pneumonia in Paediatric population"*** submitted by Dr. Twinkle Yadav, JRI, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2371/Ped/22 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation not done • Guardian consent form submitted but PI Child should also be submit Child Assent form (As children of 1 yr. to 12 yrs. of age will be recruited) **PGTSC Comment:** • As above **PGTSC Decision:** Modifiy & Re-submit with table giving point wise response to comments ***Ref. code: XIV-PGTSC-IIA/P32***
33.	Research proposal entitled ***"The study of correlation between serum vitamin D3 and HBV DNA levels in hepatitis B virus infected Children: A prospective observational study"*** submitted by Dr. Moses Riamei, JRI, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2369/Ped/22 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Detailed sample size calculation not done, only reference is given. • Guardian consent and Assessment form are same. PI to submit separate Child

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Assent form. **PGTSC Comment:** • As above **PGTSC Decision:** Modifiy & Re-submit with table giving point wise response to comments. ***Ref. code: XIV-PGTSC-IIA/P33***
34.	Research proposal entitled ***"Utility of lung ultrasound, lymphocyte: monocyte and neutrophil: lymphocyte in differentiating bacterial and viral pneumonia in children"*** submitted by Dr. Prachi Joshi, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2652/Ped/22 dated 22nd October, 2022. ***Recommendation of Primary reviewer:*** • Detailed sample size calculation not done. • Guardian and Child Assent form are not complete and E/H versions are not similar. Please resubmit Guardian consent and Child Assent form separately. • Case record form should be given separately from Questionnaire. **PGTSC Comment:** • As above **PGTSC Decision:** Modify & Re-submit with table giving point wise response to comments. ***Ref. code: XIV-PGTSC-IIA/P34***
35.	Research proposal entitled ***"Study to evaluate diagnostic accuracy of serum CA125, HE4 and expression of P53 in varied spectrum of epithelial ovarian neoplasm"*** submitted by Dr. Eva Raman, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3044/22 dated 12th October, 2022. ***Recommendation of Primary reviewer:*** • In Inclusion criteria Age specificity of Women having ovarian CA not mentioned. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P35***
36.	Research proposal entitled ***"Sonographic predictors of adverse outcome in pregnancy complicated by hyperglycemia in pregnancy"*** submitted by Dr. Aayushi Saini, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3045/22 dated 12th October, 2022. ***Recommendation of Primary reviewer:*** • Questionnaire not attached • Case record form – not given **PGTSC Comment:** • As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P36***
37.	Research proposal entitled ***"Comparative evaluation of effect of mode of delivery of artificial tears on level of interleukin 6 (IL-^) and matrix metallopeptidase 9 (MMP-9) in anophthalmic sockets with ocular prosthesis-A randomized controlled trial"*** submitted by Dr. Pushpa Kumari, JRI, Department of Prosthodontics & Crown & Bridge, Faculty of Denttal Sciencrs, King George's Medical University, U.P., Lucknow vide letter no. 420/22 dated 12th October, 2022. ***Recommendation of Primary reviewer:*** • Consort guidelines not fully followed – PI to mention about blinding and submit flow chart of methodology. • In addition to regular ICF, the Guardian consent and Child Assent form is also needed. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P37***
38.	Research proposal entitled ***"A comparative study of naltrexone, baclofen and naltrexone-baclofen and naltrexone-baclofen combination in patient with alcohol dependence"*** submitted by Dr. Mohd Aman Naqvi, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1606/Psy/22 dated 27th October, 2022. ***Recommendation of Primary reviewer:*** • As it is randomized trial –PI should mention. i. Randomization method in protocol. ii. Flow chart of methodology. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P38***
39.	Research proposal entitled ***"Study of death anxiety, perceived stress, sleep quality, cardiac illness denial and subjective well-being among stable patients with acute myocardial infarction"*** submitted by Dr. Abhilash Boda, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1610/Psy/22 dated 28th October, 2022. **PGTSC Decision:** Approved ***Ref. code: XIV-PGTSC-IIA/P39***
40.	Research proposal entitled ***"A study of mental capacity in acute and transient psychotic disorders"*** submitted by Dr. Farzana Rizvi, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1590/Psy/22 dated 20th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	October, 2022. ***Recommendation of Primary reviewer:*** • IEC-SOP form Vulnerable pts column –ticked by PI as No-should be corrected • LAR Consent must be included in ICF and Given ICF English version should be started from new page. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P40***
41.	Research proposal entitled ***"Effect of Virtually Reality glasses and melody on cortisol and ACTH levels in patients of knee replacement surgery under combined spinal epidural anaesthesia"*** submitted by Dr. Nisha Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1166/2022 dated 2nd September, 2022. ***Recommendation of Primary reviewer:*** • In Scientific Review Committee, the name and signature of Chief Guide Prof. Monika Kohli is there –please justify or resubmit. • In Investigators page the Department's name of two Co-guides is wrongly mentioned-should be corrected. • Method of randomization not mentioned. • ICF-H/E –attached but not similar –should be corrected **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XIV-PGTSC-IIA/P41***
42.	Research proposal entitled ***"Efficacy of transdermal buprenorphine in management of pain in children with cancer: A prospective observational study"*** submitted by Dr. Simran Kapoor, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2358/Ped/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Guardian consent form –E/H not similar –should be revised • Separate Child Assent Form should also be submitted. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XIV-PGTSC-IIA/P42***
43.	Research proposal entitled ***"Anthropometry of lip nose complex of unilateral cleft lip deformity and normal children by 3D digital photogrammetry and analysis and scoring***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 21st December, 2022

	of preoperative and postoperative deformity" submitted by Dr. Prachi Varshney, SR, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1126 dated 22nd October, 2022. ***Recommendation of Primary reviewer:*** • Inclusion criteria did not mentioned Age and sex of the subjects **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P43***
44.	Research proposal entitled ***"Comparative study to evaluate response of intra articular injection of trialmcinolone vs hyaluronidase to rehabilitate stiff finger joints"*** submitted by Dr. Namrata Asthana, SR, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1128 dated 22nd October, 2022. ***Recommendation of Primary reviewer:*** • Inclusion criteria did not mentioned Age and sex of the subjects **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P44***
45.	Research proposal entitled ***"Hyperbaric oxygen therapy for second-degree burn wound healing"*** submitted by Dr. Bhimavarapu Gowtham Reddy, SR, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1127 dated 22nd October, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation not done • Inclusion criteria –Sex specificity not mentioned **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P45***
46.	Research proposal entitled ***"Prospective observational case control study on prevalence of non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) in overweight and obese as compared to normal weight children in pediatric population"*** submitted by Dr. Sonal Luniyal, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2363/Ped/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Sample size is not clear, whether total 60 cases or 60 cases and 60 control –please specify ICF-E/H not same and Child Assent Form is missing- should be corrected. **PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P46***
47.	Research proposal entitled ***"Adrenal insufficiency in children with nephritic syndrome a prospective cohort study"*** submitted by Dr. Anjali Barua, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2360/Ped/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Detailed sample size calculation not given. • Patient information sheet –not related to study. • ICF (Guardian consent)-H/E–Attached but not similar. Child Assent form missing-should be included. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P47***
48.	Research proposal entitled ***"Correlation of first trimester blood sugar levels with obstetric outcome"*** submitted by Dr. Neelima Singh, JRI, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3090/22 dated 20th October, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P48***
49.	Research proposal entitled ***"Socio-demographic profile, diagnosis and treatment delay and associated comorbidities in autism-A prospective observational study"*** submitted by Dr. Richa Jha, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2372/Ped/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Tools- Modified Chart for Autism in Toddler (MCHAT), Indian Scale for Assessment of Autism, Developmental Behavioral Checklist- Autism Screening Algorithm- **not attached** • Patient information sheet not related to study – should be revised • ICF-H/E –attached, but not similar (English version is incomplete). • Child Assent form should also be submitted • Tools –required are not attached- please attach **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P49***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

50.	Research proposal entitled ***"To study frequency of linezolid resistance among multidrug resistant mycobacterium tuberculosis isolates from pulmonary samples"*** submitted by Dr. Senjuti Sengupta, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 899/2022 dated 29th September, 2022. ***Recommendation of Primary reviewer:*** • In Inclusion criteria–PI did not mentioned the Age /Sex specificity of Patients having myc. Tub. from which the isolates will be derived- please give the detail. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P50***
51.	Research proposal entitled ***"A study to estimate circulating level of serum osteoprotegerin (OPG) and analysis of it's gene expression"*** submitted by Dr. Kriti Kathuria, JRI, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/646/2022 dated 3rd November, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P51***
52.	Research proposal entitled ***"Assessment of growth and complications amongst neonates receiving total parentral nutrition"*** submitted by Dr. Varsha Chaudhary, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2651/Ped/2022 dated 22nd September, 2022. ***Recommendation of Primary reviewer:*** • Regular ICF-H/E –Attached, but PI should submit Guardian consent form. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P52***
53.	Research proposal entitled ***"Role of neonatal sequential organ failure assessment score (nSOFA) for prediction of mortality among preterm neonates with respiratory distress syndrome"*** submitted by Dr. Vaishali Sahu, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2364/Ped/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Sample size discrepancy in SOP form (53 cases) and protocol (113 cases) , please specify the sample size and its calculation. • Revise and submit Guardian consent form (E/H version) **PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P53***
54.	Research proposal entitled ***"Hemodynamic assessment in newborn infant with sepsis: A prospective observational study"*** submitted by Dr. Tapan Singh, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2364/Ped/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • There are 5 Co-PIs from the same department with overlapping roles. • Sample size is mentioned as 53 in the IEC form and as 288 in the synopsis. • Sponsor is mentioned as Government; however, details of expenditure are not given. • 'Devices' is ticked in the Clinical Trial saction of the IEC form. • Which devisce is being tested? • Use of body fluids is not ticked in the IEC form but blood and spinal fluids are being used. • Section on compensation in the IE is not filled. • Direct identifiers are being used. • Contact details of PI are not present on the IC form. **PGTSC Comment:** • As above **PGTSC Decision:** Modify & Resubmit with table giving point wise response to comments ***Ref. code: XIV-PGTSC-IIA/P54***
55.	Research proposal entitled ***"Vincristine induced peripheral neuropathy in children on treatment for acute lymphoblastic leukemia: A prospective observational study"*** submitted by Dr. Shreya Agarwal, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2362/Ped/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P55***
56.	Research proposal entitled ***"Incidence risk factors and outcome of neonates with ventilator associated pneumonia in nicu: A prospective observational study"*** submitted by Dr. Ananyaa Priyadarshi, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2365/Ped/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XIV-PGTSC-IIA/P56
57.	Research proposal entitled ***"A study to assess risk factors associated with febrile seizures in Children under five years of age"*** submitted by Dr. Harikeshwar Mishra, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2367/Ped/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • One of the Co-PIs(Dr. Sciddhartha) hs not signed the IEC form. • Sponsor has been mentioned as 'Government' with no details of expenses. • 'Devices' has been ticked in the section on Clinical Trials without details of the device in the synopsis. • Number of subjects has not been mentioned in the IEC form. • Section on biological material doesn't mention blood collection. • Gene sequencing ha not been mentioned in the consent form. • Assent form has not been attached. • In the section on vulnerable subjects, Children have not been ticked. • Section on Compensation has not been completed. **PGTSC Comment:** • As above **PGTSC Decision:** Modify & Resubmit with table giving point wise response to comments. ***Ref. code: XIV-PGTSC-IIA/P57***
58.	Research proposal entitled ***"Prevalence of early hyponatraemia and its association with AKI in critically ill Children in PICU"*** submitted by Dr. Chandra Prakash, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2355/Ped/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Government is mentioned as Sponsor of the study, but no budget is given. • In the section on biological/Hazardous material blood collection for hematological investigations is not mentioned. • In the Methodology section blood collection and hyuponatremia estimation/grading is not mentioned. • No mention is made of the treatment protocol to be followed in children who are detected with early hyponatremia. • Assent form is not attached to the proforma. **PGTSC Comment:** • As above **PGTSC Decision:** Modify & Resubmit with table giving point wise response to comments. ***Ref. code: XIV-PGTSC-IIA/P58***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

59.	Research proposal entitled ***"Incidence and risk factors of metabolic bone disease among very low birth weight neonates in NICU"*** submitted by Dr. Ranvijay Patel, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2373/Ped/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Involvement of Vulnerable subjects not mentioned in the IEC form. • Collection of blood for biochemical parameters is not mentioned in the section on biological/hazardous materials. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P59***
60.	Research proposal entitled ***"Rates and determinants of early initiation of breast feeding and exclusive breast feeding at discharge in neonates born by caesarian section in a tertiary care hospital with a comprehensive lactational management center"*** submitted by Dr. Charu Kanoujia, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2366/Ped/2022 dated 21st September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P60***
61.	Research proposal entitled ***"Microsatellite instability and brca-1 in epithelial ovarian cancers"*** submitted by Dr. Richa Singh, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1366/2022 dated 14th November, 2022. ***Recommendation of Primary reviewer:*** • Section on Biological/hazardous material has been ticked 'No' whereas ovarian tissue is being used for HPE and IHC. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P61***
62.	Research proposal entitled ***"Association of urinary vitamin D binding protein and neutrophil gelatinase associated lipocalin with steroid responsiveness in idiopathic nephritic syndrome of Childhood"*** submitted by Dr. Tanya Gupta, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2750/Ped/2022 dated 5th November, 2022. ***Recommendation of Primary reviewer:*** • Sponsor is mentioned as government but no budget is given. • Devices are ticked in the Clinical trials sections without mentioning which device is being tested.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 21st December, 2022

	• Section on biological/hazardous material doesn't mention the use of bodily fluids. • Section on compensations has been left blank. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P62***
63.	Research proposal entitled ***"Estimation of urinary [TIMP-2] X [IGFBP7] and serum procalcitonin level in septic acute kidney injury"*** submitted by Dr. Neha Singh, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2084/MED/2022 dated 3rd November, 2022. ***Recommendation of Primary reviewer:*** • Number of subjects not mentoned in IEC form. • Vulnerable subjects/Special group subjects not mentioned in IEC form. • Use of body fluids not mentioned in the section on Biological/ Hazardous material in the IEC form. • Section on Risk not filled properly. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P63***
64.	Research proposal entitled ***"Role of vascular endothelial growth factor(VEGF) procalcitonin and serial levels of c-reactive protein (CRP) versus blood culture in early diagnosis of septicemia"*** submitted by Dr. Monika Chaudhary, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1051/2022 dated 5th November, 2022. ***Recommendation of Primary reviewer:*** • Most of them have overlapping roles. • Sponsor is listed a 'Government' with no budget details. • Number of subjects not mentioned in the IEC form. • Section on use of body fluids has been ticked 'No' • PI has mentioned in the IEC form that 'pre-existing/stored/left over samples' will be used.Please explain. • PI has mentioned that samples from patients will be banked for future research. • This has to be mentioned specifically in the consent. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P64***
65.	Research proposal entitled ***"Determination of anatomical landmarks for ansa cervicalis: A human cadaveric observational study"*** submitted by Dr. Khushboo Yadav,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 395/ANAT/2022 dated 11st November, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P65***
66.	Research proposal entitled ***"Correlation of sentinel lymph node using ICG with frozen, Histo-Pathology and immune-Histochemistry in Oral Cancer"*** submitted by Dr. Anmol Bansal, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3415/2022 dated 20th October, 2022. ***Recommendation of Primary reviewer:*** • The project has 10 C0-PIs with 8 Co-PIs from the same department besides the PI himself.Please justify • Please rationalize the number of investigators in the study. • Section on Vulnerable subjects/ Special group subjects not filled. • Section on biological/hazardous material not filled. • Proper disposal of material is ticked 'No' • Section on consent is incompletely filled. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P66***
67.	Research proposal entitled ***"Study of Physiological and psychological effects of screen time in young adults"*** submitted by Dr. Shiraza Haque, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2742/PHY/2022 dated 18th October, 2022. ***Recommendation of Primary reviewer:*** • Sections on Vulnerable subject/special group subjects/biological and hazardous material/patient consent are not filled properly. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P67***
68.	Research proposal entitled ***"Heart rate variability with dynamic and static exercise"*** submitted by Dr. Ehsan Ahmad, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2750/PHY/2022 dated 2nd November, 2022. ***Recommendation of Primary reviewer:*** • Sections on vulnerable subject/special group subjects, use of biological/hazardous material, consent are not filled. • Number of subject is different in the IEC form and the synopsis (150 and 190)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P68***
69.	Research proposal entitled ***"Resistance and heteroresistance to colistin in carbapenemase producing gram-negative infections from adult intensive care units"*** submitted by Dr. Sufia Talib, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1050/2022 dated 5th November, 2022. ***Recommendation of Primary reviewer:*** • There are 7 Co-PIs to the project out of which 4 are from one department. Addition of Co-PIs to the project must be rational and need based. • Sample size needs to be mentioned in the IEC form too. • Details regarding sample collection are missing form the IEC form as well as the synopsis. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P69***
70.	Research proposal entitled ***"Diagnosis and antifungal susceptibility pattern of candida auris in critically III patients: A prospective observational study"*** submitted by Dr. Manisha Singh, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1017/2022 dated 2nd November, 2022. ***Recommendation of Primary reviewer:*** • The project has 7 Co-PIs besides the candidate/PI herself. • Number if subjects/ sample seze has not been mentioned in the IEC form. • Sectiones on vulnerable subjects, biological/hazardous material and risk and benefit have been left incomplete. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P70***
71.	Research proposal entitled ***"An observational study to determine blood stream infections in febrile neutropenic Paediatric cancer patients & their co-relation with blood procalcitonin level"*** submitted by Dr. Tanya Pandey, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1047/2022 dated 5th November, 2022. ***Recommendation of Primary reviewer:*** • Sections on vulnerable subjects, special group subjects, biological/hazardous material, patient consent and risk and befits are incompletely filled. • Sample size is different in IEC form and in the synopsis (106vs227)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Study design mentioned is prospective, observational study but in the data collection section the PI mentions two groups. • Acronym CRE has been used without clarification. **PGTSC Comment:** • As above **PGTSC Decision:** Modify & Resubmit with table giving point wise response to comments. ***Ref. code: XIV-PGTSC-IIA/P71***
72.	Research proposal entitled ***"Antifungal susceptibility testing of newer topical antifungal agents against dermatophytes in north India"*** submitted by Dr. Tanya Sachan, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1046/2022 dated 5th November, 2022. ***Recommendation of Primary reviewer:*** • Section on biological/hazardous material is incompletely filled. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P72***
73.	Research proposal entitled ***"Determination of vancomycin resistant enterococci (VRE) and vancomycin variable enterosocci (VVE) in urinary tract infections amongst hospitalized patients"*** submitted by Dr. Riya Singh, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1045/2022 dated 5th November, 2022. ***Recommendation of Primary reviewer:*** • Number of subjects must be mentioned in the IEC form also. • Section on vulnerable subjects is incompletely filled. • Section on biological/hazardous material hs been incompletely filled. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P73***
74.	Research proposal entitled ***"A study of spectrum and outcome of liver disorders in pregnant women admitted in a tertiary care centre in North India"*** submitted by Dr. Shivangi Sharma, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3157/2022 dated 4th November, 2022. ***Recommendation of Primary reviewer:*** • Sections on vulnerable subjects, special group subjects, use to biological/hazardous material and patient consent are incompletely filled. **PGTSC Comment:** • As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P74***
75.	Research proposal entitled ***"Assessment of serum fibrinogen levels as a predictive marker for postpartum haemorrhage"*** submitted by Dr. Vinita Kumari, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3119/2022 dated 26th October, 2022. ***Recommendation of Primary reviewer:*** • Section on vunerable subjects, special group subjects, use of biological/hazardous materials, patient consent and risk and benefits are not completely filled. • Sample size given in the IEC form and in the synopsis sample size calculation are different (110 and 80) **PGTSC Comment:** • As above **PGTSC Decision:** Modify & Resubmit with table giving point wise response to comments. ***Ref. code: XIV-PGTSC-IIA/P75***
76.	Research proposal entitled ***"Correlation of vaginal microbiome during pregnancy with obstetric outcome"*** submitted by Dr. Ojasvini Agrawal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3128/2022 dated 28th October, 2022. ***Recommendation of Primary reviewer:*** • Sample size in IEC form and in the synopsis sample size calculation are different (120 and 300) • No details regarding how the vaginal microbiome will be estimated has been given in the methodology. • Collection of biological specimen is not mentioned in the IEC form in the concerned section on biological/hazardous material. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P76***
77.	Research proposal entitled ***"Clinical audit on maternal and fetal outcomes in cases of APH in tertiary care centre"*** submitted by Dr. Monika Sagwal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3078/2022 dated 18th October, 2022. ***Recommendation of Primary reviewer:*** • Sections on Type of subjects, vulnerable subjects, special group subjects, use of biologival/hazardous material and patient consent are incompletely filled.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P77***
78.	Research proposal entitled ***"Variational anatomy of cervical part of phrenic nerve: an observational human cadaveric study"*** submitted by Dr. Ankit Sharma, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 402/ANAT/2022 dated 16th November, 2022. **PGTSC Decision:** Approved ***Ref. code: XIV-PGTSC-IIA/P78***
79.	Research proposal entitled ***"First trimester glycosylated hemoglobin as a predictor of gestational diabetes mellitus"*** submitted by Dr. Sadaf Khan, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3087/2022 dated 19th October, 2022. ***Recommendation of Primary reviewer:*** • Sections on vulnerable subjects, use of biological material, risk and benefit and patient conent are incompletely/incorrectly filled. • Sample size in IEC form and synopsis is different (120 vs 138). • Are the Investigations being conducted on the subjects' part of normal antenatal checkup? If not, who will bear the cost of the additional tests? **PGTSC Comment:** • As above **PGTSC Decision:** Modify & Resubmit with table giving point wise response to comments. ***Ref. code: XIV-PGTSC-IIA/P79***
80.	Research proposal entitled ***"Comparision of DIPSI criteria and WHO criteria for diagnosis of gestational diabetes mellitus in early pregnancy"*** submitted by Dr. Nida Aara, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3080/2022 dated 18th October, 2022. ***Recommendation of Primary reviewer:*** • Blood samples are being collected for blood sugar estimation. Use of body fluids must be ticked in the section on biological/hazardous materials. • Section on vulnerable subjects must mention pregnant women. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P80***
81.	Research proposal entitled ***"Open label randomized control trial to study effect of piroxicam in improving pregnancy rate in intrauterine insemination"*** submitted by Dr.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Sadhana Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3079/2022 dated 18th October, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P81***
82.	Research proposal entitled ***"A randomized controlled trial comparing combination of letrozole and clomiphene citrate of letrozole alone for ovarian stimulation in infertile women"*** submitted by Dr. Anamika Kumari, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3129/2022 dated 28th October, 2022. ***Recommendation of Primary reviewer:*** • It is not clear which samples will be collected, as mentioned in the materials and methods section? **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P82***
83.	Research proposal entitled ***"Estimation of urinary timp2 and IGFBP7 in critically ill obstetrics patients and prediction of AKI and its association with fetomaternal outcome"*** submitted by Dr. Himani Chaudhary, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3089/2022 dated 19th October, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P83***
84.	Research proposal entitled ***"The effect of preoperative biliary drainage and other factors (patient/disease/operative)influencing post operative pancreatic fistula after pancreaticoduodenectomy"*** submitted by Dr. Deeban G, SR, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SG/547/2022 dated 16th September, 2022. ***Recommendation of Primary reviewer:*** • Kindly rewrite the inclusion and exclusion criteria as it is not mentioned if patients undergoing pancreaticoduodenectomy will be included in the study. Moreover, other cancers and conditions will also be excluded. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P84***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

85.	Research proposal entitled ***"To compare efficacy between I/V pentaglobin and I/V vitamin C in sepsis of burn patients: A prospective randomized study"*** submitted by Dr. Naveen Kunar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1139/2022 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • Consent form needs correction as it is mentioned that informed consent will be taken from the patient. When the patient will be on a ventilator then how can that be done? **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P85***
86.	Research proposal entitled ***"To study the various medical oxygen supply systems in tertiary care Government Teaching Hospital at Lucknow"*** submitted by Dr. Umesh Dhar Dubey, JRI, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/453/2022 dated 17th November, 2022. ***Recommendation of Primary reviewer:*** • It is mentioned that the work will be started w.e.f. 21st March 2022, How without ethical clearance that is done? **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P86***
87.	Research proposal entitled ***"Assessment of stress and force applied by different archwire and materials with curve of SPEE -A finite element study"*** submitted by Dr. Saraswati Chandra, JRII, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 999/Ortho/2022 dated 21st October, 2022. ***Recommendation of Primary reviewer:*** • Objectives not given. • Bibliography not given. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P87***
88.	Research proposal entitled ***"Comparison of lignocaine-dexamethasone and lignocaine- triamcinolone infiltration along spinal epidural needle pathway to prevent backache after lower abdominal surgeries"*** submitted by Dr. Ankit Soni, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1164/2022 dated 7th September, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 21st December, 2022

	Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P88***
89.	Research proposal entitled ***"Effect of rajayoga meditation on anxiety level, hemodynamic parameters, and serum cortisol level in patients undergoing modified radical mastectomy-A prospective randomsed control study"*** submitted by Dr. Sreelakshmi. P, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1140/2022 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • No review of literature included in the project. • Method of estimation for serum cortisol not given. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P89***
90.	Research proposal entitled ***"Comparison of levobupivacaine and ropivacaine in quadrates lumborum block for postoperative analgesia after abdominal surgery"*** submitted by Dr. Akhil O Nair, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1145/2022 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • References mentioned in the bibliography but are not cited in the text. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P90***
91.	Research proposal entitled ***"Comparision between erector spinae block and thoracic epidural block in post operative analgesic effect in thoracotomy patients"*** submitted by Dr. Manish Kumar Rawat, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1136/2022 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P91***
92.	Research proposal entitled ***"A prospective randomized control trial: role of ultrasound guided scalp nerve block in prevention of chronic post craniotomy headache in patient undergoing supratentorial tumor surgery"*** submitted by Dr. Rajesh Kumar Baranwal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1148/2022 dated 7th September, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P92***
93.	Research proposal entitled ***"Comparing the efficacy of sphenopalatine ganglion block with palatal block for analgesia in children with cleft palate undergoing palatoplasty under general anesthesia: A randomized control study"*** submitted by Dr. Priya Tiwari, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1143/2022 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • References mentioned in the text are not given in the bibliography and those in the bibliography are not cited in the text. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIV-PGTSC-IIA/P93***
94.	Research proposal entitled ***"Effect of two different concentrations of oxygen on postoperative nausea vomiting after laparoscopic cholecystectomy: A prospective, randomized comparative study"*** submitted by Dr. Nahas K, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1155/2022 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P94***
95.	Research proposal entitled ***"A clinical comparison of blind intubation using LMA blockbuster™ and AMBU AURAGAIN™ in adult patients under general Anaesthesia: A prospective randomized comparative clinical study"*** submitted by Dr. Jyoti Kumari, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1141/2022 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P95***
96.	Research proposal entitled ***"Effect of ultrasound guided serratus anterior plane block using dexmedetomidine as an adjuvant to bupivacaine for postoperative analgesia after modified radical mastectomy"*** submitted by Dr. Nidhi Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1142/2022 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XIV-PGTSC-IIA/P96
97.	Research proposal entitled ***"A randomized double blind control trial of ADD-ON duloxetine on symptom severity and quality of life in irritable bowel syndrome"*** submitted by Dr. Vrinda Purshottam, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1713/Psy/2022 dated 16th November, 2022. ***Recommendation of Primary reviewer:*** • References mentioned in the text are not given in the bibliography e.g. Kaplan et. al. and those in the bibliography are not cited in the text. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P97***
98.	Research proposal entitled ***"To study the cost of treatment in patients with acute stroke presenting to the Department of Neurology at a tertiary care Government University Hospital Lucknow, India"*** submitted by Dr. Sairaj Subhash Chodankar, JRI, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/462/2022 dated 21st November, 2022. ***Recommendation of Primary reviewer:*** • Aims and objectives not clear. **PGTSC Comment:** • As above **PGTSC Decision:** Modify & Resubmit ***Ref. code: XIV-PGTSC-IIA/P98***
99.	Research proposal entitled ***"A randomized comparison of I-gel, ambu auragain, baska mask & LMA protector for airway management of obese surgical patients"*** submitted by Dr. Apoorva Gupta, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. nil dated 7th September, 2022. ***Recommendation of Primary reviewer:*** Approved ***Ref. code: XIV-PGTSC-IIA/P99***
100.	Research proposal entitled ***"Faecal carriage of carbapenem-resistant enterobacterales (CRE) and analysis of risk factors among ICU patients"*** submitted by Dr. Mukesh Kumar Patwa, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1055/22 dated 7th November, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P100***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

101.	Research proposal entitled ***"Maternal plasma soluble neurolipon 1 in fetal growth restriction versus appropriate for age fetus: A prospective case control study"*** submitted by Dr. Shalini Yadav, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3247/22 dated 16th November, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P101***
102.	Research proposal entitled ***"Etiology and biofilm formation of Orthopaedic implant infections"*** submitted by Dr. Asma Khan, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 998/22 dated 29th October, 2022. ***Recommendation of Primary reviewer:*** • Methodology improper. E.g. method for detection of biofilm by tissue culture plate method not given. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit with table giving pointwise response to comments. ***Ref. code: XIV-PGTSC-IIA/P102***
103.	Research proposal entitled ***"Utility of GATA-3 and CK-14 immunohistochemical expression in urothelial carcinoma of urinary bladder and its clinicopathological correlation"*** submitted by Dr. Anjana Sankhwar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1335/Patho/22 dated 12th November, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P103***
104.	Research proposal entitled ***"Arterial SPIN labeling MRI in central nervous system infections"*** submitted by Dr. K. Elangovan, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 1010/RD/22 dated 16th November, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P104***
105.	Research proposal entitled ***"Role of ribroscan/elastography in PRE and POST management of chronic liver diseases"*** submitted by Dr. Shalini Attri, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 21st December, 2022

	1009/RD/22 dated 16th November, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P105***
106.	Research proposal entitled ***"Magnetic resonance imaging and histopathological correlation in the diagnosis of the suspicious breast lwsions on ultrasonography"*** submitted by Dr. Charu Vats, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 998/RD/22 dated 12th November, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P106***
107.	Research proposal entitled ***"Spectrum of visceral organ injury: management of life threatening haemorrhage with angioembolization and its outcome"*** submitted by Dr. Nitin Bharti, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 997/RD/22 dated 12th November, 2022. ***Recommendation of Primary reviewer:*** • Please specify who among the investigators, will perform angioembolization? • Explain the procedure in detail in ICF. Specify the outcome parameters. **PGTSC Comment:** • As above **PGTSC Decision:** Modify & Resubmit ***Ref. code: XIV-PGTSC-IIA/P107***
108.	Research proposal entitled ***"Role of CT coronary angiography in patients with acute chest pain with normal ECG and TROPONIN levels"*** submitted by Dr. Shakeb Zaidi, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 996/RD/22 dated 12th November, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation has been not provided. **PGTSC Comment:** • As above **PGTSC Decision:** Modify & Resubmit ***Ref. code: XIV-PGTSC-IIA/P108***
109.	Research proposal entitled ***"Percutanneous imagr guided management of vascular malformations and comparison of sclerosing agents and their outcome"*** submitted by Dr. Shaivya Sirohi, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 995/RD/22 dated 12th November, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • Kindly provide details of all sclerosing agents, which will be used during intervention along with their indications and efficacy. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIV-PGTSC-IIA/P109***
110.	Research proposal entitled ***"To find the spectrum of DTI abnormalities in chikdren eith neuridevelopmental delay"*** submitted by Dr. Sumant Kumar Gupt, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 983/RD/22 dated 10th November, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P110***
111.	Research proposal entitled ***"Role of multiprmetric MRI in gradine of glioma"*** submitted by Dr. Daljeet Kaur, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 982/RD/22 dated 10th November, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P111***
II-B	**Nursing KGMU Institute**
1.	Research proposal entitled ***"Effectiveness of balloon blowing exercise on pulmonary function and quality of life among COPD patients"*** submitted by Ms. Victoria Angela Fernandez through her Guide Mrs. Rashmi P. John, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P1***
2.	Research proposal entitled ***"Assess the risk factor of cervical cancer among early adolescent girls and knowledge on HPV vaccination among mothers of early adolescent girls at selected rural area, Lucknow"*** submitted by Ms. Vibha Yadav through his Guide Mr. Rohitash Kumar, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: As above ***Ref. code: XIV-PGTSC-IIB/P2***
3.	Research proposal entitled ***"Assess the effectiveness of structured teaching programme on knowledge and attitude regarding caring skills and coping abilities of primigravida mothers with preterm babies"*** submitted by Ms. Ritika Kushwaha through her Guide Mrs. Rashmi P. John, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P3***
4.	Research proposal entitled ***"Effectiveness of music therapy on ICU induced anxiety and physiological parameters among patients admitted in intensive care unit"*** submitted by Ms. Swati Rai through her Guide Mrs. Rashmi P. John, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P4***
5.	Research proposal entitled ***"Effectiveness of telenursing rehabilitation program on home based self-care among acute coronary syndrome patients"*** submitted by Ms. Sehnaz Khatun through her Guide Dr. Suchana Roy Bhowmik, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P5***
6.	Research proposal entitled ***"Comparison of fingertip vs palm site sampling for capillary blood glucose monitoring on pain perception and variation in blood glucose level among admitted diabetes mellitus patients"*** submitted by Ms. Shweta Singh through her Guide Mrs. Rashmi P. John, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12nd September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P6***
7.	Research proposal entitled ***"Effect of brief intervention on readiness to change and treatment initiation in patients with hypertension using tobacco"*** submitted by Ms.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Rimmi, Through her Guide Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P7***
8.	Research proposal entitled ***"Effectiveness of infrared radiation on healing of diabetic foot ulcer among type2 diabetes patients admitted in surgery wards"*** submitted by Ms. Chetna Mishra through her Guide Mrs. Rashmi P. John, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P8***
9.	Research proposal entitled ***"Effect of progressive muscle relaxation technique on depression & anxiety among antenatal women with pre eclampsia"*** submitted by Ms. Vaishanvi through her Guide Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P9***
10.	Research proposal entitled ***"Effect of nurse led education programme on knowledge & expressed practice regarding rheumatoid arthritis and its self-care among adult population residing in rural area, Lucknow, U.P."*** submitted by Ms. Akshita Awasthi, Through her Guide Mr. Rohitash Kumar, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P10***
11.	Research proposal entitled ***"Assess the factors influencing compliance to DOTS therapy among tuberculosis patients under national tuberculosis elimination program at DOTS center, KGMU, Lucknow."*** submitted by Mr. Ashutosh Sharma through her Guide Mr. Rohitash Kumar, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P11***
12.	Research proposal entitled ***"Assessment of the awareness on adolescent reproductive and sexual health (ARSH Clinic) among adolescent girls in selected school of sarojini Nagar, Lucknow."*** submitted by Ms. Mradula Devi through her Guide Mr. Rohitash Kumar, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P12***
13.	Research proposal entitled ***"Assess the risk factors for high-risk pregnancy and effectiveness of teaching programme on knowledge regarding prevention of high-risk pregnancy among antenatal mothers attending antenatal clinics in selected urban area"*** submitted by Ms. Arti Singh Chauhan through her Guide Mr. Rohitash Kumar, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1338/X.51 dated 12th September, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P13***
14.	Research proposal entitled ***"A study to assess the effectiveness of structured teaching program on knowledge regarding premenstrual syndrome and it's management among adolescent girls in selected School at Lucknow, Uttar Pradesh"*** submitted by Mr. Robin Singh, Mr. Syed Sebtain, Mr. Sabbir Ansari, Mr. Shahid Mushtaq, Ms. Sadhana Devi, Mr. Saket Mishra, Ms. Sameeksha Arya, Mr. Satish Kumar Singh, Mr. Shashank Mishra, Ms. Shazia Jamal, Mr. Shivam Chaturvedi through their Mentor Mr. G. Srinivasan, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1654/X.51 dated 1st November, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P14***
15.	Research proposal entitled ***"A study to assess the nocturnal eating pattern and its leading factors among students at selected Colleges of Lucknow, U.P."*** submitted by Mr. Prachand Pratap, Mr. Prashant Mishra, Mr. Praveen Kumar, Ms. Preety Satyarthi, Ms. Priyanka Chaudhary, Ms. Priyanka Verma, Ms. Priyanka Rawat, Mr. Rahul Deo, Mr. Rajan Pandey, Ms. Ranjana Bharti, Ms. Reema Devi through their Mentor Ms. Loveena Arpita Samuel & Ms. Amanjeet Kaur, Department of KGMU College of Nursing, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no.1653/X.51 dated 1st November, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P15***
16.	Research proposal entitled ***"A study to assess the risk factors of pulmonary tuberculosis among adult population residing at selected urban areas of Lucknow Uttar Pradesh"*** submitted by Mr. Shiwam Kushwaha, Ms. Shivani Kumari, Ms. Sonam Tiwari, Mr. Sonu Chaurasiya, Ms. Suman Kumari, Mr. Sunil Kr. Trtipathi Ms. Tanya Sharma, Mr. Ujjwal Mishra, Mr. Umang Dixit, Mr. Vipul Singh, Mr. Vivek Chauhan, Mr. Vivek Kr. Yadav, Ms. Chitranshi Verma through their Mentor Mr. Migron Rubin, & Ms. Aditi Mecarty, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1655/X.51 dated 1st November, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P16***
17.	Research proposal entitled ***"A study to assess the effectiveness of structured Teaching programme on knowledge regarding home care remedies of diarrhea and common cold among mothers of under-five Children in selected rural Area, Lucknow, U.P."*** submitted by Mr. Meraj Ahmad, Miss. Mahima Singh, Mr. Nan Babu, Miss. Neetu Kumari, Miss. Nazian Malik, Miss. Nidhi Kumari, Miss. Nidhi Singh, Miss. Nidhi Verma, Mr. Nilesh Kumar, Miss. Pooja Tripathi, Miss. Poonam Kumar, Miss. Prabhleen Kaur through their Mentor Mrs. Versha Rani Verma & Mrs. Kumkum Yadav, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1652/X.51 dated 1st November, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P17***
18.	Research proposal entitled ***"A study to assess the effectiveness of structured teaching program on knowledge regarding menstrual blood stem cell banking among nursing students from selected nursing Colleges of Lucknow, Lucknow, U.P."*** submitted by Mr. Ankur Sharma, Mr. Annu Yadav, Ms. Anshika Saxena, Ms. Anshika Singh, Ms. Archana Arya, Mr. Arjun Kr. Sharma, Ms. Aashu Kumari, Mr. Abhishek Shukla, Mr. Aditya Singh, Mr. Akash Patel, Mr. Aman Kr. Singh, Mr. Amber Singh through their Mentor Ms. Monica Nancy Lal & Ms. Manisha Anand, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1649/X.51 dated 1st November, 2022. ***Recommendation of Primary reviewer:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P18***
19.	Research proposal entitled ***"A descriptive study to assess the relationship between emotional intelligence and self-esteem among patients living with HIV/AIDS (PLWHA) in KGMU Lucknow"*** submitted by Mr. Amit Kr. Patel, Ms. Amrita Singh, Ms. Anjali Bharti, Ms. Anjali Rai, Ms. Anju Vishwakarma, Mr. Ankit Chaudhary, Ms. Ankita Singh, Mr. Ashish Patel, Mr. Ashish Kumar, Mr. Ashish Kr. Patel, Mr. Ashraf Ahmed, Mr. Awanish Kumar Patel through their Mentor Mrs. Priyanka Singh, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1780/X.51 dated 15th November, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P19***
20.	Research proposal entitled ***"A study to assess the knowledge and attitude regarding immunization among mothers of under six children at selected urban slums areas of Lucknow, U.P."*** submitted by Miss. Ayesha Rehman, Miss. Deeksha Gupta, Miss. Deepti Singh, Miss. D.R. Ayushi, Mr. Dilip Kumar, Miss. Dipti Devi, Miss. Drishti, Miss. Gazala Hassan, Mr. Gaurav Sharma, Miss. Geeta Joshi, Miss. Gunjan Pathariya through their Mentor Mrs. Supriya Singh & Mr. Ankit Raj, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1650/X.51 dated 1st November, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P20***
21.	Research proposal entitled ***"A descriptive study to assess knowledge regarding prevention of rhinitis among School going Children of various selected Schools of Lucknow"*** submitted by Mr. Himanshu Agnihotri, Mr. Indal Pal, Mr. Irfan Ali, Mr. Jay Prakash Singh, Mr. Jainendra Kumar Patel, Ms. Kumari Akrati, Mr. Krishna Azad, Ms. Leelawati Rajak, Mr. Mukesh Maurya, Mr. Mohd. Shadab, Mr. Mohd. Shaban through their Mentor Mr. Nayan Paul, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1651/X.51 dated 1st November, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIB/P21***

The next EC Meeting will be held on 10th February, 2023 from 02.00 PM virtual.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University U.P.,
Institutional Ethics Committee
Lucknow - 226003 (UP) India

Prof. Shally Awasthi
Member Secretary, IEC

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

No. 1924 **/Ethics/2023**

Dated: 19/01/2023

To,

Dr. Alok Dhawan,
Director,
Centre of Biomedical Research (CBMR),
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Raebareli Road,
Lucknow, U.P.226014

Sub.: Reg. Minutes of 120th Institutional Ethics Committee Meeting held on 21st December, 2022.

Dear Sir,

Please find enclosed herewith the Minutes of 120th Institutional Ethics Committee Meeting held on 21st December, 2022, for your kind signature.

Thanking you,
With regards

Encl: As above

Yours Sincerely

(Shally Awasthi)
Member Secretary, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 121st ECM held on 10th February, 2023

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the 121st Institutional Ethics Committee Meeting *virtually* held on **10th February, 2023 from 2:00 PM.**

The following Members were present in the Meeting:

1. Dr. Alok Dhawan -Chairman
2. Dr. G.G. Agarwal -Member
3. Dr. K.K. Yadav -Member
4. Mr. Ujjawal Krishna -Member
5. Dr. Akash Agarwal -Member
6. Mrs. Akanksha Dubey -Member
7. Mrs. Vasundhara Kumari -Member
8. Dr. Rajendra Nath -Member
9. Dr. D.N. Upadhayay -Member
10. Dr. Anita Rani -Member
11. Dr. Anupam Mishra -Member
12. Dr. Shally Awasthi -Member-Secretary, IEC

The following Members were not present in the Meeting:

1. Dr. Shubha R Phadke -She has given her written comment
2. Dr.A.A. Mahdi -He has given his written comment

I	**Previous Meeting held on 21-12-2022. The following documents have been brought from the last meeting because the quorum was incomplete.**
IA	**Action Taken-21-12-2022**
1-	Clarification of research protocol no. EX6018-4758 Study Phase:3 a entitled **"ZEUS -** ***Effects of ziltivekimab versus placebo on cardiovascular outcomes in participants with established atherosclerotic cardiovascular disease, chronic kidney disease and systemic inflammation*****"** sponsored by M/s Novo Nordisk India Private Ltd, submitted by Prof.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Rishi Sethi, Department of Cardiology King George's Medical University, U.P., Lucknow, vide letter no. 421/Cardio/Res/2022 dated 17th November, 2022.

Previous EC Comment	PI response
Approval attached. approval, for export of biological samples: not there is a process and certificate for as attached with proposal 720.	As per Gazette of India part 2 section 3 subsection 2 dated 4 Aug 2016; notification number 19/2015-2020, the import of human biological samples by the Indian diagnostic laboratories/Indian Clinical Research Centers for lab analysis D testing or export of these materials to foreign laboratories is permitted by Customs authorities at the port of entry/ exit without prior approvals (import/ export license) from any Government agency provided the concerned Indian company submits an undertaking that they are following and will follow all applicable rules, regulations and procedures for safe transfer and disposal of biological samples being imported or exported as per related norms/ regulations set by WHO/ DGFT/ Ministry of Environment, Forest, climate change, Government of India, to the Customs authorities at port of entry/ exit along with details of such samples. Hence, no approval for export of biological samples required. Novo Nordisk confirms that all above stated norms related to safe transfer and disposal of biological samples are bring Followed.
Can samples send, if CDSCO Approves.	CDSCO does not provide approvals for sending samples. As per Gazette of India part 2 section 3 subsection 2 dated 4 Aug 2016; notification number 19/2015-2020, no approval from any.

The reply from PI to the above Comments was forwarded to PR:-
Second opinion of PR:

- Direct identifiers will be used: Why?
- KGMU policy for biological material sharing to decide on biological sample transport.

The reply from PR to the above Comments was forwarded to PI:- Response received from PI Which was forwarded to PR vide letter no.1626/Ethics/2022 dated 19th December, 2022.
Recommendation of PR: Approved
The following documents were reviewed in the Meeting:-

S.No.	Documents
1-	PROTOCOL Protocol Version 1.0 dated 16-April-2021 Protocol attachment 1: Global list of key staff and relevant departments and suppliers of clinical relevance.
1.	**INVESTIGATOR'S BROCHURE**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Investigator's Brochure Ziltivekimab (subcutaneous administration) edition 4 dated 24-Mar-2021
	2.	**3.1** Subject Information/Informed Consent Form Version 1.0 IN English (EN) dated 30-April-2021 Status: Final **3.2** Subject Information/Informed Consent Form Version 1.0 IN Hindi (HI) dated 07 June 2021 Status: Final **3.3** Subject Information/Informed Consent Form Version 1.0 IN_HI_BT dated 07 June 2021 Status: Final
	3.	**4.1** Subject Information/Informed Consent Form for male partner of female subject in case of an abnormal pregnancy Version 1.0 IN English (EN) dated 30-April-2021 Status: Final **4.2** Subject Information/Informed Consent Form for male partner of female subject in case of an abnormal pregnancy Version 1.0 IN Hindi (HI) dated 07 June 2021 Status: Final **4.3** Subject Information/Informed Consent Form for male partner of female subject in case of an abnormal pregnancy Version 1.0 IN_HI_BT dated 07 June 2021 Status: Final
	4.	**4.1** Subject Information/Informed Consent Form for male partner of female subject in case of an abnormal pregnancy Version 1.0 IN English (EN) dated 30-April-2021 Status: Final **4.2** Subject Information/Informed Consent Form for male partner of female subject in case of an abnormal pregnancy Version 1.0 IN Hindi (HI) dated 07 June 2021 Status: Final **4.3** Subject Information/Informed Consent Form for male partner of female subject in case of an abnormal pregnancy Version 1.0 IN_HI_BT dated 07 June 2021 Status: Final
	5.	**5.1** Subject Information/Informed Consent Form for Future Research Echocardiography Version 1.0 IN English (EN) dated 30-April-2021 Status: Final **5.2** Subject Information/Informed Consent Form for Future Research Echocardiography Version 1.0 IN Hindi (HI) dated 07 June 2021 Status: Final **5.3** Subject Information/Informed Consent Form for Future Research Echocardiography Version 1.0 IN_HI_BT dated 07 June 2021 Status: Final
	6.	**6.1** Subject Information/Informed Consent Form for Future Research Biomarkers Version 1.0 IN English (EN) dated 30-April-2021 Status: Final **6.2** Subject Information/Informed Consent Form for Future Research Biomarkers Version 1.0 IN Hindi (HI) dated 07 June 2021 Status: Final **6.3** Subject Information/Informed Consent Form for Future Research Biomarkers Version 1.0 IN_HI_BT dated 07 June 2021 Status: Final
	7.	**7.1** Subject Information/Informed Consent Form for Optional Pre-screening Version 1.0 IN English (EN) dated 30-April-2021 Status: Final **7.2** Subject Information/Informed Consent Form for Optional Pre-screening Version 1.0 IN_Hindi (HI) dated 07 June 2021 Status: Final

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		7.3 Subject Information/Informed Consent Form for Optional Pre-screening Version 1.0 IN_HI_BT dated 07 June 2021 Status: Final
	8.	**8.1** Subject Information/Informed Consent Form for Direct Shipment of IMP Version 1.0 IN English (EN) dated 30-April-2021 Status: Final **8.2** Subject Information/Informed Consent Form for Direct Shipment of IMP Version 1.0 IN Hindi (HI) dated 07 June 2021 Status: Final **8.3** Subject Information/Informed Consent Form for Direct Shipment of IMP Version 1.0 IN_HI_BT dated 07 June 2021 Status: Final
	9.	**.1** Subject Information/Informed Consent Form for Home Health Care Service Version 1.0 IN English (EN) dated 30-April-2021 Status: Final **9.2** Subject Information/Informed Consent Form for Home Health Care Service Version 1.0 IN Hindi (HI) dated 07 June 2021 Status: Final **9.3** Subject Information/Informed Consent Form for Home Health Care Service Version 1.0 IN_HI_BT dated 07 June 2021 Status: Final
	10.	Scientific Recruitment and Retention Materials: English (EN) : Animation movie on inflammation subtitles-version 1.0_EN Certificate of achievement-version 1.0_EN Contact persons checklist-version 1.0_EN Every patient counts-version 1.0_EN Guidance for supporting HCPs-version 1.0_EN Inclusion exclusion criteria reference-version 1.0_EN Informed consent FAQ-version 1.0_EN Living well booklet-version 1.0_EN Managing infection risk-version 1.0_EN Patient check-in-version 1.0_EN Patient ID-visit reminder card-version 1.0_EN Patient recruitment advertisement-version-digital 1.0_EN Patient recruitment advertisement-version-poster 1.0_EN Patient newsletter 1-version 1.0_EN Patient newsletter 2-version 1.0_EN Patient newsletter 3-version 1.0_EN Patient newsletter 4-version 1.0_EN Patient study booklet-version 1.0_EN Patient support network booklet-version 1.0_EN Patient thankyou letter-version 1.0_EN Patient visit overviewpocket-version 1.0_EN Patient visit overview-version 1.0_EN Patient welcome letter-version 1.0_EN Protocol cover-version 1.0_EN Subject participation feedback questionnaire-version 1.0_EN Treatment action plan-version 1.0_EN **Hindi (HI) :** Animation movie on inflammation subtitles-version 1.0_HI

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Certificate of achievement-version 1.0_HI Contact persons checklist-version 1.0_HI Every patient counts-version 1.0_HI Guidance for supporting HCPs-version 1.0_HI Inclusion exclusion criteria reference-version 1.0_HI Informed consent FAQ-version 1.0_HI Living well booklet-version 1.0_HI Managing infection risk-version 1.0_HI Patient check-in-version 1.0_HI Patient ID-visit reminder card-version 1.0_HI Patient newsletter 1-version 1.0_HI Patient newsletter 2-version 1.0_HI Patient newsletter 3-version 1.0_HI Patient newsletter 4-version 1.0_HI Patient recruitment advertisement-version-digital 1.0_HI Patient recruitment advertisement-version-poster 1.0_HI Patient recruitment advertisement-version-trifold 1.0_HI Patient study booklet-version 1.0_HI Patient support network booklet-version 1.0_HI Patient thank you letter-version 1.0_HI Patient visit overview pocket-version 1.0_HI Patient visit overview-version 1.0_HI Patient welcome letter-version 1.0_HI Protocol cover-version 1.0_HI Subject participation feedback questionnaire-version 1.0_HI Treatment action plan-version 1.0_HI J048077_Certifcate of translation Hindi (India)
	11.	Other information to subjects: **English (EN):** Patient App Supporting Document dated 28-April-2021 Patient App Content dated 28-April-2021 Patient app user guide Version 1.0 dated 28-April-2021 ZEUS Device Instructions Version 1.0 Instruction Video Pre-filled Syringe Video Version 1.0 dated 19-April-2021 **Hindi (HI):** Patient App Supporting Document dated 14-June-2021 Patient App Content dated 14-June-2021 Patient app user guide Version 1.0 dated 14-June-2021 J048151_Certifcate of Translation_Hindi
	12.	Directions for use (Ziltivekimab B15 mg/ml/Placebo)-English (EN)-Version DFU_DV3430_A_V_1.00 Directions for use (Ziltivekimab B15 mg/ml/Placebo)-Hindi (HI)-Version DFU_DV3430_A_V_1.00
	13.	Sample CRF Version 1.0 (Annotated Study Book for Study Design: EX6018-4758;

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Study Design Version: 11.1) Sample CRF Additional Version 1.0 (AE form, Technical Complaint form, Safety Information form and Pregnancy forms and their instruction pages)
	14.	Central Lab Manual (ICON Laboratory Services, Inc. Version 1.0 dated 28-April-2021)
	15.	HOT system User Manuals
	16.	Notarized Global Insurance (Policy No: DK00000831LI21A and Validity: 01-May-2021 to 30-April-2022
	17.	CV, MRC and GCP of Principal Investigator Investigator's Undertaking signed by PI
	18.	DCGI Submission letter dated 04 June 2021
	19.	Draft Clinical Trial Agreement
	20.	Direct to Patient 20.1 Patient Home Pick-Up (DFP)/Delivery (DTP) Booking Form Version 06 dated 12 Nov 2019 20.2 Trial site/pharmacy instruction for shipment of trial product to patients' homes Version 1.0 dated 26 April 2021 20.3 Corona Virus task force_Option 1_Version 3.0_English 20.4 Corona Virus task force_Option 1_Version 3.0_Hindi **20.5** Corona Virus task force_Option 2_Version 3.0_English **20.6** Corona Virus task force_Option 2_Version 3.0_Hindi **20.7** Corona Virus task force_Option 3a_Version 3.0_English **20.8** Corona Virus task force_Option 3b_Version 3.0_English **20.9** Coronavirus task force_change log_Alternative dispensing templates **20.10**Memo_Alternative dispensing methods due to the Coronavirus_ver.3.0 **20.11** Translation Certificate
	21.	COVID-19_local guidance on remote SDR/SDV_IN_1.0

EC Decision: Approval subject to fulfillment of administrative formalities.

Ref. code: 116th ECM IIC/P1

2- Clarification of proposal entitled ***"A randomized, multicentre, double blind, placebo controlled, parallel-group, study to evaluate the efficacy and safety of linaclotide once daily of Dr. Reddy's laboratories limited in patients with chronic constipation"*** sponsored by Dr. Reddy's laboratories limited submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P.,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/28/2022 dated 9th November, 2022.

Previous EC Comment	PI response
Section 3(ii) ad 3(iv) is contradictory if Drug has not been approved else were. It is a IND/ND.	Section 3(ii) was inadvertently mentioned "None", I would like to clarify that Study drug (Linaclotide) has been approved in US, Canada, Japan, China and EMA region, however Linaclotide have not been marketed in India yet. Sponsor (Dr. Reddy's Laboratories Limited) is planning to market the product in India. As per Regulatory requirement, sponsor has decided to conduct phase III clinical trial in India. Section 3(iv) The investigational drug has been already approved in other countries however study drug (Linaclotide) has not been approved in India yet. Investigator Brochure copy and DCGI Approval letter had been submitted along with EC dossier. After the Correction Annexure 7 copy attached for the reference.
The total study duration needs to be mentioned.	Total study duration around 16 weeks (4 weeks screening including pre-treatment period, 12 weeks treatment period). We had captured this information in Annexure 07.
Why use direct identifiers?	We would like to clarify that patient confidentiality would be maintained strictly as per guideline through-out the study and we are capturing only subject initials and subject number in the source note. We will not share any subject related confidential information except for Regulatory Authority requirements.

The reply to above Comments was forwarded and reviewed by PR:-
Second opinion of PR:

- Using direct identifiers is not acceptable.

The reply from PR to the above Comments was forwarded to PI:- Response received from PI which was forwarded to the PR vide this office letter no. 1627/Ethics/2022 dated 19th December, 2022.
Recommendation of PR:-

- Explanation and description of indirect identifiers not acceptable.

The following documents were reviewed in the Meeting:-

S.No	Document	Date
1-	Study Protocol	Ver. 2.0, 02-05-2022
2-	Study Protocol Signature Page	NA
3-	Investigator brochure	Ver. V 1.0, 13-05-2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

4-	Patient Information Sheet English	Ver. 2.0, 02-05-2022
5-	Patient Information Sheet Hindi	Ver. 2.0, 02-05-2022 translated from English to Hindi on 08 Jun 2022
6-	ICF English	Ver. 2.0, 02-05-2022
8-	Patient Diary English	Ver. 2.0, 02-05-2022
9-	Translation Certificate	NA
10-	Case Report Form	Ver 1.0 dated 15 Mar 2022
11-	DCGI Approval letter	25-04-2022
12-	Clinical Trials Insurance Policy	01 Mar 2022 to 28 Feb 2023
13-	Investigator Undertaking	NA

EC Decision: Approval subject to fulfillment of administrative formalities with condition ***"does not use any subject identifiers except initials & subject".***

Ref. code: 117th ECM IIC/P2

3- Clarification of research Protocol no. GLK-2101 entitled ***"A randomized, assessor-blind, placebo controlled, multi center, clinical endpoint bioequivalence study to compare the efficacy and safety of generic fluticasone propionate inhalation aerosol USP 44mcg (Glenmark Pharmaceuticals Ltd) to flovent HFA (Fluticasone propionate inhalation aerosol) 44mcg (GSK Group of Companies) in treatment of patients with bronchial asthma"*** sponsored by M/s Glenmark Pharmaceuticals Ltd. B/2 Mahalaxmi Chamber submitted by Prof. R.A.S Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. RM/CT/07/2022 dated 21st November, 2022.

Previous EC Comment	PI response
PI needs to know the difference between study duration and duration of subject participation.	As per the sponsor study completion date is expected Dec 2023 the study duration is started after the EC approval for KGMU site. Total Study Duration is 04 week per enrolled subject, as per the study design total 07 days is screening period and 14 days is a Run in period and 04 weeks is a treatment period for each enrolled subject in the study.
PI to kindly furnish document by DCGI that states that Direct Identifiers should be used.	As per your valuable comment we would like to clarify that patient confidentiality would be maintain strictly as per guideline through-out the study and we are capturing only subject initials and subject number in the source note and

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	subject file. We will not share any subject related confidential information except for Regulatory Authority requirement.
Does the PI doesn't consider that blood and urine as body fluids.	As per the section 07 HbA1c, Hematology, Blood Chemistry and urine pregnancy test (for Female subject only) will be tested for safety parameters.
Correct and updated form not submitted.	After the correction updated form submitted for your reference.

The reply to above Comments was forwarded and was reviewed by PR:-
Recommendation of PR: Provisionally Approved
The following documents were reviewed in the Meeting:-

1. Protocol GLK-2101_Version 2.0 dated 10-Jan-2022.
2. Investigator Brochure Version 1.0 dated 07-Dec-2021.
3. Case Report Form_ GLK-2101_CRF_V2.0_01-Mar-2022
4. Patient Information Sheet & Consent form in Core_2.0 dated 04-Mar-2022
5. Patient Information Sheet & Consent form in Core_2.0_Hindi_2.0 dated 09-Mar-2022
6. Patient Information Sheet & Consent form in Core_2.0_Hindi_2.0 dated 09-Mar-2022 Back Translated from Hindi to English on 10 Mar 2022
7. GLK-2101 Subject Diary Run In Period Version 1.0 Dated 13-Jan-2022
8. GLK-2101 Subject Diary Run In Period Version 1.0 Dated 13-Jan-2022 Translated from English to Hindi on 01-Feb-2022
9. GLK-2101 Subject Diary Run In Period Version 1.0 Dated 13-Jan-2022 Back Translated from Hindi to English on 01-Feb-2022
10. GLK-2101 Subject Diary Treatment Period Version 1.0 Dated 13-Jan-2022
11. GLK-2101 Subject Diary Treatment Period 1.0 Dated 13-Jan-2022 Translated from English to Hindi on 01-Feb-2022
12. GLK-2101 Subject Diary Treatment Period Version 1.0 Dated 13-Jan-2022 Back Translated from Hindi to English on 01-Feb-2022
13. GLK-2101 Rescue Medication: Subject Instructions for Use Leaflet Version 1.0 Dated 13-Jan-2022
14. GLK-2101 Rescue Medication: Subject Instructions for Use Leaflet Version 1.0 Dated 13-Jan-2022 Translated from English to Hindi on 01-Feb-2022
15. GLK-2101 Rescue Medication: Subject Instructions for Use Leaflet Version 1.0 Dated 13-Jan-2022 Back Translated from Hindi to English on 01-Feb-2022
16. GLK-2101 Study Drug: Subject Instructions for Use Leaflet Version 2.0 Dated 11-May-2022
17. GLK-2101 Study Drug: Subject Instructions for Use Leaflet Version 2.0 Dated 11-May-2022 Translated from English to Hindi on 13-May-2022
18. GLK-2101 Study Drug: Subject Instructions for Use Leaflet Version 2.0 Dated 11-May-2022 Back Translated from Hindi to English on 13-May-2022
19. Translation Certificates of Subject Diary and Leaflets
20. Insurance Certificate Number: 4067-GLK-2101 Valid from 01 July 2021 to 30 June 2022
21. CTRI_Published Dataset
22. GLK-2101_FORM CT-17_16-Feb-2022 (License Number TLCT22000053)
23. GLK-2101_Revised ICF_Version 2.0_Notification to DCGI_11-Mar-2022
24. CT NOC Version 1.0 dated 16-Feb-2022
25. CT NOC correction letter dated 25-Feb-2022
26. PI CV & MRC

EC Decision: Approval subject to fulfillment of administrative formalities.

Ref. code: 117th ECM IIC/P9

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

4- Clarification of research proposal entitled AVT06-GL-C01 Version: Version 2.0,21 December 2021 entitled "*A randomized, double-masked, parallel-group, multicenter clinical study to evaluate the efficacy and safety of AVT06 compared with EU-Eylea® in subjects with neovascular (Wet) age-related macular degeneration (ALCOEYE)*" sponsored by M/s Alvotech Swiss AG Thurgauerstrasse submitted by Prof. Sandeep Saxena, Department of Ophthalmology, King George's Medical University, U.P., Lucknow, vide letter no. 1567/OPh/2022 dated 18th November, 2022.

Previous EC Comment	PI response
The Sponsor information in form and DCGI documents is different.	As mentioned in the DCGI Submission letter dated 17 May 2022 ,duly submitted to the Ethics Committee dated .....Kindly note that IQVIA is the CRO applicant and submitted the study details to the DCGI on behalf of the sponsor(ALVOTECH). A Letter of Authorization has been submitted to DCGI. Hence in the DCGI. Approval letter it was addressed to IQVIA. the sponsor name is not mentioned in DCGI letter as CRO IQVIA has submitted the application to DCGI to conduct the CT in India. The sponsor 2 name mentioned in form is correct and same is mentioned in Protocol and DCGI Submission Letter. The Sponsor name and Address is Alvotech Swiss AG Thurgauerstrasse 54 8050 Zurich Switzerland.
What investigations will be done locally?	Below investigations will be done locally- 1. Informed Consent 2. Demographics 3. Medical History 4. Complete physical examination including height and weight 5. Vital Signs 6. 12 Lead ECG 7. Examinations of Eyes (BCVA, IOP, Slit lamp, Indirect Ophthalmoscopy, SD-OCT, Fundus Angiography, Fundus Photography) 8. Urine Pregnancy test 9.Blood Sampling (Hematology, Clinical Chemistry and Urinalyses) Blood will be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	withdrawn at site i.e locally and processed and will be sent to central laboratory for the results. Local laboratory results are only required in the event that the central laboratory results are not available in time for either study treatment administration and/or response evaluation. If a local sample is required, it is important that the sample for central analysis is obtained at the same time. Additionally, if the local laboratory results are used to make either a study treatment decision or response evaluation, the results must be entered into the eCRF.
What tests and imaging will be done for this study and how will data be transferred securely for central imaging review?	SD-OCT, Fundus Fluoresceine Angiography and Fundus Photography will be performed by using subject ID given by sponsor maintaining confidentiality and securely from certified device the images will be transferred to pendrive and then will be uploaded in imaging portal of central imaging center.
PI Needs to know difference between study duration and duration of subject Participation.	As mentioned in the protocol the total study Duration is 56 weeks for each subject participation. The duration of study depends on the (competitive) enrollment period and the number of subjects enrolled at the site level.
Confidentiality and privacy section not filled.	Confidentiality and privacy section updated in enclosed form.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:

- Despite pointing out, PI is unable to address the difference between study duration and duration of subject participation needs to be clarified. Subject recruitment cannot go on or ever.

The reply from PR to the above Comments was forwarded to PI:- Response received from PI which was forwarded to PR:-
Recommendation of PR:

- The proposal was discussed in the meeting held at KGMU and comments given.

EC Comment:

- Study Design, Please clarify:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Recruitment Period, Please clarify:

EC Decision: Approval subject to modification

Ref. code: 118th ECM IIC/P1

5- Clarification of research protocol no. ODM-203-201 entitled ***"A phase II open-label trial evaluating the efficacy and safety of once daily Oral ODM-203 in patients with unresectable transitional cell urothelial carcinoma with FGFR3 mutation (TEJAS-1)"*** sponsored by M/s Aurigene Discovery Technologies Ltd. submitted by Dr. Sudhir Singh, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 278/RT/2022 dated 18th June, 2022.

S.no.	Previous EC Comment	Response by PI
1-	Mention the duration of study in section III	Study duration-02 years
2-	Mention that there could be minimum discomfort on eating the tablet.	Minimum discomfort while consuming tablet size is not large.
3-	Do not use the direct identifier	We are not using the direct identifiers; details of patients will be in coded format.

The reply from PR to the above Comments was forwarded to PI:- Response received from PI which was forwarded to PR:-
Recommendation of PR:
Approved

The following documents were reviewed in the Meeing:-

S.No.	Name of Documents	Version/Reference No. and Date of the Document
1	Clinical Trial protocol	Version 1.0, Dated: 22-Feb-2021
2	Protocol Signature Page (PSP)	Signed date: 13-dec-2021
3	Investigator Brochure (IB)	Version 9.0, Dated: 22-Feb-2021
4	Informed consent form- English	**1.**Pre-Screening Consent Form Version-1.2 dated 220ct 2021 (Consent Form-A) **2.** Informed Consent Form Version 1.1 dated 21 Jul 2021 (Consent Form-B) **3.** Patient consent for audio-visual (av) consenting process Version 1.1 dated 21 Jul 2021 (Consent Form-C) **4.** Informed Consent for Pharmacokinetic (Pk) Sample Collection in Cycle -1 Version 1.1 dated 21 Jul 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			(Consent Form-D) 5. Informed Consent for Pharmacokinetic (Pk) Sample Collection for Cycle -2 Or Onwards Version 1.1 dated 21 Jul 2021(Consent Form-E) 6. Patient Diary: Version 1.0 dated 21 Jul 2021
	5	Translate Informed consent form- Hindi	1.Pre-Screening Consent Form Version-1.0 dated 17/Aug/2021 (Consent Form-A) 2.Informed Consent Form Version 1.0 dated 17/Aug/ 2021 (Consent Form-B) 3. Patient consent for audio-visual (av) consenting process Version 1.0 dated 17/ Aug/ 2021 (Consent Form-C) 4. Informed Consent for Pharmacokinetic (Pk) Sample Collection in Cycle -1 Version 1.0 dated 17/Aug/ 2021 (Consent Form-D) 5. Informed Consent for Pharmacokinetic (Pk) Sample Collection for Cycle -2 Or Onwards Version 1.0Dated 17/Aug/2021(Consent Form-E) 6. Patient Diary: Version 1.0 dated 17/ Aug/2021
	6	Translation Certificate-Hindi	Dated: 17/Aug /2021 (Consent form B, C, D, E and Patient Diary final)
	7	Back-Translated Informed Consent Forms - Hindi	1.Pre-Screening Consent Form Version 1.0, dated 2/sep/2021 (Consent Form-A) 2.Informed Consent Form Version 1.0, dated 2/Sep/2021 (Consent Form-B) 3.Patient consent for audio-visual (AV) consenting process Version 1.0, dated 2 Sep 2021 (Consent Form-C) 4.Informed Consent for Pharmacokinetic (Pk) Sample Collection in Cycle -1 Version 1.0, dated 2/Sep/2021 (Consent Form-D) 5.Informed Consent for Pharmacokinetic (Pk) Sample Collection for Cycle -2 Or Onwards Version 1.0, dated 2/Sep/2021 (Consent Form-E) 6.Patient Diary: Version 1.0, dated 2 Sep 2021
	8	Back Translation Certificate-English to Hindi	Consent form-A ODM-203-201 Prescreeing consent form Version 1.2 22/ct/2021
	9	FACT-BL-English	Version 4 date 16 Nov 2017
	10	FACT-BL-English_Hindi	Version 4 date 13 Sep 2017

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	11	FACT-BL Scoring Guidelines	Version 4
	12	Note to file	PK time points and PK manual
	13	Note to file	FGFR Mutation test
	14	Investigator Undertaking	--------
	15	Principal investigator CV/ Medical Registration Certificate	Signed date: 16/Jan/2022
	16	FDA3455 of Principal Investigator	Dated: 25/Feb/2022
	17	CT Insurance Risk cover letter	Policy No. 030P000403700000 Dated: 27/Sep/2021 Time Period: 15th November2021 to 14th November 2022
	18	DCGI Approval Letter	CT-06 No. CT/ND/83/2021
	19	CTRI NO.	REF/2021/08/046579
	20	EC registration No.	ECR/262/Inst/UP/2013/RR-19
	21	Bioanalytical Accreditation Certificate	IND-19.6620/U, dated:12/Mar/2019
	22	Central Lab CAP certificate	CAP No; 7142801
	23	Central lab Accreditation certificate	MC-3124, Issue Dated: 03/02/2019
	24	SAE reporting form	Draft
	25	Pregnancy form Part A	Draft
	26	Pregnancy form Part B	Draft
	27	Clinical Trial agreement	Draft
	28	Case Report form	Draft
	23	Central lab Accreditation certificate	MC-3124, Issue Dated: 03/02/2019
	EC Decision: Approval subject to fulfillment of administrative formalities. ***Ref. code: 117th ECM II C/P1***		
IIC	**Review of New Drug Trial**		
1.	Research protocol no. 22-07 entitled "*An active post-marketing surveillance study to*		

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	evaluate the safety of measles & rubella vaccine (Live) I.P. (Freeze Dried) of M/s Zydus life-sciences limited in healthy subjects aged 9-12 months" sponsored by M/s Zydus Lifesiences Limited submitted by Dr. Nishant Verma, Additional Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow, vide letter no. 2500/Ped/2022 dated 6th October, 2022. ***Recommendation of Primary reviewer:*** • Attached documents -1. Subject diary card (E/H) 2. Investigator brochure and Undertaking by investigator 3. DCGI permission letter 4. CTA document (but not signed by PI) 5. Budget-Rs. 11,000/per subject 6. Insurance- till 19-03-2023 7. CTRI –missing and according to PI will be given to EC before screening of 1st subject. • IP –Measles and Rubella combined vaccine (live) I.P. (freeze dried) at 9 months of age. • Co-investigator, Dr. Neeraj Anand's details are missing • Sample size detail is not given (only total subjects number-1900 is given) • Details of different other centers in the country where study is going on are missing • Separate summary of Synopsis/ Protocol by PI is not given • PI to submit CTRI document to EC before screening of 1st subject as told by him • Insurance must be renewed after 19-03-2023 **EC Comment:** • As above **EC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: 120th ECMIIC/P1***
2.	Research protocol no. CP/03/22; NV-05-1387-2022 entitled "***A randomized, double blind, placebo-controlled, prospective, multicentre, phase2, dose-finding study of itraconazole administered as a dry powder for inhalation (PUR 1900) in adult subjects with asthma and allergic bronchopulmonary aspergillosis (ABPA)***" sponsored by M/s Cipla Ltd. submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. Res/CT/26/2022 dated 1st October, 2022. ***Recommendation of Primary reviewer:*** • Details of centres to be involved in the study trial across India not given • CTA document with budget is attached but PI mentioned in summary is not applicable-please specify. • CTRI document not attached? –Whether after approval from EC/ after start of trial –please specify. • Insurance is going to expire on 31st March, 2023–should be renewed. **EC Comment:** • As above **EC Decision:** Approval subject to modification, give responses in a tabular format.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 120th ECMIIC/P2
3.	Research protocol no. MC/PLX/22-002 version 1.0/05 May, 2022 entitled ***"An open label, randomized, prospective, multicentric clinical trial to evaluate the efficacy and safety of parenteral placentrex with oral Azitjromycin ve oral asithromycin alone in chronic and recurrent pelvic inflammatory disease"*** sponsored by M/s Albert David Limited, Kolkata, India submitted by Prof. Amita Pandey, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1972/22 dated 16th September, 2022. ***Recommendation of Primary reviewer:*** • Can SR be taken as Co-PI in clinical trials –please justify (open discussion in EC) • PI did not submitted summary of Protocol • Details of other sites involved in this trial –please mention • CTA –Document not signed • ICF- not attached (but given in summary of documents) • CTRI document missing (Whether after approval from EC/ after start of trial)– please specify. **EC Comment:** • As above **EC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: 120th ECMIIC/P3***
4.	Research protocol no. LYT-100-2022-204 entitled ***"A randomized double-blind, four-arm active and placebo-controlled dose-finding trial to evaluate the efficacy, tolerability, safety and dose response of LYT-100 in patients with idiopathic pulmonary fibrosis (IPF)"*** sponsored by M/s Pure Tech LYT 100 Inc.6 Tide street, Suite 400 Boston MA 02210 submitted by Prof. Santosh Kumar, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1236/22 dated 17th November, 2022. ***Recommendation of Primary reviewer:*** • In Scientific review committee no Faculty from Respiratory Medicine or Medicine Department has taken part (All members are from Department of Surgical Oncology) -Please revise or justify • PI did not submitted summary of Protocol • CTRI document–missing (Whether after approval from EC/ after start of trial)– please specify. **EC Comment:** • As above **EC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: 120th ECMIIC/P4***
III A-	**Additional Document**
1.	Additional of research protocol no. EX9536-4388 SELECT entitled ***"Semaglutide effects***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	on cardiovascular outcomes in people with overweight or obesity" submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 361/Cardio/Res/22 dated 19th October, 2022. *Recommendation of Primary reviewer:* • The trial is near its completion. • Attachments approved & noted **EC Decision:** Approval subject to fulfillment & Administrative formalities. ***Ref. code: 92nd ECM IIC/P1***
III-B	**Modification**
2.	Modification of research protocol entitled ***"Tools for the integrated management of childhood illness evaluation of pulse oximetry and clinical decision support algorithms in primary care pragmatic cluster randomized controlled trial, with embedded mixed methods, cost and cost-effectiveness studies in India and Tanzania"*** submitted by Prof. Shally Awasthi, Head, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 380/PATH/10/2022 dated 10th October, 2022. *Recommendation of Primary reviewer:* • Project has already been approved during a previous meeting of the IEC. Proposed modifications to the Protocol/ICF may be approved. **EC Decision:** Approval subject to modification. ***Dr. Shally Awasthi did not take part in the discussion & making decision.*** ***Ref: code: 103rdECM IC/P2***
3.	Modification of research protocol no. EX9536-4388 version 7.0 SELECT entitled ***"Semaglutide effects on cardiovascular outcomes in people with overweight or obesity"*** submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 344/Cardio/Res/2022 dated 11th October, 2022. *Recommendation of Primary reviewer:* • Project has already been approved during a previous meeting of the IEC. Proposed modifications to the Protocol/ICF may be approved. ***The following documents were reviewed in the Meeting:-***

Section No.	Documents
1.	Protocol Protocol Version 7.0 dated 09 Feb 2022-10-03 Track Change of approved protocol from version 6.0 to version 7.0
2.	Subject Information/Informed Consent – Genotyping 2.1 Version_1.0_IN_EN Dated 04 March 2022 Forward Translation 2.2 Version_1.0_IN_HI Dated 15 March 2022. Back Translation 2.3 Version_1.0_IN_HI_BT Dated 28 March 2022. Translation certificate: Hindi
3.	Subject Information/Informed Consent - Home Health Care Service 3.1 Version_1.0_IN_EN Dated 22 Feb 2022-10-03

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Forward Translation 3.2 Version _1.0_IN_HI Dated 15 March 2022 Back Translation 3.3 Version_1.0_IN_HI_BT Dated 28 March 2022 Translation certificate: Hindi
	4.	Subject Information/Informed Consent - COVID 19 Co-Participation 4.1 Version_1.0_IN_EN Dated 20 March 2022 Forward Translation 4.2 Version_1.0_IN_HI Dated 28 March 2022 Back Translation 4.3 Version_1.0_IN_HI_BT Dated 31 March 2022 Translation certificate: Hindi

EC Decision: Approval subject to fulfillment & Administrative formalities

Ref: code: 92nd ECM IIC/P1

Minutes of 121st IEC Meeting virtually held on 10-02-2023 from 2.00 PM.

A — **Action taken**

1- Clarification of research proposal entitled ***"Effect of vocational rehabilitation in myocardial infarcation patients and returning back to their work after myocardial infarction"*** submitted by Ms. Meenakshi Mishra, Ph.D. Scholar 2019 under the guidance of Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 564/Cardio/Res/2023 dated 19th January, 2023.

Previous EC Comments	PI response
This appears to be a PhD Thesis of 2019 enrollment. It's at least 3 years from enrollment time and research work has not yet been approved.	It is true that my enrollment for the PhD program happened in 2019, dated 30-Oct.,'19.The delay in submission is gratefully acknowledged & is explained as underneath. Please bear in mind that it was around the same time the initial reports of Covid-19 pandemic also started trickling in and we had, by Dec..'19 started masking ourselves etc. which continued as late as March/April 2022. These were extraordinary times when normal lives at the workplace, homes, society, country & at the International level were thrown completely out of gear. What was badly affected was our daily professional lives

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		in the department such as meeting deadlines, patients needs, staggered presence of the personnel etc, tasks which could not be compromised at any costs! Needless to mention, we lost a large number of colleagues & struggled to ensure our living with safety. Despite all the existing dangers & calamities, I continued devoting time to my departmental assignments including my efforts to identify a research proposal with my mentor, Prof. Dwivedi. He was kind enough to provide me time to draw a thumbnail sketch of what we wished to pursue for my PhD program, in spite of the ongoing, unprecedented COVID crisis adversely affecting departmental affairs. Our efforts succeeded when we got the approval for the constitution of the Doctoral Committee on 23 May,'20 before I could begin my mandatory PhD Foundation Course. Subsequent to the approval of Doctoral Committee on 8 Oct.,'21, I submitted my proposal for Ethical Committee (EC) clearance on 13 Oct.,'21 whose meeting was held on 4 Dec.,'21 which suggested some recommendations for modifications/clarifications delivered to me on 22 Dec.,'21. Only after the final result of my PhD Foundation Course, I was technically eligible for reviewing and rewriting my proposal as per EC comments and resubmitted to EC on 24

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	appreciate your help and consideration.
Can a PhD candidate be called PI?	Yes, a PhD candidate can be called PI for their research proposal. Since a PhD candidate will be responsible for their review of literature, gathering of data & its collation under the guidance of their mentor, results, conclusions drawn from the study etc., this seems to be logical.
The PI mentions in section 10 that the risks are unreasonable, when compared to benefits, to conduct this study. Thus, the research is unethical and cannot be approved.	I tender my humble apologies for the error that has crept into my inadequate expression of the risks & benefits issues. There would be minimal risk(s) involved with the patient's visits to the department since they have to commute plus they would be exposed to other patients in the department when they visit for follow ups. However, these risks are 'minimal' considering the benefits that would be derived from conducting the study. We are simply collecting the data, organizing it properly, deriving our results & concluding the study etc. which should be of immense help to the scientific community in general as well as to the patients in particular.

The above Comment forwarded to PI was reviewed by PR vide this office letter no. 1931/Ethics/2023 dated 20th January, 2023.

Recommendation of PR:

- No statistical plan is mentioned.
- The revisions mentioned in the table have not been incorporated into the proposal.
- I don't think that 15 patients will be good enough to tease out the difference in the 2 groups.
- Computer based randomization is not a type of randomization.
- The fact that Heathify. Me is an Indian app doesn't justify the privacy issues, Multiple other issues.
- Would suggest that another Committee member reviews it.

EC Comment:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Kindly correct the title of the proposal. **EC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref: code: 113th ECM IIB-Ph.D/P3***
2-	Clarification of research proposal entitled "***Identification and characterization of novel molecular biomarkers with prospects of targeted drug therapy development in pediatric B-Cell acute lymphoblastic leukemia (ALL) with diverse genetic subgroups***" submitted by Dr. Nishant Verma, Additional Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no.146/Ped/2023 dated 11th January, 2023.

Previous EC Comments	PI response
Bio-Banking will be done. This has not been mentioned in the consent form.	The consent and assent forms have been revised to include this point.
Where the consent form is also that bio-banking will follow the Institutional IPR policy for out cases of bio-banking.	The consent and assent forms have been revised to include this point.

The above Comment forwarded to PI was reviewed by PR vide this office letter no. 1930/Ethics/2023 dated 20th January, 2023.
Recommendation of PR:

- The IEC number and title of the submitted proposal and one given in checklist don't match.

EC Decision: Approved

Ref. code: 114th ECM IIA/P19

3- Clarification of research proposal entitled "***Lung oscillometry registry for patients with various Respiratory disorders and healthy subjects (LEAD Study)***" submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1319/2022 dated 10th December, 2022.

Previous EC Comment	PI response
The sponsor information indicates that private sponsor is both from India as well as international. The name is not indicated. There is no address indicated as well. Kindly indicate the name of sponsor and Its correspondence with principal investigator officially.	The study is self-sponsored by Chest Research and Training (CREST) where the study is initiated.
A few responses in annexure are left blank such as use of existing/ leftover samples.	There are no biological samples involved in this study.
The study procedure indicates that study is going on in & quote; 18 different centers of the world The list of investigators attached show 18 centers in	This is NOT an internationally sponsored research. As of now, we are not receiving any data from international sites. Since it's a newly initiated network, there is

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	India- So what other centers of world are collaborating in this international sponsored private party research? Kindly indicate.	only one International university with whom we have an agreement signed. But the study has not been initiated. With regards to National sites, the numbers of sites who have registered in the network till date are 31 registered doctors across India. The number of investigators will keep on getting added as doctors across the country wish to be a part of this registry research.
	Kindly also mention the various centers where these 18 investigators are based in India. Who is the lead person? Will multi-Centre data is combined for analysis? If Yes then where exactly the analysis will be done? What will be the situation of Intellectual property rights issue?	The number of investigators will keep on changing as and when doctors register. For more details please visit the following link: https://lungoscillometry.com/arise-network-members-India/. The lead of the study is Dr Sundeep Salvi, as this study has been proposed by him, however all the investigators will be the Co-PIs. Yes multi-centre data will be combined for analysis. The analysis will be conducted by the statistics Department at Chest Research and Training (CREST) and ARISE Network in Pune. The IP, in terms of site data will always be the IP of the respective investigator. And all investigators who contribute to the data will be duly cited in the publications. If the research idea belongs to a particular investigator he/she will be the PI for that research idea.
	Give a brief account on outcome parameters and statistical analysis	The outcome parameters have been well explained in the protocol that has been shared by the ARISE team with the KGMU team.
	What is the speculated sample size overall and in KGMU (expected).	There is no particular estimated sample size as this is a registry. As per the site and its capacity, the data can be shared accordingly. The sequence of authorship in publication will be as per the number of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Subjects data shared by each site.
While undertaking by principal investigator indicates that it is a multicentric international study, the name and address of other medical institutes/Hospital is missing.	Physicians- Dr Mahesh PA (Mysore), Dr B V Murali Mohan (Bangalore), Dr Deepak Talwar (Noida), Dr Surya Kant Tripathi (Lucknow), Dr Parthasarathi Bhattacharyya (Kolkata), Dr Nandagopal Velayuthaswamy(Coimbatore),Dr Jaymohan Unnithan (Coimbatore), Dr Srikanth Krishnamurthy(Coimbatore), Dr Nagarajan Srinivisan (Coimbatore), Dr Saibal Moitra (Kolkata), Prof. (Dr) Sajal De, (Chattisgarh), Dr Lancelot Pinto (Mumbai), Dr Suhas Bardapurkar (Aurangabad), Dr Harshavardhan Vhora (Baramati), Dr Syed Tousheed (Bangalore), Dr Suma P Kumar, (Bangalore), Dr Atri Gangopadhyay, (Jharkhand) Dr V. Nagarjuna Maturu (Hyderabad), Dr Saili Bendre (Mumbai), Dr Vivek Vardhan Veerapaneni (Hyderabad), Dr Rahul Sharma (Noida), Dr Ragini Diwan (Kolhapur), Dr P Arjun (Trivandrum), Dr Swati Behera Sharan (Jharkhand), Dr N.K. Kalappanavar (Karnataka), Dr Nirupam Sharan (Jharkhand) Paediatricians- Dr Indu Khosla (Mumbai), Dr Ilin Kinimi (Bangalore), Dr Sagar Warankar (Mumbai), Dr Sainath Powar (Kolhapur), Dr. Rashmi Kapoor (Kanpur).
In executive summary the methodology indicates following locations in India as well as from international countries but neither any Indian nor foreign Centre is Mentioned.	The protocol shared by ARISE to team KGMU does include details of the other investigators. However kindly refer to the link for all members who are registered as this will keep changing as and when Investigators register.
The methodology selection further states that data will be captured at clinics and hospitals while study Centre (in material and methods) indicates only KGMU. Kindly resolve the discrepancy.	Physicians- Dr Mahesh PA (Mysore), Dr B V Murali Mohan (Bangalore), Dr Deepak Talwar (Noida), Dr Surya Kant Tripathi (Lucknow), Dr Parthasarathi Bhattacharyya (Kolkata), Dr Nandagopal Velayuthaswamy(Coimbatore), Dr Jaymohan Unnithan (Coimbatore),

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Dr Srikanth Krishnamurthy(Coimbatore), Dr Nagarajan Srinivisan (Coimbatore), Dr Saibal Moitra (Kolkata), Prof. (Dr) Sajal De, (Chattisgarh), Dr Lancelot Pinto (Mumbai), Dr Suhas Bardapurkar (Aurangabad), Dr Harshavardhan Vhora (Baramati), Dr Syed Tousheed (Bangalore), Dr Suma P Kumar, (Bangalore), Dr Atri Gangopadhyay, (Jharkhand) Dr V. Nagarjuna Maturu (Hyderabad), Dr Saili Bendre (Mumbai), Dr Vivek Vardhan Veerapaneni (Hyderabad), Dr Rahul Sharma (Noida), Dr Ragini Diwan (Kolhapur), Dr P Arjun (Trivandrum), Dr Swati Behera Sharan (Jharkhand), Dr N.K. Kalappanavar (Karnataka),Dr Nirupam Sharan (Jharkhand) Paediatricians- Dr Indu Khosla (Mumbai), Dr Ilin Kinimi (Bangalore), Dr Sagar Warankar (Mumbai), Dr Sainath Powar (Kolhapur), Dr. Rashmi Kapoor (Kanpur). The protocol shared by ARISE to team KGMU does include details of the other investigators. However kindly refer to the link for all members who are registered investigators register.
The only single investigator may be over burdened with this non-funded study. Will it be feasible all alone by a single Investigator?	Yes	

The reply from PI to the above Comments was forwarded to PR vide this office letter no.1805/Ethics/2023 dated 2nd January, 2023.

Recommendation of PR:

- To attach the original proposal (Correspondence) of CREST and ARISE network.
- To attach the full designation of all the investigators involved.
- To attach patient information sheet both in English & Hindi.
- Kindly mention the names of various centers involved in the study (National & International) rather than referring the EC to link.

EC Comment:

- As above

EC Decision: Approval subject to modification, give responses in a tabular format.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: 115th ECM IIA/P13

4- Clarification of research protocol no. CA-170-302 entitled ***"A phase IIB/III, randomised, double-blind, placebo-controlled, study title: A multicentre, study of CA-170 in combination with chemotherapy in patients with stage IV non-squamous non-small cell lung cancer (ASIAD-3)"*** sponsored by M/s Aurigene Discovery Technologies Limited submitted by Dr. Sudhir Singh, Associate Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 1401/RT/2022 dated 20th December, 2022.

Previous EC Comment	PI response
PI needs to know the difference between Study duration and the duration of subject participation and specify accordingly.	Study duration-50 years duration of subject:- 1- Treatment induction-02 years 2- We will watch subjects after induction at last for 03 years.
PI is rigid on the use of direct identifiers, despite being advised against it. PI to kindly furnish document by DCGI/ justification that states that Direct Identifiers should be used.	We are not using the direct identifiers.
Why use vulnerable subjects like Pregnant women?	We are not using vulnerable subjects in this study like pregnant women.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Provisionally Approved
The following documents were reviewed in the Meeting:-

S. No	Name of Documents	Version/Reference No. and Date of the Document
1	Clinical Trial protocol	Version 1.0, dated 21 Jun-2021
2	Protocol Signature Page (PSP)	02-Nov-2021
3	Investigator Brochure (IB)	(Version 5.0, dated 18-Jun-2021)
4	Informed consent form- English	12-Aug-2021 Version 1.1, 12 Aug 2021
5	Prescreening Informed Consent Forms-English	Version 1.1, 12 Aug 2021
6	Patient Diary	Version 1.1, dated 05-Aug-2021
7	Informed consent form- Hindi	Version1.0, dated 08-Sep-2021
8	Patient Diary	Version1.0, dated 08-Sep-2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

9	Prescreening Informed consent form-Hindi	Version1.0, dated 08-Sep-2021
10	Translation certificates-Hindi	08-Sep-2021
11	Translation certificates-English	25-Sep-2021
12	Back Patient diary- English	Version 1.0, dated 25-Sep-2021
13	Back Translated Informed Consent forms-English	Version 1.0, dated 25 Sep-2021
14	QLQ- LC13 English	EORTC QLQ- LC13
15	QLQ-LC13 Hindi	EORTC QLQ- LC13
16	QLQ-C30 English	EORTC QLQ- C30
17	QLQ-C30 Hindi	EORTC QLO- C30
18	Investigator Undertaking8	7-Dec-2021
19	Principal Investigator.CV	16-Jan-2022
20	Principal Investigator MRC	16-Jan-2022
21	FDA	12-JULY-2021
22	CT Insurance	Policy No.030P0004022000000 Dated: 21-Sep-2021
23	DCGI approval letter	CT-06 No.CT/ND/107/2021 Dated: 28-Jul-2021
24	CTRI Registration	REF-2021/09/047198
25	Bioanalytical accreditation certificate	IND-19.6620/U, Dated: 12-Mar-2019
26	Central Lab CAP Certificate	CAP No: 7142801
27	Central Lab Accreditation Certificate	Certificate No. MC-3124,Dated: 03-02-2019
28	SAE Reporting Form	Final
29	Pregnancy Form Part- A	Final
30	Pregnancy Form Part-B	Final
31	Clinical Trial Agreement	Draft

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

EC Decision: Approval subject to fulfillment & Administrative formalities.

Ref. code: 116th ECM IIC/P4

5- Clarification of research proposal entitled ***"Premature greying of hair in children and adolescents-a case control study analysis of nutritional and biochemical parameters"*** submitted by Dr. Parul Verma, Associate Professor, Department of Dermatology Venerology & Leprosy, King George's Medical University, U.P., Lucknow vide letter no. 06/Skin/23 dated 5th January, 2023.

Previous EC Comments	PI response
Patient information sheet to be attached as per SOP	As per suggestion, now the patient's information sheet has been added.
Sample size calculation need to be elaborated step by step.	Now the detailed sample size calculation has been done.
The prospective outcome variables should be briefly mentioned and categorized as continuous and categorical before detailing the analytical method.	The prospective outcome variables have been categorized as continuous and categorical data. Also, applicable statistical analysis has been mentioned.
Does counting of hairs via hand lens constitute an accepted method (mention reference) or an indigenous way adopted by the investigator?	By indigenous way.
Since the ICF has to be signed by the parents only, the language has to be modified somewhat.	Now the consent has been modified as per the parent's declaration.

The reply from PI to the above Comments was forwarded to PR:-
Second opinion of PR:

- Kindly provide the Guidelines of Patient Information Sheet in English & Hindi as per the SOP of the IEC.

The above comments forwarded to the PI vide this office letter no. 1827/Ethics/2023 dated 10th January, 2023, Reply pending.

EC Decision: Reminder to be sent to Principal-Investigator.

Ref. code: 117th ECM IIA/P20

6- Clarification of research proposal entitled ***"A prospective study to assess the micronutrient levels in COVID-19 recovered patients in a tertiary care Hospital of Northern India"*** submitted by Dr. Arpit Singh, Associate Professor, Department of Orthopedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 6006/OS/22 dated 31st December, 2022.

Previous EC Comment	PI response
Kindly provide sample size calculation.	Sample Size=57, considering a

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Prevalence of 70.4% as per a previous study (Ref:Jothimani, D.; Kailasam, E.; Danielraj, S.; Nallathambi, B.; Ramachandran, H.; Sekar, P.; Manoharan, S.; Ramani, V.; Narasimhan, G.; Kaliamoorthy, I.; et al. COVID-19: Poor outcomes in patients with zinc deficiency. Int. J. Infect. Dis. 2020, 100, 343–349.), Confidence Level of 90% and 10% margin of error. $n = \frac{z^2 \times \hat{p}(1-p)}{\varepsilon^2}$ Formula used is: z is the z score ε is the margin of error N is the population size p̂ is the population proportion
Is all investigations part of Standard protocol? Kindly provide documentary support?	The following micronutrient investigations are prescribed as standard by the Department of Orthopaedic Surgery, KGMU, Lucknow: • Calcium • Iron • Zinc • Selenium • Phosphorus • Vitamin A • Vitamin D • Vitamin B12 • Folate Further documentary support can be retrieved from the article: (Ref: Awasthi S, Kumar D, Mahdi AA, et al. Prevalence of specific micronutrient deficiencies in urban school going children and adolescence of India: A multicenter cross-sectional study. PLoS One. 2022;17(5):e0267003. Published 2022 May11. doi:10.1371/journal.pone.0267003)

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
EC Decision: As above

Ref. code: 117th ECM IIA/P26

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

7- Clarification of research protocol no. BSV-01-2021 entitled ***"A real world prospective study to evaluate the geographical distribution of prevalence, sensitization rate, and utilization of prophylactic treatment of Rh-negative women in India"*** sponsored by M/s Bharat Serum and vaccine limited submitted by Prof. Rekha Sachan, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/CT/13/2022 dated 30th December, 2022.

Previous EC Comment	PI response
Why use direct identifiers?	We are capturing only subject initials and subject number in the source note. We will not share any subject related confidential information to anyone.

The following documents were reviewed in the Meeting:-

S.No	Document	Date
01	Study Protocol	Ver. 1.0 , 30-11-2021
02	Study Protocol Signature Page	Dated 08-07-2022
03	Investigator brochure	NA
04	Case Report Form	Dated 17-01-2022
05	ICF English	Ver. 1.0 , 30-11-2021
06	ICF Hindi	Ver. 1.0 , 30-11-2021
07	Translation Certificate	Dated 30-11-2021
08	Investigator Undertaking	Dated 08-07-2022
09	Investigator CV MRC	Dated 07-05-2022
10	Draft clinical Trial Agreement	NA
11	CTRI Registration Date	CTRI/2022/01/039101
12	Sample Size Justification	NA
13	Study Insurance Justification	Observational Study Insurance not required
14	DCGI Approval Justification	NA

EC Decision: Approval subject to fulfillment & Administrative formalities.

Ref. code: 117th ECM IIC/P10

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

8- Clarification of research proposal entitled *"Correlation of mitochondrial (mtDNA) DNA copy number with toxicity of heavy metals and pesticides in women with unexplained infertility"* sponsored by ICMR, New Delhi submitted by Prof. Sujata Deo, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3698/23 dated 18th January, 2023.

Previous EC Comment

- The sample size is mentioned differently at different place-150 in IEC form and 63/100+100 in the summary.

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of PR:

Provisionally approved

EC Decision: Approved

Ref. code: 118th ECM IIA/P6

9- Clarification of research proposal entitled *"Determinants of readmission to the intensive care unit: A Hospital data based approach"* submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 299/CCU/2022 dated 30th December, 2022.

Previous EC Comment	PI response
There are different annexure including patient consent form, but the proposal details are missing.	Attached

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of PR:

Provisionally approved

EC Decision: Approved

Ref. code: 119th ECM IIA/P2

10- Clarification of research proposal entitled *"Effect of dopamine as VEGF antagonist on progression of sepsis to septic shock, ALI (acute lung injury) and AKI (acute kidney injury)"* submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 349/CCU/2022 dated 30th December, 2022.

Previous EC Comment	PI response
To mention the incidence of septic shock ALI/ AKI in severe sepsis and how much reduction is anticipated? Sample size to be mentioned accordingly.	Six million cases annually in world. One third reduction is expected.
Proper patient information sheet needs to be attached both in English and Hindi.	Attached
The aim indicates estimation of VEGF levels, while no biological samples will be collected as per the submission- How will	Methodology is revised and being submitted. Blood sample is collected for this study.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

assess of VEGF levels be made. As there is no co-investigator other than Department of anaesthesiology where will this VEGF be estimated and how? Also all relevant lab work on such patients may be mentioned in methodology section.	
How will the third aim be assessed i.e. survival benefit? Whether it would be a short-term survival benefit or long-term survival outcomes? What data will be collected in this regard?	Short term Survival benefits will be assessed by three month morality.
A part from describing the methodology in detail also attached the data collecting sheet/ protocol to support the aims and objectives.	Attached
If no biological specimen is to be obtained then what is the role of cytogenetic lab?	Blood sample will be collected.
What will be the dosing schedule of dopamine? Will it be over and above of routine clinical requirement- if yes, then what will be the anticipated adverse effects that further needs to be mentioned in informed consent form?	Dopamine 2-4 mcg/kg/minute. it will be above clinical requirement of the patient and mild tachycardia is anticipated advert event.
The project needs to be re-written with the literature, review, methodology, anticipated data, outcomes and statistical analysis according to all the three aims and objectives.	Done.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:

- Although sample size calculation is submitted, it still needs to be elaborated in terms of specific objective & a proper reference of earlier study needs to be mentioned.
- Not complied. Patient information sheet need to be submitted both in English & Hindi as per SOP.
- Methodology grossly incomplete in relevance to objectives, The CO PI for cytogenetic lab needs to be mentioned. It has to be made clear if the work has to be done in CFAR KGMU or outsourced, in letter case mention the place/opening.
- Needs to be detailed in methodology. Methodology needs to be mentioned in PICO format to make it better. The population aspect is satisfactory but intervention, comparison & outcome categories need to be elaborated.
- Apart from describing the methodology in detail also attach the data collecting

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	sheet/ protocol to support the aims and objectives- Not attached. • Anticipated adverse event is still not added in ICF. • Not complied. Methodology to be rewritten as per the points raised earlier. ***The was forwarded to PI:-*** ***The reply of PI:-*** Pending **EC Decision:** Reminder to be sent to the Principal-Investigator. ***Ref. code: 119th ECM IIA/P3***
11-	Clarification of research proposal entitled "***A study on assessing the role of circulating tumor DNA/circulating free DNA (ctDNA/CfDNA) ratio in oral squamous cell carcinoma progression through RNA sequencing meta-analysis and subsequent real-time PCR***" submitted by Prof. Shaleen Chandra, Head, Department of Oral Pathology & Microbiology FODS, King George's Medical University, U.P., Lucknow vide letter no. 1088/OralPath/23 dated 20th January, 2023. **Previous EC Comments:** • Principal-Investigator has stated that the project is an ICMR multi-centric project; however no communication regarding the same from ICMR has been attached to the proforma. • Budget approximation is presented but the approval from ICMR is not attached. • Answer to the question 'is the risk reasonable' has been mentioned as 'No'. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Second recommendation of PR:*** • Approval of the Multi-centric project from ICMR with inclusion of KGMU as one of the sited and the proper as one of the Co-PIs. • Budget approval from ICMR for expenses related to the study so that the expenses are not passes on to the subjects participating in the study. ***The was forwarded to PI:-*** ***The reply of PI:-*** Pending **EC Decision:** Reminder to be sent to the Principal-Investigator. ***Ref. code: 119th ECM IIA/P7***
12-	Clarification of research proposal entitled "***A comparative study on orientation to adult learning of facilitators of King George's Medical University Lucknow between teaching of undergraduate and postgraduate students***" submitted by Dr. Dilutpal Sharma, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/877/23 dated 10th October, 2022. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **EC Decision:** Approved ***Ref. code: 119th ECM IIA/P14***
13-	Clarification of research proposal entitled "***Evaluation of lignocaine HCl as a therapeutic and diagnostic tool in myofascial pain dysfunction syndrome (MPDS0 and internal derangement***" submitted by Prof. U.S Pal, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

vide letter no. OMSD/182/23 dated 2nd February, 2023.

Previous EC Comment	PI response
What is the need for direct identifiers?	Study involves indirect identifiers. Sample population will be coded in alphabetical order for data recording. Changes have been made in the ethical form.
Efficacy measures are not mentioned.	Efficacy measures are added in the study proforma.
Sample size calculation is not correct.	Corrections have been mad and revised in the proforma.
Case record format is not attached	Case record format has been attached.
As this is an intervention study, and adverse effects can happen, needs to be reported, compensation should be accounted for.	Patch test will be done for every individual before injecting lignocaine to prevent allergic reactions. Nerve palsy after injecting lignocaine will be rare, if oocurs will be transient and resolves on its own. Injection site infection, if occurs will be maganged with appropriate antibiotics. As lignocaine injection is already being used for diagnostic purpose in Temporomandibular disorders, no serious events has been reported in literature till date.

The comments forwarded to PI was reviewed by PR :-

Recommendation of PR:-

- There are 4 groups of patients: Patients who will not have effect of Lignocaine, MPDS, ID, ID+MPDS.
- Measurements are made at 4 time points.
- A difference to detect a difference of 1.3% (of what?) will be detected in 20 patients.
- I don't think this is feasible.
- Outcome measure will be what type of measurements: N/O/I/R?
- Why will direct identifiers be used?

EC Comment:

- As above

EC Decision: Approval subject to modification, give responses in a tabular format.

Ref. code: 119th ECM IIA/P18

14- Clarification of research proposal entitled "***Study of virological profile in Hepatitis B virus infected women of reproductive age***" sponsored by CST-UP submitted by Dr. Sumit Rungta, Head, Additional Professor, Department of Medicine Gastroenterology,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow vide letter no. 1864/MedGastro/23 dated 25th January, 2023.

Previous Comments	PI response
Aims & Objectives	Seroprevalence of HBsAg in women at reproductive age. To study virological profile of reproductive age group of females. To study the spectrum of liver disease severity in reproductive age group of females.
Study Design	In this project we will examine the seroprevalence of hepatitis B surface antigen (HBsAg) prospectively and retrospectively, in the women at reproductive age living in different district of Uttar Pradesh, India.
Methodology	This is a retrospective and prospective study, in which we will examine the seroprevalence of hepatitis B surface antigen (HBsAg), hepatitis Be antigen (HBeAg), antibody to hepatitis B e antigen (anti-HBe) and Serum HBv-DNA will be calculated using a sensitive, commercially available, quantitative PCR assay in the women at reproductive age who are living in different districts of Uttar Pradesh, India. We also access the spectrum/stages of liver disease with the investigation by USG Abd, Fibroscan, and other non-invasive Investigations. This study was carried out in the department of Medical Gastroenterology KGMU, in collaboration with the Dept of Gastroenterology, SGPGIMS Lucknow, India.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Sample Size	Confidence Level: 95%, with the Margin of Error: 5% and the population size 10000, then the sample size will be 385. (This means 385 or more measurements/surveys are needed to have a confidence level of 959% that the real value is within +5% of the measured/surveyed value.)
	Statistical Analysis	Prevalence (Total and Subgroup) with 95% CI will be estimated using a cluster sample approach. The chi-square test will be applied to compare proportions between different subgroups.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 120th ECM IIA/P2

15- Clarification of research proposal entitled "***Comprehensive metabolic fingerprinting of cancer patients: An attempt towards the development of partially non-invasive tool for diagnostic, therapeutic and disease progression***" submitted by Dr. Teerthraj Verma, Additional Professor, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 50/RT/23 dated 21st January, 2023.

Previous EC Comment	PI response
Proposal is incomplete.	Proposal has been revised and completed.
"Aims & Objectives" are not given.	Aims & Objectives are mentioned in Summary of research proposal.
Study design, methodology, sample size calculation, statistical analysis sections are missing.	Study design, methodology, Sample size calculation, statistical analysis mentioned in Summary of research proposal.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 120th ECM IIA/P3

16- Clarification of research proposal entitled "***24 hour glucose profile and beta cell function in women with early gestational diabetes mellitus***" submitted by Prof. Amita Pandey, Department of Obstetrics & Gynecology, King George's Medical University,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

U.P., Lucknow vide letter no. OG/3701/2022 dated 19th January, 2023.

Previous EC Comment	PI response
There are too many primary objectives. There should be one primary objective. The rest should be included into secondary objectives.	Primary objective 1- To study 24 hour glucose profile in women diagnosed with GDM in early pregnancy using the WHO 2013 criteria and compare with women of similar gestational age with normal glucose tolerance. Secondary Objectives 2- To assess beta cell function in women with early GDM 3- To assess maternal and fetal outcomes in women diagnosed with GDM in early pregnancy
After identifying the study variables and study parameters, the objective should be converted into research hypothesis in terms of the study parameters.	Hypothesis: Gestational Diabetes Mellitus (GDM) in early pregnancy is associated with high glycemic variability in comparison to pregnant women with similar gestational age with normal glucose tolerance.
Study design is mentioned as prospective case control study. Case control study is retrospective.	For the primary objective it is a cross-sectional case control study.
Sample size calculations are missing.	Sample size was mentioned in the protocol. It was calculated as 201 with the assumptions of prevalence of early GDM as 38% (data from AIIMS, New Delhi) and 7% margin of error of prevalence at minimum 95% CI. Considering 10% loss to follow up, the size was calculated as 221. We will screen 221 pregnant women <20 weeks to get adequate number of GDM and controls
Statistical analysis section is very general. It should be specific to the research hypothesis.	SPSS version 25.0 will be used for data analysis. All variables will be tested for normality using the Shapiro–Will test, Continuous

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			variables with normal distribution will be presented as mean ± SD. while not normally distributed data will be expressed as median values with their interquartile ranges (IQRs) (25th–75th quartiles) Categorical data will be expressed as counts and percentages. The baseline maternal demographic, clinical and biochemical characteristics of the study group will be compared using ANOVA followed by Tukey (normally distributed parameters) or Kruskal–Wallis followed by Dunn's (for not normally distributed parameters) as appropriate. All outcome measures of glycemic metrics derived from the data from CGMS (AUC, IQR, SD. and amplitude), hourly median values and percentages of time spent in range (blood glucose value 70-180 mg/dl), time in hyperglycemic range (blood glucose vale >180 mg/dl) or time in hypoglycemic range (<70 mg/dl) within the glucose ranges will be compared using Kruskal–Wallis, followed by Dunn's correction. P value < .05 will be considered significant.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:
Provisionally approved
EC Decision: Approved

Ref. code: 120th ECM IIA/P4

17-	Clarification of research proposal entitled "***Growth and development outcomes in severe acute malnutrition (SAM) children discharged from Nutrition rehabilitation centre (NRC): A community based follow up study***" submitted by Mr. Rohitash Kumar, Assistant Professor, KGMU College of Nursing under the guidance of Prof. Monica Agarwal, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 75/2023 dated 16th January, 2023. ***Previous EC Comment:-*** • Revise consent Form as it is being given by the legal Guardian. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Provisionally approved

EC Decision: Approved

Ref. code: 120th ECM II A/P18

18- Clarification of research proposal entitled "***Evaluation of Hyperbric oxygen therapy in OSMF***" submitted by Prof. U.S. Pal, Department of Oral & Maxillofacial Surgery Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 181/OMSD/2023 dated 2nd February, 2023.

Previous EC Comment	PI response
EC comment 1 Annexure needs to be filled up completely such as section of clinical trials,vulnerable subjects,data monitoring and list of attached documents	Present study is not a clinical trial but a prospective study to evaluate HBO therapy in OSMF patients. Role of HBO therapy in OSMF is already described and quoted in references. As this is not clinical trial Data monitoring is not required. Vulnerable subjects are in exclusIon criteria
EC comment 2 The patient information sheet is not attached as per the standard operating procedure contrary to data indicated in annexure I	Patient consent form again filled and attached
EC comment 3 Brief description under required headings is missing	Headings has been put and described
EC comment 4 Review of literature in terms of rationale of using hyperbaric oxygen therapy is not supported by references.the s ide effects of HBOT to be mentioned	As there is not much study conducted, Review of literature is limited. Available literature of HBO in OSMF has been quoted in text. Side effects of HBO therapy has been mentioned
EC comment 5 Recent history of lung diease and chronic lung disease to be added in exclusion criteria	Recent history of ear surgery and chronic lung infection added in exclusion criteria
EC comment 6 In case of dysplasia/malignat changes in osmf are to be excluded ,then biopsy need to be considered in material and methods section.if biopsy to be undertaken in every caseof OSMF ,then this needs	There is no need of biopsy in every case of OSMF, clinical diagnosis is sufficient. If there is any ulcerative lesion incisional biopsy will be done if it comes as dysplasia or malignancy subject will be excluded and added in methodology

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	to be mentioned before hand	section.
	EC comment 7 The study procedure in consent form need to be elaborated in terms of ruling of lung diseases apart from dysplasia /malignant changes.theree area well known remote complications of HBOT .these need to be explained to the patient.	Remote complications added in patient consent form
	EC comment 8 Methodology need to be elaborated a) what is the inclusion criteria specially age b)what pre-therapy investigations need to be carried out c)How will the improvement in mouth opening be judged d)what will be the criteria of declaring significant subjective improvement in spicy food tolerance e)what will be the duration of follow up period	1. Inclusion criteria • Age less than 65 year • Oral sub mucous fibrosis with mouth opening less than 25 mm 2. Pre therapy investigations • In pre-treatment investigations, ophthalmology, ENT and pulmonary clearance will be done to exclude any related pathology 3. Change in mouth opening will be assessed by a surgical scale from upper incisor edges to lower incisor edges during pre-treatment and after treatment. 4. Symptomatic improvement will be assessed by improvement in quality of life. 5. Patient will follow up in duration of after 1 week of every cycle of HBO therapy to monitor results of therapy and any side effects, up to 1 year.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:

- List of attached documents need to be marked in annexure-1
- Patient information sheet is not attached.
- Anticipated statistical analysis needs to be briefed.

EC Comment:

- As above

EC Decision: Approval subject to modification, give responses in a tabular format.

Ref. code: 120th ECM II A/P26

19- Clarification of research proposal entitled "***A retrospective case-note review of subjects with compulsions and obsessions presenting to Geriatric Medicine Health***" submitted by Prof. Shrikant Srivastava, Head, Department of Geriatric Medicine Health, King George's Medical University, U.P., Lucknow vide letter no. 18491/DGMH dated 27th January, 2023.

Previous EC Comment	PI response
To fill in the left out gaps in annexure 1.	Section 6.2 of Annexure 1 been filled as- **Duration of project:6 months from ethical**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		approval.
	The anticipated sample size, duration of project/ analysis may be mentioned	**1-Sample size: According to our current clinical records** database, we have records of 25 cases with Obsessive-Compulsive disorder from the last five years. Following this pattern, we anticipate at least 18 cases with.>_ 1 follow-up visit. **2-Duration of project/analysis:** 6 months from date of ethical approval.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:
Approved
EC Decision: As above

Ref. code: 120th ECM II A/P30

20- Clarification of research proposal entitled "***Efficacy of grid-based dental rubrics as an effective assessment tool when compared to traditional assessment methods for undergraduate students managing a class II carious defect***" submitted by Dr. Rhythm, Professor Jr. Grade, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 464/Coms & Endo/23 dated 16th December, 2023.

Previous EC Comment:-

- Kindly fill the checklist

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR:

- Section 8: Consent elements: not checked
- Outcome measures not mentioned
- Statistical plan: not mentioned
- On what outcome measure the sample size is calculated: not mentioned

EC Comment:

- As above

EC Decision: Approval subject to modification, give responses in a tabular format.

Ref. code: 120th ECM II A/P31

21- Clarification of research proposal entitled "***Role of DNA methylation and autophagy regulator genes in prognosis of non-muscle invasive bladder cancer***" sponsored by CST-UP submitted by Mr. Anil Kumar, Ph.D Scholar under the guidance Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 87/URO dated 19th January, 2023.

Previous EC Comment	PI response
This appears to be a PhD Thesis of 2019 enrollment. It's at least 3 years from enrollment time and research work has not yet been approved. Institute to decide if	**Response:** I had submitted my proposed thesis work entitled Comprehensive

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	this is alright.	transcriptional characterization of ependymoma dated on 10-02-2020 under the supervision of Dr. Neetu Singh, Associate Professor, Department of Centre for Advance Research, KGMU. Due to covid-19 pandemic and also my previous guide left this university, according to university rules in the absence of guide, co-guide Dr. B. K Ojha, Professor, Department of Neurosurgery became as guide to continue the same work. Due to lack of budget and some other reasons, I was unable to continue proposed work further. Therefore, I changed the guide from Dr. B. K. Ojha to Dr. Vishwajeet Singh, Professor, Department of Urology, KGMU, and then I had to change the whole PhD thesis work mentioned as above to current thesis work. For this the new doctoral committee was approved by Hon'ble Vice Chancellor of this university dated on 18-04-2022. The current proposed PhD thesis work was approved in first doctoral committee meeting held on 2 August 2022. Hence after that this proposal was submitted for ethical approval dated on 6th September 2022.
	Can a PhD candidate be called PI?	**Response:** Yes
	The PI mentions in section 10 that the risks are unreasonable, when compared to benefits, to conduct this study. Thus, the	**Response:** Previously it was done by mistake, now it has been corrected in current version of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	research is unethical and cannot be approved.	ethical in section 10. That the risk is reasonable compared to benefits to the subject/ community/ country?

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of PR:

- The title and objectives don't match.
- Why will pre-existing tissue samples be used?
- From where will pre-existing blood samples be collected?
- Where is the consent for bio-banking?
- What is the direct benefit to patients?
- Outcome measures not mentioned.
- Statistical methodology not mentioned.
- 51 samples will not be enough to either prognosticate or profile bladder cancer.

EC Comment:

- As above

EC Decision: Approval subject to modification, give responses in a tabular format.

Ref. code: 120th ECM II B-Ph.D./P1

22	**Minutes of ADR sub Committee-DCGI**
22	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 10th February, 2023 from 01.30 PM. ***virtual.***

The following Members were present in the Meeting:

- Dr. Alok Dhawan -Chairman
- Mrs. Akansha Dubey -Member
- Mrs. Vasundhara Kumari -Member
- Mr. Ujjawal Krishna -Member
- Dr. Rajendra Nath -Member
- Dr. D.N. Upadhyaya -Member
- Dr. Shally Awasthi -Member-Secretary, IEC

I-	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no.445/Neuro/22 dated 14th December, 2022 &

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

607/Neuro/22 dated 15th December, 2022.

Patient ID & age and gender: S-45-3-307/59 years/Male
Patient Diagnosis: Right Ganglio-capsular intracranial bleed with mass effect with IVE Hypertension.

Patient enrollment date: 18.11.2022
Patient follow up under study-Expired on 21-11-2022 during hospital stay.
Follow up visit completed-Expired
Planning on visit- 6th Month
SAE detected on date: 21-11-2022
Follow up visit remaining: Expired
24 hours, notified to EC, Sponsor-Yes
14 days analysis report submitted to EC-NA
Subject History:

Subject S.P.M.59 years/Male, known case of CAD post PTCA and Hypertension, admitted on 18th November, 2022 in the Emergency medical ward with c/o left hemiparesis and altered sensorium with GCS score of 7 and diagnosed to have right intracerebral (Gangliocapsular) bleed, volume approximately 50.9 ml. Since, he was fulfilling inclusion criteria so he was recruited after written informed consent from family and randomized to experimental arm and received tranexamic acid (2 gm I/V bolus). He was kept in emergency medical ward ICU had received treatment with parenteral antihypertensive to lower blood pressure, decongestive therapy (Inj Mannitol) and intravenous fluids but his GCS score dropped to 4 at about 2 pm so he underwent elective intubation and repeat NCCT head which showed haematoma expansion(volume approx, 64.4 ml). Subsequently, he was on ventilator support and neurosurgery opinion was taken who advised for surgery, but family members gave negative consent. So, he was continued on medical treatment. His deteriorating condition was related with haematoma expansion and treatment options and prognosis were discussed with the family members. He continued same state and by next day his GCS score dropped further to 3. The NCCT head at 24 hours after admission showed further expansion of haematoma volume (67.5 ml). Further, His blood pressure started falling so mannitol was stopped and he was put on initially single and later double ionotropic support due to falling blood pressure. He suffered a cardiac arrest, was given CPR but could not be revived and declared dead at 2.01 pm on 21.11.2022. The immediate cause of death was supposed to be large intracerebral bleed and its complications only.

Recommendation of Primary reviewer:

- The subject was enrolled on 18th November, 2022 when the subject was brought to the hospital with intra-cerebral bleed.
- SAE occurred on 21st November, 2022 during the same admission as recruitment due to expansion of intra-cerebral hematoma and non-consent of LAR to allow surgery.
- SAE doesn't appear to be related to the study but due to the expanding intra-cerebral hematoma perse.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	ADR sub Committee Comment: • No casual association & no compensation required. **ADR sub Committee Decision:** Noted ***Ref. code: 115 ECM IIA/P5***
2-	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Shukla, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter nos. 535/Neuro/22 dated 22nd October, 2022 & 550/Neuro/22 dated 2nd November, 2022. **Patient ID & age and gender:** S-45-3-121/40 years/Male **Patient Diagnosis:** Left Ganglio-capsular intracranial bleed with mass effect with IVE Hypertension. **Patient enrollment date:** 07.10.2022 **Patient enrollment date-**Intervention **Patient follow up under study-**Yes **Follow up visit completed-**No **Planning on visit-** Yes **SAE detected on date:** 20-10-2022 **Follow up visit remaining:** Yes (90) **24 hours, notified to EC, Sponsor-**Yes **14 days analysis report submitted to EC-**No**Subject History:** Subject A.G.40 yrs/Male, know case of Diabetes Mellitus Type-2, Hypertension, admitted on 07.10.2022 in the Emergency medical ward with c/o right hemiparesis and altered sensorium diagnosed to have right intracerebral (Gangliocapsular) bleed, volume approximately 50 ml. He was randomized to experimentalarm and received tranexamic acid (2 gm I/V bolus). He was transferred to Neurology stroke ward on 08.10.2022 and received treatment with Inj. Mannitol, Intravenous Fluids, Inj Piperacillin+tazobactam (due to raised counts on CBC) and Insulin for blood sugar management. He gradually improved and started accepting orally continued to have motor aphasia. The nasoganstric tube and indwelling catheter were removed on eighth day of admission and he was discharged on 10th day (17.10.2022). As per the family members he remained fine for one day at home subsequently from 19.10.2022 his oral intake started decreasing and he became drowsy, his urine output also decreased, and he became developed anuria next day, so we were contacted by the family members so, Patienwas called for readmission. Now, he has been diagnosed as sepsis with shock with acute renal injury. He is currently under treatment. ***Recommendation of Primary reviewer:*** • SAE (Hospitalization due to drowsiness and anuria and sepsis) is likely due to disease outcome (Left Ganglio-capsular intracranial bleed with hypertension and

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	T2DM) and not due to intervention (inj. Tranexamic acid ,IV ,bolus) as patient was randomized in treatment arm on 07-10-2022 and SAE occurred on 19-10-2022,almost 10 days have elapsed after taking intervention, therefore SAE seems not to be related to intervention. • Causal relationship can not be established and no compensation is required as patient was properly treated in hospital and discharged on 01-11-2022 in improved state with the instructions to come to OPD after 2 weeks for review. • (Document /Email regarding, notification to EC within 24 hrs. is not attached). **ADR sub Committee Comment:** • Causal relationship can not be established and no compensation is required as patient was properly treated in hospital and discharged on 01-11-2022 in improved state with the instructions to come to OPD after 2 weeks for review. **ADR sub Committee Decision:** Noted ***Ref. code: 115 ECM IIA/P5***
3.	ADR of research proposal entitled ***"Comparision of the efficacy of a 7 day versus a 14 day course of Intravenous antibiotics in the treatment of uncomplicated neonatal bacterial sepsis: a randomized controlled non inferiority trial"*** submitted by Prof. Mala Kumar, Department of Paediatrics, K.G`s Medical University, U.P., Lucknow vide letter no. 2787/Ped/22 dated 10th November, 2022 preliminary email dated 11th Oct, 2022 at 2:14 PM.. **Patient ID & age and gender:** 0621/1 month and 1 day/male **Patient Diagnosis:** 28-30 week premature very low birth weight (VLBW0 baby with respiratory distress syndrome (RDS) and early onset sepsis (EOS) **Patient enrollment date:** 08-10-2022 **Patient enrollment in arm**-14 day trial arm **Patient follow up under study**-35 days **Follow up visit completed**-19-11-2022 **Planning on visit**- Still hospitalized **SAE detected on date:** 23-10-2022 **Follow up visit remaining:** 17 days **24 hours, notified to EC, Sponsor**-29-10-2022 **14 days analysis report submitted to** EC-09-11-2022 **Subject History:** The neonate was 28:30 weeks premature appropriate for gestational age with very low birth weight (1200gm). Baby was suspected of respiratory distress syndrome (RDS) with early onset sepsis (EDS), Baby was started on bubble CPAP and given surfactant. Antibiotics Ampicillin BD and Gentamysin OD were started from 8th October to 10 October and then from 10 October onwards on Amikacin OD (after blood culture sensitivety was available). After completion of 7 days of sensitive antibiotic

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	administration baby was well and then we randomized. Randomization came to be in 14 day trial arm. The last dose of Amikacin was given on 22nd October, 2022. The next day baby became lethargic and had gastric haemorrhage. Sepsis screen was sent on 23rd October, 2022 which turned out to be negative (CRP = 0.59), blood culture sample was misplaced and CSF examination was normal. Piptaz was started from 23rd October, 2022 but condition did not improve. Hemoglobin (Hb) also dipped to 8.8 g/dL so PRBC transfusion was done on 24 October after which Hb improved to 13.2g/d/L. Repeat CRP was sent on 26th October, 2022 which turned out positive with value of 13.32. Blood culture sample was sent on 27th October which came sterile on 30th October, 2022. One more transfusion of PRBC was done on 28th October. However due to clinical deteoration in the form of Respiratory distress from 27th October, 2022 antibiotics were upgraded to Meropenem and the next day Vancomycin was also added. Baby was put on NIV mode of ventilation on 28th October, 2022. On 2 November, 2022 repeat CSF examination was normal and CSF culture came sterile on 4 November, 2022. Baby gradually improved and at present is stable on room air and mother's breast feed (MBF) with ongoing antibiotics. ***Recommendation of Primary reviewer:*** • SAE (continued hospitalization due to lethargy and gastric hemorrhage) is likely due to disease outcome (LBW with Sepsis and Respiratory distress syndrome) and not due to intervention (parenteral antibiotics) as patient was enrolled on 08-10-2022 and randomized in 14 day trial arm and after 7 days of parenteral antibiotics baby was well. SAE was detected on 23-10-2022 after completion of parenteral antibiotic (Amikacin) course (i.e. on 22-10-2022).Patient has received transfusion of PRBC two times (on 24th and 28th October) due to low Hb levels .Patient is still in hospital and under treatment due to deterioration of his clinical condition ,which is now stable. • Causal relationship can not be established and as patient is still in hospital at the site and getting proper management and is gradually improving and presently is stable on room air and mother's breast feed, so no compensation is required. • (Document/Email regarding, notification to EC within 24 hrs. is not attached). **ADR sub Committee Comment:** • Causal relationship can not be established and as patient is still in hospital at the site and getting proper management and is gradually improving and presently is stable on room air and mother's breast feed, so no compensation is required. **ADR sub Committee Decision:** Noted ***Ref. code: 100 ECM IIA/P6***
4.	ADR of research proposal entitled ***"A multicenter, single arm, open label,phase 4 study to evaluate the safety and efficacy of Vedolizumab in Indian patients with Ulcerative Colitis and Crohn's disease"*** submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, K.G's Medical University, U.P., Lucknow vide letter no. 2214/Med/22 dated 26th November, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Patient ID & age and gender: TAK-23-182 **Patient Diagnosis:** UC **Patient enrollment date:** 30-08-2022 **Patient enrollment in arm-**Vedolizumab 4020 **Follow up visit completed-**No **Planning on visit-** No **SAE detected on date:** 21-11-2022 **Follow up visit remaining:** 05, V-6,7,8,9,10 **24 hours, notified to EC, Sponsor-**Yes **14 days analysis report submitted to EC-**No (Initial report submitted) **Subject History:** The subject TAK-23-182 screened on 18th July, 2022 and enrolled on date 30th August, 2022. Subject was a known case of ulcerative colitis with pseudopolyposis for 5 years. She attended visit 5 here with loose stools. Sigmoidoscopy showed mucosal healing but pseudo-polyps persisting. Histopathological examination from rectal pseudopolyp showed adenocarcinoma. ***Recommendation of Primary reviewer:*** • SAE (permanent disability in the form of detection of Adenocarcinoma rectum) detected (on 21-11-2022) is likely due to disease progression (Ulcerative colitis with Pseudopolyposis ,rectum) and is unrelated to intervention (Vedolizumab) as patient was enrolled on 30-08-2022 and more than two and a half month has elapsed in treatment arm and Pt. completed 4th successful visit before detection of SAE on 5th visit ,when patient complains of loose stools and on sigmoidoscopy and histopathological examination, adenocarcinoma was detected. • Causal relationship can not be established and as SAE is most likely due to disease progression instead of intervention, therefore no compensation is required. • (Document /Email regarding , notification to EC within 24 hrs. is not attached) **ADR sub Committee Comment:** • Causal relationship can not be established and as SAE is most likely due to disease progression instead of intervention, therefore no compensation is required. **ADR sub Committee Decision:** Noted ***Ref. code: 114thECMIIC/P1***
5-	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 445/Neuro/22 dated 14th December, 2022 & 607/Neuro/22 dated 15th December, 2022. **Patient ID & age and gender:** S-45-3-421(RS)/50 years/Male **Patient Diagnosis:** Left basal ganglia bleed with hypertension.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Patient enrollment date: 05-12-2022
Patient enrollment arm-Intervention arm
Patient follow up under study-Yes.
Follow up visit completed-No
Planning on visit- Yes
SAE detected on date: 12-12-2022
Follow up visit remaining: Yes (90 days)
24 hours, notified to EC, Sponsor-Yes
14 days analysis report submitted to EC-NA

Subject History:
A letter was received in the office of the Ethics Committee on 15th December, 2022 vide letter no.445/Neuro/22 dated 14th December, 2022 by PI, the subject RS, 50 years/Male, known case of hypertension, dyslipidemia not on medication presented with complaint of slurring of speech as well as right upper and lower limb weakness. System onset was at 11.00 AM on 5th December, 2022 and the patient was admitted at 12:41 PM in neurology emergency. At presentation, the heart rate was 65 BMP, BP was 191/122 and GCS was 15 and diagnosed to have left basal ganglia bleed with a volume of approximately 5.09 ml. Since he was fulfilling inclusion criteria so he was recruited after written informed consent from family and randomized to the intervention arm received tranexamic acid (2gm I/V bolus). He was kept in neurology and received treatment with antihypertensive to lower blood pressure. He was discharged on the 6th day (10/12/2022). As per family members. He remained fine for one day at home later the patient developed chest pain and pain radiating to left forearm since one hour. ECG suggestive of Inferior wall MI associated with Right ventricle infarction. Patient was admitted immediately to Cardiology ICU on 12th December, 2022. Conservative management was followed and patient is stabilized on 12th December, 2022. He is currently under treatment.
Also, A letter was was received in the office of the Ethics Committee on 15th December, 2022 vide letter no.607/Neuro/22 dated 15th December, 2022, which in mention by the PI the subject was recovered completely from the event which had been reported to you and he is being discharged on 14th December, 2022. His discharged summary and a copy of the resolution are attached with this letter.

After that, A letter was received in the office of the Ethics Committee on 3rd January, 2023 vide letter no.01/Neuro/23 dated 3rd January, 2023 by PI. The subject was discharged from the PI side on 10th December, 2022 and his further follow-up is due on 5th March, 2023 (90th day visit). As per his proxy on today (27-12-2022) his mRS& GCS is 3 and 15 respectively with distal weakness of right upper limb and able to walk without assistance. On 12th December, 2022, patient developed chest pain, ECG suggestive of inferior wall MI associated with right ventricle infarction for which the PI had reported to EC. On today's follow-up he has been advised to continue medication. The PI shall

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

update the EC further about his health after following him up on the above said date.

Recommendation of PR:-

SAE (Hospitalization due to chest pain) is likely due to disease outcome (CVA Hemorrhage with Rt. Sided hemiparesis with Inferior wall / Rt. Ventricular / Posterior wall MI) and not due to intervention (inj. Tranexamic acid ,IV ,bolus) as patient was randomized in treatment arm on 05-12-2022 and SAE occurred after one day i.e. on 12-12-2022.

Causal relationship can not be established. SAE is unlikely related to Intervention as Pt was discharged just one day back (10-12-2022) after getting treatment for Left basal ganglia bleed and was again admitted in hospital (12-12-2022). As he was given proper treatment after admission and was discharged on 14th December after complete recovery ,therefore no compensation is required .

(Document /Email regarding , notification to EC within 24 hrs. is not attached)

ADR sub Committee Comment:

- Causal association not established no compensation required.

ADR sub Committee Decision: Noted

Ref. code: 115 ECM IIA/P5

6. ADR of research proposal entitled ***"Comparision of the efficacy of a 7 day versus a 14 day course of Intravenous antibiotics in the treatment of uncomplicated neonatal bacterial sepsis: a randomized controlled non inferiority trial"*** submitted by Prof. Mala Kumar, Department of Paediatrics, K.G's Medical University, U.P., Lucknow vide letter no. 3190/Ped/2022 dated 23rd December, 2022.

Patient ID & age and gender: 0621-132/1 year and 2 month/Male

Patient Diagnosis: Prematurity with appropriate for gestational age with low birth weight with respiratory distress syndrome with perinatal asphyxia with neonatal hyperbilirubinemia with early onset sepsis.

Patient enrollment date: 25 September 2021

Patient enrollment in arm-7 Day trial Arm
Patient follow up under study-35 days
Follow up visit completed-11-11-2021
Planning on visit- Discharged
SAE detected on date: 17-10-2021
Follow up visit remaining: 0 days
24 hours, notified to EC, Sponsor-30-11-2022
14 days analysis report submitted to EC-30-11-2022
SAE initials: B/O SS

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

SAE term: Sepsis (Pneumonia)
Course of event: Randomization in NICU
Causality: No
Outcome: Discharged

Subject History:

A letter was received in the office of the Ethics Committee on 23rd December, 2022 vide letter no.3190/Ped/2022 dated 23rd December, 2022. The PI informed to the EC that the baby was admitted with above mentioned complaints. Patient was managed with ventilator support, warmer care, vital monitoring, iv antibiotics and ionotropes. Patients were intubated 1/v/o low GC, bradycardia and poor respiratory efforts. Relevant investigations were sent. First sepsis screen came out to be negative but 1/v/0 clinical deterioration repeat sepsis screen was done which came out to be positive. Blood culture was sterile; iv antibiotics were added and upgraded a/t culture sensitivity. Swab for respiratory viruses were sent which was positive for RSV. During the course of hospital stay patient condition improved and ventilator support was gradually weaned off. Currently baby is hemodynamically stable, maintaining saturation on room air, taking MBF well, passing stool and urine normally, antibiotic course has been completed, therefore being discharged with advise to follow up in pediatric OPD on Wednesday after taking prior appointment on ors.gov.in

Recommendation of PR:-

SAE (hospitalization) is likely due to disease outcome (LBW with Sepsis and Respiratory distress syndrome) and not due to intervention (parenteral antibiotics) as patient was enrolled on 08-10-2022 and randomized in 14 day trial arm and completed follow up visit ,after 14 days of parenteral antibiotics baby was well. SAE was detected on 23-10-2022 after completion of parenteral antibiotic course(i.e. on22-10-2022). Patient is now hemodynamically stable, maintaining saturation on room air and antibiotic course has been completed, therefore being discharged with advice to follow up in pediatric OPD.
Causal relationship can not be established and as patient was given proper management and was gradually recovered and was stable on room air and mother's breast feed and therefore being discharged, so no compensation is required. (Document /Email regarding , notification to EC within 24 hrs. is not attached)

ADR sub Committee Comment:

- Causal relationship can not be established and as patient was given proper management and was gradually recovered and was stable on room air and

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	mother's breast feed and therefore being discharged, so no compensation is required. **ADR sub Committee Decision:** Noted ***Ref. code: 100 ECM IIA/P6***
7	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Shukla, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no 4414/ neuro/ 22 dated 14-12-2022 & 651/Neuro/22 dated 30th December, 2022. **Patient ID & age and gender:** S-45-3-376(VK)/45 years/Male **Patient Diagnosis:** Left basal ganglia bleed with intraventricular extension with hypertension. **Patient enrollment date:** 26-11-2022 **Patient enrollment arm**-Control arm **Patient follows up under study**-Yes. **Follow up visit completed**-No **Planning on visit**- Yes **SAE detected on date:** 09-12-2022 **Follow up visit remaining:** Yes **24 hours, notified to EC, Sponsor**-Yes **14 days analysis report submitted to EC**-NA **Subject History:** A letter from the PI of the project was received in the office of the Ethics Committee on 15th December, 2022 vide letter no. 444/Neuro/22 dated 14th December, 2022. It was revealed that the subject VK, 45 years/Male, a known case of hypertension, was on irregular medication and presented with a complaint of weakness of the right upper & right lower limb and sudden onset altered sensorium admitted on 26th November, 2022 in the Emergency medical ward with GCS score of 14. He was diagnosed to have a left basal ganglia bleed with an intraventricular extension volume of approximately 16.84 ml. Since he was fulfilling inclusion criteria so recruited after obtaining written informed consent from the family and randomized to the control arm. He was kept in the emergency medical ward ICU had received treatment with parenteral antihypertensive to lower blood pressure, later the patient was diagnosed with Hepatitis B via HbsAg surface antigen test on ELIZA. This infection is unrelated to treatment protocol and the patient wasn't previously aware of his status. On admission, routine labs reported hepatitis B rapid antigen test positive. Since the sensitivity and specificity of this test is low, hence ELIZA testing was done. The report arrived on 9th December, 2022. Gastroenterology and

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

medicine reference have been done. Antiviral therapy has been initiated.

After that, a letter was received in this office on 30th December, 2022 vide 651/Neuro/22 dated 30th December, 2022. It was informed by the PI that subject VK was discharged from his side on 10th December, 2022 and his further follow-up is due on 5th March, 2023 (90th day visit). As per his proxy on today (27th December, 2022), It is observed that his mRS & GCS is 4 and 15 (E4V5M6) respectively with residual right hemiparesis and unable to walk and attend to his own bodily needs without assistance. This patient was diagnosed with hepatitis B positive on 9th December, 2022 for which PI had reported to EC. On today's follow-up, he has been advised to continue follow-up and treatment for hepatitis B at medical gastroenterology. The PI shall update you further about his health after following up on the above-said date.

Recommendation of PR:-

SAE (Hospitalization) is likely due to disease outcome (Left basal ganglia bleed with IVE hypertension) and Hepatitis B infection and not due to intervention, as patient was enrolled in control arm on 26-11-2022.

Causal relationship can not be established and no compensation is required as patient was properly treated in hospital for complication and Hepatitis B infection which was detected on 09-12-2022 and was unrelated to protocol. He has been advised to continue follow up.

(Document /Email regarding , notification to EC within 24 hrs. is not attached)

ADR sub Committee Comment:

- Causal relationship can not be established and no compensation is required as patient was properly treated in hospital for complication and Hepatitis B infection which was detected on 09-12-2022 and was unrelated to protocol. He has been advised to continue follow up.

ADR sub Committee Decision: Noted

Ref. code: 115 ECM IIA/P5

Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 10th February, 2023 from 01.30 PM. ***virtual.*** **(Non-DCGI)**

The following Members were present in the Meeting:

- Dr. Alok Dhawan -Chairman
- Mrs. Akansha Dubey -Member
- Mrs. Vasundhara Kumari -Member

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Mr. Ujjawal Krishna -Member • Dr. Rajendra Nath -Member • Dr. D.N. Upadhyaya -Member • Dr. Shally Awasthi -Member-Secretary, IEC
1-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized-placebo controlled trial*** submitted by Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 354/Cardio/Res/22 dated 14th October, 2022 preliminary email dated 4th October, 2022 at 5:0 PM. **Subject ID: 008** **Subject initial: S-D** **Patient diagnosis:** RHD/Sev-MS/MVA 0.8 cm **Patient enrollment date**-29-04-2022 **Patient enrollment in arm**- Digoxin **Patient follow up under study**-6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit**- 6th Month **SAE detected on date:** 03.10.2022 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor**-04-10-2022 **14 days analysis report submitted to EC**-14-10-2022 **Subject History:** A letter was received in the office of the Ethics Committee on 15/10/2022. Patient was admitted i/v/o Echymotic patches over body with deranged INR and severe Anaemia. During hospital stay 3 unit of PRBC and 4 unit of FFP were given and now patient is being discharged in hemodynamically stable condition ***Recommendation of Primary reviewer:*** • The subject was enrolled on 29th February, 2022. 1 month follow-up was completed. Awaiting 6 months follow-up. • SAE detected on 3rd October, 2022. Hospitalization from 3rd October, 2022 to 6th October, 2022. Patient presented with breathlessness, weakness and ecchymosis. INR was 16. Patient was managed with 3 units PRBC and 4 units FFP. • Patient is on Digoxin which can be a rare cause of drug-induced immune-thrombocytopenia. The subject needs to be investigated, monitored and explanation for the same sought form the PI. No reason for the elevated INR has

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	been furnished by the PI. **ADR sub Committee Comment:** • No reason for the elevated INR has been furnished by the PI. **ADR sub Committee Decision:** Noted ***Ref. code: 102nd ECM IIA/P24***
2-	ADR of research proposal entitled ***"International study of comparative health effectiveness with Medical and Invasive approaches"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter nos.433/Cardio/Res/22 dated 23rd November, 2022 preliminary email dated 11th November, 2022 at 1:26 PM. **Death** **Subject Initial:** S N Y **Subject no.:** 091019-156 **Subject gender:** Male **Patient diagnosis:** Coronary Artery Disease/Chronic Stable Angina **Patient enrollment date**-27-01-2017 **Patient follow up under study**-Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic Follow up till 5 year. **Follow up visit completed**- Randomization visit, Month 1.5, Month 3, Month, 6, Month 12, Month 18. **Planning on visit**- Telephonic Follow-up visit of month of November, 2022 **SAE detected on date:** 11-11-2022 **Follow up visit remaining:** Telephonic visits (Every Month) till 2025 **24 hours, notified to EC, Sponsor by Email**- 11-Nov-2022 **14 days analysis report submitted to EC**-23-11-2022 **Subject History:** A letter was received in the office of the Ethics Committee on 24/112022. The Principal-Investigator informed that subject was randomized in Conservative Arm of the study. The site person have made a scheduled monthly follow up call to subject on 11th November, 2022 at 11:00 hrs. Subject's LAR informed him that subject passed away on 25th October, 2022 at around 08:00 hrs. LAR informed that subject was feeling down from last few days and had no other major symptoms, on 24th October, 2022 at 21:00 hr. He had taken medicine, skipped his dinner and then slept. Subject did not awaken after that and in morning he found dead. As he was not admitted anywhere, no documents are available and No autopsy was done. *Recommendation of Primary reviewer:*

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The subject was enrolled on 18th November, 2022 when the subject was brought to the hospital with intra-cerebral bleed. • SAE occurred on 21st November, 2022 during the same admission as recruitment due to expansion of intra-cerebral hematoma and non-consent of LAR to allow surgery. • SAE dose'nt appear to be related to the study but due to the expanding intra-cerebral hematoma parse. **ADR sub Committee Comment:** • SAE doesn't appear to be related to the study but due to the expanding intra-cerebral hematoma parse. **ADR sub Committee Decision:** Noted ***Ref. code: 60th ECM IIA/P13***
3-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 556/Cardio/Res/2023 dated 12th January, 2023 & preliminary email dated 3rd January, 2023 at 1:47 PM. **Patient ID & age and gender:** 064/52 year/Female **Patient Diagnosis:** RHD/Mod-MS/MVA 1.3 cm. **Patient enrollment date:** 21-04-2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit**- 6th M **SAE detected on date:** 30-12-2022 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor**-3rd January, 2023 **14 days analysis report submitted to EC**-12-01-2023 **Subject History:** A letter was received in the office of the Ethics Committee on 12th January, 2023 by PI, the subject LAR informed to PI that the subject passed away on 31st December 2022 at 3:00 PM. The subject had complaints of breathlessness and discomfort since the last few days she collapsed at home. Local practitioner was called and he confirmed subject's death. No hospital records are available and no autopsy was done as she expired at home. The PI does not have the exact records to ascertain the cause of death. ***Recommendation of PR:-*** Enrolment date 21-04-2022. 6th month follow up was due in October which was missed. SAE occurred on 31-12-2022 and was reported on 03-01-2023.(late) Clarification may be sought on why the 6 month follow up was skipped and why was the SAE reported late if it was detected on 31-12-2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	ADR sub Committee Comment: • Why was 6 month follow-up missed? • Why SAE reported late? **ADR sub Committee Decision:** Noted ***Ref. code: 102nd ECM IIA/P24***
4-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Praveen Kumar Shukla, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 555/Cardio/Res/2023 dated 12th January, 2023 & preliminary email dated 31st December, 2022 at 12:30 PM. **Patient ID & age and gender:** 003/42 year/Female **Patient Diagnosis:** RHD/Mod-MS/MVA 1.3 cm. **Patient enrollment date:** 21-04-2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th M,12th M, 18th M, 24th M, 30th M, 36th M. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit**- 6th M **SAE detected on date:** 30-12-2022 **Follow up visit remaining:** 6th M,12th M, 18th M, 24th M, 30th M, 36th M **24 hours, notified to EC, Sponsor**-31st December, 2022 **14 days analysis report submitted to EC**-12-01-2023 **Subject History:** A letter was received in the office of the Ethics Committee on 12th January, 2023 by PI, The PI made many follow-up calls to the patient for a 6 months actual follow-up visit at the site, but the call was not answered as informed by the PI, the subject's LAR came with the patient on 30th December, 2022 with complaints of breathlessness and dyspnoea. The PI also informed to the patient was admitted in the emergency department for stabilization. The patient is currently under observation for the same and there is no definite diagnosis made yet. So, PI is not sure that patient comes under SAE or AE. The PI had informed to the EC that he will provide his detail for the same within 14 days of the window period. *Recommendation of PR:-* • Randomized date 21-04-2022. SAE date 29.12.2022. SAE detected on 30-12-2022. Reported on 31-12-2022. • Date on SAE Narrative (report) is 12-10-2023-it may be corrected. • Subject has skipped the 6 month follow up and reported with SAE on 30-12-2022. • Subject was admitted for treatment and later discharged in a stable condition as

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	per the PI. • SAE doesn't appear to be related to the drug. Clarification/corrections as noted above may be sought. **ADR sub Committee Comment:** • Why was 6 month follow-up missed? • There is a typing error on date, Kindly get it corrected. **ADR sub Committee Decision:** Noted ***Ref. code: 102nd ECM IIA/P24***
II-A	**New Proposal**
1.	Research proposal entitled "***Elucidating mechanisms underlying increased expression and activity of oncogenic kinases and their downstream targets regulating metastasis in breast cancer***" sponsored by CSIR, New Delhi submitted by Prof. M.L.B. Bhatt, Head, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 1372/RT/22 dated 10th December, 2022. ***Recommendation of Primary reviewer:*** • Identify the study variables and population parameters. • Specify one primary objective and club the rest into secondary objectives. • Convert the primary objective into proper research hypothesis using the study variables and population parameters. • What is the study design? • Sample size calculation is missing. • Data management and statistical analysis details are not given • Processing of samples and experimentation shall be done at CSIR-CDRI. (I suppose Dr. Arun Kumar Trivedi shall be assisting in it. He should be from CDRI. It is not mentioned in Role of different co-investigators.). **EC Comment:** • As above **EC Decision:** Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121st ECM IIA/P1***
2.	Research proposal entitled "***Engineering conditionally replication competent SARS-CoV-2 viral molecular clones and evaluation of cross-variant neutralization***" sponsored by CSIR-CDRI submitted by Prof. Avinash Agrawal, Head, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1092/22 dated 5th December, 2022. ***Recommendation of Primary reviewer:*** • There are three sections: (i) Hypothesis and objectives, (ii) Aim, and (iii) Objective. • Specify one primary objective and club the rest into secondary objectives. • Identify the study variables and population parameters. • Convert the primary objective into proper research hypothesis using the study

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	variables and population parameters. • What is the study design used? • What is the sampling method? • Sample size calculation is missing. In data analysis para, it is mentioned that 100 patients shall be used. Where does this number come from? • Statistical analysis details are not provided. **EC Decision:** Organize a Meeting with PI, Co-PI with Prof. G.G. Agarwal alongwith Prof. Shally Awasthi, Member-Secretary, IEC. ***Ref. code: 121st ECM IIA/P2***
3.	Research proposal entitled "***Study of various parameters and nutrient foramina in talus: A dry bone study***" submitted by Dr. Arvind Kumar Pankaj, Additional Professor, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 461/ANAT/22 dated 16th December, 2022. **EC Decision:** Approved ***Ref. code: 121st ECM IIA/P3***
4.	Research proposal entitled "***Evaluation of the safety and efficacy of ganges water phage therapy in H. pylori related dyspepsia: A randomized controlled pilot-trial***" submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1430/MED/22 dated 24th December, 2022. **EC Comment:** • People may be drinking Ganga water of their own but to ask them to drink under research settings has ethical issues as there are huge reservations about the quality about potability of Ganga water. • Will the quality of Ganga water for potability tested and how? Bacterial, e coli count and other standard methods. • What will be the source of water? • Patient information is very sketchy and not in Hindi. There is mention of 'Cancer'. Why? • No mention about standard care drugs. • What are the criteria for dyspepsia and relief from it? • Will the study document bacteriophage [quantity and types] in Ganga water. • As cases with only dyspepsia will be included, how the improvement or lack of it will be judged. • Though not major harm is expected, and it may be ethically approved, I have reservations about the study. • The participants should be clearly informed in the brochure that untreated Ganga water will be given and the risk of gastrointestinal and liver infections can not be ruled out. • And this should be monitored before and after [upto 3 months] by pre and post clinical and lab evaluation and data of gastroenteritis should be maintained.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121st ECM IIA/P4***
5.	Research proposal entitled "***To identify the levels of UBA52 and peripheral inflammatory cytokines in blood and cerebrospinal fluid of parkinson's disease patients to establish its diagnostic significance***" submitted by Dr. Shweta Pandey, Additional Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 644/Neuro/22 dated 29th December, 2022. ***Recommendation of PR:*** • Language of materials and methods section needs corrections as everything is written in the past tense as if the work has already been completed. • Duration of study not mentioned. **EC Comment:** • As above **EC Decision:** Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121st ECM IIA/P5***
6.	Research proposal entitled "***A prospective, interventional, single-arm post-marketing clinical follow-up study evaluating copper IUD insertion procedure using Yanae® associated with crossGlide™ technology in women desiring long-term contraception***" sponsored by Mr. Ranjit Gaikwad Pregna International Limited submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3540/22 dated 22nd December, 2022. ***Recommendation of PR:*** • Project is very sketchy. • Sample size, inclusion or exclusion of subjects not included. • No reference cited. **EC Comment:** • As above **EC Decision:** Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121st ECM IIA/P6***
7.	Research proposal entitled "***To elucidate MAP kinase activation role in the hypertensive placenta***" sponsored by Department of Health Research, Ministry of Health & Family Welfare, Government of India, New Delhi submitted by Prof. Shyam Pyari Jaiswar, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3620/23 dated 3rd January, 2023. ***Recommendation of PR:*** • Discrepancy in the title of project. • Patient Information sheet: Kindly explain to the patient: why she has been selected, instead of saying that she fulfils inclusion criteria. • ICF: Kindly explain the study procedure. That her placental tissue will be utilized for study and will be kept in deep freezer. **EC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• As above **EC Decision:** Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121st ECM IIA/P7***
8.	Research proposal entitled "***Systematic assessment of neurodegenerative disorders by video-oculography- A prospective exploratory***" sponsored by UPCST, Lucknow submitted by Prof. Hardeep Singh Malhotra, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 16/Neuro/23 dated 17th January, 2023. ***Recommendation of PR:*** • According to PI, VNG machine is available in the ENT department and one Co PI will be from ENT department but the list is not expressing the same. Kindly add one CO PI from ENT department. • ICF: Study Procedure states Standard Guidelines. It has been assumed that patient is aware of Standard Guidelines. Kindly explain the whole procedure in simple words. • Patient Information Sheet: is not attached. **EC Comment:** • As above **EC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: 121st ECM IIA/P8***
9.	Research proposal entitled "***Development of novel antimicrobial peptides: Analysis of the antimicrobial and antibiofilm activity of lactoferrin and casein from human and bovine against Multidrug Resistance and Susceptible (MDR) and Pseudomonas aeruginosa and Acinetobacter baumannii clinical isolates***" submitted by Dr. Sheetal Verma, Additional Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1398/23 dated 19th January, 2023. **EC Comment:** • Ask for CV of Dr. Manoj Kumar of IITR. • Send project sanction letter. **EC Decision:** Approved ***Ref. code: 121st ECM IIA/P9***
10.	Research proposal entitled "***Efficacy and safety of Tyrosine Kinase inhibitors in downstaging and palliation in patients with advanced papillary thyroid cancer-A Multicenter study***" submitted by Dr. Pooja Ramakant, Additional Professor, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/2023/15 dated 9th January, 2023. ***Recommendation of Primary reviewer:*** • Approximate Number of subjects is not mentioned • Duration of subject participation is greater that duration of study? Explain • The proposal has been written in past tense? Has the research already been conducted and is ethical clearance been asked later? • How can one calculate accurate sample size in a retrospective study?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• What are appropriate statistical tests? • How will data of different endpoints be calculated from in-patient records? Most patients don't need admission at every point of contact. • How will the safety profile of TKIs be assessed? • Which version of RECIST will be used? • Define lost to follow up (as mentioned in exclusion criteria) • Residents cannot be included as co-PIs. **EC Comment:** As above **EC Decision:** Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121st ECM IIA/P10***
11.	Research proposal entitled "***A comprehensive retrospective analysis of road traffic accidents treated in the trauma surgery department of a tertiary care hospital in Lucknow district***" submitted by Dr. Rajeev Mishra, Assistant Professor, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1142/CM dated 27th January, 2023. ***Recommendation of Primary reviewer:*** • The role of 12 Co-Investigators needs to be justified. • Clearly innumerate the outcome variables anticipated beforehand. • Mention the anticipated statistical analysis. • To also submit the data record sheet for the study **EC Comment:** As above **EC Decision:** Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121st ECM IIA/P11***
II-B	**New Ph. D Proposal**
1.	Research proposal entitled "***Prevalence and determinants of hepatitis B & Hepatitis C among pregnant women in Lucknow district***" submitted by Mr. Abhishek Yadav, Ph.D. Scholar 2019 under the guidance Prof. Monika Agarwal, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 964/CM/22 dated 10th December, 2022. ***Recommendation of Primary reviewer:*** • First page of Annexure 1 us missing. • Patient information sheet both in English and Hindi needs to be submitted. • Anticipated statistical analysis needs to be submitted. • The semi structured questionnaire needs to be submitted that will be used to assess the risk factor and determinants amongst pregnant women. • The set proforma for follow-up also needs to be submitted. • Also submit the pretested structured questionnaire and indicate where this pre-testing has been done along with its pre-testing outcomes.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: As above **EC Decision:** Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121st ECM II B-Ph.D/P1***
2.	Research proposal entitled "***Morphogenic and Morphometric study of coronary sinus in cadaveric heart***" submitted by Mr. Rakesh Mishra, Ph.D. Scholar under the guidance Prof. Rakesh Kumar Diwan, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 437/ANAT/22 dated 2nd December, 2022. ***Recommendation of Primary reviewer:*** • Justification of sample size needs to be added. • Innumerate the parameters to be studied and their anticipated statistical analysis. **EC Comment:** • What is the novelty of this work? **EC Decision:** Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121st ECM II B-Ph.D/P2***
3.	Research proposal entitled "***Role of miRNAs in ankylosing spondylitis: A case-control study***" submitted by Ms. Shatakshi Pant, Ph.D. Scholar under the guidance Prof. R. N. Srivastava, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3048/OS/22 dated 19th December, 2022. ***Recommendation of Primary reviewer:*** • Identify the study variables and population parameters. • Specify one primary objective and club the rest into secondary objectives. • Convert the primary objective into proper research hypothesis using the study variables and population parameters. • The sample size calculation is arbitrary. It can be done after defining proper research hypothesis. • Statistical analysis details are not given. **EC Comment:** As above **EC Decision:** Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121st ECM II B-Ph.D/P3***
4	Research proposal entitled "***Role of stromal-epithelial interaction in breast cancer progression and efficacy of withania sommifera as an antimetastatic and repurposed agent***" submitted by Ms. Aditi Srivastava, Ph.D. Scholar under the guidance Dr. Rumana Ahmad, Department of Biochemistry, Era's Lucknow Medical College & Hospital, Era University, Lucknow & Co-Guide Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/2329/22 dated 30th December, 2022. ***Recommendation of PR:*** • Principal Investigator is a Ph.D. student from an outside Institution. • It is mentioned that the *Withania somnifera* plant will be verified and reference

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	specimens will be deposited at Integral University, Lucknow, however, there is no involvement of Integral University in the project (no Co-Guide has been included from there). • Dose of *Withania somnifera* not mentioned. • Patient to be included in the study are not described and no inclusion or exclusion criteria are mentioned. **EC Comment:** • As above **EC Decision:** Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121st ECM II B-Ph.D/P4***
II-C	**Review of New Drug Trial**
1.	Research protocol no. RVP-30-001 RECOVER entitled "***Brilaroxazine (RP5063), phase 3, randomized, 28 days, double-blind, placebo-controlled, multicenter study to assess the safety and efficacy of brillaroxzine (RP5063) in subjects with an acute exacerbation of schizophrenia, followed by a 52-week open-label extension***" sponsored by M/s Revive Pharmaceuticals Holdings. Inc. submitted by Prof. Adarsh Tripathi, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1785/Psy/2022 dated 1st December, 2022. ***Recommendation of PR:*** • Sample will be sent abroad–Clearance obtained -written in SOP–Checklist, but document for this is not attached. **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 121st ECMIIC/P1***
2.	Research protocol no. DEN302 entitled "***A randomized, double-blind, placebo-controlled, phase 3 trial to investigate the safety and immunogenicity of a dengue tetravalent vaccine (Live Attenuated) (TDV) administered subcutaneously to healthy subjects aged 4 to 60 years in India***" sponsored by M/s Takeda Vaccines, Inc. submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/35/2022 dated 28th December, 2022. ***Recommendation of Primary reviewer:*** • Permission for sending samples abroad–In SOP-Checklist–ticked yes, but document missing. • DCGI Permission letter–awaited **EC Comment:** As above **EC Decision:** Approval subject to modification

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 121st ECMIIC/P2
3.	Research protocol no. 20210025 Romosozumab (EVENITY®) entitled "***An open-label, single-arm, multicenter phase 4 study to evaluate safety and tolerability of romosozumab (EVENITY®) in postmenopausal women in India with osteoporosis and a high risk of fracture***" sponsored by M/s One Amgen Center Drive Thousand Oaks submitted by Prof. Ashish Kumar, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. CT/OS/02/2022 dated 29th December, 2022. ***Recommendation of Primary reviewer:*** • Budget in CTA document is missing **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 121st ECMIIC/P3***
4.	Research protocol no. RLS/RES/2020/02: Version 4.0, Dared 12 Oct, 2021 entitled "***Prospective, multi-center, open-label, single arm, clinical study to evaluate efficacy and safety of omaliRel® in patients with moderate to severe persistent asthma***" sponsored by M/s Dhirubhai Ambani Life Sciences Centre Plot R-282, TTC Area of MIDC Thane Belapur Road Rabale, Navi Mumbai submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. Res/CT/29/2022 dated 24th December, 2022. ***Recommendation of Primary reviewer:*** • Vaccine is ticked in the section on Clinical trials. Is this correct? • Section on Vulnerable subjects is not filled. • Section on Biological/hazardous material mentions use of Fetal tissue or aborts and use of pre-existing/stored samples. Please explain. • Section 5 of the IEC form has been copy-pasted from the Clinical experience section of the protocol submitted by the sponsor and does not match with the details in the Study Design section of the above-mentioned protocol. • Number of subjects in the IEC form and submitted protocol also do not match (112 vs 220). • ICF does not have details of the the PI **EC Comment:** As above **EC Decision:** Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121st ECMIIC/P4***
5.	Research protocol no. DRL-IND-NDA01-DXMF/2019 entitled "***A prospective, multicenter, randomized, open label, active controlled, phase II study to evaluate the efficacy, safety, and tolerability of fixed dose combination (FDC) of doxycycline hyclate and metformin hydrochloride (10%W/W+1%W/W)gel in the treatment of adults with periodontitis***" sponsored by M/s Dr. Reddy's Laboratories Ltd submitted by Prof.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Umesh Pratap Verma, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. PD/CT/01/23 dated 5th January, 2023. ***Recommendation of Primary reviewer:*** • Sections on vulnerable and special groups have both been ticked. Please explain. • ICF does not have details of the PI. • Details regarding previous use of Metformin in gel form for treatment of periodontitis are lacking. • Please clarify if Metformin's clinical use as gel in adults with periodontitis is established or not. **EC Comment:** As above **EC Decision:** Revise & Re-submit, give responses in a tabular format. ***Ref. code: 121stECMIIC/P5***
III A-	**Additional Document**
1.	Additional of research protocol LYT-100-2022-204 entitled "***A randomized double-blind, four-arm active and placebo-controlled dose-finding trial to evaluate the efficacy, tolerability, safety and dose response of LYT-100 in patients with idiopathic pulmonary fibrosis (IPF)***" sponsored by M/s Pure Tech LYT 100 Inc.6 Tide street, Suite 400 Boston MA 02210 submitted by Prof. Santosh Kumar, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 21/23 dated 4th January, 2023. ***Recommendation of Primary reviewer:*** Approved ***The following documents were reviewed in Its Meeting:-***

Documents
1. Main Informed Consent Form a. LYT-100-2022-204_ICF_Main ICF_King George's Medical University_ Dr. Santosh Kumar_English_Version 1.0 dated 20 Dec 2022 b. LYT-100-2022-204_ICF_Main ICF_King George's Medical University_ Dr. Santosh Kumar_Hindi_Version 1.0 dated29 Dec 2022 Translated From English ICF_Version 1.0_20 Dec 2022 c. LYT-100-2022-204_ICF_Main ICF_King George's Medical University_ Dr. Santosh Kumar_BkTr_English_Version1.0dated 29 Dec 2022 Back Translated From Hindi ICF_Version 1.0_29 December 2022 d. LYT-100-2022-204_ICF_Main ICF_King George's Medical University_ Dr. Santosh Kumar_Hindi_FT and BT Translation Certificate dated 29 Dec 2022
2. Optional Blood Sample Collection for Genetic Study ICF

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	a. LYT-100-2022-204_ICF_Optional Blood Sample Collection for Genetic Study_ King George's Medical University_DrSantosh Kumar_English _V1.0_20Dec2022 b. LYT-100-2022-204_ICF_Optional Blood Sample Collection for Genetic Study_ King George's Medical University_Hindi_V1.0_29Dec2022 Translated From English ICF_Version 1.0_20 December 2022 c. LYT-100-2022-204_Optional Blood Sample Collection for Genetic Study ICF_ King George's MedicalUniversity_BkTr_ English _V1.0_29Dec2022 Back Translated From Hindi ICF_Version 1.0_29 December 2022 d. LYT-100-2022-204_Optional Blood Sample Collection for Genetic Study ICF_ King George's MedicalUniversity_ Hindi _FT and BT Translation Certificate dated 29 Dec 2022.		
	3- Pregnant Partner Informed Consent Form a. LYT-100-2022-204_ICF_Pregnant ICF_India_King George's Medical University_Dr. Santosh Kumar_English_Version1.0 dated 20 Dec 2022 b. LYT-100-2022-204_ICF_Pregnant ICF_India_King George's Medical University_Dr. Santosh Kumar_Hindi_ Version1.0_29 Dec 2022 Translated From English ICF_Version 1.0_20 Dec 2022 c. LYT-100-2022-204_ICF_Pregnant ICF_India_King George's Medical University_Dr. Santosh Kumar_BkTr_English_Version 1.0_29 Dec 2022 Back Translated From Hindi ICF_Version 1.0_29 December 2022 d. LYT-100-2022-204_ICF_Pregnant ICF_India_King George's Medical University_Dr. Santosh Kumar_Hindi_FT and BT Translation Certificated dated 29 Dec 2022.		
	4- AV Informed Consent Form a. LYT-100-2022-204_ICF_Audio Video Informed Consent Form_ King George's Medical University_ Dr. Santosh Kumar_English_ Version 1.0 dated 20 Dec 2022 b. LYT-100-2022-204_ICF_Audio Video Informed Consent Form_ King George's Medical University_ Dr. SantoshKumar_Hindi_ Version 1.0 dated 29 Dec 2022 Translated From English ICF_Version 1.0_20 December 2022 c. LYT-100-2022-204_ICF_Audio Video Informed Consent Form_ King George's Medical University_ Dr. SantoshKumar_BkTr_English_ Version 1.0_29 Dec 2022 Back Translated FromHindi_Version 1.0_29 December 2022 d. LYT-100-2022-204_ICF_Audio Video Informed Consent Form_ King George's Medical University_ Dr. SantoshKumar_Hindi_FT and BT Translation Certificated dated 29 Dec 2022		
	5.Patient questionnaire- Kings Brief Interstitial Lung Disease Questionnaire (K-BILD) a.K-BILD-English AU1.0 b.K-BILD-English_Translation Certificate dated 31-Aug-2022 c.K-BILD-Hindi AU1.0 d.K-BILD-Hindi_Translation Certificate dated 31-Aug-2022	V1.0	2011
	6. DCGI Approval letter	NA	23Dec 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Approved *Ref. code: 120th ECMIIC/P4*
III-B	**Modification**
1.	Modification of research protocol no. GLK-2101 Version 4.0 Dated 10-Jun-2022 entitled ***"A randomized, assessor-blind, placebo controlled, multi center, clinical endpoint bioequivalence study to compare the efficacy and safety of generic fluticasone propionate inhalation aerosol USP 44mcg (Glenmark Pharmaceuticals Ltd) to flovent HFA (Fluticasone propionate inhalation aerosol) 44mcg (GSK Group of Companies) in treatment of patients with bronchial asthma"*** sponsored by M/s Glenmark Pharmaceuticals Ltd. B/2 Mahalaxmi Chamber submitted by Prof. R.A.S Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. RES/CT/29/2022 dated 5th December, 2022. ***Recommendation of Primary reviewer:*** Approved ***The following documents were reviewed:-*** 1. Protocol GLK-2101_Version 4.0 dated 13-Oct-2022. 2. Protocol Amendment Summary of Changes 3. Patient Information Sheet and Informed Consent Form in Core_3.0 dated 14 Oct 2022 (English) 4. Patient Information Sheet and Informed Consent Form in Core_3.0_Hindi_1.0 dated 24-Oct-2022 5. Patient Information Sheet and Informed Consent Form in Core_3.0_Hindi_1.0 dated 24-Oct-2022 Back 6. Translated from Hindi to English on 08-Nov-2022 7. GLK-2101_Version-4.0 DCGI Submission letter with ack. 8. IB dated 30-12-2022 9. Form 1572 for PI dated 30-12-2022 10. Form 3455 FDF for PI dated 30-12-2022 11. Form 3455 FDF for Co-I dated 30-12-2022 **EC Decision:** Approval subject to fulfillment and administrative formalities *Ref: code: 117th ECMIIC/P9*
2.	Modification of research protocol no. GLK-2101 Version 3.0 Dated 10-Jun-2022 entitled ***"A randomized, assessor-blind, placebo controlled, multi center, clinical endpoint bioequivalence study to compare the efficacy and safety of generic fluticasone propionate inhalation aerosol USP 44mcg (Glenmark Pharmaceuticals Ltd) to flovent HFA (Fluticasone propionate inhalation aerosol) 44mcg (GSK Group of Companies) in treatment of patients with bronchial asthma"*** sponsored by M/s Glenmark Pharmaceuticals Ltd. B/2 Mahalaxmi Chamber submitted by Prof. R.A.S Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. RES/CT/28/2022 dated 5th December, 2022. ***Recommendation of Primary reviewer:*** Approved ***The following documents were reviewed:-*** • Protocol GLK-2101_Version 3.0 dated 10-Jun-2022. • Protocol Amendment Summary of Changes • GLK-2101_CT NOC_version-3.0 Approval

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- GLK-2101 Rescue Medication: Subject Instructions for Use Leaflet Version 2.0 Dated 07-Nov-2022
- GLK-2101 Rescue Medication: Subject Instructions for Use Leaflet Version 2.0 Dated 07-Nov-2022 Translated from English to Hindi on 21-Nov-2022
- GLK-2101 Rescue Medication: Subject Instructions for Use Leaflet Version 2.0 Dated 07-Nov-2022 Back translated from Hindi to English on 22-Nov-2022
- Certificates of Rescue Medication Leaflet
- IU dated 30-12-2022
- Form 1572 for PI dated 30-12-2022
- Form 3455 FDF for PI dated 30-12-2022
- Form 3455 FDF for Co-I dated 30-12-2022

EC Decision: Approval subject to fulfillment and administrative formalities

Ref: code: 117th ECMIIC/P9

3. Modification of research protocol no. QPT-ORE-006 entitled ***"A Phase 2, Double-blind, placebo-controlled, multicenter clinical trial comparing chemoimmunotherapy (Paclitaxel-Carboplatin-Oregovomab) versus chemotherapy (Paclitaxel-carboplatin-Placebo) as neoadjuvant therapy in patients with advanced epithelial ovarian, fallopian tube or peritoneal carcinoma"*** sponsored by M/s Onco Quest Pharmaceuticals Inc submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/2100/2022 dated 8th December, 2022.

Recommendation of Primary reviewer:

Approved

The following documents were reviewed:-

Sl.No.	Documents	Version	Date
1.	DCGI Submission Letter for Protocol Amendment and ICF version 04 along with change in name of Sponsor	NA	21 October 2022
2.	Investigator Brochure	OVA-IB-Q8	16 June 2022
3.	Clarification note for Investigator Brochure Edition Number OVA-IB-Q8 Dated 16 June 2022	NA	21 July 2022
4.	Protocol Amendment	1.1	7 October 2022
5.	Patient Information Sheet And Informed Consent Form - in English	Version 05	08 November 2022
6.	Summary of changes to Patient Information Sheet And Informed Consent Form	NA	NA

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	7.	Patient Information Sheet And Informed Consent Form in Hindi (Translated from English to Hindi) with its translation certificate on 9 Nov 22	Version 05	08 November 2022
	8.	Patient Information Sheet And Informed Consent Form – (Back Translated from Hindi to English with its translation certificate on 9 Nov 22)	Version 05	08 November 2022
	9.	Patient Identification Card	Version 1.0	20 October 22
	10.	Patient Identification Card in Hindi (Translated from English to Hindi) with its translation certificate on 25 Oct 22	Version 1.0	20 October 22
	11.	Patient Identification Card – (Back Translated from Hindi to English with its translation certificate on 25 Oct 22)	Version 1.0	20 October 22
	12.	CTRI Registration Copy (CTRI/2022/10/046210)	NA	16 November2022
	13.	Partially executed Clinical Trial Agreement	NA	24 Jun 2022
	14.	Proposed Patient Accrual Method	NA	NA

EC Decision: Approval subject to fulfillment and administrative formalities

Ref: code: 117th ECMIIC/P4

4. Modification of research protocol no. C3601002 entitled ***"A Phase 3 Prospective, Randomized, Multicenter, Open Label, Central Assessor Blinded, Parallel Group, Comparative Study To Determine The Efficacy, Safety And Tolerability of Aztreonam Avibactam (ATM AVI) ± Metronidazole (MTZ) Versus Meropenem ± Colistin (MER ± COL) For the Treatment of Serious Infections Due to Gram – Negative Bacteria, Including Metallo β-Lactamase (MBL)–Producing Multidrug Resistant Pathogens, For Which There Are Limited Or No Treatment Options"*** M/s Parexel submitted by Prof. Sandeep Tiwari, Head, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. TS/813/2022 dated 14th December, 2022.

The following documents were reviewed:-

S.No	Documents	Version/Date
1	234454_C3601002_India dr. sandeep Tiwari ICF_English_V 5.0, 20/Jul/2022 Based on study level ICD version 7.1; dated 23/Jun/2022	5.0 20/Jul/2022
2	234454_C3601002_India Dr. Sandeep Tiwari ICF_Hindi_V 5.0, 20/Jul/2022 Based on study level ICD version 7.1; dated 23/Jun/2022 Back Translated from Hindi to English on 12/aug/2022	5.0 20/Jul/2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		by RWS	
	3	234454_C3601002_India Dr. Sandeep Tiwari ICF_Hindi_V 5.0, 20/Jul/2022 Based on study level ICD version 7.1; dated 23/Jun/2022 Translated from English to Hindi on 12/aug/2022 by RWS	5.0 20/Jul/2022
	4	234454_IND_1064_Main ICF English 20220414 V5.0 TC	5.0 14/Apr/2022
	5	C3601002 Protocol Amendment 2 18/May/2022_clean Site Distribution	
	6	C3601002_Investigator Protocol Acceptance from_Protocol Amendment 2_20220518	
	7	C3601002_Protocol Amendment 2_Summary of Changes_18/May/2022	

EC Decision: Approval after full fulfillment & Administrative formalities.

Ref: code: 89th ECMIIC/P9

5. Modification of research protocol no. EX6018-4758 Study Phase:3 a entitled **"ZEUS - *Effects of ziltivekimab versus placebo on cardiovascular outcomes in participants with established atherosclerotic cardiovascular disease, chronic kidney disease and systemic inflammation*"** sponsored by M/s Novo Nordisk India Private Ltd submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 531/Cardio/Res/2022 dated 28th December, 2022.

Recommendation of PR:-

- Approved

The following documents were reviewed:-

Section No.	Documents
1.	Protocol Protocol Version 7.0 dated 09 Feb 2022-10-03 Track Change of approved protocol from version 6.0 to version 7.0
2.	Subject Information/Informed Consent – Genotyping 2.1 Version_1.0_IN_EN Dated 04 March 2022 Forward Translation 2.2 Version_1.0_IN_HI Dated 15 March 2022. Back Translation 2.3 Version_1.0_IN_HI_BT Dated 28 March 2022. Translation certificate: Hindi
3.	Subject Information/Informed Consent - Home Health Care Service 3.1 Version_1.0_IN_EN Dated 22 Feb 2022-10-03 Forward Translation 3.2 Version _1.0_IN_HI Dated 15 March 2022 Back Translation 3.3 Version_1.0_IN_HI_BT Dated 28 March 2022 Translation certificate: Hindi

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		4.	Subject Information/Informed Consent - COVID 19 Co-Participation 4.1 Version_1.0_IN_EN Dated 20 March 2022 Forward Translation 4.2 Version_1.0_IN_HI Dated 28 March 2022 Back Translation 4.3 Version_1.0_IN_HI_BT Dated 31 March 2022 Translation certificate: Hindi

EC Decision: Approval subject to fulfillment and administrative formalities

Ref: code: 116th ECMIIC/P1

6. Modification of research proposal entitled "***The effect of maternal HIV and antiretroviral exposure on immunity to TB in HIV exposed uninfected infants***" submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 43/MED/2023 dated 9th January, 2023.

Recommendation of Primary reviewer:

- The modification of Co-Investigator may be registered.

EC Decision: Approved

Ref: code: 96th ECMIIA/P45

7. Modification of research protocol no. 209682 entitled "***A phase 4, open-label, single arm, 24-week, study to evaluate the safety and efficacy of mepolizumab 100 mg SC administered every 4 weeks in Indian participants aged≥18 years with severe eosinophilic asthma (PRISM)***" sponsored by M/s Glaxo Smith Kline Pharmaceuticals Ltd. submitted by Dr. Ajay Kumar Verma, Additional Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. RES/CT/21/2022 dated 31st December, 2022.

Recommendation of Primary reviewer:

Approved

The following documents were reviewed:-

Sl.No.	Documents
1-	**1. Study Protocol** 1.1. Study Protocol Number 209682 [Amendment 04] dated 23 Aug 2022 1.2. Sponsor Protocol signature Page [Amendment 04], dated 23 Aug 2022 1.3. Investigator's Protocol Signature Page [Amendment 04] dated 06 Dec 2022.
2-	**2. Informed Consent Form:** 2.1. English language site specific ICF "India, Centre No. 244727 PI Name Dr.Ajay Kumar Verma ICF Version Number_03, Dated: 17 Dec 2022, based onModel ICF Version Number 05, Dated: 13 Dec 2022. 2.2. Translated ICF: Hindi language site specific ICF "India, Centre No. 244727 ICF Translated from English to Hindi Version Number 03, Dated 19 Dec 2022."

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		2.3. Back translated ICF: Hindi to English translated ICF "India, Centre No. 244727 ICF Translated from Hindi to English Version Number 03, Dated 20 Dec 2022. 2.4. Translation Certificate and Back Translation Certificate of Hindi ICF
	3.	3. Case Report Form 3.1. CRF version 4.0 dated 19 Dec 2022.
	4.	4. Regulatory Documents 4.1. DCGI Submission letter for protocol amendment 04 dated 23 Aug 2022 4.2. DCGI Approval letter for protocol amendment 04 dated 25 Nov 2022. 4.3. CTRI Registration letter dated 15 Dec 2022
	5.	5. Laboratory Instruction Manual 5.1. Laboratory Instruction Manual Version 4.0 dated 23 Aug 2022
	6.	6. Site Specific Documents 6.1. Investigator undertaking dated 06 Dec 2022 6.2. Signed and dated PI's CV and Signed and dated PI's Medical Registration Certificate with GCP certificate
	EC Decision: Approval subject to fulfillment and administrative formalities ***Ref: code: 111th ECMIIC/P1***	
IV	**Other Matter**	
1-	Reg. request for permission to change the Sponsor name M/s CanariaBio Inc in place of M/s OncoQuest Pharmaceuticals Inc. under the research protocol no. QPT-ORE-006 entitled ***"A Phase 2, Double-blind, placebo-controlled, multicenter clinical trial comparing chemoimmunotherapy (Paclitaxel-carboplatin-oregovomab) versus chemotherapy (Paclitaxel-carboplatin-Placebo) as neoadjuvant therapy in patients with advanced epithelial ovarian, fallopian tube or peritoneal carcinoma"*** sponsored by M/s Onco Quest Pharmaceuticals Inc submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/192/23 dated 4th February, 2023. **EC Decision:** Take approval from CDSCO, New Delhi ***Ref. code: 117th ECMIIC/P4***	
2-	**Reg. request to correct the status as Ph.D. Scholar** in the research proposal entitled ***"Growth and development outcomes in severe acute malnutrition (SAM) children discharged from Nutrition rehabilitation centre (NRC): A community based follow up study"*** submitted by Mr. Rohitash Kumar, Assistant Professor, KGMU College of Nursing under the guidance of Prof. Monica Agarwal, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 76 dated 16th January, 2023.	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Permission granted ***Ref. code: 120th ECM II A/P18***
3.	Reg. permission to add the name of Dr. Vanadan Solanki, Additional Professor, Department of Obst. & Gynaecology, KGMU in place of Prof. Smriti Agarwal has gone for deputation under the research proposal entitled ***"Evaluation of maternal and fetal outcomes in women diagnosed with GDM or normoglycaemia using IADPSG criteria, among women diagnosed with normoglycaemia by DIPSI criteria: prospective multi-centre observational cohort study"*** sponsored by ICMR New Delhi submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynaecology of this University via letter no. OG/3640A/22 dated 22nd December, 2022. **EC Decision:** Kindly provide the approval from ICMR, New Delhi & submit to Ethics Committee for necessary action. ***Ref. code: 102nd ECM IIA/P20***
V	**Brought to Ethics Committee after XV-PGTSC held on 25th January, 2023.**
	Minutes of XV-PG Thesis sub Committee" of "Institutional Ethics Committee" Meeting held on 25th January, 2023 from 3.00 PM **virtual.** ***The following members were present in the Meeting:-*** 1. Dr. G.G. Agarwal - Member 2. Dr. A.A. Mahdi - Member 3. Dr. Rajendra Nath -Member 4. Dr. Anita Rani -Member 5. Dr. Shally Awasthi -Convener ***The following member was not present in the Meeting:-*** 1- Dr.D.N. Upadhyaya -He has given his written comments
I-A	**Action taken**
1-	Clarification of research proposal entitled ***"Laparoscopic renal surgery: outcome analysis at a tertiary care center"*** submitted by Dr. Nitish Dev, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 794/Uro/22 dated 29th December, 2022.

Previous PGTSC Comment	PI response
Title should be: Assessment of outcomes of Laparoscopic renal surgery.	"Assessment of outcomes of Laparoscopic Renal surgery".
Aims and objective in proper format.	Retrospective review of records (June 2017 to June 2021) to determine the clinical outcome results of all cases who underwent laparoscopic renal surgery for various indications in department of Urology, King George's Medical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		University, Lucknow and also the data of those patients who will be subjected to laparoscopic renal surgery prospectively from June 2021 to Jan 2023 will be included in analysis of outcome results and complications rate, rate of.conversion from laparoscopic to open surgery and feasibility of laparoscopic radical nephrectomy for>7cm renal tumors.
	Study variables, to defined properly with primary and secondary outcomes.	Primary outcome: To determine rate of conversion from laparoscopic to open surgery. Secondary outcomes: Analysis of outcome results and complications rate feasibility of laparoscopic radical nephrectomy for >7cm Renal tumors.
	Study design is not clear.	Retrospective and Prospective study.
	Sample size and Statistical Analysis is not clear.	The sample size was calculated based on the previous study that reported the prevalence of. Complications of laparoscopic surgery is 6.5%. globally (Elsamra et al 2010) 95% level of confidence and error rate , usually set at 0.05. Total.94 (minimum) patients will be included in this.study. n= Z 2 P(1-P)/d 2 Where • n= sample size • Z=Z statistic for level of confidence, for the level of.confidence of 95% which is conventional ,Z value is.1.96 • P= Expected prevalence of proportion (in proportion.of one ,if 6.5% ,P=0.065) • d= precision (in proportion of one: if 5% d =0.05).

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		n=1.96 x 1.96 x 0.065 x 0.935/0.052.=93.38=94

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XI-PGTSC-IIA/P3

2- Clarification of research proposal entitled ***"Growth of urology in India as compared to other surgical branches"*** submitted by Dr. Sandeep Kumar Patel, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 795/Uro/22 dated 29th December, 2022.

Previous PGTSC Comment	PI response
Title should be "Growth of urology as compared to other surgical branches in India"	Growth of urology as compared to other Surgical Branches in India.
The attributes on which growth will be evaluated should be specified.	2.The attribution on growth evaluated in- a-Growth in number of urology (M.Ch/DNB) seat in India from 2015 to 2021 as compared to other surgical branch. b. Growth in number of female urologist working in India. c.To know the contribution from India to the creation of medical literature in the form of scientific articles as compared to other country published in PubMed /Scopus journal for paper published in urology for last 20 years.
How the results will be presented.	Result will be presented in term of. percentage, graph and chart.
Data collection form must be enclosed.	Data collection form attached.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XI-PGTSC-IIA/P4

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

3- Clarification of research proposal entitled ***"A prospective study of grading the complexity of PCNL procedures using " GUY'S STONE SCORE"*** submitted by Dr. Ankush Sadotra, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 84/Uro dated 19th January, 2023.

Previous PGTSC Comment	PI response
The sample size calculation is not given.	The sample size was calculated based on the previous study that reported the prevalence of renal stones was 12% in India (Prakash et.al., 2019; Sofia et.al., 2016), 95% level of confidence and error rate , usually set at 0.05. Total 162 (minimum) patients will be included in this study. $n= Z^2 P(1-P)/d^2$ Where • n= sample size • Z=Z statistic for level of confidence , for the level of confidence of 95% which is conventional ,Z value is 1.96 • P= Expected prevalence of proportion (in proportion of one ,if 6.5% ,P=0.065) • d= precision (in proportion of one: if 5% d =0.05). $n=1.96 \times 1.96 \times 0.12 \times 0.88/0.05^2$ = 162.27 = 162
The detail for evaluating "reliability" and "validity" of "Guy's stone score" is missing.	Many studies has been done to show the reliability and validity of "Guy's stone score". I am quoting a few studies :- 1.Utility of the Guy's Stone Score in predicting different aspects of percutaneous nephrolithotomy (M.Khalil et.al.) 2. Validation of S.T.O.N.E nephrolithometry and Guy's stone score for predicting surgical outcome

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	after percutaneous nephrolithotomy (Nasir Khan et.al.) 3. STONE score versus Guy's Stone Score - prospective comparative evaluation for success rate and complications in percutaneous nephrolithotomy (Ujwal Kumar et.al.)
Has it been validated in Indian?	Yes
Include a Biostatistician as Co-guide	I have included Prof. Vijay Kumar Singh, Deptt. of Community Medicine & Public Health, KGMU, Lucknow as a co-guide in my study.

Recommendation of Primary reviewer:
Approved
PGTSC Decision: As above

Ref. code: XI-PGTSC-IIA/P5

4- Clarification of research proposal entitled ***"Assessment of quality of urological care and services in a tertiary care centre"*** submitted by Dr. Jayant Maurya, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 753/Uro/22 dated 15th December, 2022..

Previous PGTSC Comment	PI response
Would like to see "SWOPS' questionnaire.	Attached SWOPS questionnaire.
Is this instrument applicable in Indian context?	Yes this instrument is applicable in Indian context.
Study period is "June 2021-October-2022	The study period is July 2021-October 2022.
Has the study already started?	The study has already started.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XI-PGTSC-IIA/P6

5- Clarification of research proposal entitled ***"To determine the basic and demographic, clinical and biochemical risk factors associated with pediatric tuberculosis (Pulmonary and extrapulmonary tuberculosis"*** submitted by Dr. T. Sudhakar, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

3171/Ped/22 dated 21st December, 2022.

Previous PGTSC Comment	PI response
They are proposing to find out the risk factors.	Attached separately
For doing, this experimental study is required.	Attached separately
Proper research hypothesis, study variables, outcome measures etc. are required.	Attached separately
Sample size calculation is arbitrary.	Attached separately
Statistical analysis section is also very general and not specific to the aim/objective of the study.	Attached separately

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XI-PGTSC-IIA/P7

6- Clarification of research proposal entitled ***"DIC scoring among newly diagnosed children with acute leukemia in a pediatric wardsor a north Indian teaching university: A prospective observational study"*** submitted by Dr. Karan Gond, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3172/Ped/22 dated 21st December, 2022.

Previous PGTSC Comment	PI response
This seems to be an incidence/prevalence study.	Attached separately
For finding incidence or prevalence, the theoretical population, target population, sampling frame, sampling methods should be clearly specified.	Attached separately
Sample size calculations are missing.	Attached separately

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XI-PGTSC-IIA/P8

7- Clarification of research proposal entitled ***"To study thecomplications of percutaneous nephrolithotomy"*** submitted by Dr. Udham Singh, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 86/Uro dated 19th January, 2023.

Previous PGTSC Comment	PI response

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Study design in Protocol - Prospective observational study from June -21 to June-22 ? If study has already not started then how it is possible. In ICF the study design mentioned is Combined Retrospective and Prospective study.	• Study design is Prospective observational study. • Study period is June 2021 to October 2022. • Study has already started.
	Sample size -All adult pts will be included, exact calculated sample size not given.	The sample size was calculated based on the previous study that reported the prevalence of kidney stones is ~10% globally (Saeed R. Khan et al 2017) 95% level of confidence and error rate, usually set at 0.05. Total 139 **(minimum)** patients will be included in this study. $n= Z^2 P(1-P)/d^2$ Where • n= sample size • Z=Z statistic for level of confidence , for the level of confidence of 95% which is conventional ,Z value is 1.96 • P= Expected prevalence of proportion (in proportion of one ,if 10% ,P=0.1) • d= precision (in proportion of one: if 5% d =0.05). n=1.96 x 1.96 x 0.1 x 0.935/0.052 =138.29

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	=139
In Exclusion criteria – it is mentioned that pt below 12 yrs of age not included (In methodology it has been mentioned that analysis of prospectively maintained data of more than 12 yrs of age)- – please Clarify the Age of the patients being included.	All the patients at or above 18 years of age undergoing the procedure percutaneous nephrolithotomy are being included in the study. Patients below 18 years of age are being excluded from study.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:

- PI already started the study before getting approval from IEC, why? Please clarify.

PGTSC Decision: As above

Ref. code: XI-PGTSC-IIA/P10

8- Clarification of research proposal entitled ***"Complications associated with ureterorenoscopy (URS) related to treatment of urolithiasis: A prospective study"*** submitted by Dr. Jigardeep Singh, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 85/Uro dated 19th January, 2023.

Previous PGTSC Comment	PI response
Sample size -not mentioned (All pts above 18 yrs of age Undergoing ureteroscopic stone removal) -Justify	➢ The sample size was calculated based on the previous study that reported the prevalence of urolithiasis is 10 % globally (Jacob Lang et al 2021) 95% level of confidence and error rate , usually set at 0.05. Total **139 (minimum)** patients will be included in this study. $n= Z^2 P(1-P)/d^2$ Where • n= sample size • Z=Z statistic for level of confidence , for the level of confidence of 95%

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		which is conventional ,Z value is 1.96 • P= Expected prevalence of proportion (in proportion of one ,if 10% ,P=0.1) • d= precision (in proportion of one: if 5% d =0.05). n= 1.96 x 1.96 x 0.1 x 0.9/0.0025 = 138.29 = 139 Only the patients more than 18 years of age are included in present study.
	It is a prospective observational study and PI mentioned that pts from June-2021 to June 2022 will be included - Is PI already started the study or pts will be taken retrospectively -Please specify	• Prospective observational study • **Study period** :June 2021 to December 2022 • Study has been already started.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:

- PI already started the study before getting approval from IEC, why? Please clarify.

PGTSC Decision: As above

Ref. code: XI-PGTSC-IIA/P11

9- Clarification of research proposal entitled ***"Psychological distress and health related quality of life in lung cancer patients"*** submitted by Dr. Arun Kumar, JR, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1370/22 dated 23rd December, 2022.

Previous PGTSC Comment	PI response
Is it really health-related quality of life HRQOL	We firstly used to measure HRQOL in the study but omitted this

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

measurement study?	parameter due to time constraints. We are using DASS-21 for the measurement of psychological distress. So the topic for the study is **"A study on psychological distress in lung cancer patients"**. Kindly provide approval for the study.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P4

10- Clarification of research proposal entitled ***"Prospective analysis of pre-operative assessment of duodenal involvement in gallbladder cancer"*** submitted by Dr. Rohit Jain, SR, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SGE/805/22 dated 18th October, 2022.

Previous PGTSC Comment	PI response
1. Sample size calculation and proper justification.	Sample Size: is calculated on the basis of Daniel sample size formula N= Z 2 P(1-P)/d 2 Were, Z: static for level of confidence =3.96 P: expected prevalence = 0.002 (www.ncbi.nlm.gov/pmc/articles/PMC5473118) d : precision = 5%

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Therefore, N= 3.96*0.002*99.998*10 4 /25 = 316.79 Approximately only 10 % of gallbladder cancer patients are operated (10% of 317=31.7) Therefore 30 subjects will be included in this study.	
	2. In inclusion criteria, it is not clear what the sentence "All patients suspected to have GBC will undergo an ultrasound examination of the abdomen" means.	USG abdomen will be performed in the suspected Gall bladder cancer cases to rule out metastatic disease with Liver nodules and ascites. So that we include only those patients, who do not have metastatic disease.	
	3. Exclusion criteria are not proper.	Revised Inclusion /exclusion criteria Inclusion Criteria- a) > 18 years of age b) Patient undergoing surgery for non- metastatic gallbladder cancer c) Patient who are willing to participate in the study Exclusion criteria-	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	a) < 18 years of age b) Patient who are unfit for surgery c) Patient with metastatic disease d) Patient unwilling to participate in the study.
4. In the consent form, it is mentioned that.complications will be none, although in the.above line it is mentioned that it is major Surgery. Surgery related complications shall be given.	In the consent form (complication section) there was a typographical error, Surgical complications is added, that will be explained before the consent.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P10

11- proposal entitled ***"A study of predictive factors for unfavourable outcome of tubercular cervical lymphadenitis"*** submitted by Dr. Nagendra Kumar, JRIII, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1380/22 dated 28th December, 2022.

Previous PGTSC Comment	PI response
In IEC-SOP form, Privacy & Confidentiality Column Ticked by PI as –No (should be changed in revised SOP form)	In IEC-SOP form, privacy and confidentiality column was ticked as-no it has been changed to yes in the revised SOP form.
In Inclusion criteria -Age specificity not mentioned.	Age criteria-between 18 years to 55 years.
In Exclusion criteria, other co-morbities ,pregnancy and lactation and TB of other organs not mentioned.	Exclusion criteria-Type 2 diabetes mellitus, pregnancy & lactation, TB other than tubercular cervical lymphadenitis are included in the exclusion criteria.
Patient information sheet attached is not related to disease –should be rewritten.	Patient information sheet rewritten and attached.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P26

12- Clarification of research proposal entitled ***"Effect of face masks on six minute walk test in apparently healthy individuals"*** submitted by Dr. Md. Tanveer, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2861/PHY/23 dated 13th January, 2023.

PGTSC Comments	PI response
IEC-SOP form not ticked properly many details left vacant-should be revised.	IEC form attached separately
In Inclusion criteria–PI written that apparently healthy individuals will be taken, but in SOP form PI mentioned that Patients will be taken- please clarify.	Attached separately
In role of Investigators-The name of PI and Chief Investigator written are same (Dr. Md. Tanveer). The name and role of Prof. Shraddha Singh has not been given- Please correct.	Role of investigators-Attached separately
From where the Healthy individuals will be recruited-please clarify.	Those who have no previous history of disease and any present symptoms of any disease.
Inform Consent Forms–English / Hindi not similar–should be revised.	ICF form attached separately

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
- PI has still not mentioned that from where he will recruit the healthy individuals-Please Clarify.

PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P27

13- Clarification of research proposal entitled ***"Effect of smartphone usage on neck muscle and hand grip strength"*** submitted by Dr. Keerti, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2862/PHY/23 dated 12th January, 2023.

Previous PGTSC Comment:
- IEC Form in incorrectly and incompletely filled. Please fill the form properly and

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

resubmit for approval.

The above Comment forwarded to PI was reviewed by PR:-
Approved

PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P28

14- Clarification of research proposal entitled ***"Relationship of triglyceride glucose index with body fat percentage and various anthropometric parameters in apparently healthy adults"*** submitted by Dr. Shivani Verma, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2863/PHY/23 dated 13th January, 2023.

PGTSC Comments	PI response
IEC Form in incorrectly and incompletely filled. Please fill the form properly and resubmit for approval.	IEC form attached separately
Where will the hematological investigations be done?	S.Triglycerides, Fasting blood glucose
Who will bear the cost of these?	PI will be bearing the cost

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved

PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P29

15- Clarification of research proposal entitled ***"Comparative evaluation of implant stability in welded immediate implant with and without bicortical anchorage: A randomized controlled trial"*** submitted by Dr. Akshi, JRI, Department of Prosthodontics Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 623/22 dated 21st December, 2022.

Previous PGTSC Comment	PI response
Time duration of follow up not given.	Time duration is mentioned under the study design has been highlighted and text in red (0 months, 3 months, 6 months). The same has also been added to materials and method. A copy of same is attached herewith.
How will post-intervention radiology be correlated to implant stability?	Post intervention radiology has been used for measurement of crestal bone loss and not

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		for implant stability. It is also mentioned under materials and methods, has been highlighted and text in red. A copy of same is attached herewith.
	Suggest changing the term 'Randomized Controlled Trial" in the title of the study to 'Randomized Controlled study'	The suggestion has been considered and the title has been. Changed from Randomized Controlled Trial to Randomized Controlled Study. Changes made are highlighted and text in red. A copy of same is attached herewith.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P33

16- Clarification of research proposal entitled ***"Effectiveness of helfer skin tap technique in pain reduction among infants undergoing intramuscular vaccination at Pediatric outdoor at tertiary care center"*** submitted by Ms. Priya Kumari, through her Guide Mr. Subin Sudarsanan, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2032 dated 12th December, 2022.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIB/P2

17- Clarification of research proposal entitled ***"Effectiveness of CAUTI bundle approach to reduce urinary catheter associated infection rate among Children admitted in Pediatric unit"*** submitted by Ms. Anju Shukla, through her Guide Mr. Subin Sudarsanan, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no. 2005/PF dated 17th December, 2022.

Previous PGTSC Comment	**PI response**
Tools: 1. demographic data (E/H) 2. Assessment of infection(pre test/	1. As per comment I have attached the demographic data. 2. As per comment I have attached the tool for assessment of infection (pre test/post test).

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

post test) (E/H) 3. CAUTI maintenance checklist (E/H) – attached.	3. As per comment I have attached the CAUTI maintenancechecklist.
Methodology details regarding experimental and control grouping in study design is missing- flow chart of the study is needed.	As per comment I have corrected and attached the methodology details regarding the experimental and control group design that is prospective cohort design and I also attached the flowchart of study design as per comment.
Review literature (background of study) regarding CAUTI bundle approach with reference is missing.	As per comment review literature (background of study) regarding CAUTI bundle approach with reference areattached.
ICF- Guardian consent and child assent form instead of Adult ICF is needed as patient below 15 years of age will be recruited in the study.	ICF- Guardian consent and child assent form attached.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIB/P3

18- Clarification of research proposal entitled ***"Suicide risk, perceived stress and coping among adult patients with dissociative disorder"*** submitted by Miss. Sushmita, through her Guide Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2019 dated 10th December, 2022.

Previous PGTSC Comment	PI response
1.Socio-demographic and clinical variables form(E/H),	It is self structured tool made by investigator itself as per the instructions of research guide.(annexure -I)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

1. Columbia- suicide severity rating scale(E/H) 2. Perceived stress scale 3. Coping scale with permission (E/H)-attached	These all tools are already attached with their particular permission letter. I am attaching again all tools with their particular permission letter.(annexure-I)
In SOP from against type of subject – PI-ticked – volunteer column instead of patients.	I am attaching corrected annexure with it. (annexure-II)
Study design details not given- whether descriptive observational /cross-sectional etc.	Study design has been mentioned(cross-sectional) in corrected annexure & that I am attaching with it.(annexure-III)
Why ICD-10 classification for diagnosis has been chosen when latest ICD-11 is available.	I have chosen ICD-10 for the diagnosis because in our hospital setting ICD -10 is being widely used by the doctors & latest version (ICD-11) is not practiced yet, that is why I preferred this.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIB/P5

19- Clarification of research proposal entitled ***"Effectiveness of coconut oil massage therapy on weight gain among preterm neonate admitted in neonatal unit Queen Mary Hospital, KGMU, Lucknow, U.P."*** submitted by Mr. Arun Singh, through his Guide Mr. Subin Sudarsanan, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2006/PF dated 17th December, 2022.

Previous PGTSC Comment	PI response
Tools: 1. Interview/ Observation schedule on weight gain -i) Background data of the mother ii) Background data of Neonates iii) Observation schedule on weight gain (E/H) -attached.	Tool 1- Demographic variables related to mother attached. Tool 2- Demographic variables related to neonates attached. Tool 3- Schedule on weight monitoring are attached.
Experimental and control grouping not discussed in methodology and in sample size section of Protocol - please give	Methodology: Research Design- Quasi experimental design

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	details.	(non- randomized control group designs) Sample size- Sample size calculated using acceptable formula for pre- experimental study as stated below: Sample size for infinite population n = p(1-p)/d2 where, n= minimal sample size Z = standard normal deviation for 95% confidenceinterval Z score is 1.960 p = Expected prevalence population or proportion (Assumed as 50% or 0.5) d = Margin of error = 5% So, n=(1.96)2 *0.5(1-0.5)/0.05*0.05 s=385 Adjusted Sample Size = s/(1+(s-1)/population) = 385/ (1+(384)/200) = 132 So that, n= 132 Experimental group sample size- 66 Control group sample size is 66
	Adult ICF attached but as Neonates will be recruited in this study therefore Guardian consent form is needed–ICF should be revised.	Guardian consent form attached.

The above Comment forwarded to PI was reviewed by PR:-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of PR: Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIB/P6***
20-	Clarification of research proposal entitled ***"Assess demoralization, religious belief and emotional regulation among patient with obsessive compulsive disorder (OCD)"*** submitted by Mr. Aditya Gautam, Through his Guide Mrs. Sudha Mishra, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1992 dated 16th December, 2022. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIB/P7***
21-	Clarification of research proposal entitled ***"Early identification of diabetes mellitus and risk factors among relatives of patient admitted with coronary artery disease in Tertiary Care Hospital"*** submitted by Ms. Aparna Pandey through her Guide Dr. Suchana Roy Bhowmik, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.2018 dated 10th December, 2022. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIB/P8***
22-	Clarification of research proposal entitled ***"Compliance of pediatric patients during ocular prosthesis fabrication with and without midazolam conscious sedation: a pilot randomized control"*** submitted by Dr. Anshu Baid, JRI, Department of Prosthodontics Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 772/23 dated 19th January, 2023.

Sl.no.	Previous PGTSC Comments	PI response
1-	There is nothing like pilot RCT.	It has been changed to pilot study in research proposal title. A copy of the same has been attached herewith.
2-	It should be simply a pilot study.	It has been changed to pilot study in research proposal title. A copy of the same has been attached herewith.
3-	There are too many primary objectives. There should be one primary objective. The rest should be included into secondary objectives.	**Primary Study Objectives:** •To evaluate prosthetic outcome & ease of fabrication of ocular prosthesis in pediatric subjects with and without conscious sedation.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			Secondary study objectives: • To compare time taken in fabrication of ocular prosthesis in pediatric subjects with and without conscious sedation. • To compare employment of physical restraint while fabricating ocular prosthesis in pediatric subjects with and without conscious sedation. • To evaluate the above mentioned parameters on the basis of age and gender. A copy of the same has been attached herewith.
	4-	After identifying the study variables and study parameters, the objective should be converted into research hypothesis in terms of the study parameters.	Research hypothesis has been included. **Research Hypothesis:** The ease of fabrication of ocular prosthesis will be improved when using midazolam conscious sedation as compared to using no sedation. A copy of the same has been attached herewith.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P1

23- Clarification of research proposal entitled *"Sustained virological response to direct acting antiviral therapy in chronic hepatitis C patients with compensated and Decompensated liver cirrhosis-A pilot study"* submitted by Dr. Shailja, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1396 dated 18th January, 2023.

Previous PGTSC Comments	PI response
After identifying the study variable and study parameters, the objective should be converted into research hypothesis in terms of the study parameters.	In this study we have just one variable that is to observe Sustained virological response to Direct acting antiviral therapy in patients of Hepatitis C related compensated and decompensate liver cirrhosis ,once there will be data available we may state a hypothesis. However, currently we have hypothesized that decompensate liver cirrhosis due to Chronic hepatitis C virus infection responds poorer to Direct acting antiviral therapy.
This is comparative study. The	Study design is modified as below-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

study design should be properly defined here it is mentioned simply as observational study.	1.This is a hospital-based case control Pilot study. 2.Patients of Hepatitis C related compensated and decompensated liver cirrhosis will be put on DAA and SVR will be monitored in all patients at 12 and 24 weeks of treatment.
Statistical analysis section should be more specific.	Effect of Direct acting antiviral therapy in patients of Hepatitis C related compensated and decompensate liver cirrhosis in terms of Sustained virological response will be analysed using t test, and chi -square test.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved

PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P2

24- Clarification of research proposal entitled ***"A comparative evaluation of effect of osseodensification on bone density around dental implants: A randomized control trial"*** submitted by Dr. Bhujbal Rushikesh Bhau, JRI, Department of Prosthodontics Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 770/23 dated 19th January, 2023.

Sl. No.	PGTSC Comment	Response of PI
1	Fundamentals for RCT	
	I) Research Hypothesis	Mentioned on page no-
	II) study variables	Mentioned on page no-
	III) outcome measures	Mentioned on page no-
	IV) methods used for random allocation	Mentioned on page no-
	V) how double blinding is done	Mentioned on page no-
2	Sample size calculation is arbitrary. It should be specific to research hypothesis	Sample Size is calculed using the master aticle given by Aseel R Hindi et. Al[11] Sample size is calculated on the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		basis of maximum variation in bone density among study techniques. Mentioned on page number-
3	Clinical Trial Registry is required	We will register clinical trial in clinical trial registry of India at www.ctrin.nic.in after ethical approval and before enrolling first participant.
4	Statistical Methods used to compare groups for primary outcomes, methods for additional analyses such as subgroup analysis and adjusted analysis	Mentioned on page number-
5	Participants flow Outcomes and estimation Adverse events	Mentioned on pg no- Adverse events will be recorded if any.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P10

25- Clarification of research proposal entitled ***"Evaluating the effect of osseodensification technique versus conventional technique of implant placement on bone marker (BMP-9) and clinical implant parameters: A randomized controlled trial"*** submitted by Dr. Husbana Bakrolwala, JRI, Department of Prosthodontics Crown & Bridge, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 771/23 dated 19th January, 2023.

Sl. no.	PGTSC Comment	Response of PI
1.	Fundamentals for RCT	
	I) Research Hypothesis	Mentioned on page no-
	II) study variables	Mentioned on page no-
	III) outcome measures	Mentioned on page no-
	IV) methods used for random allocation	Mentioned on page no-
	V) how double blinding is done	Mentioned on page no-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	VI) success of masking assessment	Mentioned on page no-
2.	Sample size calculation is arbitrary. It should be specific to research hypothesis	Mentioned on page number-
3.	Clinical Trial Registry is required	We will register clinical trial in clinical trial registry of India at www.ctrin.nic.in after ethical approval and before enrolling first participant. Mentioned on page no-
4.	Statistical Methods used to compare groups for primary outcomes, methods for additional analyses such as subgroup analysis and adjusted analysis	Mentioned on page no-
5.	Participants flow Outcomes and estimation Adverse events	Mentioned on pg no- Mentioned on pg no- Mentioned on pg no-

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P11

26- Clarification of research proposal entitled ***"Computed tomography versus ultrasound guided cricoids cartilage diameter measurement as a tool to determine the size of double lumen tube in thoracic surgery-a prospective randomized comparative study"*** submitted by Dr. Roshni Mariam Mathew, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/22/23 dated 7th January, 2023.

Previous PGTSC Comment	**PI response**
After identifying the study variables and study parameters, the objective	Research hypothesis of the study will be to establish superiority of ultrasound guided and computed tomography guided double lumen tube assessment over conventional method. To establish superiority of ultrasound guided and computed tomography guided

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	should be converted into research hypothesis in terms of the study parameters.	double lumen tube assessment over conventional method.
	This is comparative study. The study design should be properly defined.	Prospective Randomised Comparative Study single centre study.
	The sample size calculation is arbitrary. It can be properly done only after defining the proper research hypothesis.	**Sampl** **e size** In this study, we will enroll patients of thoracic surgery requiring one lung ventilation Sample Size at 80% Power of Study Sample size is calculated on the basis of proportion of accuracy in DLT size assessment in the USG & CT guided groups using the formula $$n = \frac{\left(z_\alpha + z_\beta\right)^2}{\left[\ln\left(1-e\right)\right]^2}\left[\frac{1-p_1}{p_1} + \frac{1-p_2}{p_2}\right]$$ Where p_1 = 0.902 (90.2%) proportion of accuracy in DLT size assessment in the USG group p_2 = 0.940 (94.0%) proportion of accuracy in DLT size assessment in the CT group (Ref. Zhang C, Qin X, Zhou W, He S, Liu A, Zhang Y, Dai Z and Yin J (2021) Prediction of Left Double-Lumen Tube Size by Measurement of Cricoid Cartilage Transverse Diameter by Ultrasound and CT Multi-Planar Reconstruction. Front. Med. 8:657612.) $e = 0.15(p_1/p_2)$, the risk ratio considered to be clinically significant Type I error, α=5% Type II error β=20% for detecting results with power of study 80% The sample size is n = 40 each group

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Statistical analysis section is missing.	SPSS latest available version and MS Excel will be use for statistical analysis of the data. The Kolmogorov-Smirnov test will be applied to check whether the data fits normal distribution, Continuous variables conforming to a normal distribution will be expressed as mean ± standard deviation, continuous variables not conforming to normal distribution will be expressed as median and inter-quartile range. Counting data will be expressed as number and percentages. The independent-samples t-test will be used for inter-group analysis of quantitative data such as age, height, weight etc. The $\chi 2$ test will used to compare the proportion data between the groups and the intubation accuracy of the two groups. In all of the statistical analyses, $P<0.05$ will be considered to be statistically significant.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P16

27- Clarification of research proposal entitled ***"A study of cardiovascular hemodynamic assessment in normotensive vs pre-eclamptic pregnancies and its association with maternal outcomes"*** submitted by Dr. Sneha Agarwal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3706/23 dated 19th January, 2023

Previous PGTSC Comment	PI response
The study variables and study parameters should be identified.	Echo parameters– left ventricular end-diastolic volume (LV EDV), left ventricular end systolic volume (LV ESV),left ventricular systolic mass(LV MS),left ventricular diameter, stroke volume(SV), ejection fraction (EF) will be noted by TTE(Transthoracic echocardiography) using phased array transducer probe placed on patient's chest in left lateral position in 3 different views i.e Parasternal long axis, Apical 4 chamber, Parasternal short axis view. Apical view is also used to measure LV ESV which corresponds to end of T wave on ECG. It is measured from medial annulus then traced along whole of endocardium, before opening of mitral valve. Parasternal short axial view is used to measure LVM in end diastolic phase. Parasternal long axis view is used to measure LVD. It is measured from below level of mitral leaflet to septal endocardial border till posterior border of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		endocardium. Serum Pro BNP will be measured using venous blood sample of patients. A minimum of 1ml of blood will be drawn and collected in EDTA vial. BNP level >100pg/ml may be a sign of cardiac failure in any age.
	The aim and objectives should be converted into proper research hypothesis in terms of study parameters. The study design is mentioned as "prospective case control study". Case-control study is retrospective.	**NULL HYPOTHESIS-** There is no difference in the cardiovascular parameters (ECHO and Pro BNP) between normotensive and pre-eclamptic women. **ALTERNATE HYPOTHESIS-** Pre-eclamptic women are more likely to have changes in cardiovascular parameters (ECHO and Pro BNP) than normotensive women. **AIMS AND OBJECTIVES:** • To evaluate cardiovascular parameters using echocardiography(left ventricular end-diastolic volume (LV EDV), left ventricular end systolic volume (LV ESV),left ventricular systolic mass(LV MS),left ventriculardiameter and ejection fraction (EF) and serum pro brain natriuretic peptide(BNP) in normotensive and pre-eclamptic women. • To identify co-relation between serum Pro BNP and cardiac dysfunction in pre-eclamptic women through echocardiographic parameters(LV EDV, LV ESV,LV MS,LVDand EF). • To study the association of echocardiographic parameters and serum Pro BNP with maternal outcome (Pulmonary edema, cardiac failure, DCMP,mortality) in normotensive and pre eclamptic women The study design is "Prospective cohort study".

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Group 1 - 1. Women with pre-eclampsia with gestational age >=34weeks 2. Age 18 – 45years 3. Singleton pregnancy 4. Patient giving consent for the enrolment in the study Group 2 1. Normotensive women with matched gestational age. 2. Age 18 – 45years 3. Singleton pregnancy 4. Patient giving consent for the enrolment in the study
	The sample size calculation is arbitrary. It should be done after properly formulating the research hypothesis.	The sample size was calculated based on a previous study that reported that the prevalence of the preeclampsia is 5.4% in Indian (Eclampsia/ National Health Portal of India, https://www.nhp.gov.in/disease/gynaecology-and-obstetrics/preeclampsia), 95% level of confidence and Error rate, usually set at 0.10. Total 79 patients will be included in each group of the study. $Z2\ P(1-P)/d^2$ Where, n = sample size, Z = Z statistic for a level of confidence, for the level of confidence of 95%, which is conventional, Z value is 1.96.; P = expected prevalence or proportion (in proportion of one; if 5.4%, P = 0.054), d = precision (in proportion of one; if 5%, d = 0.05). $n=1.96x1.96x0.054x0.946/0.05^2$ n=79
	Statistical analysis section is also very general. It should be planned according to the research hypothesis.	**Statistical Analysis:** Data was calculated and analysed. The Chi-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	square test will be used to compare the categorical variables and independent t-test will be used to compare discrete variables between groups. More than two groups will be analysed by ANOVA test. The p value <0.05 will be considered significant. **STATISTICAL TOOLS EMPLOYED** The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 21.0 statistical Analysis Software. The values were represented in Number (%) and Mean ± SD.

Recommendation of Primary reviewer:
Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P22

28- Clarification of research proposal entitled ***"Randomised, single blind, control trial of transcranial direct current stimulation in adults with obsessive compulsive disorder as early augmentation"*** submitted by Dr. Lokesh Kumar, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1476/Psy/22 dated 29th September, 2022.

Previous PGTSC Comments	PI response
Proper formulation of research hypotheses	Proper formulation of research hypotheses is added in the revised document attached herein (page 3 & 4).
Study variables	Study variables are added in the revised document attached herein (page 4).
Primary and secondary outcome measures	Primary and secondary outcome measures are added in the revised document attached herein (page 4).
Method used to generate the random allocation sequence	Randomization method **(Computer generated block randomization table)** is added in the revised document attached herein (page 5).
Regarding blinding of the study	This is a **SINGLE BLIND** study, (not a DOUBLE BLIND study), other details are mentioned on page no. 5
The sample size calculation.	The sample size is calculated through "**G*Power: Statistical Power analyses 3.1.9.7" application.** Details are added in the revised document attached herein (page 5 & 6).
The clinical trial registry.	**Clinical trial registration can be done only after institutional ethics committee approval is obtained.** Clarification regarding clinical trial

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		registry is added in the revised document attached herein (page 6).
	The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses.	The various statistical methods used to compare groups are added in the revised document attached herein (page 7, 8 & 9).
	Participants flow	**Participants flow chart** is added in the revised document attached herein (page 10).
	Baseline data	Details of baseline data obtained during recruitment are added in the revised document attached herein (page 11).
	Outcomes and estimation	Details of various Outcomes and estimation are added in the revised document attached herein (page 11).
	Adverse events	Possible adverse events are mentioned in the revised document attached herein (page 11).
	The clinical trial registry.	**Clinical trial registration can be done only after institutional ethics committee approval is obtained.** Clarification regarding clinical trial registry is added in the revised document attached herein (page 6).

The above Comment forwarded to PI was reviewed by PR:-
Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P26

29- Clarification of research proposal entitled ***"Sonographic predictors of adverse outcome in pregnancy complicated by hyperglycemia in pregnancy"*** submitted by Dr. Aayushi Saini, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3702/23 dated 19th January, 2023.

Previous PGTSC Comments	PI response
Questionnaire not attached	Attached separately
Case record form – not given	Attached separately

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
- Kindly provide Questionnaires.

PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P36

30- Clarification of research proposal entitled ***"A comparative study of naltrexone, baclofen and naltrexone-baclofen and naltrexone-baclofen combination in patient with alcohol dependence"*** submitted by Dr. Mohd Aman Naqvi, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1606/Psy/22 dated 27th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

October, 2022.

Previous PGTSC Comments	PI response
Randomization method in protocol.	Randomization method is added in the revised document attached herein (page 4)
Flow chart of methodology.	The flow chart has been added in methodology in the revised document attached herein (page 9)

The above Comment forwarded to PI was reviewed by PR:-
Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P38

31- Clarification of research proposal entitled ***"To study frequency of linezolid resistance among multidrug resistant mycobacterium tuberculosis isolates from pulmonary samples"*** submitted by Dr. Senjuti Sengupta, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1397 dated 18th January, 2023.

Previous PGTSC Comment:-

- In Inclusion criteria–PI did not mentioned the Age /Sex specificity of Patients having myc. Tub. from which the isolates will be derived- please give the detail.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P50

32- Clarification of research proposal entitled ***"Microsatellite instability and brca-1 in epithelial ovarian cancers"*** submitted by Dr. Richa Singh, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 32 dated 10th January, 2023.

Previous PGTSC Comment:

- Section on Biological/hazardous material has been ticked 'No' whereas ovarian tissue is being used for HPE and IHC.

The above Comment forwarded to PI was reviewed by PR:-
Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P61

33- Clarification of research proposal entitled ***"Heart rate variability with dynamic and static exercise"*** submitted by Dr. Ehsan Ahmad, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2875/PHY/2022 dated 19th January, 2023.

Previous Comment	PI response
Sections on vulnerable subject/special group subjects, use of	Not applicable-Attached separarely

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	biological/hazardous material, consent are not filled.	
	Number of subject is different in the IEC form and the synopsis (150 and 190	Total sample size is 190 human healthy volunteers.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of Primary reviewer: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P68

34- Clarification of research proposal entitled ***"To study the various medical oxygen supply systems in tertiary care Government Teaching Hospital at Lucknow"*** submitted by Dr. Umesh Dhar Dubey, JRI, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/2023/003 dated 3rd January, 2023.

Previous Comment	PI response
It is mentioned that the work will be started w.e.f. 21st March 2022, How without ethical clearance that is done?	Due to human error the date was incorrectly mentioned in the study period. The correct study period would be from 31st March, 2023 to 1st April, 2024.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of Primary reviewer: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P86

35- Clarification of research proposal entitled ***"Effect of rajayoga meditation on anxiety level, hemodynamic parameters, and serum cortisol level in patients undergoing modified radical mastectomy-A prospective randomized control study"*** submitted by Dr. Sreelakshmi. P, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/25/23 dated 7th January, 2023.

Previous Comment	PI response
No review of literature included in the project.	Review of literature has been included as advised. I accept the mistake, the correction has been done.
Method of estimation for serum cortisol not given.	Method of estimation of serum cortisol level (CMIA-Chemiluminescent Microparticl Immunoassay) has been included as advised. I accept the mistake and the correction has been done.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of Primary reviewer: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P89

36- Clarification of research proposal entitled ***"A randomized double blind control trial of ADD-ON duloxetine on symptom severity and quality of life in irritable bowel syndrome"*** submitted by Dr. Vrinda Purshottam, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1713/Psy/2022 dated 16th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

November, 2022.

Previous Comment	PI response
References mentioned in the text are not given in the bibliography e.g. Kaplan et. al. and those in the bibliography are not cited in the text.	Review of literature has been included as advised. I accept the mistake, the correction has been done.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of Primary reviewer: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P97

IB — **Expedited review**

1- Expedited review of research proposal entitled ***"A prospective study of delivery room Neonatal Resucitative interventions, intervention based modified APGAR score and early neonatal outcome"*** submitted by Dr. Alia Zehra, JR-I, Department of Paediatrics, K.G's Medical University, U.P., Lucknow vide letter dated 21st January, 2023.

The above research proposal forwarded to two both reviewers, reply have given by both reviewers with following comments:-

Comments of first Primary reviewer:

- There are too many primary objectives.
- Identify one primary (main) objective. Rest should be grouped into secondary objectives.
- Identify the study variables and population parameters.
- Define research hypothesis (corresponding to primary objective) in terms of study parameters.
- Sample size calculation should be based on main research hypothesis.
- Statistical section should be more specific towards the objectives of the study.

Comments of Secondary Primary reviewer:

- Guardian consent form instead of regular ICF is to be attached.

The above comments forwarded to the PI, reply has given by PI which was forwarded to both reviewers:

Recommendation of first Primary reviewer:- Approved

Recommendation of Secondary Primary reviewer:-

- PI said that she would attach the Guardian consent form, but did not attaché.

PGTSC Comment: As above

PGTSC Decision: Approval subject to modification.

Ref. code: XV PGTSC IB/P1

II-A — **New Thesis-Resident**

1. Research proposal entitled ***"TMJ reconstruction using stock prosthesis: A study"*** submitted by Dr. S. Hemanth Kumar, JR1, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	no. 923/OMSD/22 dated 29th November, 2022. ***Recommendation of Primary reviewer:*** • The study design is not mentioned. • Aims and objectives should be converted into proper research hypothesis in terms of the study variables and parameters. • Sample size calculation is arbitrary. It can be done only after identifying the study design and the research hypothesis. • Statistical analysis section is incomplete. It can also be done only after identifying the proper research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Study of menstrual irregularities and disorders and its impact on quality of life (QOL) in medical undergraduates"*** submitted by Dr. Deepa Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3222/22 dated 11th November, 2022. ***Recommendation of Primary reviewer:*** • The study is on the evaluation of Quality of Life (QOL) instrument. • There is checklist for evaluating such scales. • Where the items come from? Were they assessed for (i) comprehension, (ii) lack of ambiguity? • Was the scale checked for internal consistency: Does it have good test-retest reliability? • Has the instrument been checked for any kind of validity? • The sample size calculation is arbitrary. It should be based on reliability coefficient. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P2***
3.	Research proposal entitled ***"A study of maternal liver dysfunction in early pregnancy and its correlation with gestational diabetes mellitus"*** submitted by Dr. Arushi Chaudhary, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3305/22 dated 23rd November, 2022. ***Recommendation of Primary reviewer:*** • There are too many objectives. • There should be one primary objective and the rest should be grouped into secondary objectives. • The primary objective should be converted into proper research hypothesis in terms of study parameters.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Sample size calculation and statistical analysis section should be in accordance with the research hypothesis. • What are the cohorts in the study design? **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Assessment of need, acceptance & outcome of menopausal hormone therapy in gynecological cancer cases"*** submitted by Dr. Vaishali Anand, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3328/22 dated 26th November, 2022. ***Recommendation of Primary reviewer:*** • Identify one primary objective and classify the rest into secondary objectives. • Convert the primary objective into research hypothesis in terms of study parameters. • Sample size calculation and statistical analysis should be in coherence with the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P4***
5.	Research proposal entitled ***"Evaluation of plasma OREXIN-A, inflammatory cytokines and reductive stress in patients with idiopathic and atypical parkinsonism"*** submitted by Dr. Prashant Panday, JRI, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/695/22 dated 18th November, 2022. ***Recommendation of Primary reviewer:*** • This is prospective cohort study. • Define the two cohorts exclusively. • Identify one primary objective and classify the rest into secondary objectives. • Convert the primary objective into research hypothesis in terms of study parameters. • Sample size calculation and statistical analysis should be in coherence with the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Study of intraocular pressure variation in subjects with type II diabetes mellitus"*** submitted by Dr. Afreen Saif, JRI, Department of Physiology, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. 2772/PHY/22 dated 20th November, 2022. ***Recommendation of Primary reviewer:*** • This is prospective cohort comparative study. • Define the two cohorts exclusively. • Identify one primary objective and classify the rest into secondary objectives. • Convert the primary objective into research hypothesis in terms of study parameters. • Sample size calculation is arbitrary. • Sample size calculation and statistical analysis should be in coherence with the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P6***
7.	Research proposal entitled ***"Comparison of kettlebell and cycling exercise on heart rate variability"*** submitted by Dr. Aman Paisal, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2737/PHY/22 dated 10th October, 2022. ***Recommendation of Primary reviewer:*** • Aims and objectives are not clear. • Identify one primary objective and classify the rest into secondary objectives. • Convert the primary objective into research hypothesis in terms of study parameters. • Study design says: Cross sectional (Pilot Study). • It should be properly identified. • Sample size calculation is missing. • Statistical analysis section is missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Combination therapy of standard antidepressant with oral ketamine as first-line therapy in late-life depression: A open-label trial"*** submitted by Dr. Shubha Joshi, SRI, Department of Geriatric Medicine Health, King George's Medical University, U.P., Lucknow vide letter no. 1854/DGMH/22 dated 26th November, 2022. ***Recommendation of Primary reviewer:*** • Sampling technique (purposive sampling) is not correct. • Sample size calculation is inconsistent to the objective of the study. • Sample size calculation and statistical analysis should be in coherence with the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P8***
9.	Research proposal entitled ***"Magnesium and zinc supplementation in the patients of essential hypertension"*** submitted by Dr. Suresh Kumar Singh, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2791/PHY/22 dated 30th November, 2022. ***Recommendation of Primary reviewer:*** • There are too many aim and objectives. • Identify one primary objective and classify the rest into secondary objectives. • Convert the primary objective into research hypothesis in terms of study parameters. • Study design is not clear. • Sample size calculation is arbitrary. • Sample size calculation and statistical analysis should be in coherence with the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Effect of black coffee and green tea on plasma C-peptide level and fasting blood glucose level in apparently Healthy adults"*** submitted by Dr. Anupam Mittal, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2776/PHY/22 dated 21st November, 2022. ***Recommendation of Primary reviewer:*** • This seems to be a comparative study between two groups. • These two groups are not mentioned anywhere in "aim and objectives". • Identify these two groups exclusively. • Define aims and objectives, research hypothesis, study design etc. after identifying these comparative groups. • Sample size calculation and statistical analysis should be in coherence with the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Comparative assessment of hand grip exercise and 6-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	minute walk test in chronic obstructive pulmonary disease patients" submitted by Dr. Toyaj Kumar, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2775/PHY/22 dated 21st November, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XV-PGTSC-IIA/P11***
12.	Research proposal entitled ***"A study of Psychiatric morbidity, sexual functioning and quality of life in perimenopausal women"*** submitted by Dr. Yamini Agnihotri, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1474/Psy/22 dated 29th October, 2022. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XV-PGTSC-IIA/P12***
13.	Research proposal entitled ***"Randomised, single blind, control trial of transcranial direct current stimulation in adolescents with major depressive disorder as early augmentation"*** submitted by Dr. Saumya Upadhyay, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1451/Psy/22 dated 26th October, 2022. ***Recommendation of Primary reviewer:*** • How will consent be taken, if patient is blind? Please clarify. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P13***
14.	Research proposal entitled ***"A comparative analysis of extra hepatic biliary system anatomy during laparoscopic cholecystectomy with and with and without biliary mapping using methylene blue"*** submitted by Dr. Ravendra Kumar, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3617/22 dated 17th November, 2022. ***Recommendation of Primary reviewer:*** • Is use of Methyline blue a standard procedure for intra operative • The review of literature mentions that in difficult laparoscopic cases methyene tracking of EBA is helpful with positive outcome. Kindly justify the need of study. • Kindly clarify the number of participants: 200 or 50, the steps of calculation are not complete. • Provide Details of surgical procedure. • ICF: Please explain study procedure to patient in easy language. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P14***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

15.	Research proposal entitled ***"Effect of total body fat and anthropometric parameters on blood pressure in adolescents"*** submitted by Dr. Aaqib Husain Ansari, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2744/PHY/22 dated 21st October, 2022. ***Recommendation of Primary reviewer:*** • ICF: Kindly explain the procedure to the study participants instead of writing cross sectional study) **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P15***
16.	Research proposal entitled ***"Role of endocrine disrupting chemical (BISPHENOLA) in the etiopathogenesis of PCOS"*** submitted by Dr. Smriti Yadav, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3221/22 dated 11th November, 2022. ***Recommendation of Primary reviewer:*** • ICF: Kindly explain the procedure to the study participants. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P16***
17.	Research proposal entitled ***"A study of serum ferritin levels in women with preeclampsia and its correlation with pregnancy outcomes"*** submitted by Dr. Rachael Cherubin, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3219/22 dated 11th November, 2022. ***Recommendation of Primary reviewer:*** Approved ***Ref. code: XV-PGTSC-IIA/P17***
18.	Research proposal entitled ***"Conventional vs physics dental extraction forcer: A comparison-A double blind randomized controlled trial"*** submitted by Dr. Heena Yadav, JRI, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 934/8OMSD/22 dated 3rd December, 2022. ***Recommendation of Primary reviewer:*** Approved ***Ref. code: XV-PGTSC-IIA/P18***
19.	Research proposal entitled ***"A cross-sectional study of multiparametric cerebellar neuroimaging in patients with alzheimer; s dementia"*** submitted by Dr. Richa Shukla, SRI, Department of Geriatric Medicine Health, King George's Medical University, U.P., Lucknow vide letter no. 1817/DGMH/22 dated 31st October, 2022. ***Recommendation of Primary reviewer:*** Pending ***Ref. code: XV-PGTSC-IIA/P19***
20.	Research proposal entitled ***"Relationship between hand dexterity function and brain regional volumetry in patients of cognitive impairment-A cross sectional study"*** submitted by Dr. Roshni Basu Roy, SRI, Department of Geriatric Medicine Health, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. 1818/DGMH/22 dated 31st October, 2022. ***Recommendation of Primary reviewer:*** Kindly explain: • Is functional MRI in respect to treatment decision or prognosis, beneficial for the patient having cognitive impairment? If not, then the patient must be informed that this investigation is not a routine process and he/she has to express the willingness to participate in the study. • Please mention clearly that what is the cost of investigation and who will bear it? Patient or investigator. It should be clearly mentioned in the ICF. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P20***
21.	Research proposal entitled ***"To evaluate the predictors of extent and pattern of response to neoadjuvant chemotherapy in breast cancer with emphasis on MAGEE3 equation"*** submitted by Dr. Shehla Fayyaz, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1373/22 dated 17th November, 2022. ***Recommendation of Primary reviewer:*** • Design of study is mentioned as retrospective in the cover letter and retrospective ad prospective in the Material and Methods section. Please clarify. • Sample size is mentioned as 200 at one place and 125 at another. • PI has asked for consent waiver but the design of study is prospective with consent and collection of date being done in prospective manner. • The PI has also included a consent form in the proforma. • Consent cannot be waived if patients are involved in the study. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P21***
22.	Research proposal entitled ***"Quantification of level of endotoxins and lipoteichoic acid (LTA) after photodynamic therapy (PDT) in teeth with secondary endodontic infection: A clinical study"*** submitted by Dr. Dhaniba. K.C, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.394/Coms&Endo/22 dated 29th November, 2022. ***Recommendation of Primary reviewer:*** • The study has six investigators from the same department, including the PI, with overlapping roles. Please reduce the number of Co-PIs or define their individual roles. • The IEC form is incompletely filled. • Please fill the form properly and re-submit. • Consent form does not have contact details/phone number of PI/Co-PI. **PGTSC Comment:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P22***
23.	Research proposal entitled ***"Outcome analysis of pituitary adenoma patients: a retrospective study of last 5 years at a tertiary care centre"*** submitted by Dr. Sanjeev Kumar, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/1670/22 dated 29th November, 2022. *Recommendation of Primary reviewer:* • Design of the study is mentioned as retrospective but data is also being collected prospectively from patients. • No sample size is mentioned in the study. • Patients are being subjected to repeat scanning on follow-up for the study. Who will bear the cost of the scans if the scan is not part of the standard follow-up protocol? • Vulnerable subjects' section has to be filled in by the PI. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P23***
24.	Research proposal entitled ***"Seroprevalence of hepatitis E (HEV) antibody in pregnant female"*** submitted by Dr. Meghna, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3223/22 dated 11th November, 2022. *Recommendation of Primary reviewer:* • Sample size is mentioned as 500 at one place and 100 at another. • A gastroenterology faculty from another Institution has been included as Co-PI while KGMU itself has a Gastro department. • Is there a specific reason for this? **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P24***
25.	Research proposal entitled ***"Effects of equiosmolar 3% hypertonic saline, 8.4% sodium bicarbonate and 20% mannitol on intracranial pressure and metabolic changes in patients undergoing supratentorial craniotomy & tumors excision: A prospective, randomized controlled study"*** submitted by Dr. L.P. Huimila, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1144/22 dated 7th September, 2022. *Recommendation of Primary reviewer:* • Number of subjects not mentioned in the IEC form. • Section on vulnerable subjects, special group subjects and biological and hazardous material not filled. • Sample size mentioned as 9(30x3) but sample size calculation has not been done.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P25***
26.	Research proposal entitled ***"Study of blood pressure variability during different phases of menstrual cycle in apparently healthy females"*** submitted by Dr. Shweta Singh, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2747/PHY/22 dated 22nd October, 2022. ***Recommendation of Primary reviewer:*** • Topic mentions the study is for healthy females but in IEC from 'type of subjects' is mentioned as patients instead of volunteers. • Sample size calculation has not been done and not mentioned o IEC form. • Aim of the study is mentioned as calculation on Intra-ocular pressure in subjects with Type II Diabetes Mellitus. • Measurement of salivary cortisol seems to have been added later as it is not mentioned in Aims or Objectives. • 'No' is ticked in use of body fluids in the section on Biological and Hazardous material. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P26***
27.	Research proposal entitled ***"Outcome analysis of adult patients with tubercular meningitis and sequale managed medically and surgically: A prospective study"*** submitted by Dr. Bishal Paul, SR, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/1657/22 dated 25th November, 2022. ***Recommendation of Primary reviewer:*** • The project has 6 Investigators form one department and three from other making a total of nine. • The Secretary IEC kindly takes a call on this. • Sample size calculation is 139. • How many subjects will be recruited for the study has not been mentioned in the IEC form. • Section on 'Use of Biological material' has been incompletely/incorrectly filled as CSF samples/sputum samples are being collected. • Recruitment form both sexes has been marked as 'No'. Will only males or females be recruited for the study? **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P27***
28.	Research proposal entitled ***"Cross sectional study of intraoperative monitoring of***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	evoked potentials during elective neurosurgeries" submitted by Dr. Deep Shikha, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2743/PHY/22 dated 20th October, 2022. ***Recommendation of Primary reviewer:*** • Sample size is given as 100 but sample size calculation has not been done. • For patients above 2 years and below age of maturity, Assent form is required. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P28***
29.	Research proposal entitled ***"Association between exercise capacity and health markers in adolescents"*** submitted by Dr. Chandra Mani, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2793/PHY/22 dated 1st December, 2022. ***Recommendation of Primary reviewer:*** • Since the study is on subject with an age range of 12-18 years and Assent form for children must be included in the proforma. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P29***
30.	Research proposal entitled ***"Nerve conduction velocity of sural nerve in type 2 diabetic patients"*** submitted by Dr. Lavkush Maurya, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2794/PHY/22 dated 1st December, 2022. ***Recommendation of Primary reviewer:*** • Special group subjects are ticked but details are not given in the IEC form. • Direct identifiers are being used with confidential handling of data. • Sections on Consent and Risks and Benefits are incompletely filled. • Sample size calculation has not been done. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P30***
31.	Research proposal entitled ***"Effect of lemon TEA and Black coffee on heart rate variability and blood pressure recovery time of the moderate exercise"*** submitted by Dr. Pradeep Kumar Chauhan, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2795/PHY/22 dated 1st December, 2022. ***Recommendation of Primary reviewer:*** • Objectives of the study not written properly – need to be revised. • Subjects to be included in the study not defined. • Inclusion and exclusion criteria for recruitment of subjects not given. • Sample size calculation not included.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• No references included or listed. • Consent form to be specific for the study. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P31***
32.	Research proposal entitled ***"Blood stream associated Hospital acquired infection in a Paediatrics population: A tertiary care hospital experience"*** submitted by Dr. Mohd Junaid Khan, JR, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1056/22 dated 7th November, 2022. ***Recommendation of Primary reviewer:*** • No references included or listed. • Consent form needs to be corrected. It shall be from the parent or legal guardian of the child. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P32***
33.	Research proposal entitled ***"Assessment of Psychological Health of Women with gynaecological cancers"*** submitted by Dr. Zaheen Fatima, JR, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3131/22 dated 28th October, 2022. ***Recommendation of Primary reviewer:*** • References not as per any pattern (e.g. Vancouver style etc.) **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P33***
34.	Research proposal entitled ***"Gender differences in clinical spectrum of spondyloarthritis patients: A clinical observational study in a tertiary health care centre"*** submitted by Dr. Parag Vijayvergia, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/959/22 dated 21st December, 2022. ***Recommendation of Primary reviewer:*** • It is mentioned that the study will be started w.e.f. January 2023. Has the candidate started work without ethical clearance?? • Rest fine, may be approved. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P34***
35.	Research proposal entitled ***"Utility of infrared thermoscopy in assessing synovitis in rheumatoid arthritis patients: an observational study"*** submitted by Dr. Nidhish

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Chandra M, SR, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/955/22 dated 21st December, 2022. ***Recommendation of Primary reviewer:*** • Under whom Investigations (including biochemical parameters) will be carried out? • Improper exclusion criteria. Needs to be rechecked. • It is mentioned that the study will be started w.e.f. January 2023. Has the candidate started work without ethical clearance? **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P35***
36.	Research proposal entitled ***"To study the response of tofacitinib in patients with spondyloarthritis refractory to nsaids and conventional dmards"*** submitted by Dr. Buddha Sanjay Pruthvi Raj, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/956/22 dated 21st December, 2022. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XV-PGTSC-IIA/P36***
37.	Research proposal entitled ***"Study of prevalence, progression and response to therapy in connective tissue disease associated disease associated pulmonary artery hypertension"*** submitted by Dr. Lily Kumari, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/957/22 dated 21st December, 2022. ***Recommendation of Primary reviewer:*** • Please recheck the title • Sample size calculation not included. • Why is consent not from the patient? • It is mentioned that the study will be started w.e.f. December 2022. Has the candidate started work without ethical clearance? **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P37***
38.	Research proposal entitled ***"Effect of cyclophosphamide on ovarian function in systemic lupus erythematous and comparison with other immunosuppressant-azathioprine and mycophenolate mofetil"*** submitted by Dr. Shweta Bhardwaj, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/958/22 dated 21st December, 2022. ***Recommendation of Primary reviewer:*** • Sample size calculation not mentioned.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• If the candidate is not sure of getting sufficient number of subjects then make it a pilot study. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P38***
39.	Research proposal entitled ***"Comparative study of role of hyperbaric oxygen therapy versus traditional modalities for anti-aging therapy"*** submitted by Dr. Mehvesh Khan, SR, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1387/22 dated 27th December, 2022. ***Recommendation of Primary reviewer:*** • It is mentioned that the study will be started w.e.f. November 2022. Has the candidate started work without ethical clearance? • Sample size calculation not included. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P39***
40.	Research proposal entitled ***"Expression of RUNX2 and C-MYC in gall bladder carcinoma, correlate with tumour infiltrating lymphocyte and clinicopathological parameters"*** submitted by Dr. Pankaj Gautam, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1467/22 dated 12th December, 2022. ***Recommendation of Primary reviewer:*** • Methods for estimation of biochemical markers not given. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P40***
41.	Research proposal entitled ***"A study of structural and resting state functional MRI in child and adolescent with specific learning disorder"*** submitted by Dr. Avneendra Kumar Singh, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1849/Psy/22 dated 15th December, 2022. ***Recommendation of Primary reviewer:*** • There are four Co-PIs with same role –Please justify • One Co-guide's (Dr. Uttam Kumar) affiliation is different in Undertaking and SOP-IEC Investigator documents –Please correct • PI will do the comparative study taking healthy control and patients, but in methodology grouping has not been explained (whether it is prospective case control study or cross-sectional study-PLEASE CLEAR)- please attach flow chart of the study. • The brief description of some tools is given but they are not attached–please attach all concerned tools (including semi-structured proforma)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P41***
42.	Research proposal entitled ***"A study of comparative efficacy of double lumen tube and EZ blocker for lung Isolation surgeries: A randomized comparative study"*** submitted by Dr. Gaurav Chandela, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1154/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • In Scientific review committee the name and signature of Guide (Dr. Shefali Gautam, Addl. Prof. Psychiatry) is included–please correct or revise the committee. • Patient information sheet is not related to study- please resubmit. • Sample size and its calculation has not been mentioned in Protocol (Only mentioned in IEC-SOP form)- please include. • Flow chart of methodology giving detailed grouping is required. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P42***
43.	Research proposal entitled ***"Comparison of intrathecal morphine vs erector spine plane block for perioperative analgesia in patients undergoing lumbar spine surgery: A prospective, single blind, randomized controlled trial"*** submitted by Dr. Arpita, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1153/22 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • Scientific review committee needs modification (The name and signature of Guide-Prof. G. P. Singh and Co-guide–Dr. Manish Kr. Singh is also there) – please justify or revise. • Patient information sheet is not related to study –please modify • As this is RCT –therefore PI should mention randomization method and include the Flow chart of the study. • Case record form and Demographic profile proforma is missing.- please attach • Is Clinical trial registry has been done? If not then after registering trial the document may be send to Ethics Committee. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P43***
44.	Research proposal entitled ***"Study of single nucleotide polymorphism in foxo3 gene and correlation with prognosis in glioblastoma"*** submitted by Dr. Shamanaz, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1434/22 dated 2nd November, 2022.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • Methodology and sample size details did not mentioned the grouping for tissue samples taken from cases and control-please give detail. • In Inclusion criteria –Age /sex criteria are missing- please include. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P44***
45.	Research proposal entitled ***"A study of untargeted plasma metabolomic profile in children and adolescents with attention deficit hyperactivity disorders"*** submitted by Dr. Brijesh Kumar Yadav, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1878/Psy/22 dated 20th December, 2022. *Recommendation of Primary reviewer:* • All Co-guides and Guide have similar roles–please justify • Study design – In setting part of protocol–PI mentioned it as Prospective case control study and in methodology the data of cases and control subjects are given ,it seems that this is prospective case control study-PI should clear the discrepancy of study design and mention it separately in Protocol. • In Inclusion criteria –Sex specificity not mentioned **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P45***
46.	Research proposal entitled ***"Evaluation of adverse drug reactions in the tuberculosis patients taking anti tubercular treatment under the programmatic management of drug resistant TB (PMDT)"*** submitted by Dr. Aman Kumar, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 13/Pharm/2023 dated 6th January, 2023. *Recommendation of Primary reviewer:* • Approved **PGTSC Decision:** As above ***Ref. code: XV-PGTSC-IIA/P46***
47.	Research proposal entitled ***"Artificial intelligence to predict pulmonary tuberculosis using chest X-Ray of symptomatic population"*** submitted by Dr. Saroj Yadav, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 17/RD/23 dated 7th January, 2023. *Recommendation of Primary reviewer:* • Co-PI expert in AI system has not been included in the study –Please justify or Include. • In Inclusion criteria–Age /Sex specificity not mentioned and as it is case control study, therefore inclusion criteria for control subjects should also be mentioned. • IEC-SOP Form not filled properly as many sections not ticked –Please resubmit SOP form.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIA/P47***
II-B	**MBBS Student**
1.	Research proposal entitled "***Incidence and risk factors associated with phlebitis in Paediatric population: an observational study from a tertiary care centre of North India***" submitted by Mr. Vishesh Sachan & Mr. Amol Srivastava, MBBS, III-Year Through their Mentor Dr. Sarika Gupta, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2719/Ped/22 dated 2nd November, 2022. *Recommendation of Primary reviewer:* • IEC-SOP form not filled properly, many sections are not ticked-should be resubmit. • Guardian consent form instead of general ICF should be attached **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: XV-PGTSC-IIBMBBS-S/P1***
II-C	**MHA**
III	**Modification**
1.	Modification of research proposal entitled ***"A study of phenomenology of major depressive disorder & its correlation with inflammatory markers among COVID-19 recovered elderly"*** submitted by Dr. Shashank Saurabh Sinha, SR-II, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 01/DGMH/2023 dated 6th January, 2023. *Recommendation of Primary reviewer:* • Signature of Dr. Jyoti Bajpai is not there on progress report and on Investigator signature page –Please submit signed documents from all Co-PIs. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with table giving point wise response to comments. ***Ref. code: IV-PGTSC-IIA/P51***

The next Meeting will be held on 17th March, 2023 from 1:30 PM

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University U.P.,
Institutional Ethics Committee
Lucknow - 226003 (UP) India

Prof. Shally Awasthi
Member Secretary, IEC

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

To,

Dr. Alok Dhawan,
Director,
Centre of Biomedical Research (CBMR),
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Raebareli Road,
Lucknow, U.P. 226014

No. 2527 **/Ethics/2023**

Dated: 25/03/2023

Sub.: Reg. Minutes of 121st & 122nd Institutional Ethics Committee Meeting held on 10th February, 2023 & 17th March, 2023 respectively.

Dear Sir,

Please find enclosed herewith the Minutes of 121st & 122nd Institutional Ethics Committee Meeting held on 10th February, 2023 & 17th March, 2023 respectively, for your kind signature.

Thanking you
With regards

Encl.: As above

Yours Sincerely

(Shally Awasthi)
Member Secretary, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 122nd IEC Meeting held on 17th March, 2023

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of 122nd "Institutional Ethics Committee" Meeting held on 17th March, 2023 from 1:30 PM ***virtual.***

The following Members were present in the Meeting:-

1. Dr. Alok Dhawan -Chairman
2. Dr. G.G. Agarwal -Member
3. Dr. Akash Agarwal -Member
4. Dr. A.A. Mahdi -Member
5. Dr. Anupam Mishra -Member
6. Dr. Rajendra Nath -Member
7. Dr. Shally Awasthi -Member

The following members were not present in the Meeting:-

1. Dr. Shubha Phadke - Sent her written comments
2. Dr. D.N. Upadhyaya -Sent his written comments
3. Dr. K.K. Yadav - Sent his written comments
4. Dr. Anita Rani - Sent her written comments
5. Mrs. Vasundhara Kumari
6. Mr. Ujjawal Krishna
7. Mrs.Akansha Dubey

I-A	Action taken
1-	Clarification of research proposal entitled **"*Engineering conditionally replication competent SARS-CoV-2 viral molecular clones and evaluation of cross-variant neutralization*"** sponsored by CSIR-CDRI submitted by Prof. Avinash Agrawal, Head, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1092/22 dated 5th December, 2022. ***Recommendation of Primary reviewer:*** • There are three sections: (i) Hypothesis and objectives, (ii) Aim, and (iii) Objective.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Specify one primary objective and club the rest into secondary objectives. • Identify the study variables and population parameters. • Convert the primary objective into proper research hypothesis using the study variables and population parameters. • What is the study design used? • What is the sampling method? • Sample size calculation is missing. In data analysis para, it is mentioned that 100 patients shall be used. Where does this number come from? • Statistical analysis details are not provided. **Previous EC Decision:** Organize a Meeting with PI, Co-PI with Prof. G.G. Agarwal along with Prof. Shally Awasthi, Member-Secretary, IEC **EC Comment:** • Dr. Agarwal presented his proposal to EC Members. The EC Members gave suggestions and told him that it is the patient's sheet. Only part of the work will be done in KGMU. Dr. Agarwal has to make a summary of changes done in a tabular format and submit it with the revised proposal for approval at the earliest. **EC Decision:** Approval subject to modification. ***Ref. code: 121st ECM IIA/P2***
2-	Clarification of research proposal entitled AVT06-GL-C01 Version: Version 2.0,21 December 2021 entitled ***"A randomized, double-masked, parallel-group, multicenter clinical study to evaluate the efficacy and safety of AVT06 compared with EU-Eylea® in subjects with neovascular (Wet) age-related macular degeneration (ALCOEYE)"*** sponsored by M/s Alvotech Swiss AG Thurgauerstrasse submitted by Prof. Sandeep Saxena, Department of Ophthalmology, King George's Medical University, U.P., Lucknow, vide letter no. 1856/OPH dated 15th March, 2023. ***Previous recommendation of PR:*** • The proposal was discussed in the meeting held at KGMU and comments given. **Previous EC Comment:** • Study Design, Please clarify • Recruitment Period, Please clarify. **Reply of PI** 1. **Study Design:** As per the Protocol AVT06-GL-C01 – Version 2.0, 21 Dec 2021 section 4.1, the study consists of a screening period of up to 4 weeks, a treatment period of 48 weeks, and a follow-up period of 4 weeks until Week 52 (end of study). The **total study duration per subject is 56 weeks** including screening period e.g. if The Subject gets enrolled in Jun 2023 then the subject participation in study will be completed somewhere in July 2024. Means subject study participation is for approx. 1 year.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 17th March, 2023

	2. **Recruitment Period:** It is extended till beginning of Jun-2023 (Sponsor India Newsletter is attached, Page number 03) *The above Comment forwarded to PI was reviewed by PR:-* **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 118th ECM IIC/P1***
3-.	Clarification of research proposal entitled "***Mechanisms of autophagy-mediated cell survival in breast cancers and its implication in therapeutics and diagnostics***" submitted by Prof. M.L.B. Bhatt, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 208/RT/2023 dated 27th February, 2023. **Previous EC Comment** | **PI response** No patient information brochure. Hindi translation of title of proposal is incorrect. | It has been attached as annexure VII in both Hindi & English languages. *The above Comment forwarded to PI was reviewed by PR:-* • Clarification related AUTOPHAGY RELATED GENES IN BREAST CANCER. • Looks ok. Autophagy related genes-can be simplified. • Just as studies related to genes which can be important modifies of effects of therapies. • Word [UTAK] for tissue sample-can be replaced by ट्यूमर का नमूना या सर्जरी से निकाले गये ट्यूमर का थोड़ा हिस्सा। • Retrospective data analysis, no identifiers in the data. • Patients will not be contacted for missing information. **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 116th ECM IIA/P7***
4.	Clarification of research proposal entitled "***Study to establish validity of rubric based assessment tool for evaluation of analytical cognitive skills in neuroanatomy module in first phase MBBS course***" submitted by Prof. Anita Rani, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 616/ANAT/23 dated 14th February, 2023. *Previous EC Comment:* • References not attached *The above Comment forwarded to PI was reviewed by PR:-* *Recommendation of PR:* Provisionally approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

EC Decision: Approved
Dr. Anita Rani did not take part in the discussion & making decision.
Ref. code: 120th ECM IIA/P17

5. Clarification of research proposal entitled **"*Obesity and its impact on public Health: An epidemiological study on Uttar Pradesh population*"** submitted by Dr. Suchit Swaroop, Associate Professor, Department of Zoology, Co-PI Prof. Satyendra Kumar Sonkar, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 529/Med/23 dated 28th February, 2023.

Previous EC Comment	PI response
While for "Use of Biological material" it is indicated as "NA" it means no blood will be collected, on the other hand second objectives related to "Biochemical Profiling" and the data collection sheet contains 'blood details'	Since it is a cross sectional observational study and based on case histories / questionnaire, therefore, there is no need of blood collection from patients. Collection of data will be done from patient's case history reports and available biochemical routine test reports from the case record.
Patient information sheet is still not attached as per SOP.	Patient information sheet has been attached in both English and Hindi versions.
Statistical analysis will obviously be done after data collection but PI is expected to submit the anticipated Statistical analysis on the basis of anticipated outcome parameters.	ICF was submitted both in Hindi and English along with IEC submission form. And also attached herewith.
Statistical analysis will obviously be done after data collection but PI is expected to submit the anticipated Statistical analysis on the basis of anticipated outcome parameters.	Statistical analysis will be performed using statistical software SPSS (IBM Statistical Package for Social Sciences, Statistic for Windows, Version 28.0. Armonk, NY: IBM Corp). All values will be expressed as mean ± SD, and p-value (<0.05) will be considered as statistically significant. The continuous variables in accordance with the normal distribution will be expressed by mean ± standard deviation, and the quantitative data will be compared by independent sample t-test. The BMI will be converted to a z-score by this equation: (BMI-BMImean)/BMISD. WC, HC and WC/HC will be also transformed to z-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		scores by the same equation. The association between each z-score and Obesity will be measured by the logistic analysis, and adjusted factors (age, gender, drinking and smoking conditions). Chi-square test or Fisher' s exact test would be use to compare the prevalence of disease among individuals. ANOVA, Pearson correlation, logistic regression and linear regression will also be used analyse the results.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Provisionally approved
EC Decision: Approved

Ref. code: 120th ECM II A/P25

6. Clarification of research proposal entitled "***Right ventricular dysfunction in critically ill: prognostic impact on short and long term mortality***" submitted by Dr. Nitin Rai, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/279/23 dated 14th February, 2023.

Previous EC Comment	PI response
Scientific review committee report is missing.	Duly noted and the Scientific review committee report has been attached.
Duration of study	The total duration of study will be 1 year of recruitment and there will be follow up period of 6 months following the discharge from ICU.
Missing sample size calculation.	Duly noted and sample size calculation has been included.
Kindly fill in the gaps which are left over in annexure 1.	Duly noted and addressed.
The patient information sheet in Hindi is incomplete.	Duly noted and rectified

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Provisionally approved
EC Decision: Approved

Ref. code: 120th ECM II A/P27

I-B **Expedited review**

1. Expedited review of research proposal entitled "***Elucidation of novel prognostic markers and their role in progression of diabetes mellitus-associated neurocognitive***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	disorder (DMAND)" sponsored by DHR submitted by Prof. Shailendra Kumar Saxena, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/1035/23 dated 30th January, 2023. ***The above research proposal was forwarded to two Primary reviewers.*** ***Recommendation of First PR:-*** • Identity one primary objective and group the rest into secondary objectives. • Primary objective should be converted into a proper research hypothesis in terms of the study parameters and study variables. • The study design is not given. • There is no sample size calculation. • Statistical analysis section is arbitrary. It should be specific to the research hypothesis and the other objectives of the study. ***Recommendation of Secondary PR:-*** • In Scientific review committee-the name and signature of Principal-Investigator (Prof. Shailendra Saxena) is there-Please clarified or revise scientific review committee. • In Inclusion/Exclusion criteria-Mention of Pregnant and lactating women is missing. • Sample size and its calculation is missing from Protocol (Only total no.84 is given in SOP-Check-list) • Study design and detailed methodology flow chart is missing from Protocol. • MMSE Tool for diagnosing neurocognitive disorder not attached. ***The above Comment forwarded to PI was reviewed by both PR:-*** ***Recommendation of both PR:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 122nd ECM IB/P1***
2.	Expedited review of research proposal entitled ***"A study to identify diagnostic salivary markers for assessment of alveolar ridge resorption in edentate subjects"*** sponsored by Science & Engineering Research Board (SFRB), New Delhi submitted by Dr. Deeksha Arya, Additional Professor, Department of Prosthodintics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 866/23 dated 24th February, 2023. ***The above research proposal was forwarded to two Primary reviewers.*** ***Recommendation of First Primary reviewer:-*** • This is a well written proposal. Some minor modifications are required. • Identify one primary objective, and the rest should be grouped into secondary objectives. • Convert the primary objective into a proper research hypothesis in terms of the study parameter and study variables. • The sample size calculation is arbitrary. It is for prevalence study. • This is not a prevalence study. Define the outcome measure for the main event

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	"salivary markers". • Use this in calculating the sample size accordingly as it is a continuous or categorical variable. • Statistical Analysis section should be more specific. ***Recommendation of Secondary Primary reviewer:-*** • Sponsor information-The PI has ticked both Central Government and National Industry. • Budget for the study in the IEC form is mentioned as Rs.16,57,252 while this sum is not mentioned in the SERB Approval letter. • The PI is using direct identifiers. • Use of body fluids has been ticked 'No' but saliva is being used. • In the section on Data monitoring the answer to the question 'Is there plan of reporting adverse events' is mentioned as 'No'. ***The above comments forwarded to PI were reviewed by PRs:*** ***Recommendation of First PR--*** Approved ***Recommendation of Secondary PR***-Approved **EC Decision:** Approved ***Ref. code: 122nd ECM IB/P2***
II-A	**New Proposal**
1.	Research proposal entitled ***"Combination treatment with low dose amantadine and escitalopram in atypical parkinsonian disorders-A retrospective study"*** submitted by Dr. Shailendra Mohan Tripathi, Associate Professor, Department of Geriatric Medicine Health, King George's Medical University, U.P., Lucknow vide letter no. 07/DGMH/23 dated 7th January, 2023. ***Recommendation of PR:*** Approved **EC Decision:** As above ***Ref. code: 122nd ECM IIA/P1***
2.	Research proposal entitled ***"3D generated markers for intra-operative planning of bile duct identification and repair in a case of post cholecystectomy complex benign biliary stricture"*** submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SG/119/23 dated 8th February, 2023. ***Recommendation of PR:*** Approved **EC Decision:** As above ***Ref. code: 122nd ECM IIA/P2***
3.	Research proposal entitled ***"Comparative evaluation of post operative facial nerve injury in conventional 45° incision v/s modified 90° incision in AL-KAYAT bramley and hemi-coronal approach"*** submitted by Prof. Geeta Singh, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 242/OMDS/23 dated 14th February, 2023

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Waiver of consent Approved ***Ref. code: 122nd ECM IIA/P3***
II-B	**New Ph. D Proposal**
1.	Research proposal entitled "***Morphpmetric, morphological and histological study of placenta, in still births, intra uterine deaths and live births***" submitted by Dr. Mah Paiker, Ph.D. Scholar under the guidance Prof. Mahboobul Haque, Head, Department of Anatomy, IIMS&R, Lucknow through Prof. S.P. Jaiswar, Co-guide, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3697/23 dated 18th January, 2023. ***Recommendation of PR:*** • Identify one primary objective, and the rest should be clubbed into secondary objectives. • Identify the study variables and population parameters. • Convert the primary objective into a proper research hypothesis. • Sample size is given to be 90. There is no formula given. • Everything including sample size calculation, statistical analysis etc. should be in accordance with the research hypothesis. In the present form it is very arbitrary. **EC Comment:** As above **EC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: 122nd ECMIIB-Ph.D/P1***
2.	Research proposal entitled "***Exploring the role of miRNAs in oral cancer***" submitted by Mrs. Pooja Nayak, Ph.D. Scholar under the guidance Dr. Mohammad Kaleem Ahmad, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/2023/1057/23 dated 15th February, 2023. ***Recommendation of PR:*** • Identify one primary objective, and the rest should be clubbed into secondary objectives. • Identify the study variables and population parameters. • Convert the primary objective into a proper research hypothesis. • The sample size calculation is arbitrary. • Everything including sample size calculation, statistical analysis etc. should be in accordance with the research hypothesis. **EC Comment:** As above **EC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: 122nd ECMIIB-Ph.D/P2***
3.	Research proposal entitled "***The development, validation and standardization of "antenatal anxiety inventory" to assess anxiety among antenatal Women in Department of Obstetrics & Gynecology in KGMU.***" submitted by Mrs. Suman Lata, Ph.D. Scholar under the guidance Prof. Sujata Deo, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/4051/23 dated 22nd February, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of PR: Approved **EC Decision:** As above ***Ref. code: 122nd ECMIIB-Ph.D/P3***
4.	Research proposal entitled "***Role of metabolites in progression of non muscle invasive bladder cancer***" sponsored by ICMR submitted by Mr. Mukul Kumar Singh, Ph.D. Scholar under the guidance Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow, vide letter no. 208/URO/23 dated 28th February, 2023. *Recommendation of PR:* Approved **EC Decision:** As above ***Ref. code: 122nd ECMIIB-Ph.D/P4***
5.	Research proposal entitled "***To explore the relationship between periodontitis and preterm delivery with FCγ receptor polymorphisms as genetic susceptibility factor***" submitted by Dr. Iman Baig, Ph.D Scholar, under the guidance Prof. Pavitra Rastogi, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2802/P/23 dated 28th February, 2023. *Recommendation of PR:* • Project is very sketchy. • No introduction or review of literature included. • Materials and methods not given. • Sample size calculation, inclusion or exclusion of subjects not included. • Duration of study not mentioned. • No references cited. **EC Comment:** As above **EC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: 122nd ECMIIB-Ph.D/P5***
II-B	**Research Scientist**
1.	Research proposal entitled "***3-D bioprinting of immunocompetent skin equivalent model for safety assessment of cosmetics & personal care products***" sponsored by DHR submitted by Dr. Ashish Dwivedi,Scientist & Assistant Professor, Department of Photobiology Laboratory, Systems Toxicology & Health Risk Assessment Group, CSIR-IITR, Lucknow through Dr. Swastika Survirya, Additional Professor, Department of Dermatology Venerology & Leprosy, King George's Medical University, U.P., Lucknow vide letter no. 16/Skin/23 dated 27th January, 2023. *Recommendation of PR:* Approved **EC Decision:** As above ***Ref. code: 122nd ECMIIB/P1***
2.	Research proposal entitled "***PNA FISH analysis for diagnosis of candida infection in blood and CSF: comparison with conventional methods, gene expression for virulence***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	factors and fluconazole resistance" sponsored by DHR submitted by Ms. Shivangi Tripathi through her Mentor Prof. Gopa Banerjee, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. DHR/CAND08/23 dated 7th February, 2023. ***Recommendation of PR:*** Approved **EC Decision:** As above ***Ref. code: 122nd ECMIIB/P2***
II-C	**Review of New Drug Trial**
1.	Research protocol no. 18F-MC-GPIJ entitled "***A phase 3, randomized, double-blind, placebo-controlled study to investigator the effects of tirzepatide on the reduction of morbidity and mortality in adults with obesity***" sponsored by M/s Eli Lilly Company Legal Registered submitted by Prof. Gaurav Chaudhary, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no.494/Cardio/Res/2022 dated 16th December, 2022. ***Recommendation of PR:*** - CTRI -Approval number awaited **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 122nd ECMIIC/P1***
2.	Research protocol no. DRL-IND-NDA03-ELO/2022 entitled "***A randomized, multicentre, double blind, placebo controlled, parallel-Group study to evaluate the efficacy and safety of elobixibat once daily of Dr. Reddy's Laboratories Limited in patients with chronic constipation***" sponsored by M/s Dr. Reddy's Laboratories Limited submitted by Prof. Abhijit Chandra, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow, vide letter no. SGE/CT/03/23 dated 20th January, 2023. ***Recommendation of PR:*** - CTRI -Approval number awaited **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 122nd ECMIIC/P2***
3.	Research protocol entitled "***A phase III, multicentre, randomized, double-blinded, placebo-controlled, interventional study on efficacy and safety of standardized fraction of picrorhiza kurroa royal ex Benth (Picroliv®) for 24 weeks in the management of non-alcoholic fatty liver disease (NAFLD)***" sponsored by M/s ICMR submitted by Prof. Satyendra Kumar Sonkar, Department of Medicine, King George's Medical University, U.P., Lucknow, vide letter no. 489/MED/23 dated 23rd February, 2023. ***Recommendation of PR:*** Approved **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 122nd ECMIIC/P3***
4.	Research protocol entitled "***A phase 2, multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the clinical efficacy and safety of VTX002***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	in subjects with moderately to severely active ulcerative colitis*"** sponsored by M/s Oppilan Pharma Ltd submitted by Prof. Abhijit Chandra, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SGE/CT/05/23 dated 22nd February, 2023. ***Recommendation of PR: • CTRI form has been submitted. CTRI approval is pending. Needs to be submitted • DCGI permission not present. • Optional Genetic testing is being ordered from outside the country-Central Lab. Labcorp Development, Singapore. • Is pregnant partner and fetus of a subject receiving the test drug covered under the Insurance scheme? • Could not fine the budget approval letter in the application. • Sample size mentioned by the PI in the IEC form is 180. However, in the CTRI application the sample size from India in mentioned as 25 • Section on Biological/hazardous material in incorrectly filled as blood is being collected for Optional Genetic Sampling and is being sent abroad. • Section on Compensation says, compensation will be paid by Sponsor not the Insurance Company. Is this correct? **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 122nd ECMIIC/P4***
5.	Research protocol no. TILD-19-07 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF experienced subjects with active psoriatic arthritis I (INSPIRE 1)***" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow, vide letter no. Rh/CT/20/23 dated 25th February, 2023. ***Recommendation of PR:*** • IEC form section on Clinical Trials part ii (approval and Marketing) is not filled. • Section on Special Group subjects, Confidential handling of data, who will obtain consent, compensation for injury is not filled. • DSMB is ticked yes but adverse events are being reported to IEC and Sponsor. Please correct. • Use of biological materials denies any sample collection but next section says samples will be sent abroad. Reason for this is not mentioned. • DCGI application does not mention KGMU site/KGMU PI. • DCGI application attached but not approval. • Clinical trial agreement is only a format without and details like KGMU site/Budgetary allocation. **EC Decision:** Defer to the next Meeting because quorum was incomplete.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 122nd ECMIIC/P5
6.	Research protocol no. TILD-19-19 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF naive subjects with active psoriatic arthritis II (INSPIRE 2)***" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow, vide letter no. Rh/CT/21/23 dated 25th February, 2023. ***Recommendation of PR:*** • IEC form section on Clinical Trials part ii (approval and Marketing) is not filled. • Section on Special Group subjects, Confidential handling of data, who will obtain consent, compensation for injury is not filled. • DCMB is ticked yes but adverse events are being reported to IEC and Sponsor. Please correct. • Use of biological materials denies any sample collection but next section says samples will be sent abroad. Reason for this is not mentioned. • DCGI application attached but not approval. • Clinical trial agreement is only a format without any details like KGMU site/Budgetary allocation. **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 122nd ECMIIC/P6***
III A-	**Additional Document**
1.	Additional of research protocol no. CLNA043A12202 entitled "***A 5-year, randomized, double-blind, placebo-controlled, multi-center study assessing the efficacy, safety, and tolerability of intra-articular regimens of LNA043 versus placebo in patients with symptomatic knee osteoarthritis (ONWARDS)***" sponsored by M/s Novartis Healthcare Pvt. Ltd submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 12/P/OS/23 dated 16th February, 2023. **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 114th ECMIIC/P3***
2.	Additional of research protocol no. CTQJ230A12301 entitled "***A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease (Horizon Study)***" sponsored by M/s Novartis Health Care Pvt. Ltd. submitted by Prof. S.K. Dwivedi, Head, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 645/Cardio/Res/23 dated 24th February, 2023. **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 101st ECMIIC/P18***
III-B	**Modification**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

1.	Modification of research protocol no. LTE15174 Protocol Version 5 Dated 12 Oct 2022 entitled **"ATLAS-OLE:** ***An open label long term safety and efficacy study of fitusiran in patients with hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX"*** submitted by Dr. S.P. Verma, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. CH/02/CT/23 dated 7th January, 2023. **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref.code:90th ECMIIC/P1***
2.	Modification of research protocol no. CKJX839B12302 entitled ***"A randomized, double-blind, placebo-controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT)"*** sponsored by M/s Novartis Healthcare Pvt. Ltd submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 612/Cardio/Res/23 dated 10th February, 2023. ***Recommendation of PR:*** • Summary of changes seen–OK and Noted • Other documents related to clinical trials e.g.-CTA document, DCGI Permission, Insurance etc. are not attached. **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 114th ECMIIC/P4***
3.	Modification of research protocol entitled ***"A pilot observation study to assess the role of centralized monitoring in general medicine wards"*** sponsored by M/s Turtle Shell Technologies Pvt. Ltd. submitted by Dr. Ambuj Yadav, Assistant Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/02/23 dated 28th February, 2023. ***Recommendation of PR:-*** • Project already approved previously. Requested changes to the protocol may kindly be approved. **EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 117th ECMIIC/P7***
IV	**Extension**
1-	Extension of research proposal entitled ***"Deciphering FLT3-ITD elicited signaling pathways in AML cell growth and block in differentiation: hunt for therapeutic targets and inhibitors for mutant FLT3 proteins"*** submitted by Prof. M.L.B. Bhatt, Ex-Hon'ble Vice Chancellor & Head, Department of Radiotherapy, K.G's Medical University, U.P., Lucknow vide letter no. 218/RT/23 dated 1st March, 2023. ***Recommendation of PR:*** Pending **EC Decision:** Approved for extension. ***Ref. code: 103rd ECM IIA/P23***
V	**Brought to Ethics Committee after XVI-PGTSC held on 14th March,**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

2023.

Minutes of XVI-PG Thesis sub Committee" of "Institutional Ethics Committee" Meeting ***virtually*** held on 14th March, 2023 from 1.30 PM.

The following Members were present in the Meeting:

1. Dr. G.G. Agarwal - Member
2. Dr. A.A. Mahdi - Member
3. Dr. Rajendra Nath - Member
4. Dr. D.N. Upadhyaya - Member
5. Dr. Shally Awasthi -Convener

The following Member was not present in the Meeting:

1. Dr. Anita Rani- She has given her written comment.

I-A **Action taken**

1- Clarification of research proposal entitled ***"To study thecomplications of percutaneous nephrolithotomy"*** submitted by Dr. Udham Singh, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 211/URO/23 dated 1st March, 2023.

Previous PGTSC Comment	PI response
Study design in Protocol - Prospective observational study from June -21 to June -22 ? If study has already not started then how it is possible. In ICF the study design mentioned is Combined Retrospective and Prospective study.	Study design is Prospective observational study. □ Study period is June 2021 to October 2022. □ Study has already started.
Sample size -All adult pts will be included , exact calculated sample size not given	The sample size was calculated based on the previous study that reported the prevalence of kidney stones is ~10% globally (Saeed R. Khan et al 2017) 95% level of confidence and error rate, usually set at 0.05. Total 139 (minimum) patients will be included in this study. n= Z 2 P(1-P)/d 2 Where • n= sample size • Z=Z statistic for level of confidence , for the level of confidence of 95% which is conventional ,Z value is 1.96 • P= Expected prevalence of proportion (in

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		proportion of one ,if 10% ,P=0.1) • d= precision (in proportion of one: if 5% d =0.05). n=1.96 x 1.96 x 0.1 x 0.935/0.052 =138.29 =139
	In Exclusion criteria – it is mentioned that pt below 12 yrs of age not included (In methodology it has been mentioned that analysis of prospectively maintained data of more than 12 yrs of age)– please Clarify. The Age of the patients being included.	All the patients at or above 18 years of age undergoing the procedure percutaneous nephrolithotomy are being included in the study. Patients below 18 years of age are being excluded from study.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XI-PGTSC-IIA/P10

2- Clarification of research proposal entitled ***"Complications associated with ureterorenoscopy (URS) related to treatment of urolithiasis: A prospective study"*** submitted by Dr. Jigardeep Singh, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 210/URO/23 dated 1st March, 2023.

Previous PGTSC Comment	PI response
Sample size -not mentioned (All patients above 18 yrs of age Undergoing ureteroscopic stone removal)-Justify	□ The sample size was calculated based on the previous study that reported the prevalence of urolithiasis is 10 % globally (Jacob Lang et al 2021) 95% level of confidence and error rate , usually set at 0.05. Total 139 (minimum) patients will be included in this study. n= Z 2 P(1-P)/d 2 Where • n= sample size • Z=Z statistic for level of confidence , for the level of confidence of 95% which is conventional ,Z value is 1.96 • P= Expected prevalence of proportion (in proportion of one ,if 10% ,P=0.1) • d= precision (in proportion of one: if

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	5% d =0.05). n= 1.96 x 1.96 x 0.1 x 0.9/0.0025 = 138.29 = 139 □ Only the patients more than 18 years of age are included in present study.
It is a prospective observational study and PI mentioned that patients from June-2021 to June 2022 will be included. Is PI already started the study or pts will be taken retrospectively -Please specify	Prospective observational study patients will be taken retrospective □ Study period :June 2021 to December 2022 □ Study has been already started.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XI-PGTSC-IIA/P11

3- Clarification of research proposal entitled ***"Efficacy of nasolabial flap in post mucor infrastructure maxillectomy defects"*** submitted by Dr. Ravi Katrolia, SR, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 245/OMSD/23 dated 15th February, 2023.

Previous PGTSC Comment	PI response
This is a before and after treatment study.	Yes, this is a before and after type of prospective study. Changes have been made in the ethical form.
Study variables and parameters should be properly defined for the study.	Proforma was revised accordingly
Research hypothesis should be formulated in terms of the parameters.	To evaluate the efficacy of nasolabial flap in rehabilitation of post mucor infrastructure maxillectomy defects in terms of nutritional status, speech and swallowing ability.
Sample size calculation is required.	Sample calculation is attached to the profoma.
Statistical analysis section is required.	All the values will be tabulated pre and post surgically based on the grading system provided. Data will be analysed using SPSS software to generate the results.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: As above ***Ref. code: XII-PGTSC-IIA/P1***
4-	Clarification of research proposal entitled ***"The effect of concentrated growth factor (SGF) and platelet rich fibrin (PRF) on post endodontic surgery healing: A randomized clinical trial"*** submitted by Dr. Supriya Choudhary, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 490/Coms & Endo/2023 dated 25th January, 2023. ***Recommendation of Primary reviewer:*** • If it is really, RCT, all the fundamentals are missing. • Clinical trial registry is required. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary in the absence of proper research hypothesis. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P8***
5-	Clarification of research proposal entitled ***"Clinicophysiological outcome after peroral endoscopic myotomy (POEM) vs heller's cardiomyotomy for achalasia cardia"*** submitted by Dr. Sanjay Kumar Tripathi, SR, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. 122/23 dated 9th February, 2023.

Previous PGTSC Comment	PI response
Research hypothesis should be stated after properly identifying the study variables and parameters.	Hypothesis of this study that the suboptimal clinical response observed with LHM in the treatment of achalasia is due to an inadequate myotomy length, and POEM allows for a longer myotomy, hence it may be more successful in achieving clinical response. So aims of this study is to compare the effectiveness and safety of POEM and LHM for the treatment of patients with achalasia.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Sample size calculation is missing.	**Sample size:** Sample size was calculated using 98 % clinical response in POEM group and 80.8% in LHM group (As per the study by Vivek Kumbhari, et.al.2014 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4486039/pdf/10-1055-s-0034-1391668.pdf). The β error was taken as 20% (study power-80%) and alpha error of 5%. **Formula** n = (Zα/2+Zβ)2 * (p1(1-p1)+p2(1-p2)) / (p1-p2)2, Zα/2 is the critical value of the Normal distribution at α/2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Zβ is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84) p1 and p2 are the expected sample proportions of the two groups. The minimum calculated sample size is 50 patients in each group.
	Statistical analysis section is arbitrary. It should be specific to the research hypothesis in question.	Data Management and Statistical analysis: Data will be entered on excel sheet. Statistical analysis will be performed using the software Statistical Package for the Social Sciences (SPSS Version 16.0, Chicago, IL) for windows or using Graph pad prism (Version 5.0). For continuous variables, multiple groups were compared using one-way ANOVA and by student t-test for two groups. Categorical data's will be analysed using Chi-square test with Yates' correction or Chi- square test for trend or Fisher exact test. Correlation analysis will be performed using Pearson correlation method. Patient survival will be estimated using the Kaplan-Meier method and the difference between the survival curves will be analyzed by the log-rank test. Cox proportional hazard analysis will be used for estimating the hazard of failure. Two-tailed p value less than 0.05 will be considered to be statistically significant.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIII-PGTSC-IIA/P9

6- Clarification of research proposal entitled ***"Comparison between landmark method and real time ultrasound technique to determine the correct depth of inscrtion of central venous catheter in right internal jugular vein in pediatric neurosurgical patients: A prospective randomized controlled trial"*** submitted by Dr. Shagun Paliwal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/68/2023 dated 20th January, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous PGTSC Comment:- • Kindly confirm the number of cases (100 or 126) 2. Mention the process for Randomization of Patients. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P17***
7-	Clarification of research proposal entitled ***"Effect of face masks on six minute walk test in apparently healthy individuals"*** submitted by Dr. Md. Tanveer, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2956/PHY/23 dated 28th February, 2023. ***Recommendation of Primary reviewer:*** • IEC-SOP form not ticked properly many details left vacant-should be revised. • In Inclusion criteria–PI written that apparently healthy individuals will be taken, but in SOP form PI mentioned that Patients will be taken- please clarify. • In role of Investigators-The name of PI and Chief Investigator written are same (Dr. Md. Tanveer). The name and role of Prof. Shraddha Singh has not been given- Please correct. • From where the Healthy individuals will be recruited-please clarify. • Inform Consent Forms–English / Hindi not similar–should be revised. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIII-PGTSC-IIA/P27***
8-	Clarification of research proposal entitled ***"Comparison of efficacy transforaminal epidural injection of autologous platelet rich plasma vs triamcinolone in patient of lumbar disc herniation with radicular pain: A prospective randomized control study"*** submitted by Dr. Amit Kumar, JR, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anae/127/23 dated 4th February, 2023.

Previous PGTSC Comment	PI response
IEC form is incompletely filled.	New IEC form attached separately
CTRI registration will be required.	CTRI registration applied.
Inclusion criteria must include patients.	Patients giving written consent will be taken □ All patient in the age group of 20 to 60 years. □ ASA grade I & II □ Low back pain more than 3 months

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		and unilateral lower limb with radicular pain □ Posterolateral lumbar disc herniation of L4/L5 or L5/S1 segment on CT and corresponding clinical symptoms and signs □ Pain level on VAS ≥5 □ No symptoms of severe nerve damage include motor paralysis, muscle atrophy and cauda equine syndrome □ No history of spinal surgery
	Who have been recommended non-operative management by clinician/Neurosurgeon/orthopedic surgeon?	Clinician
	A neurosurgeon/orthopedic surgeon must be included as a co-supervisor who can help in management of patient's problems.	Neurosurgeon – Dr. Awadhesh Kumar Yadav Additional professor Department of Neurosurgery KGMU, Lucknow Included in the study
	The above Comment forwarded to PI was reviewed by PR:- ***Recommendation of PR:*** Approved **PGTSC Decision:** As above	
		Ref. code: XIII-PGTSC-IIA/P30
9-	Clarification of research proposal entitled ***"Comparision of effects of intratracheal with intravenous dexmedetomidine on recovery from general anaesthesia after laparoscopic surgeries: A randomized controlled double blind study"*** submitted by Dr. Esha Batra, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/130/23 dated 6th February, 2023. ***Previous PGTSC Comment:-*** • Too many Co-PIs from the same department. • No Co-PI from the department of general surgery from where the patients will be recruited. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above	
		Ref. code: XIII-PGTSC-IIA/P36
10-	Clarification of research proposal entitled ***"Determinants of re-admission in ICU***	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

survivors" submitted by Dr. Ratnesh Kumar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1534/22 dated 10th February, 2023.

Previous PGTSC Comment	PI response
The study variables and study parameters should be identified.	**AIMS AND OBJECTIVES** **Aim:** • To study the determinants of re-admission in ICU survivors and post discharge 90 days mortality in trauma centre **Primary Objectives** • To findout the determinants of re-admission in ICU **Secondary Objectives:** • To determine the 90 days mortality in ICU survivors. • To findout the incidence of readmission
The research hypothesis should be properly formulated in terms of study parameters.	To assess the outcome of patients with ICU admission, and find out the risk factors of mortality among patients.
The sample size calculation is arbitrary. It can be done only after defining the research hypothesis. Statistical Analysis section is missing.	On the basis of previous study, Hua M et al (2015). The sample size (n) = $2\ (Z\alpha/_2 + Z_{[1-\beta]})^2 \times \sigma^2/(\mu1-\mu2)^2$, assuming 0.05 level significance ($Z_{\alpha/2}$ =1.96), and 90% power ($Z_{[1-\beta]}$)=1.28) was 34.88=35. Due to follow-up loss, in this study we will enroll 35 patients. $$n = \frac{2\ (Z\alpha/_2 + Z_{[1-\beta]})^2 \times \sigma^2}{(\mu1-\mu2)^2}$$ $$n = \frac{2\ (1.96 + 1.28)^2 \times 1.80^2}{(7.0-5.31)^2}$$

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		n=35 *Hua M, Gong MN, Brady J, Wunsch H. Early and late unplanned rehospitalizations for survivors of critical illness*. Crit Care Med. 2015 Feb;43(2):430-8.*
	Statistical Analysis section is missing.	The statistical analysis was done using SPSS 21.0 version (Chicago, Inc., USA) windows software. The data was expressed as mean and standard deviation (SD) or median, range and percentage as appropriate. All the categorical data was compare by using chi square test. Continuous variables in two groups was compared by t- test. The p-value <0.05 was considered as significant.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P4

11 Clarification of research proposal entitled ***"Assessment of midterm estimated GFR(EGFR) by different formula (24HRS CREATININE CLEARANCE, MDRD, CKD-EPI & NANRA) in patients of hypertensive disorders of pregnancy and its association with fetomaternal outcomes"*** submitted by Dr. Priya Agarwal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3868/2023 dated 3rd February, 2023

Previous PGTSC Comment	PI response
The study variables and study parameters should be identified.	Midterm eGFR will be calculated in all pregnant women between 14-28 weeks coming to Department of Obstetrics & Gynecology, KGMU in both OPD and IPD for antenatal care. using different formulae (CKD-EPI, MDRD, NANRA) and will be compared with gold standard 24-hour urine creatinine clearance. Primary outcome will be studied in form of sensitivity and specificity of the other methods of eGFR calculation (CKD-EPI, MDRD, NANRA) as compared to gold standard 24-hour urine creatinine clearance Secondary outcome will include

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		correlation of eGFR with adverse fetomaternal outcomes. **Adverse maternal outcome will be measured in form of** - Women developing Hypertensive disorder of pregnancy (HDP) which could be gestational hypertension, non-severe preeclampsia, severe preeclampsia or eclampsia. -Placental Abruption -Oligohydramnios -Pulmonary Edema -Hepatic dysfunction /HELLP Syndrome -Cardiovascular accidents **Adverse fetal outcome will be measured in form of** - Preterm birth - IUGR - Antepartum fetal demise - Need for NNU /NICU admission
	The research hypothesis should be properly formulated in terms of study parameters.	**NULL HYPOTHESIS-** 1) The other methods of eGFR calculation (CKD-EPI, MDRD, NANRA) are not better as compared with gold standard 24-hour urine creatinine clearance. 2) eGFR has no association with fetomaternal outcomes. **ALTERNATE HYPOTHESIS** 1) The other methods of eGFR calculation (CKD-EPI, MDRD,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		NANRA) are better as compared with gold standard 24-hour urine creatinine clearance. 2) eGFR has association with fetomaternal outcomes. **AIM** 1. To determine sensitivity and specificity of other methods of eGFR calculation (CKD-EPI, MDRD, NANRA) with gold standard (24-hour urine creatinine clearance) in pregnant women. 2. To determine the association of eGFR with fetomaternal outcomes. **OBJECTIVES** 1) Calculation of midterm eGFR by different formula in pregnant women (CKD-EPI, MDRD, NANRA) and compare it with gold standard (24-hour urine creatinine clearance) between 14-28 weeks gestation. 2) Association of eGFR with fetomaternal outcomes.
The sample size calculation is arbitrary. It can be done only after defining the research hypothesis. Statistical Analysis section is missing.		*According to a study Kaul A, Pandey A, Behera MR, et al. Midterm eGFR Predicts Pregnancy Outcomes: An Observational Study. J Assoc Physicians India 2022;70(12):22–25.* Sample size for present study was estimated for Fischer's exact test by using G power software. Considering the proportions of adverse outcomes (Group 1) and normal fetomaternal outcomes (Group 2) in the forementioned study (0.34 and 0.65) respectively, alpha =0.05 and power =0.95 with allocation ratio (N2/N1) 2.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		The sample size required is 129 with allocation of 43 and 86 in group 1 and group 2. In this study patients will be divided in two groups based on eGFR calculated by 24-hour urine creatinine clearance. **Group 1 having eGFR <=120 and >=150ml/min/1.72m2.** **Group 2 having eGFR between 120-150ml/min/1.73m2.** Considering the loss to follow up to be approx. 10% in each group Loss to follow up of patients in Group 1=10 % x 43= 4.3 Loss to follow up of patients in Group 2=10% x 86= 8.6 Total patients in group 1(abnormal eGFR)= { 43 + 4.3}= 47.3~ 48 Total patients in group 2(normal eGFR)= { 86 + 8.6}= 94.6~ 95 **Total sample size= 48 + 95= 143 ~ 144** The eGFR of patients enrolled in the study will be calculated by 24-hour urine creatinine clearance formula and based on that patients will be divided in two groups till the sample size is completed.
	The study design is mentioned as "prospective case control study" It should be properly mentioned as case-control study is retrospective study.	The study design is "Prospective cohort study".
	Statistical analysis section is missing.	**Statistical Analysis**: SPSS version 21.0 will be used for statistical analysis. Data will be presented as mean (standard deviation), number and percentage (%). The Chi-square and Fischer's exact test will be used to compare the categorical variables and independent t test will

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		be used to compare discrete variables between groups. The Sensitivity, Specificity, PPV, NPV and ROC curve will be used to assess the overall diagnostic of abnormal outcome. Regression analysis will be used for the estimation of relationships between a dependant variable and one or more independent variables, The p value 0.05 will be considered significant.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P6

12- Clarification of research proposal entitled ***"Clinical audit of critically ill obstetric patients in intensive care unit: A retrospective & prospective study"*** submitted by Dr. Rashi Rastogi, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/2079/22 dated 3rd October, 2022.

Previous PGTSC Comment	PI response
The type of study is mentioned as "retrospective and prospective observational study"	It has been corrected as prospective observational study.
The study can not be prospective and retrospective at the same time.	Considering the study to be prospective observational study, the relevant changes in the sample size calculation have been done .Instead of 400 as the sample size , my sample size currently obtained is 150
The research hypotheses, sample size calculations etc. would be different for two types of studies.	I have made correction in the research hypothesis and objectives. Based on audit hypothesis will be to determine the admission of patients in ICU and their outcomes. Outcomes will be : □ To analyze their Changes has been done in objectives and research hypothesis in the thesis proforma attached. clinical characteristics & the intervention required. □ To analyze the fetomaternal outcome.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: XIV-PGTSC-IIA/P7

13- Clarification of research proposal entitled ***"Measurement of changes in blood flow across coronary sinus using transoesophageal echocardiography post coronary artery bypass grafting: A single center observational study"*** submitted by Dr. Himanshu Sharma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/126/2023 dated 4th February, 2023.

Previous PGTSC Comment	PI response
This seems to be one-group pretest-posttest design.	Yes
So everything should be planned according to this	Yes
The study variables and study parameters should be identified.	We are studying one variable i.e. velocity across coronary sinus.
The research hypothesis should be properly formulated in terms of study parameters.	Research hypothesis – Pre surgery and the post surgery rest all variables that includes Heart rate, Blood pressure, oxygen saturation, temperature will be kept in 20% range for all the cases and requirement of inotropes used in maintaining the variables in 20% range will be calculated and formulated against increment in our primary variables.
The sample size calculation is arbitrary. It should be specific to research hypothesis.	Sample size calculation attached separately. Yes
Statistical analysis section is very general. It should be also specific to research hypothesis.	Attached separately

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P8

14- Clarification of research proposal entitled ***"A randomized control trial to determine effect of dopamine as vegf (Vascular endothelial growth factor) antagonist on development of acute lung injury in sepsis"*** submitted by Dr. Shivam Agarwal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/225/23 dated 2nd March, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous PGTSC Comment	PI response
Research hypothesis	This study is hypothesized to ascertain effect of dopamine infusion on progression of sepsis to acute lung injury assuming that there is no effect of dopamine on progression of sepsis to acute lung injury in ICU admitted patients.
Study variables	Progression to acute lung injury which can be assesses by following variables : VEGF levels Development of ALI on the basis of chest x-ray and Murray's score
Primary and secondary outcome measures	Primary : To assess the effect of dopamine as VEGF inhibitor on progression of sepsis to ALI Secondary: 1. To establish the relationship of VEGF level in severity of lung injury. 2. To correlate the survival benefit of Dopamine in patients with sepsis. 3. Length of ICU stay. 4. Any associated side effect of dopamine.
Method used to generate random allocation	Randomized by computer generated random number table in two groups (I & II)
Blinding	Sample will be collected and sent for analysis by the personals working in the ICU, not involved in the study so that neither the patient nor the investigator will know that what treatment patient has received.
Sample Size	The sample size will be calculated based on a previous study that reported that incidence of acute lung injury (ALI)/acute respiratory distress syndrome (ARDS) was 11.4% in India (Singh

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		et al., 2014), 8 95% level of confidence and Error rate, usually set at 0.07 level is 4. Total 78 patients will be included in this study. n=Z 2 P(1-P)/d 2 Where, • n = sample size, • Z = Z statistic for a level of confidence, for the level of confidence of 95%, which is conventional, Z value is 1.96. • P = expected prevalence or proportion (in proportion of one; if 11.4%, P = 0.11), • d = precision (in proportion of one; if 7%, d = 0.07). n=1.96x1.96x0.11x0.89/0.07 2 n=76.75=77
	CTRI registration	Will apply after ethical approval?
	Statistical Method	SPSS version 21.0 will be used for statistical analysis. Data will be presented as mean (standard deviation), number and percentage (%). The Chi-square test will be used to compare the categorical variables and independent t test will be used to compare discrete variables between groups. The Sensitivity, Specificity, PPV, NPV and ROC curve will be used to assess the overall diagnosis of lung injury. Regression analysis will be used for the estimation of relationships between a dependent variable and one or more independent variables. The p value 0.05 will be considered significant.
	How results will be presented: Participants flow, baseline data, outcome and estimation	CONSORT diagram for the same is attached separately.
	Adverse events	Any associated side effect of dopamine, including cardiovascular,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		gastrointestinal, nervous, respiratory will be noted like Irregular heartbeats, Nausea, Vomiting, Anxiety, Headache, Chills, Goosebumps, Shortness of breath and if any of these develops, infusion will be stopped and patient will be excluded from study.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P9

15- Clarification of research proposal entitled ***"Arterial lactate as independent predictor of in-hospital mortality in trauma patient admitted in intensive care unit: A prospective observational study"*** submitted by Dr. Sarvesh Kumar Vishwakarma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/194/23 dated 24th February, 2023.

Previous PGTSC Comment	PI response
After identifying the study variables and study parameters, the objective should be converted into research hypothesis in terms of the study parameters	Null Hypothesis- Study will be done to ascertain the association of lactate level with mortality assuming there is no correlation between lactate level and mortality in trauma patients admitted in ICU.
The study design is not defined.	Prospective Observational Study.
The sample size calculation is not given.	**The sample size (n=109) is now recalculated.
Statistical analysis section is very general. It should be specific the research hypothesis.	Statistical analysis Data will be entered in Microsoft excel and analysed using statistical software SPSS version 26 (Chicago, IL, USA). Categorical data will be presented in percentage/frequency and continuous variables in mean±SD. The categorical data will be compared using Chisquare test or Fisher's test. The continuous variable like mean lactate level will be compared using student-t test (parametric) or Mann-Whitney U test (non-parametric), as applicable. All the data will be analysed at 95% CI and a p values < 0.05 will be considered statistically significant.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Sample Size Calculation: The Fisher's formulae used for sample size calculation: (Jung SH, 2013) and Hayashi Y Endoh,H , Kamimura,N,Tamakawa, T ,& Nitta,M,(2020) Lactate indices as predictor of in- hospital mortality or 90 days survival after admission to an intensive care unit in unselected critically ill patients. PloS one, 2020,15(3), e0229135. Formula: $N = Z^2 \times p(1-p)$ d^2 $2.57^2 \times 0.12(1-0.88) = 6.60 \times 0.12(1-0.88)$ 0.0064 $0.6974 = 108.98 \simeq 109$ 0.0064 **Description: N = Required sample size Z = Normal deviant at the portion of 99% confidence interval = 2.57 p =Proportion of death in intermediate lactate group (12%, Bou et al., 2017) d = Margin of error at 8% (standard value of 0.08) Using this formula, minimum sample size (N) =109 ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P14***
16-	Clarification of research proposal entitled ***"Apnoeic oxygenation with low flow oxygen cannula during intubation in paediatric patients with hydrocephalus: a randomized controlled trial"*** submitted by Dr. Kartikey Vaish, JR, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.Anaes/182/23 dated 22nd February, 2023.

Previous PGTSC Comment	PI response
If it is really RCT, all the fundamentals are missing	In this study has we have defined hypothesis, group allocation, concealment, and study objectives clearly.
For example:- i. Proper formulation of research hypotheses. ii. Study variables. iii. Primary and secondary outcomes measures.	We have attached- formulation of research hypotheses, Study variables, Primary and secondary outcomes measures, Method used to generate the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	iv. Method used to generate the random allocation sequences, including details of any restriction. v. How double blinding is done vi. How success of masking assessed	random allocation sequences. Blinding was not done as it is not possible in our study.
	The sample size calculation is arbitrary. It should be specific.	Sample size calculation attached.
	Statistical analysis section is also very general. It should be specific to the research hypothesis.	Attached
	How the results will be presented: i. Participants flow, baseline data, outcomes and estimation and adverse events etc.	Flowchart, data presentation plan attached separately.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P18

17- Clarification of research proposal entitled ***"Clinical audit of acute kidney injury in critically ill obstetric patients and association with maternal outcome"*** submitted by Dr. Himani Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. 120/OG/2023 dated 9th February, 2023.

Previous PGTSC Comment:-

- The type of study is mentioned as "retrospective and prospective observational study"
- The study can not be prospective and retrospective at the same time.
- The research hypotheses, sample size calculations etc. would be different for two types of studies.
- The proposal should be very specific clearly defining the objectives, research hypotheses etc.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P19

18- Clarification of research proposal entitled ***"Study of endometrial scratching in infertile***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

couples undergoing ovulation induction and intrauterine insemination" submitted by Dr. Vertika, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3060/22 dated 14th October, 2022.

Previous PGTSC Comment	PI response	Action taken
If it is really, RCT, all the fundamentals are missing.	We are extremely sorry for this discrepancy. Appropriate amendments like randomization method and allocation have been added.	Randomization method and allocation have been described in detail in the Material and Method section.
For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed.	We are extremely sorry for this discrepancy. The following amendments are being done in the revised version (i) Research hypothesis formulated and stated (ii) study variables properly identified and stated, (iii) primary and secondary outcome measures have been identified, (iv) Method of randomization and technique used for sampling has been described, (v)The study does not involve blinding as it is an open label study, (vi) masking has not been done.	Indicated changes as per submitted response have been made in the Methodology section.
The sample size calculation is arbitrary.	Appropriate sample size calculation as per	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	It should be specific to the research hypothesis.	formulated hypothesis has been made.	
	The clinical trial registry is required.	The study is planned to be registered to Indian Clinical Trial Registry, however, they require ethical approval for submission. Once the ethical approval is obtained, the study will be submitted to trial registry.	To be done after ethical approval is obtained.
	The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses.	The statistical analysis plan has been rechecked and updated. Right now the plan is being submitted for the stated objectives only. For other possible relationships appropriate analytical plan will be devised as per need.	Statistical plan revised and updated.
	How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc.	A tentative plan has been submitted.	Incorporated under Section Data analysis.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P20

19- Clarification of research proposal entitled ***"Analysis of treatment and survival outcome of vulval carcinoma over a period of 10 years"*** submitted by Dr. Akanksha Jaiswal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3979/23 dated 15th February, 2022.

Previous PGTSC Comment	PI response
Title says: "Analysis of treatment	The title is being changed to "Analysis of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

and survival outcome of vulval carcinoma over a period of 10 years"	Disease Characteristics and survival outcome of vulval carcinoma."
The duration of study is supposed to be one year.	It is admitted that the duration of study is one year, which is going to be done by the undersigned on the basis of 10 years records available in the Department of Obstetrics and Gynaecology and Department of Radiation Oncology, KGMU, Lucknow, U.P.,(i.e. the cases diagnosed between January 2014 to December 2023).
The study variables and study parameters should be identified.	The Variables Parameters are to be studied as follows:- -Demographic variable:- age, parity, residence, menopausal status. -Disease Variable:- Risk factors, Presenting symptoms, Histological Stage of Disease. -Treatment Variable:-Surgery or Chemo-radiation. Type of Surgery [Radical velvectomy, modified radical velvectomy (with or without lymphnode dissection)]. -Survival Variable:- Overall survival Disease free survival recurrence.
The research hypothesis should be properly formulated in terms of study parameters.	The research hypothesis is-Are demographic profile, disease characteristics, survival outcome of Vulval Carcinoma similar to global data?
The study design is mentioned as "prospective and retrospective analytic study". It can not be both.	The study is mainly retrospective but cases are being diagnosed and treated during the study will also be included as prospective cases.
The sample size calculation is arbitrary. It should be done after properly formulating the research hypothesis.	Sample size is being calculated in detail as below:- The Sample Size is computed by using the formula Z 2 P(1-P)/d 2 considering 10% as the minimal clinical difference in proportion with 5% level of significance. Prevalence of vulval carcinoma is 0.67% by cancer statistics 2022. The minimum number of subject required is 24.01 adding the 20% of non response. The

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	final sample size is 28.81, which would be considered as 30.
Statistical analysis section is also very general. It should be planned according to the research hypothesis.	The Statistical Analysis will be done on SPSS 23rd version, the data will be duly entered in excel sheets. The demographic profile and clinical features of the data will be analyzed using descriptive statistics. The result will be presented in frequencies, percentage and mean +_SD and a p value of & it 0.1 will be considered statistical significant. The Kaplan–Meier curve will be used for overall survival.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P21

20- Clarification of research proposal entitled ***"To study the ultrasound and histopathological scoring system to predict prognosis of placenta accrete syndrome and its correlation with surgical and neonatal outcome"*** submitted by Dr. Akansha, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow.

Previous PGTSC Comment	PI response	Action taken
If it is really, RCT, all the fundamentals are missing.	We are extremely sorry for this discrepancy. Appropriate amendments like randomization method and allocation have been added.	Randomization method and allocation have been described in detail in the Material and Method section.
For example (i) Proper formulation of research hypothesis, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any	We are extremely sorry for this discrepancy. The following amendments are being done in the revised version (i) Research hypothesis formulated and stated (ii) study variables properly identified and stated, (iii) primary and secondary outcome measures have been identified, (iv) Method of randomization and technique	Indicated changes as per submitted response have been made in the Methodology section.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	restrictions (blocking, stratification, etc.), (v) How double blinding is done, (vi) how the success of masking assessed.	used for sampling has been described, (v) The study does not involve blinding as it is an open label study, (vi) masking has not been done.	
	The sample size calculation is arbitrary. It should be specific to the research hypothesis.	Appropriate sample size calculation as per formulated hypothesis has been made.	
	The clinical trial registry is required.	The study is planned to be registered to Indian Clinical Trial Registry, however, they require ethical approval for submission. Once the ethical approval is obtained, the study will be submitted to trial registry.	To be done after ethical approval is obtained.
	The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses.	The statistical analysis plan has been rechecked and updated. Right now the plan is being submitted for the stated objectives only. For other possible relationships appropriate analytical plan will be devised as per need.	Statistical plan revised and updated.
	How the results will be presented; (i) Participants flow; (ii) baseline data, (iii) Outcomes and estimation, (iv) adverse events, etc.	A tentative plan has been submitted.	Incorporated under section Data analysis.
	The above Comment forwarded to PI was reviewed by PR:- ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P23***		
21-	Clarification of research proposal entitled ***"Experience of repairing genitourinary***		

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

fistula-retrospective and prospective study" submitted by Dr. Krishna Kumar Bhandari, SRI, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 175/URO dated 20th February, 2023.

Previous PGTSC Comment	PI response
The type of study is mentioned as "retrospective and prospective study"	The average number of patient with genitourinary fistula being repaired in Dept. of Urology, KGMU on average is 25-30 cases per year. The estimated sample size of our study would be around 139 cases, so I have to consider retrospective analysis of patients already underwent genitourinary fistula repair over past years (as retrospective study) from 2002 to 2022 and also will take prospective data from January 2023 to December 2023 with follow up period of 2 months. The study design is thus both retrospective and prospective in nature.
The study can not be prospective and retrospective at the same time.	**Retrospective study:-** From 2002 to 2022, the outcome analysis of patients already treated in Dept. of urology KGMU will be done. This will be retrospective type of study. **Prospective Study:-** The study period will be from January 2023 to December 2023 and outcome of repaired genitourinary fistula with follow up period of 2 months will be included. The total data will be analyzed finally for a meaningful outcome result.
The research hypotheses, sample size calculations etc. would be different for two types of studies.	The estimated Sample size calculated is based on the reported success rate of genitourinary fistula which is more than 90 % globally (Priyadarshi et. al. 2006, V singh et. al. 2012, 2013) , with 95% level of confidence and Error rate, usually set as 5% , total 139 Patients will be included in this study for a meaningful outcome result. n= Z 2 P(1-P)/d 2 Where, □ n = Sample size,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		□ Z = Z Statistic for level of confidence, for the level of confidence of 95%, which is conventional, Z value is 1.96. □ P = Expected prevalence of proportion (in proportion of one; if 90%, P = 0.9). □ d = Precision (in proportion of one; if 5%, d = 0.05). n = 1.96x1.96x0.9x0.1/0.05 2 n = 138.4 n = 139
	The proposal should be very specific clearly defining the objectives, research hypotheses etc.	**Primary objective of study:** - To know the success rate of genitourinary fistula repair. The success of repair is defined as complete cure of urinary Incontinence.
	The "patient consent form" is missing (English & Hindi both)	The patient consent form has been attached in (both Hindi and English).

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P24

22- Clarification of research proposal entitled ***"Comparison of ultrasound guided continuous erector spinae plane block and epidural block for postoperative analgesia in laparoscopic nephrectomy: A prospective randomized study"*** submitted by Dr. Amita Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/94/2023 dated 30th January, 2023.

Previous PGTSC Comment	PI response
The study variables and study parameters should be identified.	AIM: The aim of the study is to compare ultrasound guided continuous Erector Spinae Plane block and Epidural block for postoperative analgesia in Laparoscopic Nephrectomy. OBJECTIVE • Primary objective: • To compare time of use of first dose of rescue analgesia • Secondary objective:to compare: • Total consumption of rescue analgesic

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		in 24 hours postoperatively in both groups. • VAS score in 24 hours postoperatively. • Perioperative hemodynamic changes. • Procedure related complications. • Total intraoperative fentanyl consumption if heart rate or blood pressure or both increase >20% of baseline. • Bowel recovery and ambulation. Primary Outcome Variable: Time taken for administration of first rescue analgesic (Injection Tramadol 100 mg IV)measured from time of giving block/epidural will be primary outcome variable. Secondary Outcome Variable: 1. Total consumption of rescue analgesia (injection Tramadol 100 mg IV) consumed in first 24 hours after surgery. 2. Post-operative VAS in first 24 hours at (0 min,30mins,1 ,2,4,6,12,24 hrs) 3. Perioperative hemodynamic (heart rate, mean blood pressure, respiratory rate, SpO2) changes at (0 min,30 mins,1,2,4,6,12,24hrs) 4. Total intraoperative fentanyl consumption if heart rate or blood pressure or both increase >20% of baseline 5. Procedure related complications. 6. Bowel recovery and ambulation
	Research hypothesis should be defined in terms of study parameters.	Research Hypothesis –To determine which of the following two blocks: ultrasound-guided continuous erect spinae block and epidural block is superior for

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		postoperative analgesia in laparoscopic nephrectomy
	Sample size calculation is arbitrary. It should be specific to the research hypothesis.	The study has power of 0.8 and type I error of 0.05. On the basis of previous study, the changes in mean Time to first rescue analgesia (h) in between Erector Spinae Plane Block group (7.0) and Thoracic Epidural Blocks (5.31) was 1.69 and the population variance ($\sigma 2$) was 1.81 (Moharam et al., 2022). The sample size (n) = 2 ($Z\alpha/2 + Z$ [1-β]) 2 × $\sigma 2$ /($\mu 1 - \mu 2$)2, assuming 0.05 level significance ($Z\alpha/2$ =1.96), and 90% power (Z [1-β])=1.28) was 24.08 in each group. Due to follow-up loss, in this study we will enroll 30 patients in each group. 2 ($Z\alpha/2$ + Z [1-β]) 2 × $\sigma 2$ n= ($\mu 1 - \mu 2$)2 2 (1.96 + 1.28)2 × 1.812 n= (7.0-5.31)2 n=24.08(minimum number of patients in each group) To account for follow-up loss, 30 patients will be included in each group. Moharam SA, Amera M. Elkeblawy, Marouf HM, Elnoamany TM. Comparison of Ultrasound Guided Thoracic Erector Spinae Plane, Thoracic Paravertebral and Thoracic Epidural Blocks for Pain Management after Nephrectomy. JAMMR 2022;34(19):44-52, 2022
	Statistical analysis section is also very genera. It should be specific to the research hypothesis.	The statistical analysis will be done using SPSS 21.0 version (Chicago, Inc., USA) windows software. The data will be expressed as mean±standard deviation (SD) or median with range and number with percentage as appropriate. All the categorical data

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		will be compared by using Chi-squared test. Continuous variables in two groups will be compared by unpaired t- test. Ordinal variables will be analyzed using Mann-Whitney U test.A two sided p-value <0.05 will be considered significant.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P25

23- Clarification of research proposal entitled ***"Efficacy and safety of carbetocin versus oxytocin in prevention of postpartum hemorrhage in highrisk women-an open label randomized control trial"*** submitted by Dr.Smriti Bag, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3988/23 dated 15th February, 2023.

Previous PGTSC Comment	PI response
Sample size discrepancy in SOP form, Protocol and flow chart –Please correct	The sample size discrepancy has been now corrected.
Inclusion criteria –Age specificity of recruiting patients not mentioned (only gestational Age is given)–Please mention.	Now the age of the women has been specify. "Women of age between 18-35 years of Gestational age of 37-42 weeks"
Patient Information sheet not related to study – please submit revised PIS	Now the PIS have been revised.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P28

24- Clarification of research proposal entitled ***"Study to evaluate diagnostic accuracy of serum CA125, HE4 and expression of P53 in varied spectrum of epithelial ovarian neoplasm"*** submitted by Dr. Eva Raman, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3723/22 dated 25th January, 2023.

Recommendation of Primary reviewer:

- In Inclusion criteria Age specificity of Women having ovarian CA not mentioned.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P35

25- Clarification of research proposal entitled ***"Comparative evaluation of effect of mode of***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

delivery of artificial tears on level of interleukin 6 (IL-^) and matrix metallopeptidase 9 (MMP-9) in anophthalmic sockets with ocular prosthesis-A randomized controlled trial" submitted by Dr. Pushpa Kumari, JRI, Department of Prosthodontics & Crown & Bridge, Faculty of Denttal Sciencrs, King 2nd February, 2023.

Previous PGTSC Comment	PI response
Consort guidelines not fully followed – PI to mention about blinding and submit flow chart of methodology.	Outcome assessor blinded randomized controlled trial. Mentioned on page no. 10
In addition to regular ICF, the Guardian consent and Child Assent form is also needed.	Mentioned on page no. 15-16 Mentioned on page no. 17-18 Mentioned on page no. 19-20

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P37

26- Clarification of research proposal entitled ***"A study of mental capacity in acute and transient psychotic disorders"*** submitted by Dr. Farzana Rizvi, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 109/Psy/23 dated 25th January, 2023.

Previous PGTSC Comment:

- IEC-SOP form Vulnerable pts column –ticked by PI as No-should be corrected
- LAR Consent must be included in ICF and Given ICF English version should be started from new page.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P40

27- Clarification of research proposal entitled ***"Effect of Virtually Reality glasses and melody on cortisol and ACTH levels in patients of knee replacement surgery under combined spinal epidural anaesthesia"*** submitted by Dr. Nisha Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/151/23 dated 11th February, 2023.

Previous PGTSC Comment:-

- In Scientific Review Committee, the name and signature of Chief Guide Prof. Monika Kohli is there –please justify or resubmit.
- In Investigators page the Department's name of two Co-guides is wrongly mentioned-should be corrected.
- Method of randomization not mentioned.
- ICF-H/E –attached but not similar –should be corrected.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XIV-PGTSC-IIA/P41
28-	Clarification of research proposal entitled ***"Anthropometry of lip nose complex of unilateral cleft lip deformity and normal children by 3D digital photogrammetry and analysis and scoring of preoperative and postoperative deformity"*** submitted by Dr. Prachi Varshney, SR, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 165/23 dated 8th February, 2023. ***Recommendation of Primary reviewer:*** • Inclusion criteria did not mentioned Age and sex of the subjects ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above
	Ref. code: XIV-PGTSC-IIA/P43
29-	Clarification of research proposal entitled ***"Comparative study to evaluate response of intra articular injection of trialmcinolone vs hyaluronidase to rehabilitate stiff finger joints"*** submitted by Dr. Namrata Asthana, SR, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1128 dated 22nd October, 2022. ***Recommendation of Primary reviewer:*** • Inclusion criteria did not mentioned Age and sex of the subjects ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above
	Ref. code: XIV-PGTSC-IIA/P44
30-	Clarification of research proposal entitled ***"Hyperbaric oxygen therapy for second-degree burn wound healing"*** submitted by Dr. Bhimavarapu Gowtham Reddy, SR, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1127 dated 22nd October, 2022. ***Previous PGTSC Comment:*** • Sample size calculation not done • Inclusion criteria –Sex specificity not mentioned ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above
	Ref. code: XIV-PGTSC-IIA/P45
31-	Clarification of research proposal entitled ***"Adrenal insufficiency in children with nephritic syndrome a prospective cohort study"*** submitted by Dr. Anjali Barua, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 546/Ped/23 dated 17th February, 2023. ***Previous PGTSC Comment:-*** • Detailed sample size calculation not given. • Patient information sheet –not related to study.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 17th March, 2023

	• ICF (Guardian consent)-H/E–Attached but not similar. Child Assent form missing-should be included. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P47***
32-	Clarification of research proposal entitled ***"Incidence and risk factors of metabolic bone disease among very low birth weight neonates in NICU"*** submitted by Dr. Ranvijay Patel, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 713/Ped/23 dated 3rd March, 2023. ***Previous PGTSC Comment:*** • Involvement of Vulnerable subjects not mentioned in the IEC form. • Collection of blood for biochemical parameters is not mentioned in the section on biological/hazardous materials. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P59***
33-	Clarification of research proposal entitled ***"Estimation of urinary [TIMP-2] X [IGFBP7] and serum procalcitonin level in septic acute kidney injury"*** submitted by Dr. Neha Singh, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 311/MED/2022 dated 7th February, 2023. ***Previous PGTSC Comment:-*** • Number of subjects not mentioned in IEC form. • Vulnerable subjects/Special group subjects not mentioned in IEC form. • Use of body fluids not mentioned in the section on Biological/ Hazardous material in the IEC form. • Section on Risk not filled properly. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P63***
34-	Clarification of research proposal entitled ***"Role of vascular endothelial growth factor(VEGF) procalcitonin and serial levels of c-reactive protein (CRP) versus blood culture in early diagnosis of septicemia"*** submitted by Dr. Monika Chaudhary, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1480/23 dated 6th February, 2023.

Previous PGTSC Comment	PI response
Most of them have overlapping roles.	We are looking association between VEGF, CRP, PCT versus blood culture.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Sponsor is listed a 'Government' with no budget details.	Sponsor is not government (it was tick by mistake). I will procure the kit by **my own** for the test.
	Number of subjects not mentioned in the IEC form.	**Sample Size:** The sample size was calculated based on a previous study that reported that the incidence of severe sepsis was 13.1% of all admissions (Todi et al., 2007), 95% level of confidence and Error rate, usually set at 0.05 level is 4. Total 174 patients will be included in this study. $n=Z^2 P(1-P)/d^2$ Where, • n = sample size, • Z = Z statistic for a level of confidence, for the level of confidence of 95%, which is conventional, Z value is 1.96. • P = expected prevalence or proportion (in proportion of one; if 13.1%, P = 0.13), • d = precision (in proportion of one; if 5%, d = 0.05). $n=1.96x1.96x0.13x0.87/0.05^2$ n=173.79 Todi S, Chatterjee S, Bhattacharyya M.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Epidemiology of severe sepsis in India. Crit Care. 2007;11(Suppl 2):P65.
	Section on use of body fluids has been ticked 'No'	It is ticked by mistake, **yes** body fluid will be used.
	PI has mentioned in the IEC form that 'pre-existing/stored/left over samples' will be used. Please explain.	I will use **fresh** samples from study subjects, not pre-existing/ stored/left over samples.
	PI has mentioned that samples from patients will be banked for future research.	**No**, samples collected will be used for this study only.
	This has to be mentioned specifically in the consent.	It will be mentioned in consent form, these samples will not be used for future research.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P64

35-. Clarification of research proposal entitled ***"Study of Physiological and psychological effects of screen time in young adults"*** submitted by Dr. Shiraza Haque, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2957/PHY/22 dated 28th February, 2022.

Recommendation of Primary reviewer:

- Sections on Vulnerable subject/special group subjects/biological and hazardous material/patient consent are not filled properly.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P67

36- Clarification of research proposal entitled ***"Resistance and heteroresistance to colistin in carbapenemase producing gram-negative infections from adult intensive care units"*** submitted by Dr. Sufia Talib, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1510/23 dated 8th February, 2023.

Previous PGTSC Comment	PI response
There are 7 Co-PIs to the project out of which 4 are from one department. Addition of Co-PIs to the project must be rational and need based.	All the Co-PI are contributing significantly in the project. Their expertise is warranted and therefore they are included as the Co-PI. We do not

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		wish to remove any names from the proposal.
	Sample size needs to be mentioned in the IEC form too.	The sample size has been mentioned in the project attached. 8.4 Sample size: Calculated using Epi info calculator software (www.openepi.com) Following assumptions are made: Confidence interval= 95% Margin of error=5% Value of normal deviate at 95% confidence interval =1% Hypothesized % frequency of outcome factor in the population (p):16%+/-5* Hence the sample size =207 * Mohapatra DP, Debata NK, Singh SK. Extensively drug-resistant and pandrug- resistant Gram-negative bacteria in a tertiary-care hospital in Eastern India: A 4-year Retrospective study. J Glob Antimicrob Resist. 2018 Dec;15:246-249. doi: 10.1016/j.jgar.2018.08.010. Epub 2018 Aug 23. PMID: 30144638.
	Details regarding sample collection are missing form the IEC form as well as the synopsis.	The sample collection has already been mentioned in the project attached. Please refer:- 8.10 Data Collection & Follow up: 207 non-duplicated gram negative clinical isolate s will be recovered from three adult ICUs (TVU, RICU, CCM) from patients with infections.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P69

37- Clarification of research proposal entitled ***"Diagnosis and antifungal susceptibility pattern of candida auris in critically III patients: A prospective observational study"*** submitted by Dr. Manisha Singh, JRI, Department of Microbiology, King George's

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Medical University, U.P., Lucknow vide letter no.1498/23 dated 7th February, 2023.

Previous PGTSC Comment	PI response
The project has 7 Co-PIs besides the candidate/PI herself.	All the Co-PIs are contributing significantly in the project. Their expertise is warranted and therefore they are included as the Co-PI. We do not wish to remove any names from the proposal.
Number if subjects/ sample size has not been mentioned in the IEC form.	Since this is an observational study so the appropriate sample size cannot be calculated and the convenient sample size would be taken depending on the annual number of patients detected with specified organism of the study (Candida auris) in culture.
Sections on vulnerable subjects, biological/hazardous material and risk and benefit have been left incomplete.	Section on vulnerable subjects, biological/hazardous material and risk and benefit has been completely filled. □ Changes have been done and copy of that has been attached.

The above Comment forwarded to PI was reviewed by PR:-
Second recommendation of PR:

- Sample size has not been mentioned and the PI has refused to mention the sample size even in the clarifications. Study cannot be approved without sample size calculation.

The above Comment forwarded to PI: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P70

38- Clarification of research proposal entitled ***"An observational study to determine blood stream infections in febrile neutropenic Paediatric cancer patients & their co-relation with blood procalcitonin level"*** submitted by Dr. Tanya Pandey, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1503/23 dated 8th February, 2023.

Previous PGTSC Comment	PI response
Sections on vulnerable subjects, special group subjects, biological/hazardous material, patient consent and risk and befits are incompletely filled.	Sections on vulnerable subjects ,special group subjects, biological/hazardous material ,patient consent and risk and benefits are completely filled and copy of that has been attached
Sample size is different in IEC form and in the synopsis (106vs227)	Sample size:106 □ n=Z2P(1-P)\D2 □ Confidence level-95%

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	□ Z=1.96 □ D=5%,PREVALENCE=7.5% □ SAMPLE SIZE=106(Approximately) □ Reference :Radhakrishnan et al . Bloodstream infections in pediatric patients at cancer institute, Chennai. Indian Journal of Cancer 51(4):p 418-419, October–December 2014.
Study design mentioned is prospective, observational study but in the data collection section the PI mentions two groups.	Data collected from All febrile neutropenic paediatric cancer patients in Oncology ward Changes has been done and copy of that has been attached.
Acronym CRE has been used without clarification.	Acronym CRE has been removed as it was mentioned by mistake Changes has been done and copy of that has been attached.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P71

39- Clarification of research proposal entitled ***"Antifungal susceptibility testing of newer topical antifungal agents against dermatophytes in north India"*** submitted by Dr. Tanya Sachan, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1502/23 dated 8th February, 2023.

Previous PGTSC Comment	PI response
Section on biological/hazardous material is incompletely filled.	The section on biological/hazardous material on completely filled and attached hereby.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P72

40- Clarification of research proposal entitled ***"Determination of vancomycin resistant enterococci (VRE) and vancomycin variable enterosocci (VVE) in urinary tract infections amongst hospitalized patients"*** submitted by Dr. Riya Singh, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1497/2023 dated 7th February, 2023.

Previous PGTSC Comment	PI response
Number of subjects must be mentioned in the IEC form also.	I have mentioned Number of subjects in the IEC form. Copy of that has been attached.
Section on vulnerable subjects is	Section on vulnerable subjects is

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	incompletely filled.	Completely filled ☐ Copy of that has been attached.
	Section on biological/hazardous material has been incompletely filled.	Section on biological /hazardous material has been completely filled ☐ Changes has been done and copy of that has been attached.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P73

41- Clarification of research proposal entitled ***"A study of spectrum and outcome of liver disorders in pregnant women admitted in a tertiary care centre in North India"*** submitted by Dr. Shivangi Sharma, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/394/23 dated 11th February, 2023.

Previous PGTSC Comment:

- Sections on vulnerable subjects, special group subjects, use to biological/hazardous material and patient consent are incompletely filled.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P74

42- Clarification of research proposal entitled ***"Correlation of vaginal microbiome during pregnancy with obstetric outcome"*** submitted by Dr. Ojasvini Agrawal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3887/23 dated 6th February, 2023.

Previous PGTSC Comment	PI response
Sample size in IEC form and in the synopsis sample size calculation are different (120 and 300)	The sample size is calculated based on previous study that reported prevalence of normal bacterial flora to be 83.5% (Gupta et al 2020).At 95% confidence level and expected prevalence taken to be 83.5%, sample size calculation will be as follows - n=Z 2 P(1-P)/d 2 n=sample size z=z staands for a level of confidence; for the level of confidence of 95% which is conventional, z value is 1.96. P=expected prevalence or proportion (in proportion of 1, if 83.5 %, P =

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		0.835) d=precision (in proportion of one ; if 5%, d=0.05) n=1.96x1.96x0.835(1-0.835)/0.05x0.05 n=211.71 ~212 subjects
	No details regarding how the vaginal microbiome will be estimated has been given in the methodology.	For vaginal microbiome estimation, 2 high vaginal swabs will be taken from each patient. One swab will be subjected to gram staining and further Nugent scoring will be done to determine normal vaginal flora versus bacterial vaginosis. The other swab will be subjected to culture on culture media like Blood and MacConkey's agar to see growth of various bacteria like staphylococcus, streptococcus, E. coli, kliebesella and pseudomonas and other lactose and non lactose fermenting bacteria that might be the present in the high vaginal swab of the patient.
	Collection of biological specimen is not mentioned in the IEC form in the concerned section on biological/hazardous material.	Attached here in.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P76

43- Clarification of research proposal entitled ***"Clinical audit on maternal and fetal outcomes in cases of APH in tertiary care centre"*** submitted by Dr. Monika Sagwal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3987/23 dated 15th February, 2023.

Recommendation of Primary reviewer:

- Sections on Type of subjects, vulnerable subjects, special group subjects, use of biologival/hazardous material and patient consent are incompletely filled.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: As above

Ref. code: XIV-PGTSC-IIA/P77

44- Clarification of research proposal entitled ***"First trimester glycosylated hemoglobin as a***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	predictor of gestational diabetes mellitus" submitted by Dr. Sadaf Khan, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3015/2022 dated 1st March, 2023 ***Previous PGTSC Comment:*** • Sections on vulnerable subjects, use of biological material, risk and benefit and patient conent are incompletely/incorrectly filled. • Sample size in IEC form and synopsis is different (120 vs 138). • Are the Investigations being conducted on the subjects' part of normal antenatal checkup? If not, who will bear the cost of the additional tests? ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P79***
45-	Clarification of research proposal entitled ***"Comparision of DIPSI criteria and WHO criteria for diagnosis of gestational diabetes mellitus in early pregnancy"*** submitted by Dr. Nida Aara, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3933/23 dated 10th February, 2023. **Previous PGTSC Comment:-** • Blood samples are being collected for blood sugar estimation. Use of body fluids must be ticked in the section on biological/hazardous materials. • Section on vulnerable subjects must mention pregnant women. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P80***
46-	Clarification of research proposal entitled ***"A randomized controlled trial comparing combination of letrozole and clomiphene citrate of letrozole alone for ovarian stimulation in infertile women"*** submitted by Dr. Anamika Kumari, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3927/23 dated 10th February, 2023.

Previous PGTSC Comment	PI response
It is not clear which samples will be collected, as mentioned in the materials and methods section?	All infertile women coming for seeking infertility treatment total 180 women will be recruited and will be randomized. No blood or any tissue samples will be taken. Ovarian stimulation will be done by Tab letrozole (5 mg) and clomiphene citrate 50 mg together verses Tab letrozole 5 mg alone in 2 groups respectively. Ovulation will seen by non invasive trans vaginal sonography.

The above Comment forwarded to PI was reviewed by PR:-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above Comment forwarded to PI: Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P82***
47-	Clarification of research proposal entitled ***"The effect of preoperative biliary drainage and other factors (patient/disease/operative)influencing post operative pancreatic fistula after pancreaticoduodenectomy"*** submitted by Dr. Deeban G, SR, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SG/134/23 dated 15th February, 2023. ***The above Comment forwarded to PI was reviewed by PR:-*** • Kindly note that the exclusion of other cancers should be mentioned in the exclusion criteria. • Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P84***
48-	Clarification of research proposal entitled ***"Comparison of levobupivacaine and ropivacaine in quadrates lumborum block for postoperative analgesia after abdominal surgery"*** submitted by Dr. Akhil O Nair, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1145/2022 dated 7th September, 2022. ***Recommendation of Primary reviewer:*** • References mentioned in the bibliography but are not cited in the text. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P90***
49-	Clarification of research proposal entitled ***"To study the cost of treatment in patients with acute stroke presenting to the Department of Neurology at a tertiary care Government University Hospital Lucknow, India"*** submitted by Dr. Sairaj Subhash Chodankar, JRI, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/2023/051 dated 6th February, 2023.. ***Recommendation of Primary reviewer:*** • Aims and objectives not clear. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P98***
50-	Clarification of research proposal entitled ***"Etiology and biofilm formation of Orthopaedic implant infections"*** submitted by Dr. Asma Khan, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no.1419/23 dated 24th January, 2023. ***Previous PGTSC Comment:*** • Methodology improper. E.g. method for detection of bio-film by tissue culture plate

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 17th March, 2023

	method not given. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIV-PGTSC-IIA/P102***
IB	**Expedited review**
1-	Clarification of Expedited review of research proposal entitled ***"A prospective study of delivery room Neonatal Resucitative interventions, intervention based modified APGAR score and early neonatal outcome"*** submitted by Dr. Alia Zehra, JR-I, Department of Paediatrics, K.G's Medical University, U.P., Lucknow vide letter dated 21st January, 2023. ***The above research proposal forwarded to two both reviewers, reply have given by both reviewers with following comments:-*** ***Comments of first Primary reviewer:*** • There are too many primary objectives. • Identify one primary (main) objective. Rest should be grouped into secondary objectives. • Identify the study variables and population parameters. • Define research hypothesis (corresponding to primary objective) in terms of study parameters. • Sample size calculation should be based on main research hypothesis. • Statistical section should be more specific towards the objectives of the study. ***Comments of Secondary Primary reviewer:*** • Guardian consent form instead of regular ICF is to be attached. ***The above comments forwarded to the PI, reply has given by PI which was forwarded to both reviewers:*** ***Recommendation of first Primary reviewer:-*** Approved ***Recommendation of Secondary Primary reviewer:-*** • PI said that she would attach the Guardian consent form, but did not attaché. ***The above comments forwarded to the PI, reply has given by PI which was forwarded to secondary Primary reviewer:-*** ***Recommendation of Secondary Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XV PGTSC IB/P1***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"Evaluation of side effect profile, quality of life and efficacy of sequential intravesical gemcitabine + docetaxel versus BCG for non muscle invasive urinary blodder cancer"*** submitted by Dr. Amber Gupta, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 781/URO/22 dated 24thDecember, 2022. ***Recommendation of Primary reviewer:-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Research hypothesis should be exclusive written for the primary objective. • Sample size formula is not clear. It is using mean, standard deviations, whereas the outcome measures are in proportions. • Statistical analysis mentioned is arbitrary. It should be given as a separate section and properly explained. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P1***
2.	Research proposal entitled ***"To identify the preoperative and intraoperative factors that are responsible for the development of sepsis after PCNL"*** submitted by Dr. Mayank Kesharwani, SRI, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 754/URO/22 dated 15thDecember, 2022. ***Recommendation of Primary reviewer:-*** • This seems to be a cause-effect relationship study. • So it should be planned according to that. Comparative groups should be identified • Proper research hypothesis should be formulated. • Study design just says "prospective study". It should be clearly mentioned. • Sample size calculation and statistical analysis section are missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Capacity of Health and wellness centres to provide non-communicable disease services in Lucknow-A cross-sectional study"*** submitted by Dr. Kaustav Halder, JRII, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1089/CM/MD/23 dated 16th January, 2023. ***Recommendation of Primary reviewer:-*** • The study requires construction of an instrument (questionnaire) to achieve the objective. It is missing. • After this the study can be planned and all the components of the study can be properly formulated/explained. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Psychological stress faced and factors associated with it at workplace and its relation to Mental Health of female healthcare workers of rural Lucknow-A cross-sectional study"*** submitted by Dr. Akshata M.A., JRI, Department of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1088/CM/MD/23 dated 16th January, 2023. ***Recommendation of Primary reviewer:-*** • To achieve the objective of the study, the proper questionnaire is required. • After this only, the study can be planned. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P4***
5.	Research proposal entitled ***"Coverage, utilization and impact of AB-PMJAY in rural areas of Lucknow-A cross-sectional study"*** submitted by Dr. Atul Verma, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1103/CM/MD/23 dated 18th January, 2023. ***Recommendation of Primary reviewer:-*** • The questionnaire is required to achieve the objective of the study. • Everything else will fall into the line according to the instrument. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Evaluation of facial and dental aesthetic determinants-A photometric study"*** submitted by Dr. Zainab Bint Shams, JRII, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1144/Ortho/23 dated 17th January, 2023. ***Recommendation of Primary reviewer:-*** • This is not "Cross-sectional Study" as mentioned in the study design. • This is prospective cohort comparative study. There are two groups under comparison. • Research hypothesis should be properly formulated after identifying the study variables and study parameters. • Sample size calculation is arbitrary. • Statistical analysis section is missing. • Why is there "Child assent form?" • The study subjects are supposed to be in the age group 18-35 years. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P6***
7.	Research proposal entitled ***"Correlation between intraoperative quantitative assessment of parathyroid gland perfusion during total thyroidectomy after gland***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	excision using indocyanine green with post-operative hypocalcemia-a prospective observational study" submitted by Dr. Ashwinee Rahalkar, SRII, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/399/22 dated 13th November, 2022. ***Recommendation of Primary reviewer:-*** • The title of the study is little confusing. The correlation is measured between two variables. What are these variable? • What is the outcome measure for assessing parathyroid gland perfusion? • Sample size calculation and statistical analysis section are missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P7***
8.	Research proposal entitled ***"A Follow up study of adolescents with depressive disorders"*** submitted by Dr. Nagendra Khatore, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1452/Psy/22 dated 26th September, 2022. ***Recommendation of Primary reviewer:-*** • The study is for adolescents. The source of sample incudes adult psychiatry OPD as well as child and adolescent psychiatry OPD. • There are quite a few instruments being used for the assessment of outcome event. But the sample size uses just one scale (BDI-21 score). • How the aggregate scores will be obtained from the different scales? **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P8***
9.	Research proposal entitled ***"Prevalence of overweight and obesity amongst adolescents along with their multidimensional factors in rural and urban school settings of Lucknow"*** submitted by Dr. Ajit Kumar Singh, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1155/CM/MD/23 dated 27th January, 2023. ***Recommendation of Primary reviewer:-*** • The questionnaire is required to study the association between obesity/overweight/underweight and the multidimensional factors. • The study can be planned only after the construction of the questionnaire. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Trend in utilization of Health Benefit package under***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	AYUSHMAN BHARAT PRADHAN mantra JAN AROGYA in tertiary care institution, Lucknow district" submitted by Dr. Ritika Chaturvedi, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1154/CM/MD/23 dated 27th January, 2023. ***Recommendation of Primary reviewer:-*** • For obtaining the objectives of the study, the proper questionnaire is required. • All the other components of the study can be described on the basis of the questionnaire. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P10***
11.	Research proposal entitled ***"A comparative evaluation of saturated KI and 10% KI in the reduction of silver diammine fluoride staining under RMGIC restoration in primary teeth: A randomized clinical trial"*** submitted by Dr. Prachi Vaish, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/19/23 dated 16th January, 2023. ***Recommendation of Primary reviewer:-*** • Identify the study variables and study parameters. • Convert the aim/objective of the study into research hypothesis in terms of the study parameters. • The sample size calculation can be done ater the formulation of research hypothesis. • What is the meaning by triple blinding? • Is clinical trial registry done? • Data analysis should be more specific in accordance with the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P11***
12.	Research proposal entitled ***"Phase 2 study of concurrent cisplatin, capecitabine and celecoxib with radiotherapy in patients with carcinoma of the esophagus"*** submitted by Dr. Bushra Khalid, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 1427/RT/22 dated 29th December, 2022. ***Recommendation of Primary reviewer:-*** • Identify the study variable and study parameters. • Convert the aim/objective of the hypothesis into research hypothesis in terms of the study parameters. • Sample size calculation and data analysis section are missing.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: • DCGI permission will be needed, if it is a Phase 2 trial. **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P12***
13.	Research proposal entitled ***"Evaluation of role of urodynamic study in the diagnosis and management of lower urinary tract symptoms in young adult males"*** submitted by Dr. Abhishek Yadav, SRI, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 782/URO/22 dated 24th December, 2022. ***Recommendation of Primary reviewer:-*** • Review of the literature is in the beginning as well as at the end of the proposal. • Identify the study variables and study parameters. • Convert the primary aim of the objective into research hypothesis in terms of the study parameters. • The study design can not ne prospective as well as retrospective. • Sample size calculations are required. • Statistical analysis section is missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P13***
14.	Research proposal entitled ***"Outcomes of PCNL in patient with CKD"*** submitted by Dr. Mohdrehan Akhtar, SRI, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 141/URO/23 dated 4th February, 2023. ***Recommendation of Primary reviewer:-*** • The proposal is incomplete. • Aims & objectives, study design, methodology, sample size calculation etc. are missing. **PGTSC Comment:** Why is there is a discussion section? **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P14***
15.	Research proposal entitled ***"Study of impact of oral health education training program on oral health knowledge, attitude, behavior, self care, self efficacy among adolescents- randomised controlled trial"*** submitted by Dr. Akulwar Srushti Jagdish, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/39/23 dated 1st February, 2023. ***Recommendation of Primary reviewer:-*** • This not an RCT. • This is prospective cohort study. There are two groups under comparison. • Identify the study variables and the study parameters.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 17th March, 2023

	• Convert the primary objective into a research hypothesis in terms of the study parameters. • Sample size calculation can be done only after identifying the research hypothesis. • Statistical analysis section has to be more specific in accordance with the research hypothesis and other objectives of the study. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P15***
16.	Research proposal entitled ***"Evaluation of dental syringe camouflage technique as a distraction method in paediatric dental patients in dental office"*** submitted by Dr. Oberoi Ashmeetkaur Sukhbirsingh, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/38/23 dated 1st February, 2023. ***Recommendation of Primary reviewer:-*** • This not an RCT. • This is prospective cohort study. There are two groups under comparison. • Identify the study variables and the study parameters. • Convert the primary objective into a research hypothesis in terms of the study parameters. • Sample size calculation can be done only after identifying the research hypothesis. • Statistical analysis section has to be more specific in accordance with the research hypothesis and other objectives of the study. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P16***
17.	Research proposal entitled ***"Comparative association of radiographic quality of obturation with postoperative pain in primary molars using KEDO-SH files, KEDO-S square files and KEDO-S plus files: A randomized clinical trial"*** submitted by Dr. Anjali Anand, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/37/23 dated 1st February, 2023. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P17***
18.	Research proposal entitled ***"A prospective study of monitoring of adverse transfusion reaction occurring in patient administered packed red blood cells (PRBC) fresh frozen***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	plasma (FFP) platelets (Random Donor Platelets) transfused patients in level-I trauma centre" submitted by Dr. Ankita Chaudhary, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 118/Pharma/23 dated 8th February, 2023. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P18***
19.	Research proposal entitled ***"Study of suspected adverse drug reactions of oral hypoglycemic agents in geriatrics type2 diabetes mellitus patients at tertiary care Hospital"*** submitted by Dr. Mohd Arif, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 119/Pharma/23 dated 9th February, 2023. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P19***
20.	Research proposal entitled ***"Effect Of Endoscopic Sinus Surgery On eustachian Tube Dysfunction"*** submitted by Dr. Parul Verma, JRI, Department of Otorhinolaryngology & Head -Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. nil dated nil. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P20***
21.	Research proposal entitled ***"The effect of Hematocrit and storage time of reconstituted whole blood on total serum bilirubin, hemoglobin and hematocrit of neonates undergoing exchange transfusion–A Pilot Study"*** submitted by Dr. Shivam Azad, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 504/23 dated 21st January, 2023. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P21***
22.	Research proposal entitled ***"Evaluation of platelet refractoriness in acute leukemia patients after Transfusion of random donor platelets"*** submitted by Dr. Somya Chahar, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 503/23 dated 21st January, 2023. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P22***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 17th March, 2023

23.	Research proposal entitled ***"Effects of therapeutic plasma exchange in patients with heavy metal poisoning-A pilot study"*** submitted by Dr. Kislay Mishra, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 507/23 dated 29th January, 2023. ***Recommendation of Primary reviewer:-*** • Kindly Attach Patient Information Sheet. • ICF: Kindly explain the procedure of plasma exchange to the patient. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P23***
24.	Research proposal entitled ***"Fosfomycin resistance in urinary Isolates from Pregnant Females: an Observational Study"*** submitted by Dr. Nandini Mishra, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1198/22 dated 12th December, 2022. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P24***
25.	Research proposal entitled ***"A comparative analysis of two different dose fractionation Regimens of high dose rate intracavitary brachytherapy in treatment of locally advanced carcinoma of uterine cervix"*** submitted by Dr. Kopal Jaiswal, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 77/RT/23 dated 28th January, 2023. ***Recommendation of Primary reviewer:-*** • Proforma is not written in the proper format. • Kindly Attach Patient Information Sheet • ICF: Kindly explain the procedure to the patient [what exactly will be done with him/her] in simple language. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P25***
26.	Research proposal entitled ***"Combination of systemic chemotherapy with short course Radiotherapy for the neoadjuvant therapy of locally advanced rectal carcinoma"*** submitted by Dr. Nirmal Kumar R, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 76/RT/23 dated 28th January, 2023. ***Recommendation of Primary reviewer:-*** • Kindly Attach Patient Information Sheet. • ICF: Kindly explain the procedure to the patient [What exactly will be done with him/her] in simple language. **PGTSC Comment:**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P26***
27.	Research proposal entitled ***"Comparison of outcome of conventional palliative Radiotherapy fractionation schedule with quad shot regimen in locally advance head and neck cancer patient"*** submitted by Dr. Srishti Puraiya, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 106/RT/23 dated 3rd February, 2023. ***Recommendation of Primary reviewer:-*** • Kindly Attach Patient Information Sheet • ICF: Kindly explain the procedure to the patient [what exactly will be done with him/her] in simple language. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P27***
28.	Research proposal entitled ***"Estimation of serial levels of carboxypeptidase a and its role as prognostic marker in acute pancreatitis"*** submitted by Dr. Vijay Kumar Yadav, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3846/22 dated 20th December, 2022. ***Recommendation of Primary reviewer:-*** • Kindly Attach Patient Information Sheet • ICF: Kindly explain the procedure to the patient [what exactly will be done with him/her] in simple language. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P28***
29.	Research proposal entitled ***"A clinical audit of anal fistula patients operated in the Department of General Surgery KGMU in last ten years"*** submitted by Dr. Shyama Charan Jha, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 106/23 dated 12th January, 2023. ***Recommendation of Primary reviewer:-*** • Kindly confirm the sample size : 200/980/80 • Confirm the study duration of 5 years /10 years. Title says 10 years and in the proforma it is mentioned 5 years. • Clarify the process of recruitment of the study population. • It appears that the PI wants to assess the outcome of patients, who have undergone anal fistula operations in the department and had been followed up for a minimum of 1 year. If so, there is no need for a written informed consent form to be signed by the patient.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 17th March, 2023

	• Therefore, the proforma should be submitted for waiver. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P29***
30.	Research proposal entitled ***"A randomized control trial comparing outcomes in patients receiving four layered bandage with hyperbaric oxygen therapy versus only four layered bandage in patients of chronic venous ulcer"*** submitted by Dr. Ayushi Raz, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 177/23 dated 18th January, 2023. ***Recommendation of Primary reviewer:-*** • Kindly Attach Patient Information Sheet • ICF: Kindly explain the procedure to the patient [what exactly will be done with him/her] in simple language. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P30***
31.	Research proposal entitled ***"Assessment of survival outcome of operableT4a and T4b oral cancer (8th AJCC)"*** submitted by Dr. Manpreet Saini, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 201/23 dated 21st January, 2023. ***Recommendation of Primary reviewer:-*** • Title needs rectification. The term operable should be replaced with operated. • Please, clarify the process of enrollment of patients. If it is a hospital record base study, PI may submit for waiver of ethical clearance. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P31***
32.	Research proposal entitled ***"Evaluation of perioperative and quality of life outcomes after laparoscopic orchidopexy in palpable canalicula and non-palpable undescended testis in adolescent and adults"*** submitted by Dr. Mohammad Nasir Ali Ansari, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3922/22 dated 29th December, 2022. ***Recommendation of Primary reviewer:-*** • Please attach validated questionnaire / outcome parameters for analysis of perioperative quality of life. • ICF: Kindly explain the procedure to the patient [what exactly will be done with him/her] in simple language. **PGTSC Comment:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P32***
33.	Research proposal entitled ***"Opportunistic cervical cancer screening by liquid based cytology-A study at a tertiary care centre"*** submitted by Dr. Sandeep Kumar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1429/22 dated 1st December, 2022. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P33***
34.	Research proposal entitled ***"To decipher the molecular role of insulin like growth factor in chronic myeloid leukemia"*** submitted by Dr. Pragati Chauhan, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1422/22 dated 6th December, 2022. ***Recommendation of Primary reviewer:-*** • Although in the material and methods section it is mentioned that the place of work will also be the Department of Medicine but there is no PI or Co-PI from the said department. • Materials and methods incomplete. • References are not written in proper format. • Overall the project is very sketchy, needs to be re-written **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P34***
35.	Research proposal entitled ***"Clinicohematological profile of refractory thrombocytopenia and immune thrombocytopenia"*** submitted by Dr. Silpa Sasi, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1443/22 dated 6th December, 2022. ***Recommendation of Primary reviewer:-*** • Objectives of the study not clear. • How they arrived on a sample size of 100 is not clear (Sample size calculation? • Material and method section incomplete. • Although the name of a Co-PI is from the Department of Clinical Hematology but it is mentioned in the text that the study will be carried out in collaboration with the Department of Oral & Maxillofacial Surgery. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, Give a tabular format give responses in a tabular format.***Ref. code: XVI-PGTSC-IIA/P35***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

36.	Research proposal entitled ***"To decipher the molecular role of vanin1 in pathogenesis of CML and its diagnostic implications"*** submitted by Dr. Shalini Verma, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1491/22 dated 16th December, 2022. ***Recommendation of Primary reviewer:-*** • Aim of the study is sketchy. • Although in the material and methods section it is mentioned that the place of work will also be the Department of Medicine but there is no PI or Co-PI from the said department. • Material and method section incomplete. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P36***
37.	Research proposal entitled ***"Comparison of diagnostic Accuracy Of 300 Versus 500 cell differential count in bone marrow smears: A prospective observational study"*** submitted by Dr. Rehna Raju, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 201/23 dated 1st January, 2023. ***Recommendation of Primary reviewer:-*** • Aims and objectives of the study not clear. • The study is to be carried out in collaboration of the Department of clinical Hematology but it is not mentioned in the Material & Method section. • Material and method section is incomplete. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P37***
38.	Research proposal entitled ***"Anthropometric analysis of the-LIP-nose complex in bilateral cleft LIP infants in north Indian population"*** submitted by Dr. Kartikeya Shukla, SRI, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 187/23 dated 14thFebruary, 2023. ***Recommendation of Primary reviewer:-*** • It is mentioned that the study will be carried out between November 2022 to December 2023. Has the candidate started work without ethical clearance?? • Rest is fine. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P38***
39.	Research proposal entitled ***"Institutional experience in liquid based cytology (LBC) in thyroid nodules: comparative analysis with conventional fine needle aspiration smears and evaluation of BRAF V600E and TERT promoter expression By***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	immunocytochemistry in malignant lesions" submitted by Dr. Garima Yadav, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1515/22 dated 21st December, 2022. ***Recommendation of Primary reviewer:-*** • Materials and methods incomplete. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P39***
40.	Research proposal entitled ***"Study of CDKN2A mutation in gliomas with cytohistological Correlation"*** submitted by Dr. Aisha Mahmood, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1500/22 dated 17th December, 2022. ***Recommendation of Primary reviewer:-*** • Materials and methods incomplete (Cite a reference for performing FISH). **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P40***
41.	Research proposal entitled ***"Study of circulating cell free tumor human papillomavirus dna in cervical cancer"*** submitted by Dr. Apoorva Gangwar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1460/22 dated 8th December, 2022. ***Recommendation of Primary reviewer:-*** • Materials and methods incomplete (Cite references for performing DNA extraction RT-PCR). **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P41***
42.	Research proposal entitled ***"Ascitic calprotectin levels in ascetic fluid and its role in diagnosis of spontaneous bacterial peritonitis in adult patients"*** submitted by Dr. Sushil Mishra, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1197/22 dated 12th December, 2022. ***Recommendation of Primary reviewer:-*** • Although it is mentioned that the study will be conducted in collaboration with the department of Medicine but no Co-PI has been included from that department. Similarly, Surgical Gastro person is there as a Co-PI but the name of that department is missing from study settings. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XVI-PGTSC-IIA/P42
43.	Research proposal entitled ***"Comparison of therapeutic and prophylactic effect of chlorhexidine varnish with fluoride varnish for active carious lesions in high risk ECC patients using '4D caries care' approach: A randomized clinical trial"*** submitted by Dr. Pallavi Parasramka, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/62/23 dated 15th February, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above
	Ref. code: XVI-PGTSC-IIA/P43
44.	Research proposal entitled ***"Efficacy of pre-operative lugol's iodine in reducing peri-operative complications in patients with graves' disease following thyroidectomy-A randomized control trial"*** submitted by Dr. Mithun Raam, SR, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/440/22 dated 1st December, 2022. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above
	Ref. code: XVI-PGTSC-IIA/P44
45.	Research proposal entitled ***"T-cell dysfunction in hemophagocytic lymphohistiocytosis"*** submitted by Dr. Sabnam Jahan, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1461/22 dated 8th December, 2022. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above
	Ref. code: XVI-PGTSC-IIA/P45
46.	Research proposal entitled ***"Study of clinico-microbiological profile of cases of chronic dacryocystitis"*** submitted by Dr. Yuvraj Gupta, JRI, Department of Otorhinolaryngology & Head -Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. nil dated nil. ***Recommendation of Primary reviewer:-*** • Type of study not clear. • Sample size not mentioned • Inclusion or exclusion of subjects not mentioned. • References not cited or listed. **PGTSC Comment:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P46***
47.	Research proposal entitled ***"The prevalence and determinants of Hypophosphatemia in children with diabetic ketoacidosis in northern India: an observational study"*** submitted by Dr. Shweta Jaiswal, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2373/Ped/22 dated 21st December, 2022. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P47***
48.	Research proposal entitled ***"Comparative study of ultrasound guided vs landmark technique of subarachnoid block in patients of ankylosing spondylitis undergoing total hip replacement"*** submitted by Dr. Rishabh Mishra, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/134/22 dated 7th December, 2022. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P48***
49.	Research proposal entitled ***"Comparative study of spray as you go technique using 2% lignocaine versus 4% lignocaine for awake fibreoptic nasotracheal intubation in oral cancer patients"*** submitted by Dr. Bhavana Priya H.G. JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1152/22 dated 7th December, 2022. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P49***
50.	Research proposal entitled ***"Chromosomal characteristics and clinical profile in juvenile nasopharyngeal angiofibroma"*** submitted by Dr. Vinod Kumar Patel, JRI, Department of Otorhinolaryngology & Head -Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. nil dated nil. ***Recommendation of Primary reviewer:-*** • SOP-Checklist - not ticked properly (to be revised) • Inclusion criteria –All patients having JNA to be taken (Age/ sex specificity) not mentioned-please clarify • Sample size calculation not done

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• If all age patients to be taken then Guardian consent/ Child Assent form should be included. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P50***
51.	Research proposal entitled ***"Evaluation of bacteriological profile and antibiotic and antibiotic susceptibility in Orthopaedics patient developing SSI following implant surgery"*** submitted by Dr. Utkarsh Upadhyay, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 5080/OS/22 dated 23rd December, 2022. ***Recommendation of Primary reviewer:-*** • All Co-guides' name and signature are there in Scientific Review Committee – please justify or revise • Name of Title should be self explanatory and no abbreviation should be there-please expand SSI abbreviation in title • Sample size calculation not done • In Inclusion /Exclusion -pregnant and lactating women criteria not mentioned • Detailed questionnaire not attached **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P51***
52.	Research proposal entitled ***"A prospective clinical study to monitor prescription pattern, therapeutic adherence, quality of life and Pharmacoeconomic analysis among patients suffering with interstitial diseases"*** submitted by Dr. Krishan Kumar Singh, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 128/Phamra/23 dated 14th February, 2023. ***Recommendation of Primary reviewer:-*** • Title should be corrected, as interstitial disease is not self explanatory, it should be Interstitial Lung Diseases-Please correct. • Tools are not attached -Please attach all mentioned tools. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P52***
53.	Research proposal entitled ***"A prospective study of monitoring of adverse transfusion reactions occurring in patients administered packed red blood cells (PRBC)/ Fresh frozen plasma (FFP)/ platelets (Random Donor Platelets) in Obstetrics and Gynecology Department"*** submitted by Dr. Pranshu Pandit, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	letter no. 127/Phamra/23 dated 14th February, 2023. ***Recommendation of Primary reviewer:-*** • In Inclusion criteria -Pregnant /lactating women criteria -not mentioned • Tools are not attached **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P53***
54.	Research proposal entitled ***"Reference values of patellotrochlear index in North Indian population: A cross sectional study"*** submitted by Dr. Rahul Kumar Tripathi, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 9022/OS/23 dated 10th February, 2023. ***Recommendation of Primary reviewer:-*** • Name and signature of Chief supervisor in SRC is there- please justify or revise • In inclusion criteria -Sex and age specification not mentioned • Sample size calculation not mentioned **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P54***
55.	Research proposal entitled ***"To study fetomaternal outcome in women with early onset vs late onset obstetric cholestasis"*** submitted by Dr. Nutan Leyangi, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/3425/22 dated 7th December, 2022. ***Recommendation of Primary reviewer:-*** • In SRC (scientific review committee) name and signature of two Co-guides are there -Please justify or revise • In Inclusion criteria – Age specificity not mentioned • SOP-Check list should be revised as many alternatives not ticked • Sample size disparity in SOP-Checklist (120 pts) and Protocol (185 pts)=Please clarify and correct. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P55***
56.	Research proposal entitled ***"A cross-sectional study on prevalence of depression, anxiety, stress, and suicidal thoughts among elderly population in Lucknow district"*** submitted by Dr. Akshay Kumar, JR, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1244/CM/23 dated 15th February, 2023. ***Recommendation of Primary reviewer:-*** • Please attach the mentioned Tools.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XVI-PGTSC-IIA/P56***
57.	Research proposal entitled ***"A study of adverse drug effect/adverse drug reactions in patients with obsessive compulsive disorder"*** submitted by Dr. Shivukumar Naik H, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 137/Pharma/23 dated 16th February, 2023. ***Recommendation of Primary reviewer:-*** • Tools not attached-Please attach mentioned tools **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XVI-PGTSC-IIA/P57***
58.	Research proposal entitled ***"To assess the efficacy of INDACATEROL/MOMETASONE vs FORMOTEROL/BUDESONIDE in patients with bronchial asthma"*** submitted by Dr. Zubair Ahmad Khan, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 138/Pharma/23 dated 16th February, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P58***
59.	Research proposal entitled ***"A cross sectional study of stress, self esteem, life satisfaction and subjective happiness in students of Medical Colleges of Lucknow"*** submitted by Dr. Divyansh Singh, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1179/CM/23 dated 31st January, 2023. ***Recommendation of Primary reviewer:-*** • PI should submit authentically developed questionnaires that will be used in study before starting the study. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XVI-PGTSC-IIA/P59***
60.	Research proposal entitled ***"Comparative study of clinicopathological characteristics of carcinoma gall bladder associated with APBDJ vs carcinoma gall bladder not associated with APBDJ"*** submitted by Dr. Ram Raj, SR, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. 117/23 dated 9th December, 2022. ***Recommendation of Primary reviewer:-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Aims & objective not mentioned in Protocol • In Title the abbreviated word APBDJ-should be expanded to make it self explanatory • Sample size discrepancy in two gps (in sample size calculation -each gp- mentioned -139 pts and in SOP-Check list total pts mentioned as 139)– please clarify • In Methodology ,please include Flow chart of study **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P60***
61.	Research proposal entitled ***"Drug utilization study and Pharmacoeconomic analysis of drugs, used in the treatment of obsessive compulsive disorders, in patients attending psychiatry outpatient Department, at tertiary care Hospital in Northern India"*** submitted by Dr. Ajay Kumar A.N, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 139/Pharma/23 dated 16th February, 2023. ***Recommendation of Primary reviewer:-*** • Tools not included in protocol **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XVI-PGTSC-IIA/P61***
62.	Research proposal entitled ***"Role of muscle transfer in anal incontinence"*** submitted by Dr. Vikramaditya, SRI, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 128/23 dated 31st January, 2023. ***Recommendation of Primary reviewer:-*** • In SOP-Check list serial no -6 -Confidentiality statement ticked as No (please correct or justify) • In Inclusion criteria - PI did not mentioned the Age / sex specificity **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P62***
63.	Research proposal entitled ***"Comparison of effectiveness and longeivity of three different restorative materials using ART versus conventional restorations with composite resin in class 1 cavities of deciduous teeth: A randomized control trial"*** submitted by Dr. Aishwarya Mukherjee, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/63/23 dated 15th February, 2023. ***Recommendation of Primary reviewer:-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• As this is RCT study therefore Flow chart should be included in Methodology • Children/subject recruitment age is between 4-8 yrs. therefore Guardian consent + Child Assent form should be submitted instead of regular ICF **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P63***
64.	Research proposal entitled ***"Tracking referred asphyxiated neonates delivered in public sector health facilities to generate action points for improving neonatal outcome: an exploratory pilot study from a tertiary care referral"*** submitted by Dr. Deepika Pandey, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2368/Ped/23 dated 21st December, 2022. ***Recommendation of Primary reviewer:-*** • In ICF-Guardian consent E/H -forms not same -please revise • nSOFA score in tools not attached **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P64***
65.	Research proposal entitled ***"A prospective study to compare clinical outcomes of mastoid cavity obliteration using integrated fascio-periosteal flap in canal wall down mastoidectomy versus conventional canal wall down mastoidectomy"*** submitted by Dr. Shazila, JRI, Department of Otorhinolaryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 907/ENT/23 dated 24th December, 2022. ***Recommendation of Primary reviewer:-*** • Flow chart in methodology section should be included • Sample size clarification – total sample size is 84, including two gps (42 in each gp) but in calculation total sample size given is 42 -please clarify • Child Assent form in addition to regular ICF should be included as Children in age gp of 15-17 yrs. will also be taken in study **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P65***
66.	Research proposal entitled ***"Clinico-radiological correlation of preoperative high resolution computed tomography temporal bone with per oberative findings in chronic otitis media squamosal type"*** submitted by Dr. Srishti Khera, JRI, Department of Otorhinolaryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 906/ENT/22 dated 24th December, 2022. ***Recommendation of Primary reviewer:-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• In Inclusion criteria age specificity has not been mentioned • ICF-H/E –Attached but if all age gp pts are to be included then Guardian consent and Child Assent form are also to be submitted -PI to clarify **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P66***
67.	Research proposal entitled ***"Prospective analysis of intra-operative neuromonitoring (IONM) in patients with intramedullary spinal cord tumors and its comparison with intramedullary surgeries without IONM: a single center study"*** submitted by Dr. Saurabh Raina, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 3010/NS/22 dated 10th December, 2022. ***Recommendation of Primary reviewer:-*** • Project has 13 Investigators with 8 from one department. This is untenable for a post graduate thesis. • Sample size mentioned 120 in the IEC form and 25 in the synopsis. • Several sections of the IEC form are left incomplete. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P67***
68.	Research proposal entitled ***"Analysis of various factors leading to vp shunt failure and its revision: A prospective study"*** submitted by Dr. Mohini Kol, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/286/22 dated 13th February, 2023. ***Recommendation of Primary reviewer:-*** • Several sections of IEC form are not filled. • Sample size not mentioned in IEC form. • Approximately 100 mentioned in synopsis. Please give exact sample size along with sample size calculation. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P68***
69.	Research proposal entitled ***"An epidemiological study of social media addiction, impulsivity and sensation seeking behavior among School-going adolescents of Lucknow"*** submitted by Dr. Smriti Verma, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1257/CM/23 dated 17th February, 2023. ***Recommendation of Primary reviewer:-*** • Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: As above *Ref. code: XVI-PGTSC-IIA/P69*
70.	Research proposal entitled ***"Phase II study of concurrent temozolomide, thalidomide plus celecoxib with radiotherapy in patients with newly diagnosed glioblastoma multiforme and its correlation with biomarkers"*** submitted by Dr. Kushal Rawal, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 107/RT/23 dated 3rd February, 2023. ***Recommendation of Primary reviewer:-*** • Is this study a trial? The topic mentions that this is a phase II study. • No CTRI registration is attached. • IEC form is incompletely filled. • Details on treatment of study related injuries/compensation/insurance for the trial are missing. • Sample size calculation has not been done. • Consent form and Patient information sheet for the trial is not attached. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit, give responses in a tabular format. *Ref. code: XVI-PGTSC-IIA/P70*
71.	Research proposal entitled ***"Study of microvascular density and expression of vascular endothelial growth factor in eyelid and ocular surface tumors"*** submitted by Dr. Priyanka, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 1675/OPH/23 dated 9th February, 2023. ***Recommendation of Primary reviewer:-*** • Section on type of subjects/vulnerable subjects/consent is left unfilled. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification *Ref. code: XVI-PGTSC-IIA/P71*
72.	Research proposal entitled ***"A comparative study of perioperative and quality of life outcomes with its ergonomic characteristics in midine totally extraperitoneal repair versus extended totally extraperitoneal repair in inguinal hernia"*** submitted by Dr. Kushagra Tyagi, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 457/23 dated 17th February, 2023. ***Recommendation of Primary reviewer:-*** • IEC form incompletely filled. Please fill it again and resubmit. • Sample size given different in the IEC form and in the synopsis (70+30 in IEC form and 60 in the synopsis) **PGTSC Comment:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P72***
73.	Research proposal entitled ***"Analysis of achievement of radiological parameters in uncemented total HIP replacement-A prospective cohort study"*** submitted by Dr. Raza Ahmad Khan, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 8039/OS/23 dated 16th February, 2023. ***Recommendation of Primary reviewer:-*** • IEC form is incompletely filled. Please complete the form and re-submit. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P73***
74.	Research proposal entitled ***"Assessment of womac index for knee osteoarthritis and its association with serum VITAMIN D and serum cytokine profile (IL 6 TNE ALPHA)"*** submitted by Dr. Mithilesh Kannaujiya, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 7040/OS/23 dated 5th January, 2023. ***Recommendation of Primary reviewer:-*** • IEC form is incompletely filled. Please complete it and re-submit. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P74***
75.	Research proposal entitled ***"To determine the role of S-100 beta metabolite in neurological recovery in acute spinal cord injuay (ASCI): A prospective case control study"*** submitted by Dr. Nagendra Kumar, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 9053/OS/23 dated 17th February, 2023. ***Recommendation of Primary reviewer:-*** • Title is misleading. Case Control studies are retrospective. Suggest deleting the word 'Case Control' from the title. • IEC form is incompletely/incorrectly filled. Please complete the form and re-submit. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P75***
76.	Research proposal entitled ***"To elucidate relationship of posterior tibial slope to functional outcome after anterior cruciate ligament reconstruction with hamstring graft"*** submitted by Dr. Mohd. Yoosuf, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 8041/OS/23 dated 27th January, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer:- • There are 9 (nine) Investigators in this project. Please reduce this number or define their unique roles. • IEC form is incompletely filled. Please fill it well and re-submit. **PGTSC Comment:** As above **PGTSC Decision:** ***Ref. code: XVI-PGTSC-IIA/P76***
77.	Research proposal entitled ***"Anatomical variation of heart in autopsied bodies along with histopathology correlation-An observational study"*** submitted by Dr. Ashutosh Kumar Rao, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 69/FMT/23 dated 21st February, 2023. *Recommendation of Primary reviewer:-* • Sections on Type of subjects, Privacy and Confidentiality etc. are not filled properly. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification, give responses in a tabular format. ***Ref. code: XVI-PGTSC-IIA/P77***
78.	Research proposal entitled ***"Evaluation of serum insulin like growth factor 1 (IGF-1) among controlled and uncontrolled type 2 diabetes mellitus in geriatric North Indian population"*** submitted by Dr. Arjun Dev J, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 140/Pharm/23 dated 16th February, 2023. *Recommendation of Primary reviewer:-* • Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIA/P78***
II-B	**Intern Ship**
1.	Research proposal entitled "***Study of patient satisfaction with hospital catering services in a Government tertiary care teaching Hospital, Lucknow, Uttar Pradesh***" submitted by Dr. Shambhavi Dwivedi, BDS, MPH 3rd Semester through her Mentor Dr. Nitin Dutt Bhardwaj, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/10/23 dated 9th January, 2023. *Recommendation of Primary reviewer:-* • Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIB /P1***
2.	Research proposal entitled ***"Assessment of patient satisfaction in outpatient Department (OLD OPD) in Government tertiary care Hospital"*** submitted by Mr.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Manvesh Kumar through her Mentor Dr. Pradeep Srivastava, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/11/23 dated 11th January, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIB/P2***
3-	Research proposal entitled "***Collection and analysis of patient satisfaction data in outpatient department in Government tertiary care Hospital***" submitted by Dr. Ruhul Ahmad Khan through his Mentor Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/32/23 dated 21st January, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVI-PGTSC-IIB/P3***

The next Meeting will be held on 19th April, 2023 from 1.00 PM.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 17th March, 2023

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 123rd IEC Meeting held on 19th April, 2023

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of 123rd "Institutional Ethics Committee" Meeting held on 19th April, 2023 from 1:00 PM ***virtual.***

The following Members were present in the Meeting:-

1.	Dr. Alok Dhawan	-Chairman
2.	Dr. G.G. Agarwal	-Member
3.	Dr. Akash Agarwal	-Member
4.	Dr. K.K. Yadav	-Member
5.	Mrs. Vasundhara Kumari	-Member
6.	Mr. Ujjawal Krishna	-Member
7.	Mrs. Akansha Dubey	-Member
8.	Dr. A.A. Mahdi	-Member
9.	Dr. Anupam Mishra	-Member
10.	Dr. Rajendra Nath	-Member
11.	Dr. D.N. Upadhyaya	-Member
12.	Dr. Nisha Mani Pandey	-Member
13.	Dr. Shally Awasthi	-Member

The following members were not Present in the Meeting:-

1.	Dr. Shubha Phadke	- Sent her written comments
2.	Dr. Anita Rani	- Sent her written comments

I	**Minutes of previous Meeting held on 17-03-2023. The following documents have been brought from the last meeting because the quorum was incomplete.**
IA	**Previous -Action Taken-17-03-2023**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

2- Clarification of research proposal entitled AVT06-GL-C01 Version: Version 2.0,21 December 2021 entitled ***"A randomized, double-masked, parallel-group, multicenter clinical study to evaluate the efficacy and safety of AVT06 compared with EU-Eylea® in subjects with neovascular (Wet) age-related macular degeneration (ALCOEYE)"*** sponsored by M/s Alvotech Swiss AG Thurgauerstrasse submitted by Prof. Sandeep Saxena, Department of Ophthalmology, King George's Medical University, U.P., Lucknow, vide letter no. 1856/OPH dated 15th March, 2023.

Recommendation of Primary reviewer:

- The research proposal was discussed in the meeting held at KGMU and comments given.

Previous EC Comment:

- Study Design, Please clarify
- Recruitment Period, Please clarify.

Reply of PI

1. **Study Design:** As per the protocol AVT06-GL-C01 – Version 2.0, 21 Dec 2021 section 4.1, the study consists of a screening period of up to 4 weeks, a treatment period of 48 weeks, and a follow-up period of 4 weeks until Week 52 (end of study). The **total study duration per subject is 56 weeks** including screening period e.g. if The Subject gets enrolled in Jun 2023 then the subject participation in study will be completed somewhere in July 2024. Means subject study participation is for approx. 1 year.

2. **Recruitment Period:** It is extended till beginning of Jun-2023 (Sponsor India News letter is attached, Page number 03)

The above Comment forwarded to PI was reviewed by Primary reviewer:-

Previous EC Decision: Defer to the next Meeting because quorum was incomplete.

The following documents were reviewed in the Meeting:-

Sl. No.	List of Documents	Version/Date
1	Investigator's Brochure	Version 2.0 Dated 17Jan2022
2.1	Study Protocol **AVT06-GL-C01**	Version 2.0 Dated 21Dec2021
2.2	Protocol Signature Page of Dr. Sandeep Saxena	Dated 25 Jan 2022
2.3	Mini Protocol cover	Version 2.0 Dated 21Dec2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	2.4	Protocol - Memo to Protocol - Fluorescein Dye-25Jan2022	NA
	2.5	Protocol - Memo to Protocol - Fluorescein Dye – 25Jan2022	Signed on Dated_05 Apr 2022
	3.1	Master ICF (English)	Main_V2.0IND (en)1.0(06Jan2022)
	3.2	Master ICF (Hindi)	Main_V2.0IND (hi)1.0(06Jan2022)
	3.3	Master ICF Translation Certificate English to Hindi	Dated 11 Feb 2022 of Main_V 2.0 IND (hi) 1.0 (06 Jan 2022)
	3.4	Back translation ICF from Hindi to English	Back translation of Main_V2.0IND (hi)1.0(06Jan2022)
	3.5	Back Translation Certificate Hindi to English	Dated 11Feb 2022 of Main_ V 2.0 IND (hi) 1.0 (06 Jan 2022)
	4.1	AV ICF (English)	Other_V8.0IND (en)1.0(23Nov2021)
	4.2	AV ICF (Hindi)	Other_V8.0IND (hi)1.0(23Nov2021)
	4.3	Translation Certificate of AV ICF-English to Hindi	Dated 11 Feb 2022 of Other_V8.0 IND (hi) 1.0 (23 Nov 2021)
	4.4	Back Translated AV ICF from Hindi to English	Back translation of Other_V8.0IND (hi)1.0(23Nov2021)
	4.5	Back Translation Certificate of AV ICF-Hindi to English	Dated 11 Feb 2022 of Other_V8.0 IND (hi) 1.0 (23 Nov 2021)
	5.1	ICF to participate in Imaging Procedures for Quality Assessment (English)	Volunteers Imaging Qualification_V1.0IND(en)1.0(06Jan2022)
	5.2	ICF to participate in Imaging Procedures for Quality Assessment (Hindi)	Volunteers Imaging Qualification_V1.0IND(hi)1.0(06Jan2022)
	5.3	Translation Certificate of ICF to participate in Imaging Procedures for Quality Assessment- English to Hindi	Dated 11 Feb 2022 of Volunteers Imaging Qualification_V1.0IND(hi)1.0(06Jan2022)
	5.4	Back Translated ICF to participate in Imaging Procedures for Quality Assessment from Hindi to English	Back translation of Volunteers Imaging Qualification_V1.0IND(hi)1.0(06Jan2022)
	5.5	Back Translation Certificate of ICF to participate in Imaging Procedures for Quality Assessment- Hindi to English	Dated 11 Feb 2022 of Volunteers Imaging Qualification_V1.0IND(hi)1.0(06Jan2022)
	6.1	Consent Form for Pregnancy Testing and appropriate Follow up (English)	Preg_V1.0IND(en)1.0(23Nov2021)
	6.2	Consent Form for Pregnancy Testing and appropriate Follow up (Hindi)	Preg_V1.0IND(hi)1.0(23Nov2021)
	6.3	Translation Certificate of Consent Form for Pregnancy Testing and appropriate Follow up (English to Hindi)	Dated 11 Feb 2022 of Preg_V1.0IND(hi)1.0(23Nov2021)
	6.4	Back Translated Consent Form for Pregnancy Testing and appropriate Follow up (Hindi to English)	Back translation of Preg_V1.0IND(hi)1.0(23Nov2021)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	6.5	Back Translation Certificate of Consent Form for Pregnancy Testing and appropriate Follow up (Hindi to English)	dated 11 Feb 2022 of Preg_V1.0IND(hi)1.0(23Nov2021)
	7	Audio Visual (A-V) Recording Declaration	V5.0IND(en)1.0(23Nov2021)
	8	Patient ID Card (English)	Patient ID Card,15 Nov 2021 [V01 Global(en)]
	8.1	Patient ID Card (Hindi)	Patient ID Card,15 Nov 2021 [V01IND(hi)]
	8.2	Translation Certificate of Patient ID Card (English to Hindi)	Dated 31 Dec 2021 of Patient ID Card, 15 Nov 2021 [V01 IND(hi)]
	9	Patient Brochure (English)	Patient Brochure, 26 Nov 2021 [V01 Global(en)]
	9.1	Patient Brochure (Hindi)	Patient Brochure, 26 Nov 2021 [V01 IND (hi)]
	9.2	Translation Certificate of Patient Brochure (English to Hindi)	Dated 31 Dec 2021 of Patient Brochure, 26 Nov 2021 [V01 IND(hi)]
	10	Visit Reminder Card (English)	Visit Reminder Card, 15 Nov 2021 [V01 Global(en)]
	10.1	Visit Reminder Card (Hindi)	Visit Reminder Card, 15 Nov 2021 [V01 IND (hi)]
	10.2	Translation Certificate of Visit Reminder Card (English to Hindi)	Dated 31 Dec 2021 of Visit Reminder Card, 15 Nov 2021 [V01 IND(hi)]
	11	Justification for inclusion of vulnerable populations	Dated 13 Dec 2021
	12	Annotated Unique forms	AVT06-GL-C01_Version_0.1_05Jan2022
	13	Data Safety Monitoring Board (DSMB) Charter	V1_18Jan2022
	14	Physician Referral Letter	07 Jan 2022 [V02 Global(en)]
	15	Patient Appreciation Items (English)	Patient Appreciation Items, 9 Dec 2021[V01 IND(en)]
	15. 1	Patient Appreciation Items (Hindi)	Patient Appreciation Items, 9 Dec 2021[V01 IND(hi)]
	15.2	Translation certificate of Patient Appreciation Items (English to Hindi)	Dated 25Jan2022 of Patient Appreciation Items, 9 Dec 2021[V01 IND(hi)
	16	Site Study Poster (English)	Site Poster, 22Feb2022 [V01 Global (en)]
	16.1	Site Study Poster (Hindi)	Site Poster, 22Feb2022 [V01 IND (hi)]
	16.2	Translation certificate of Site Study Poster (English to Hindi)	Dated 08Mar2022 of Site Poster, 22Feb2022 [V01 IND(hi)]

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	17	Draft CTA	Dated 04 Feb 2022
	18.1	CV of Dr. Sandeep Saxena	Signed on: 12 Jan 2022
	18.2	MRC of Dr. Sandeep Saxena	NA
	18.3	GCP of Dr. Sandeep Saxena	Dated 26 Jul 2019
	18.4	IU of Dr. Sandeep Saxena	Signed on: 05 Apr 2022
	18.5	Investigator Statement	Signed on: 05 Apr 2022
	19	Indian insurance Policy no. 4067/240302630/00/000	NA
	20	Indian Certificate of Insurance valid up to 30 March, 2024	Policy period: 23 Dec 2021 to 30 Mar 2024
	21	DCGI Submission letter Application Reference No. GCT/CT04/FF/2022/32118	Dated 17 May 2022

EC Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 118thECM IIC/P1

II-C **Previous - New Drug Trial**

1. Research protocol no. 18F-MC-GPIJ entitled "***A phase 3, randomized, double-blind, placebo-controlled study to investigator the effects of tirzepatide on the reduction of morbidity and mortality in adults with obesity***" sponsored by M/s Eli Lilly Company Legal Registered submitted by Prof. Gaurav Chaudhary, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.494/Cardio/Res/2022 dated 16th December, 2022.

Recommendation of Primary reviewer:

- CTRI – Approval number awaited

Previous EC Decision: Defer to the next Meeting because quorum was incomplete.

The following documents were reviewed in the Meeting:-

S.No.	Documents
1.	**Protocol I8F-MC-GPIJ dated 14 Jun 2022**
2.	**Investigator's Brochure dated 26 Oct 2021**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Patient Informed Consent Form:
	3.	**3.1** India Specific ICF Version 1.0, English dated 01 Aug 2022 **3.2** India Specific ICF Version 1.0, Hindi Forward Translation dated 01 Oct 2022 with Certificate of Translation dated 3 Oct2022
	4.	**AV Consent Form:** **4.1** Template for Privacy Notice and Consent form _ AV recording English dated 27 Nov 2013 **4.2** Template for Privacy Notice and Consent form _ AV recording Hindi Forward Translation dated 27 Nov 2013 **4.3** AV Consent Translation Certificate dated 27 Nov 2013
	5.	**Annotate Case Report Form** 02 Sep 2022
	6.	**Insurance certificate** dated 06 Sep 2022
	7.	**Draft CTA** 5 Nov 2022
	8.	**Curriculum Vitae** of PI dated 31 May 2022; MRC and GCP of PI
	9.	**PI Undertaking** dated 01 Aug 2022 and additional undertaking dated 01 Aug 2022
	10.	**Memo on contraceptive language in IB and protocol**
	11.	**GPIJ Justification for Placebo** dated 20 Jun 2022
	12.	**Paper files:** **English:** 12.1 HCRU Questions_v1_WS_Paper_English-US 12.2 Symptoms During Sleep Questions_v1_WS_Paper_English-US 12.3 EQ-5D-5L Paper Self-Complete_v1.1_WS_Paper_English-IN_17Jun2022 with certificate of translation 12.4 SF-36v2 Acute_WS_Paper_English-IN_17Jun2022 with certificate of translation 12.5 HOOS_v2.0_WS_Paper_English-IN_17Jun2022 with certificate of translation 12.6 KOOS Knee Survey_v1_WS_Paper_English-IN_23Aug2022 with certificate of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

translation

12.7 NRS Average Hip Pain 1wk_v1_WS_Paper_English-IN_17Jun2022 with certificate of Translation

12.8 NRS Average Knee Pain 1wk_v1_WS_Paper_English-IN_17Jun2022 with certificate of Translation

12.9 NRS Worst Hip Pain 1wk_v1_WS_Paper_English-IN_17Jun2022 with certificate of Translation

12.10 NRS Worst Knee Pain 1wk_v1_WS_Paper_English-IN_17Jun2022 with certificate of Translation

12.11 Patient Global Impression of Status (PGIS) for Physical Activity_v1_WS_Paper_English-IN_17Jun2022 with certificate of translation

12.12 TIRZEPATIDE-CT-GPIJ-IFU Saved- final version 06-30-22.1_enIN

Hindi:

12.13 EQ-5D-5L Paper Self-Complete_v2.0_WS_Paper_Hindi-IN_17Jun2022 with certificate of translation

12.14 SF-36v2 Acute_WS_Paper_Hindi-IN_17Jun2022 with certificate of translation

12.15 HOOS_v1_Paper_Hindi-IN_22Jun2022 with certificate of translation

12.16 KOOS Knee Survey_v1_WS_Paper_Hindi-IN_22Aug2022 with certificate of translation

12.17 NRS Average Hip Pain 1wk_v1_Paper_Hindi-IN_16Jun2022 with certificate of translation

12.18 NRS Average Knee Pain 1wk_v1_Paper_Hindi-IN_16Jun2022 with certificate of Translation

12.19 NRS Worst Hip Pain 1wk_v1_Paper_Hindi-IN_20Jun2022 with certificate of translation

12.20 NRS Worst Knee Pain 1wk_v1_Paper_Hindi-IN_20Jun2022 with certificate of translation

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		12.21 Patient Global Impression of Status (PGIS) for Physical Activity_v1_WS_Paper_Hindi-IN_17Jun2022 with certificate of translation 12.22 TIRZEPATIDE-CT-GPIJ-IFU Saved- final version 06-30-22.1_hiIN with certificate of translation
	13.	**eCOA ready files:** **English:** 13.1 HOOS_v2.0_eCOA Ready_English-IN_17Jun2022 with certificate of translation 13.2 KOOS Knee Survey_v1_eCOA Ready_English-IN_23Aug2022 with certificate of translation 13.3 NRS Average Hip Pain 1wk_v1_eCOA Ready_English-IN_17Jun2022 with certificate of translation 13.4 NRS Average Knee Pain 1wk_v1_eCOA Ready_English-IN_17Jun2022 with certificate of translation 13.5 NRS Worst Hip Pain 1wk_v1_eCOA Ready_English-IN_17Jun2022 with certificate of translation 13.6 NRS Worst Knee Pain 1wk_v1_eCOA Ready_English-IN_17Jun2022 with certificate of translation 13.7 Patient Global Impression of Status (PGIS) for Physical Activity_v1_eCOA Ready_English-IN_23Jun2022 with certificate of translation **Hindi:** 13.8 HOOS_v1_eCOA Ready_Hindi-IN_22Jun2022 with certificate of translation 13.9 KOOS Knee Survey_v1_eCOA Ready_Hindi-IN_22Aug2022 with certificate of translation 13.10 NRS Average Hip Pain 1wk_v1_eCOA Ready_Hindi-IN_20Jun2022 with certificate of translation 13.11 NRS Average Knee Pain 1wk_v1_eCOA Ready_Hindi-IN_20Jun2022 with certificate of translation 13.12 NRS Worst Hip Pain 1wk_v1_eCOA Ready_Hindi-IN_20Jun2022 with certificate of translation 13.13 NRS Worst Knee Pain 1wk_v1_eCOA Ready_Hindi-IN_20Jun2022 with certificate of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	translation 13.14 Patient Global Impression of Status (PGIS) for Physical Activity_v1_eCOA Ready_Hindi- IN_23Jun2022 with certificate of translation **EC Decision:** Approval subject to fulfillment & Administrative formalities ***Ref. code: 122nd ECMIIC/P1***
2.	Research protocol no. DRL-IND-NDA03-ELO/2022 entitled "***A randomized, multicentre, double blind, placebo controlled, parallel-Group study to evaluate the efficacy and safety of elobixibat once daily of Dr. Reddy's Laboratories Limited in patients with chronic constipation***" sponsored by M/s Dr. Reddy's Laboratories Limited submitted by Prof. Abhijit Chandra, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow, vide letter no. SGE/CT/03/23 dated 20th January, 2023. ***Recommendation of Primary reviewer:*** - CTRI-Approval number awaited **Previous EC Decision:** Defer to the next Meeting because quorum was incomplete. ***The following documents were reviewed in Its Meeting:-*** 1. Clinical Trial Protocol (Version 1.0; Dated 11-Mar-2022) 2. Investigator's Brochure (Version 01; Dated 22-Mar-2022) 3. Case Report Form (Version 1.0; Dated 15-Mar-2022) 4. Informed Consent Document (Version 1.0; Dated 14-Mar-2022 in English & Hindi) 5. Back Translated Informed Consent Document (Version 1.0; Dated 14-Mar-2022, From Hindi to English) 6. Translational and back translational certificates of Informed Consent Documents Dated 19-May-2022 7. Subject Diary (Version 1.0; Dated 14-Mar-2022 in English & Hindi) 8. Back Translated Subject Diary (Version 1.0; Dated 14-Mar-2022, From Hindi to English) 9. Translational and back translational certificates of Subject Diary Dated 23-May-2022 10. Insurance Certificate 11. DCGI Approval for Clinical Trial Conduct (CT-06), Dated 29-Mar-2022 12. Investigator's Undertaking Dated 14-Mar-2022 13. Protocol Signature Page; Dated 14-Mar-2022 14. Principal Investigator's Curriculum Vitae & Medical Registration Certificate **EC Decision:** Approval subject to fulfillment & Administrative formalities ***Ref. code: 122nd ECMIIC/P2***
3.	Research protocol entitled "***A phase III, multicentre, randomized, double-blinded, placebo-controlled, interventional study on efficacy and safety of standardized fraction of picrorhiza kurroa royal ex Benth (Picroliv®) for 24 weeks in the management of non-alcoholic fatty liver disease (NAFLD)***" sponsored by M/s ICMR submitted by Prof. Satyendra Kumar Sonkar, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 489/MED/23 dated 23rd February, 2023. ***Recommendation of Primary reviewer:*** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous EC Decision: Defer to the next Meeting because quorum was incomplete. ***The following documents were reviewed in Its Meeting:-*** 1. Trial protocol (including protocol amendments/project)Version no 3 dated 17.05.2022, 2. Sponsor Certificate. 3. Investigator's Brochure, Version 1.2, Dated 7th December 2021. 4. Screening CRF. 5. Recruited Participants CRF. 6. Patient Information Sheet and Information Consent Form (including updates if any) in Hindi, English and/or vernacular language. Version no 3 dated 17.05.2022. 7. Translation Certificate. 8. Questionnaire. 9. Subject Dairy Medication (English). 10. Subject Dairy Medication (Hindi). 11. Picroliv EC Approval (CDRI, Lucknow and AIIMS, New Delhi) 12. DCGI approval letter/submission letter. Attached. 13. Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation.: attached. 14. CTRI Picroliv. 15. Investigator's Undertaking. Attached 16. Current CV of investigator/ U.P. Medical Council Attached. 17. Clinical Trial Agreement and Picroliv Budget Statement 18. .CV,MRC of CO-I Dr. Vivek Bhosle. **EC Decision:** Approval subject to fulfillment & Administrative formalities ***Ref. code: 122nd ECMIIC/P3***
4.	Research protocol entitled "***A phase 2, multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the clinical efficacy and safety of VTX002 in subjects with moderately to severely active ulcerative colitis***" sponsored by M/s Oppilan Pharma Ltd submitted by Prof. Abhijit Chandra, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SGE/CT/05/23 dated 22nd February, 2023. ***Recommendation of Primary reviewer:*** • CTRI form has been submitted. CTRI Approval is pending. • DCGI permission not present. • Optional Genetic testing is being ordered from outside the country-Central Lab. Labcorp Development, Singapore. • Is pregnant partner and fetus of a subject receiving the test drug covered under the Insurance scheme? • Could not fine the budget approval in the IEC form is 180. However, in the CTRI application the sample size from India in mentioned as 25 • Section on Biological/hazardous material in incorrectly filled as blood is being collected for Optional Genetic Sampling and is being sent abroad. • Section on Compensation says, compensation will be paid by Sponsor not the Insurance Company. Is this correct? **Previous EC Decision:** Defer to the next Meeting because quorum was incomplete.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 122nd ECMIIC/P4***
5.	Research protocol no. TILD-19-07 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF experienced subjects with active psoriatic arthritis I (INSPIRE 1)***" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow, vide letter no. Rh/CT/20/23 dated 25th February, 2023. **Previous EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Recommendation of Primary reviewer:*** • DCGI application does not mention KGMU site/KGMU PI. • DCGI application attached but no approval is attached. • Clinical Trail Agreement is only a format without any details like KGMU site/Budgetary allocation. **EC Comment:** • As above **EC Decision:** Revise & re-submit. ***Ref. code: 122nd ECMIIC/P5***
6.	Research protocol no. TILD-19-19 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF naive subjects with active psoriatic arthritis II (INSPIRE 2)***" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow, vide letter no. Rh/CT/21/23 dated 25th February, 2023. **Previous EC Decision:** Defer to the next Meeting because quorum was incomplete. ***Recommendation of Primary reviewer:*** • DCGI application does not mention KGMU site/KGMU PI. • DCGI application attached but no approval is attached. • Clinical Trail Agreement is only a format without any details like KGMU site/Budgetary allocation. **EC Comment:** • As above **EC Decision:** Revise & re-submit. ***Ref. code: 122nd ECMIIC/P6***
III A-	**Previous -Additional Document**
1.	Additional of research protocol no. CLNA043A12202 entitled "***A 5-year, randomized, double-blind, placebo-controlled, multi-center study assessing the efficacy, safety, and tolerability of intra-articular regimens of LNA043 versus placebo in patients with symptomatic knee osteoarthritis (ONWARDS)***" sponsored by M/s Novartis Healthcare

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Pvt. Ltd. submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 12/P/OS/23 dated 16th February, 2023.

Previous EC Decision: Defer to the next Meeting because quorum was incomplete.

The following documents were reviewed in the Meeting:-

Sl.no.	Title
1.	eCOA Handheld_Acute Reaction Diary_English (India)_(Ver 2.0, 15 Mar 2022)
2.	Certificate of translation for Acute Reaction Diary eCOA Handheld Screenshots English_India (Ver2.0, 15 Mar 2022)
3.	eCOA Handheld_Acute Reaction Diary_Hindi (India)_(Ver 2.0, 15 Mar 2022)
4.	Certificate of translation for Acute Reaction Diary eCOA Handheld Screenshots Hindi_India (Ver2.0, 15 Mar 2022)
5.	Study Appointments_V00_28Feb2022
6.	Study Appointments_V00_28Feb2022, Translated from English to Hindi on 15 Mar 2022
7.	Study Appointments_V00_28Feb2022, Back Translated from Hindi to English on 21 Mar 2022
8.	Study Handout_V00_28Feb2022
9.	Study Handout_V00_28Feb2022, Translated from English to Hindi on 15 Mar 2022
10.	Study Handout_V00_28Feb2022, Back Translated from Hindi to English on 21Mar 2022
11.	Certificate of translation and back translation for Study Appointments_V00_28Feb2022 and Study Handout_V00_28Feb2022 for the Hindi language
12.	ONWARDS_Patient compliance animation_V1_28July21_English
13.	ONWARDS_Patient compliance animation_V1_28July21_Hindi
14.	ONWARDS_Patient Newsletter 4_V1_10Oct22_English (UK)
15.	ONWARDS_Patient Newsletter 4_V1_24Oct22_Hindi (India)
16.	Translation Certificate: ONWARDS_Patient Newsletter 4_V1_24Oct22_Hindi (India)
17.	Protocol 01_Version 01, Dated 29 Nov 2021
18.	Patient Information and Informed Consent Form (Version 5.0, Dated 14 Dec 2021)
19.	Patient Information and Informed Consent Form (Version 5.0, Dated 14 Dec 2021) translated from English to Hindi on 01 Jan 2022
20.	Patient Information and Informed Consent Form (Version 5.0, Dated 14 Dec 2021) back translated from Hindi to English on 08 Jan 2022
21.	Translation and back translation certificate for Patient Information and Informed Consent Form (Version 5.0, Dated 14 Dec 2021):

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

		• Hindi
	22.	Informed Consent for Optional Genetic Research (Version 2.0, Dated 14 Dec 2021)
	23.	Informed Consent for Optional Genetic Research (Version 2.0, Dated 14 Dec 2021) translated from English to Hindi on 01 Jan 2022
	24.	Informed Consent for Optional Genetic Research (Version 2.0, Dated 14 Dec 2021) back translated from Hindi to English on 08 Jan 2022
	25.	Translation and back translation certificate for Informed Consent for Optional Genetic Research (Version 2.0, Dated 14 Dec 2021) • Hindi
	26.	Site training Informed Consent_ Imagining Qualification (Version 2.0, Dated 14 Dec 2021)
	27.	Site training Informed Consent_ Imagining Qualification (Version 2.0, Dated 14 Dec 2021) translated from English to Hindi on 01 Jan 2022
	28.	Site training Informed Consent_ Imagining Qualification (Version 2.0, Dated 14 Dec 2021) back translated from Hindi to English on 08 Jan 2022
	29.	Translation and back translation certificate for Site training Informed Consent_ Imagining Qualification (Version 2.0, Dated 14 Dec 2021) • Hindi
	30.	Informed Consent for Pre-screening (Version 1.0, Dated 14 Dec 2021)
	31.	Informed Consent for Pre-screening (Version 1.0, Dated 14 Dec 2021) translated from English to Hindi on 01 Jan 2022
	32.	Informed Consent for Pre-screening (Version 1.0, Dated 14 Dec 2021) back translated from Hindi to English on 08 Jan 2022

EC Decision: Approved

Ref. code: 114thECMIIC/P3

2.	Additional of research protocol no. CTQJ230A12301 entitled "***A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of protein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease (Horizon Study)***" sponsored by M/s Novartis Health Care Pvt. Ltd. submitted by Prof. S.K. Dwivedi, Head, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 645/Cardio/Res/23 dated 24th February, 2023. **Previous EC Decision:** Defer to the next Meeting because quorum was incomplete. **EC Decision:** Approved ***Ref. code: 101stECMIIC/P18***
III-B	**Previous -Modification**
1.	Modification of research protocol no. LTE15174 protocol Version 5 Dated 12 Oct 2022 entitled "**ATLAS-OLE:** ***An open label long term safety and efficacy study of fitusiran in patients with hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX***" submitted by Dr. S.P. Verma, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. CH/02/CT/23 dated 7th January, 2023. **Previous EC Decision:** Defer to the next Meeting because quorum was incomplete. ***The following documents were reviewed in the Meeting:-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Sr. No.	Document/Language	Document Details/Versions
1-	Protocol No: LTE15174 (Clean copy)	Protocol LTE15174, Amendment 05 Dated 12 Oct 2022(Controlled Copy No: PPD/ LTE15174/Protocol Amendment 05 Dated 12 Oct 2022/001 – 004)
2-	Protocol No: LTE15174 (Track change copy)	Protocol LTE15174, Amendment 05 Dated 12 Oct 2022
3-	Protocol No: LTE15174 (Summary of changes)	Protocol LTE15174, Amendment 05 Dated 12 Oct 2022
4-	DCGI Acknowledgment for Submission Screenshot_ Protocol LTE15174, Amendment 05 Dated 12 Oct 2022	Cover Letter dated 23 Dec 2022 & Email acknowledgement dated 23 Dec 2022
5-	DCGI Acknowledgment for Submission_Main and Assent ICF_ v 6.1_India_English _dtd 28 Oct 2022	Cover Letter Dated 23 Dec 2022 E-Mail Acknowledgement dated 23 Dec 2022
6-	English Participant/ Parental ICF	LTE15174_Main ICF v6.1_India_English_ Site #:3560005_Dr Shailendra Prasad Verma _24Nov2022
7.	Hindi Participant/ Parental ICF	LTE15174_Main ICF v6.1_India_Hindi_Site #:3560005_Dr Shailendra Prasad Verma_24Nov2022
8.	Hindi to English Participant/ Parental ICF	LTE15174_Main ICF v6.1_India_English Back Translated from Hindi_Site #:3560005_Dr Shailendra Prasad Verma_24Nov2022
9.	English Assent ICF	ATLAS-OLE (LTE15174) ASSENT STATEMENT FOR

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

			CHILDREN 12 - 17 YEARS OF AGE LTE15174_Assent ICF v6.1_India_English_ Site #:3560005_Dr Shailendra Prasad Verma _24Nov2022
	10.	Hindi Assent ICF	ATLAS-OLE (LTE15174) ASSENT STATEMENT FOR CHILDREN 12 - 17 YEARS OF AGE LTE15174_Assent ICF v6.1_India_Hindi_ Site #:3560005_Dr Shailendra Prasad Verma _24Nov2022
	11.	Hindi to English Assent ICF	ATLAS-OLE (LTE15174) ASSENT STATEMENT FOR CHILDREN 12 - 17 YEARS OF AGE LTE15174_Assent ICF v6.1_India_ English Back Translated from Hindi _ Site #:3560005_Dr Shailendra Prasad Verma _24Nov2022
	12.	Front and Back Translation Certificate	

EC Decision: Approved

Ref.code:90thECMIIC/P1

2. Modification of research protocol no. CKJX839B12302 entitled "***A randomized, double-blind, placebo-controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT)***" sponsored by M/s Novartis Healthcare Pvt. Ltd. submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 612/Cardio/Res/23 dated 10th February, 2023.

Recommendation of Primary reviewer:

- Summary of changes seen–OK and Noted
- Other documents related to clinical trials e.g.-CTA document, DCGI Permission, Insurance etc. are not attached.

Previous EC Decision: Defer to the next Meeting because quorum was incomplete.

The following documents were reviewed in the Meeting:-

Sr. No	Title

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

1.	Clinical Trial Protocol (Version Number:01;Dated: 23-Mar-2022)
2.	Patient Information and Informed Consent Form (Version 2.0, Dated 24 Apr 2022)
3.	Patient Information and Informed Consent Form (Version 2.0, Dated 24 Apr 2022) translated from English to Hindi on 28 Apr 2022
4.	Patient Information and Informed Consent Form (Version 2.0, Dated 24 Apr 2022) back translated from Hindi to English on 05 May 2022
5.	Translation and back translation certificate for Patient Information and Informed Consent Form (Version 2.0, Dated 24 Apr 2022): • Hindi
6.	Informed Consent for Exploratory Genetic Research (Version 2.0, Dated 24 Apr 2022)
7.	Informed Consent for Exploratory Genetic Research (Version 2.0, Dated 24 Apr 2022) translated from English to Hindi on 28 Apr 2022
8.	Informed Consent for Exploratory Genetic Research (Version 2.0, Dated 24 Apr 2022) back translated feom Hindi to English on 05 May 2022
9.	Translation and back translation certificates for Informed Consent for Exploratory Genetic Research (Version 2.0, Dated 24 Apr 2022): • Hindi
10.	Participant Infogetter 20211117 1.0 English S03
11.	Participant Infogetter 20211117 1.0 English S03_Translated to Hindi
12.	Participant Infogetter 20211117 1.0 English S03_Back translated from Hindi to English
13.	Partcipant Information Sheet 20211117 1.0 English S03
14.	Partcipant Information Sheet 20211117 1.0 English S03_Translated to Hindi.
15.	Partcipant Information Sheet 20211117 1.0 English S03_Back translated from Hindi to English
16.	AUS Poster 20211117 1.0 English S02

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

	17.	AUS Poster 20211117 1.0 English S02_ Translated to Hindi
	18.	AUS Poster 20211117 1.0 English S02_Back translated from Hindi to English
	19.	Study Information Brochure English S04
	20.	Study Information Brochure English S04_ Translated to Hindi
	21.	Study Information Brochure English S04_ Back translated from Hindi to English
	22.	GLOBAL Digital Toolkit 20220106 1.0 English
	23.	GLOBAL Digital Toolkit 20220106 1.0 English_ Translated to Hindi
	24.	GLOBAL Digital Toolkit 20220106 1.0 English_Back translated from Hindi to English
	25.	• Translation and back translation certificate for Hindi language for- • Participant Infogetter 20211117 1.0 English S03 • Participant Information Sheet 20211117 1.0 English S03 • AUS Poster 20211117 1.0 English S02 • Study Information Brochure 20211117 1.0 English S04 • GLOBAL Digital Toolkit 20220106 1.0 English S04
	26.	AUS Newspaper Ad 20211117 1.0 English S02
	27.	AUS Participant Pathway 20211117 1.0 English S03
	28.	AUS Participant study guide 20211117 1.0 English S04
	29.	AUS Physician Infogetter 20211117 1.0 English S03
	30.	AUS Physician Referral Card 20211117 1.0 English S02
	31.	GLOBAL Eligibility Card 20211117 1.0 English S03
	32.	GLOBAL Ring of Resources20211117 1.0 English S02
	33.	CKJX839 (LI) SUSAR (S) 01oct2021 31 mar2022 blinded all arms (CT)
	EC Decision: Approved ***Ref. code: 114th ECMIIC/P4***	
3.	Modification of research protocol entitled ***"A pilot observation study to assess the role of centralized monitoring in general medicine wards"*** sponsored by M/s Turtle Shell Technologies Pvt. Ltd. submitted by Dr. Ambuj Yadav, Assistant Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/02/23 dated 28th February, 2023. ***Recommendation of Primary reviewer:-***	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Project already approved previously. Requested changes to the protocol may kindly be approved. **Previous EC Decision:** Defer to the next Meeting because quorum was incomplete. • The following documents were reviewed in Its Meeting:- • Amendment Study Protocol (DZ_KGMU_Amended_Protocol_Phase_2) • Patient Consent form English (DZ_KGMU_Amended_PIS_ICF_Phase_2) • Patient Consent form English (DZ_KGMU_Amended_PIS_ICF_Hindi_Phase_2) • Case Report Form (DZ_KGMU_Amended_CRF_Phase_2) • Draft Clinical Trial Agreement. ***The following documents were reviewed in Its Meeting:-*** • Amendment Study Protocol (DZ_KGMU_Amended_Protocol_Phase_2) • Patient Consent form English (DZ_KGMU_Amended_PIS_ICF_Phase_2) • Patient Consent form English (DZ_KGMU_Amended_PIS_ICF_Hindi_Phase_2) • Case Report Form (DZ_KGMU_Amended_CRF_Phase_2) • Draft Clinical Trial Agreement. **EC Decision:** Approved ***Ref. code: 117thECMIIC/P7***
B	**Current Agenda of 123rd IEC Meeting virtually held on 19-04-2023 from 1.00 PM.**
I-A	**Action taken**
1-	Clarification of research proposal entitled ***"Effect of vocational rehabilitation in myocardial infarction patients and returning back to their work after myocardial infarction"*** submitted by Ms. Meenakshi Mishra, Ph.D. Scholar 2019 under the guidance of Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 11/Cardio/Res/2023 dated 18th April, 2023. **Previous EC Comment:** • Kindly correct the title of the proposal-entitled ***"Effect of vocational rehabilitation in patients returning back to their work following myocardial infarction"*** ***The above Comment forwarded to Principal-Investigator was reviewed by Primary reviewer:-*** ***Recommendation of Primary reviewer:*** There is no proposal enclosed. Please check and resend. ***The above comment forwarded to Principal-Investigator & she has given her reply with full proposal vide letter no.720/Cardio/Res/23 dated 31st March, 2023 which was forwarded to Dr. Akash Agarwal vide this office letter no.27/Ethics/2023 dated 1st April, 2023.*** ***Recommendation of Primary reviewer:*** • Is this work, the PhD work? • If yes, what was the student doing since 2019. • If no, how can a PhD student become PI? • Pages 15 and 19 aims and objectives, both are vague, and different. • I have yet to come across a randomised Case control study in literature.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

	• What is the endpoint? • What is the outcome variable and of what kind? • Sample size calculation, study design, outcome variables, all three are discordant. • Time points are not mentioned for outcome measures. ***The above Comment forwarded to Principal Investigator:- The above Comment forwarded to Principal-Investigator was reviewed by Primary reviewer:-*** **EC Comment:** Approved ***Ref: code: 113th ECM IIB-Ph.D/P3***
2-	Clarification of research proposal entitled ***"Effect of dopamine as VEGF antagonist on progression of sepsis to septic shock, ALI (acute lung injury) and AKI (acute kidney injury)"*** submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 56/CCU/2023 dated 2nd March 2023. **Previous EC Comment:** • Patient information sheet is not attached. • Methodology is grossly incomplete. Kindly elaborate the details of intervention, comparison & outcome. • Kindly revise methodology & data sheet in relevance the sepsis & septic shock. • Anticipated adverse event is still not added in ICF. • Not complied. Methodology to be re-written as per the points raised earlier. ***The above Comment forwarded to PI vide letter no.2327/Ethics/2023 dated 17th March, 2023 & the first reminder send to the PI vide letter no. 2538/Ethics/2023 dated 27th March, 2023 but reply has not been received.*** Reply pending by Principal-Investigator. **EC Comment:** Second reminder will be sent to Principal-Investigator ***Ref. code: 119th ECM IIA/P3***
3-	Clarification of research proposal entitled ***"Evaluation of lignocaine HCI as a therapeutic and diagnostic tool in myofascial pain dysfunction syndrome (MPDS0 and internal derangement"*** submitted by Prof. U.S Pal, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow. ***Recommendation of Primary reviewer:-*** • There are 4 groups of patients: Patients who will not have effect of Lignocaine, MPDS, ID, ID+MPDS. • Measurements are made at 4 time points. • A difference to detect a difference of 1.3% (of what?) will be detected in 20 patients. • I don't think this is feasible. • Outcome measure will be what type of measurements: N/O/I/R? • Why will direct identifiers be used? ***Studied by another investigator at the request of the Principal Investigator after Chairman's permission.***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Secondary reviewer. PI has already made corrections according to the comments, which are valid and made by Primary Reviewer as- • PI cleared that Indirect Identifiers will be taken • Efficacy measures are added • Sample size calculation is revised • Case Record form is attached • PI has given satisfactory answer to quarries of Primary Reviewer for ADR and Compensation • Grouping has also been explained by PI • But PI has not corrected the SOP-Checklist accordingly and did not highlighted the change in protocol–PI should send the corrected SOP-Check list and protocol (Highlighted) with incorporating additional comments, <u>which are as follows:</u> 1. As this is not a Clinical Trial and the Drug Lignocaine is already approved in India, therefore SOP-Checklist must be corrected (SECTION-3 and subsections I, ii, iii). Section 6 – Privacy and Confidentiality–section–I-Indirect Identifier not ticked according to the corrections made by PI in answer to quarries made by Primary Reviewer. Secondly-in section ii- Confidential handling of data by staff is not ticked as YES (Therefore PI is required to send corrected and revised SOP-Check list) 2. In Inclusion /Exclusion criteria–Age/ Sex criteria not mentioned 3. Study design–PI mentioned it as prospective study, which is to be corrected/clarified, as the study design seems to be prospective Interventional and comparative prospective/post operative study. 4. For clarity in methodology PI should add Flow chart of the study. ***The above Comment forwarded to PI vide letter no.2539/Ethics/2023 dated 27th March, 2023 but reply has not been received.*** Reply pending from PI. **EC Decision:** Reminder will be sent to Principal-Investigator ***Ref. code: 119thECM IIA/P18***
4-	Clarification of research proposal entitled "***Evaluation of Hyperbric oxygen therapy in OSMF***" submitted by Prof. U.S. Pal, Department of Oral & Maxillofacial Surgery Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 370/OMSD/23 dated 23rd March, 2023. ***Previous EC Comment:-*** • List of attached documents need to be marked in annexure-1 • Patient information sheet is not attached. • Anticipated statistical analysis needs to be briefed. ***The above Comment forwarded to PI was reviewed by Primary reviewer:-*** ***Second recommendation of Primary reviewer:*** • The investigator has addressed all the points raised except that he still needs to submit patient's information sheet as per KGMU IEC SOP. ***The above comments forwarded to the Principal-Investigator vide this office letter no. 101/Ethics/2023 dated 12th April, 2023.*** ***Reply pending from the Principal-Investigator:*** **EC Decision:** Reminder will be sent to Principal-Investigator

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 120th ECM II A/P26
5-	Clarification of research proposal entitled "***A multicenter cross-sectional study to evaluate the clinical, immunological, and radiological profile of allergic bronchopulmonary aspergillosis (ABPA registry)***" submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 414/RESMED/23 dated 1st April, 2023. ***Recommendation of Primary reviewer:*** • Primary reviewer said that the PI has addressed most of the objections raised except that the ICF is still not as per IEC SOP protocol. ***The above Comment forwarded to PI was reviewed by Primary reviewer:-*** ***Recommendation of Primary reviewer:*** Reply pending **EC Decision:** Reminder will be sent to Principal-Investigator
	Ref. code: 120th ECM II A/P28
6-	Clarification of research proposal entitled "***Efficacy of grid-based dental rubrics as an effective assessment tool when compared to traditional assessment methods for undergraduate students managing a class II carious defect***" submitted by Dr. Rhythm, Prof. Jr. Grade, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 617/Coms&Endo/23 dated 22nd March, 2023.

Previous EC Comment	PI response
Section 8: Consent elements not checked	A written informed consent will be taken from the Patient. A checked section is being attached.
Outcome measures not mentioned	1. Outcome measures for the objective of sensitization of students and faculty will be percentage of students and/or having knowledge about using the grid-based assessment tool using a pre and post test questionnaire. 2. Outcome measure for the objective of inter observer reliability will be the scoring/grading given by instructor for each group.
Statistical plan not mentioned	Data will be analyzed using paired t-test to look for any significant differences in the scoring of the instructor in each group. Pearson's correlation will be applied to test for any significant correlations between the instructors' grading.
On what outcome measure the sample size is calculated: not mentioned.	The sample size is calculated on the basis of variation in student score in both the groups.

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer:

- Title of study (efficacy of grid based rubrics (tool) ….), primary objective (development of a tool) and outcome measures (knowledge of the tool) are discordant.
- Study design is improper to test the tool.

EC Decision: Approval subject to modification. Give changes done in a tabular form.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: 120th ECM II A/P31

7- Clarification of research protocol no. CP/03/22; NV-05-1387-2022 entitled "*A randomized, double blind, placebo-controlled, prospective, multicentre, phase 2, dose-finding study of itraconazole administered as a dry powder for inhalation (PUR 1900) in adult subjects with asthma and allergic bronchopulmonary aspergillosis (ABPA)*" sponsored by M/s Cipla Ltd. submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow, vide letter no. CT/RM/05/23 dated 10th February, 2023.

Previous EC Comment	PI response
Details of centers to be involved in the study trial across India are not given.	CT NOC- Addition of Sites dated 06-12-2022 is notified to the EC by letter dated 03-03-2023.
CTA document with budget is attached but PI mentioned in summary is not applicable please specify.	In the attached CTA study grant word is mention as per the institute EC policy.
CTRI document is not attached?- Whether after approval from EC/ after start of trial-please specify.	CTRI document CTRI/2022/12/048206 is notified to the EC on 03-Mar-2023.
Insurance is going to expire on 31st March, 2023- should be renewed	Dear Members Study Insurance is valid till 31st March 2023 and sponsor renewed the insurance as per the Insurance policy term. Then PI submits the Insurance to the EC after 31st March, 2023.

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer: Provisionally approved

Sr. No.	Documents	Version Number and Version Date
1.	Study Protocol	Version 01 dated 23 May 2022
1.a	Protocol Signature Page(s)	Signed by PI on 17 Sep 2022
2.	Financial Disclosure Questionnaire	Signed by the PI on 17 Sep 2022
3.	Investigator's Brochure	Version 01 dated 20 May 2022
4.	Investigator Undertaking	Signed on 17 Sep 2022
5.	Investigator Curriculum Vitae	CV signed on 17 Sep 2022
6.	Investigator Medical Registration Certificate	MRC registration number: 60702 signed on 17 Sep 2022
7.	Investigator GCP Certificate	GCP signed on 17 Sep 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

8.	**Patient Information sheet**	
A	English	Patient Information Sheet_ English _ Version 1.0 dated 23 May 2022
B	Hindi PIS Translations	Patient Information Sheet Version 1.0 dated 23 May 2022 Translated to Hindi on 03 Aug 2022
C	Hindi PIS Back Translations	Patient Information Sheet Version 1.0 dated 23 May 2022 Back-Translated from Hindi to English on 06 Aug 2022
D	Hindi PIS Translation Certificates	PIS Hindi FT Certificate dated 03 Aug 2022
E	Hindi PIS Back Translation certificates	PIS Hindi to English BT Certificate dated 06 Aug 2022
9.	**Informed Consent Form**	
A	English	Informed Consent Form _English Version 1.0dated 23 May 2022
B	Hindi ICF Translations	Informed Consent Form_Version 1.0 dated 23 May 2022 Translated to Hindi on 01 Aug 2022
C	Hindi ICF Back Translations	Informed Consent Form_Version 1.0 dated 23 May 2022 Back- Translated from Hindi toEnglish on 02 Aug 2022
D	Hindi Translation certificates	ICF Hindi FT Certificate dated 01 Aug 2022
E	Hindi Back Translation certificates	ICF Hindi to English BT Certificate dated 02Aug 2022
10.	**SUBJECT DIARY CARD**	
A	Diary Card English	Subject Diary_English_Version 1.0 dated 12 Aug 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	B	Diary Card Translations- Hindi	Subject Diary_English_Version 1.0 dated 12 Aug 2022 Translated to Hindi on 23 Aug 2022
	C	Diary Card Back Translations- Hindi	Subject Diary_Hindi to English_Version 1.0 dated 23 Aug 2022 Translated from Hindi to English on 24 Aug 2022
	D	Translation Certificates- Hindi	Diary Card Hindi FT Certificate dated 23 Aug 2022
	E	Back Translation Certificates- Hindi	Diary Card Hindi to English BT Certificate dated 24 Aug 2022
	11.	Insurance Certificate Policy Number OG-23-1919-3306-00000001	01 Apr 2022 to 31 Mar 2023
	12.	Draft eCRF	Draft 05 – 23 May 2022
	13.	CT NOC – Form CT-06 to conduct Clinical Trial of New Drug.	Dated of 02 Aug 2022
	14	Draft CTA	Not applicable
	A	Asthma Control Questionnaire 6 (ACQ)	
	B	Asthma Control Questionnaire 7 (ACQ)	English _ Version dated 13 Feb 2017
	C	Asthma Quality of Life Questionnaire (AQLQ)	English _Version modified on Apr 2008

EC Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 120th ECMIIC/P2

8- Clarification of research protocol no. MC/PLX/22-002 version 1.0/05 May, 2022 entitled ***"An open label, randomized, prospective, multicentric clinical trial to evaluate the efficacy and safety of parenteral placentrex with oral Azitjromycin ve oral asithromycin alone in chronic and recurrent pelvic inflammatory disease"*** sponsored by M/s Albert David Limited, Kolkata, India submitted by Prof. Amita Pandey, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. CT/02/2023/OG dated 22nd March, 2023.

Previous EC Comment	PI response
Can SR be taken as Co-PI in clinical trials-Please justify (Open discussion in EC)	SR to be replaced by the Dr. Mona Asnani Additional Professor Department of Obst. and Gynecology.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

PI did not submitted summary of protocol	As per your valuable comment Please find the attached study synopsis of the study for your reference.
Details of other sited involved in this trial-Please mention.	a. Site Name: KEM, Mumbai Principal Investigator: Dr Niranjan Mayadeo Site Address: Acharya Donde Marg, Parel East, Parel, Mumbai, Maharashtra 400012 b. Site Name: King George Hospital, Visakhapatnam Principal Investigator: Dr Isukapalli. Vani Site Address: King George Hospital, Mahranipeta, Visakhapatnam – 530002. c. Site Name: Prachee Institute for Mother and Child Care, Cuttack Principal Investigator: Dr P.C. Mahapatra. Site Address: Sector-8, CDA, Cuttack – 753014, Orissa
CTA-Document not signed	Draft CTA is attached for the EC review and approval, As per the EC policy final CTA with signatures submit to the EC after the EC approval for the study.
ICF-not attached (But given in summary of documents)	Please find attached ICF (in English and Hindi language) for the study.
CTRI document missing (Whether after approval from EC/after start of trial)-Please specify. (Whether after approval from EC/after start of trial)-Please specify.	Please find attached CTRI of the study

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer: Provisionally approved
The following documents were reviewed in Its Meeting:-

S.L. No.	Documents	Version and Date
1.	Clinical Trial Protocol	Version 1.0 Dated 05 May 2022
2.	Investigator's Brochure	Version N.A Dated 28 April 2022
3.	Informed Consent Document(ICD)-(English)	Version 1.0 Dated 11 May 2022
4.	Translated Informed Consent Document (English to Hindi) With Translation Certificates (Translated on- 28 Jun 2022)	Version 1.0 Dated 11 May 2022
5.	Back Translated Informed Consent Document (Hindi to English) With Back Translation Certificate (Back Translated on- 29 June 2022)	Version 1.0 Dated 11 May 2022
6.	Subject Diary Card –English	Version 1.0 Dated 24 May 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

7.	Translated Subject Diary Card (English to Hindi) with Translation Certificates (26 May 2022)	Version 1.0 Dated 24 May 2022
8.	Back Translated Subject Diary Card (Hindi to English) With Back Translation Certificate (Back Translated on- 27 May 2022)	Version 1.0 Dated 24 May 2022
9.	Case Report Form	Version 1.0 Dated 24 May 2022
10.	Manufacturing License	Dated 17 Dec 2020
11.	Insurance Policy [Valid From 28-May-2022 To 27-May-2023]	N.A.
12.	Investigator's Undertaking	N.A.
13.	CV, MRC and GCP of PI	N.A.
14.	Draft CTA	N.A.

EC Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 120th ECM IIC/P3

9- Clarification of research protocol no. LYT-100-2022-204 entitled "***A randomized double-blind, four-arm active and placebo-controlled dose-finding trial to evaluate the efficacy, tolerability, safety and dose response of LYT-100 in patients with idiopathic pulmonary fibrosis (IPF)***" sponsored by M/s Pure Tech LYT 100 Inc.6 Tide street, Suite 400 Boston MA 02210 submitted by Prof. Santosh Kumar, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 331/23 dated 16th March, 2023.

Previous EC Comment	PI response
In Scientific review committee no faculty from the Respiratory Medicine or Medicine Department has taken part (All members are from the Department of Surgical Oncology)	The protocol was presented in detail by the Principal-Investigator and every query put up by the review team was clarified by the PI. All the expert review committee members are actively engaged in research activities and have a good understanding of the different medical domains.
PI did not submit the summary of protocol	The short summary of the protocol has been attached with the response letter.
CTRI document-missing	CTRI has been attached with the response letter

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer: Provisionally approved
The following documents were reviewed in Its Meeting:-

DOCUMENT	VERSION	DATED
1. Protocol	V2.0	6 Jul 2022
2. Investigators Brochure	V7.0	31 Mar 2022
3. Main Informed Consent Form a. LYT-100-2022-204_Main ICF_ English b. LYT-100-2022-204_Main ICF_ Hindi Translated from English to Hindi dated 28 Aug 2022 c. LYT-100-2022-204_Main ICF_ Hindi_ Translation Certificate (English to Hindi) dated 28 Aug 2022 d. LYT-100-2022-204_Main ICF_ Hindi_ Back translation from Hindi to English dated 05 Sep 2022 e. LYT-100-2022-204_Main ICF_ Hindi_ Back Translation Certificate (Hindi to English) dated 05 Sep 2022	V1.0	2Aug 2022
4. Pregnant Partner Informed Consent Form a. LYT-100-2022-204_ Pregnant Partner ICF_ English b. LYT-100-2022-204_ Pregnant Partner ICF_ Hindi Translated from English to Hindi dated 28 Aug 2022 c. LYT-100-2022-204_ Pregnant Partner ICF_ Hindi_ Translation Certificate (English to Hindi) dated 28 Aug 2022 d. LYT-100-2022-204_ Pregnant Partner ICF_ Hindi_ Back Translation from Hindi to English dated 05 Sep 2022 e. LYT-100-2022-204_ Pregnant Partner ICF_ Hindi_ Back Translation Certificate (Hindi to English) dated 05 Sep 2022	V1.0	2Aug 2022
5. AV Informed Consent Form a. LYT-100-2022-204_ AV Consent		2Aug 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	ICF_ English b. LYT-100-2022-204_ AV Consent ICF _ Hindi Translated from English to Hindi dated 28 Aug 2022 c. LYT-100-2022-204_ AV Consent ICF _ Hindi_ Translation Certificate (English to Hindi) dated 28 Aug 2022 d. LYT-100-2022-204_ AV Consent ICF _ Hindi_ Back Translation from Hindi to English dated 05 Sep 2022 e. LYT-100-2022-204_ AV Consent ICF _ Hindi_ Back Translation Certificate (Hindi to English) dated 05 Sep 2022	V1.0	
	6. Patient ID card a. Patient ID card _English b. Patient ID card _Hindi c. Patient ID card_ Hindi_ Back translation from Hindi to English d. Patient ID card_ Hindi_ FT and BT translation certificate	V1.0	6 Mar 2022
	7. Patient Info reminders a. Patient Info reminders- English b. Patient Info reminders_ Hindi c. Patient Info reminders- Hindi_ Back translation from Hindi to English d. Patient Info reminders_ Hindi_ FT and BT translation certificate	V2.0	13 Jul 2022
	8. Patient Tip Sheet a. Patient Tip sheet- English b. Patient Tip sheet_ Hindi c. Patient Tip sheet_ Hindi_ Back translation from Hindi to English d. Patient Tip sheet_ Hindi_ FT and BT translation certificate	V3.0	7 Jul2022
	9. EQ-5D-5L a) EQ-5D-5L_ English India version 2.0 b) EQ-5D-5L_ Hindi India version	V2.0 (English) V1.0 (Hindi)	NA

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

1.0		
10. Patient questionnaire- Source Baseline Satisfaction a) Patient questionnaire- Source Baseline Satisfaction- IND English b) Patient questionnaire- Source Baseline Satisfaction_ Hindi	V1.0	22Mar 2022
11. Patient questionnaire- SGRQ-I past 3 months a) SGRQ-I past 3 months – IND English b) SGRQ-I past 3 months - Source Baseline Satisfaction_ Hindi	V1.0	November 2010
12. Patient questionnaire- Kings Brief Interstitial Lung Disease Questionnaire (K-BILD)	V1.0	29 Jul 2016
13. Patient questionnaire- Overall Satisfaction a) Overall Satisfaction – IND English b) Overall Satisfaction_ Hindi	V1.0	22 Mar 2022
14. Patient questionnaire- Patient notifications a) Patient notifications– IND English b) Patient notifications_ Hindi	V1.0	15 Jul 2022
15. Patient questionnaire- Patient reported Assessments of IPF symptoms a) Patient reported Assessments of IPF symptoms– IND English b) Patient reported Assessments of IPF symptoms_ Hindi	V1.0	22 Mar 2022
16. Patient questionnaire- Patient Reported Assessment of Side Effects a) Patient Reported Assessment of Side Effects– IND English b) Patient Reported	V1.0	22 Mar 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Assessment of Side Effects_ Hindi		
	17. Patient questionnaire- PGI-C-Cough a) PGI-C-Cough– IND English b) PGI-C-Cough_ Hindi	V1.0	22 Mar 2022
	18. Patient questionnaire- PGI-C-IPF Severity a) PGI-C-IPF Severity– IND English b) PGI-C-IPF Severity_ Hindi	V1.0	22 Mar 2022
	19. Patient questionnaire- PGI-S-Cough a) PGI-S-Cough– IND English b) PGI-S-Cough_ Hindi	V1.0	22 Mar 2022
	20. Patient questionnaire- PGI-S-IPF-Severity a) PGI-S-IPF- Severity– IND English b) PGI-S-IPF- Severity_ Hindi	V1.0	22 Mar 2022
	21. Patient questionnaire- PGI-S- Side Effects a) PGI-S- Side Effects – IND English b) PGI-S- Side Effects _ Hindi	V1.0	22 Mar 2022
	22. Patient questionnaire_Koneksa Screen Report A) Koneksa Screen Report- English B) Koneksa Screen Report- English Translation Certificate Version 1.0 dated 19-Sep-2022 C) Koneksa Screen Report- Hindi Version 1.0 dated 22-Sep-2022 D) Koneksa Screen Report- Hindi Translation Certificate	V1.0	19 Sep 2022 (English) 22 Sep 2022 (Hindi)
	23. Patient questionnaire- Koneksa Participant Guide_v1.0 a) Koneksa Participant Guide - English b) Koneksa Participant Guide - English Translation Certificate c) Koneksa Participant Guide -	V1.0	30 Sep 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Hindi d) Koneksa Participant Guide - Hindi Translation Certificate		
	24. Patient questionnaire- Koneksa End User License Agreement a) Koneksa End User License Agreement - English b) Koneksa End User License Agreement - Hindi	NA	NA
	25. Patient questionnaire-Koneksa Terms of use a) Koneksa Terms of use - English b) Koneksa Terms of use - Hindi	NA	18 Mar 2019
	26. Patient questionnaire-Koneska_Data Subject Privacy Policy a) Koneksa Data Subject Privacy Policy - English b) Koneksa Data Subject Privacy Policy - Hindi	NA	18 Feb 2020
	27. Patient questionnaire, EULA, Terms of Use, Data Subject Privacy Policy - Translation Certificates a) English Translation Certificate for EULA, Terms of Use, Data Subject Privacy Policy dated 12-Apr-2021 b) Hindi Translation Certificate for EULA, Terms of Use, Data Subject Privacy Policy dated 07-Jun-2021 c) English Translation Certificate for Patient Questionnaire dated 31-Aug-2022 d) Hindi Translation Certificate for Patient Questionnaire dated 31-	NA	NA

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Aug-2022		
	28. Case Report forms	V1.023	05 Jul 2022
	29. Insurance Certificate	NA	28 Sep 2022
	30. Curriculum Vitae- Dr Santosh Kumar (PI)	NA	29 Jul 2022
	31. MRC – Dr Santosh Kumar (PI)	NA	29 Jul 2022
	32. GCP certificate Dr Santosh Kumar (PI)	NA	12 Jul 2022
	33. Investigator Undertaking- Dr Santosh Kumar (PI)	NA	22 Aug 2022
	34. DCGI submission letter	NA	24 Aug 2022
	35. DCGI Acknowledgment letter	NA	26Aug 2022
	36. Draft Clinical Trial Agreement template_V1.0 dated 4 Aug 2022	NA	04 Aug 2022
	37. Protocol Signature Page	Protocol V2.0 dated 6 Jul 2022	09 Sep 2022
	38. IB AoR	V7.0 dated 31 Mar 2022	09 Sep 2022
	EC Decision: Approval subject to fullfillement & Administrative formalities ***Ref. code: 120th ECMIIC/P4***		
10-	Clarification of research proposal entitled "***Engineering conditionally replication competent SARS-CoV-2 viral molecular clones and evaluation of cross-variant neutralization***" sponsored by CSIR-CDRI submitted by Prof. Avinash Agrawal, Head, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1780/23 dated 18th March, 2023. **Previous EC Comment:** Dr. Agarwal presented his proposal to EC Members. The EC Members gave suggestions and told him that it is the patient's sheet. Only part of the work will be done in KGMU. Dr. Agarwal has to make a summary of changes done in a tabular format and submit it with the revised proposal for approval at the earliest. ***The above Comment forwarded to PI was reviewed by Primary reviewer:-*** ***Recommendation of Primary reviewer:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 121st ECM IIA/P2***		
11.	Clarification of research proposal entitled "***Evaluation of the safety and efficacy of***		

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

ganges water phage therapy in H. pylori related dyspepsia: A randomized controlled pilot-trial" submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 791/Med/2023 dated 3rd April, 2023.

Previous EC Comment	PI response
People may be Drinking Ganga water of their own but to ask them to drink under research settings has ethical issues as there are huge reservations about the quality about potability of Ganga water	The Ganga water, tested by a National Level Laboratory will be given to patients.
Will the quality of Ganga water for potability tested and how? Bacterial, E. coli count and other standard methods	Yes, the quality of the Ganga water will be tested by a FSSAI approved lab State Level Lab U.P. Jal Nigam).
What will be the source of water	Ganga river from Rudra prayag
Patient information is very sketchy and not in Hindi. There is mention of 'Cancer' Why?	We have attached the patient information in Hindi.
No mention of Standard Drug Care why?	It has been mentioned already in point no. and table
What are the criteria for dyspepsia and relief from it	It has been added.
Will the study document bacteriophage [quantity and types] in Ganga water	Quantifying or typing of phage is not an aim of our study.
As cases with only dyspepsia will be included, how the improvement or lack of it will be judged	It will be examined using SF-36 and WHO-QOL-BREF (Hindi and English version).
Though not major harm is expected and it may be ethically approved. I have reservation about the study.	A very few chances of any harm could be observed as the SMT (Standard Medical Therapy) and GPT (Ganga Phage Therapy) are opted with all precautions including potability, safety, efficacy etc.
The participants should be clearly informed in the brochure that untreated Ganga water will be given and the risk of gastrointestinal	As potability has been measured and with appropriate count of micro-organism has been ruled out, so there is a less harm to

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

and liver infections cannot be ruled out	subjects.
And this should be monitored before and after [up to 4 months] by pre and post clinical and Lab evaluation and data of gastroenteritis should be maintained	Lab investigations have been added at Day-1 and W-4.
People may be Drinking Ganga water of their own but to ask them to drink under research settings has ethical issues as there are huge reservations about the quality about potability of Ganga water.	The Ganga water, tested by a National Level Laboratory will be given to patients.

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer:

- The documents / certificates from government approved labs providing the water in untreated from Ganga river at Prayag should be submitted about quality of water, bacterial content, etc. To prove that it is potable.
- As far as I know, informally that the water in the river is not of quality to be used as drinkable.
- I consider that this project has ethical issues. Though people may be drinking this water, as medical doctors can not give it to patients because the city municipality treats river water before supplying to the city homes.

EC Comment:

- As above

EC Decision: Revise & re-submit. Give changes done in a tabular form

Ref. code: 121st ECM IIA/P4

12. Clarification of research proposal entitled "***To identify the levels of UBA52 and peripheral inflammatory cytokines in blood and cerebrospinal fluid of parkinson's disease patients to establish its diagnostic significance***" submitted by Dr. Shweta Pandey, Additional Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 136/Neuro/23 dated 25th March, 2023.

Previous EC Comment	PI response
Language of materials and methods section needs corrections as everything is written in the past tense as if the work has already been completed.	We apology for the grammatical mistake, Now the proposal is checked for the same and corrections done. (Page number 35)
Duration of study not mentioned.	Duration of study is given at (Page number 5)

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer: Provisionally approved
EC Decision: Approved

Ref. code: 121st ECM IIA/P5

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

13. Clarification of research proposal entitled ***"A prospective, interventional, single-arm post-marketing clinical follow-up study evaluating copper IUD insertion procedure using Yanae® associated with crossGlide™ technology in women desiring long-term contraception"*** sponsored by Mr. Ranjit Gaikwad Pregna International Limited submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/5180/23 dated 24th March, 2023.

Previous EC Comment	PI response
Project is very sketchy.	**Background information** Intrauterine Devices (IUDs) are highly effective (>99%), safe and economical methods of pregnancy prevention[1] (Birgisson et al., 2015). These devices are long acting, reversible, discreet and do not require regular monitoring. Yet, IUDs account for 17% of the global contraceptive market, while other less effective and more expensive methods have a larger share of the contraceptive mix. Increased awareness and use of IUDs could help to reduce the incidence of unplanned or mistimed pregnancy [1,2](Peipert et al., 2011; Birgisson et al., 2015). The most important problem encountered during IUD application is gaining access the cervix and uterine cavity. During the insertion, the healthcare providermust pass the IUD through the cervical canal and insert it into the uterine cavity, owing to cervical ante- or retroflexion of the cervical neck. Cervical flexion is defined as the angle formed by the uterine cervix's longitudinal axis of and the uterine body's longitudinal axis. As a result, this procedure required to be performed by a trained and experienced healthcare provider. Performing cervical traction with a single-toothed tenaculum straightens and immobilizes the cervical neck and uterus to facilitate IUD passage through the cervical canal. This is a common step in the IUD insertion procedure. However, using a single-toothed tenaculum to hold the cervix causes pain, anxiety and bleeding during the procedure. The majority of women reported mild to moderate pain from IUD placement[4] (Brockmeyer, Kishen and Webb, 2008). However, some women remain anxious about the possibility of pain or are more likely to be affected by factors such as nulliparity, or a long time period since delivery. Furthermore, anatomical, cultural or

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			psychological factors can all contribute to a more painful experience[4] (Hubacher et al., 2006). Despite recommendations to improve, such as oral or local medication, on-market IUDs fail to meet users' expectations for pain reduction during this procedure. Healthcare professional concern about difficult and/or painful placement may also discourage discussion of IUD as a contraceptive option, leading women to be counsel on other, less effective methods[5] (Black et al., 2013). CEMAG Care, Pregna International Ltd. And CrossBay Medical collaborated to develop an innovative IUD insertion in order to find a more efficient method of inserting the IUD into the uterus. Yanae® was created by combining the CrossGlide™ insertor and a 380 Y copper IUD. The CrossGlide™ insertor has a conformable inverting membrane that fits around the collapsed IUD when pressurized. The inflatable membrane is designed to pass the cervix, conform to the shape of the uterus and deliver the IUD into the uterine cavity without the use of a tenaculum, cervical distortion, or prior cervical dilation. The IUD can be precisely placed and deployed in the fundus. Yanae® overcomes one of the most significant barriers to acceptance of IUDs, women pain during insertion An in vivo test was conducted to determine the success of Yanae® insertion procedure. Without using a tenaculum, the IUD was inserted in accordance with the Yanae® IFU. An ultrasound was performed right after the procedure to verify the insertion of the IUD. Following IUD insertion, participant pain was evaluated using a VAS-10 cm scale. Both the provider and the participants also completed satisfaction surveys. An ob-gyn not familiar with the technology evaluated Yanae® procedure in 26 women. Of the total number of Yana® IUD insertions, 24 (94%) were successful with the correct fundal placement and did not require the use of a tenaculum neither a hysterometer, to measure the uterine cavity. Two women had unsuccessful IUD insertions: one was due to the Presence of adhesions in the cervical canal (visible by ultrasound), and the other was due

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			to the provider mishandling the device. Prior to IUD insertion, 19 women reported feeling anxious and stressed, particularly about getting hurt or experiencing pain during the procedure. Following IUD insertion, 14 women reported feeling moderate to light anxiety or stress. Only 17 women correctly completed the pain survey after IUD insertion. On a 10-point scale, the average and median participant pain level during IUD insertion using Yanae® was mild (score 3). All of the women were pleased with the IUD insertion procedure, and 92% (n=22) would recommend Yanae® to a friend or family member. The provider satisfaction survey found that, compared to his regular practice with other IUDs and a standard inserter, Yanae® insertion procedure practice had significantly improved. The usage of Yanae®, according to the provider, may enhance women to accept. **Summary:** A multi-centric, prospective, interventional, single-arm post-marketing clinical follow-up study evaluating copper IUD insertion procedure using Yanae (a Y shape 380 copper IUD effective for 5 years) associated with CrossGlide™ technology in women desiring long-term contraception. This inserter is an inflatable membrane that delivers the copper IUD into the uterine cavity in women who are seeking Long-Acting Reversible Contraception (LARC). **Primary objective** is to validate the efficacy of IUD insertion using Yanae® insertion procedure (without using a cervical tenaculum and without measuring the uterine cavity with a uterine sound). **Secondary objective** to assess Participant Pain score during and after IUD insertion using Yanae® procedure and Participant and provider Satisfaction associated with the use of Yanae® The healthcare provider will explain to the potential participant about the study protocol, mandatory

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		follow up (4-6 weeks) and telephonic FUs (6 and 12 months), the benefits and risk to participate wrt study. Site PI/Co PI will obtain participant informed consent and will designate an anonymized PIN. Site PI/Co PI will obtain details of participants before insertion. A transvaginal ultrasound will be performed immediately post-insertion and at on site follow visit (4-6 weeks after insertion) to assess correct placement of the IUD. Adverse device effects (ADE), Adverse Event (AE) and Serious Adverse Event (SAE) will be documented and reported. Insertion procedure questionnaire will be recorded to evaluate the correct placement of the copper IUD. Additional Questionnaires will be used to evaluate participant pain during IUD insertion and provider & participant satisfaction to the device. Endpoint of this study will be Long-term IUD insertion procedure evaluated by IUD placement at follow-up visit (4-6 weeks) and Participant and provider Satisfaction which will be evaluated by a specific survey done immediately after IUD insertion.
	Sample size, inclusion or exclusion of subjects not included.	**Sample Size Determination** Based on data collected in the pilot study in Dominican Republic (26 women) using Yanae® device in similar conditions, the number of correct fundal placement (success) was 24 subjects (92.3%, 95% CI = 74.9% - 99.1%). It is therefore expected a comparable performance in the current study with an expected rate of 90% for the calculation of sample size. The rate of 80% of correct placement is considered unacceptable and should not be compatible with observed data (95% C.I. of the observed rate must excludes the unacceptable limit of 80%). The sample size is based on an exact one-sided comparison with a binomial population. The type one error is set at 0.025 one sided, the unacceptable limit is equal to 0.80 and the expected efficacy is equal to 0.90. The sample size for a power of 95% is 164 women (exact test\) **Inclusion Criteria**: Subjects who meet all the following inclusion criteria may be included: 1. 18 years old or older, in good general health and requesting contraception. 2. Meets World Health Organization (WHO)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		medical eligibility criteria for contraceptive use 3. Desires IUD placement 4. Negative urinary pregnancy test 5. No pelvic inflammatory disease (PID) in last 3 months 6. No contraindications to IUD insertion (see exclusion criteria below) 7. Is willing to complete survey during and after the insertion 8. Is willing to attend follow-up visit at 4-6 weeks after insertion **Exclusion Criteria**: Subjects who met any of the following exclusion criteria will not be included that: 1. Malignant disease of the genital tract 2. Undiagnosed vaginal bleeding, 3. Anaemia, coagulation disorder 4. Pregnancy (known or suspected) 5. Post-partum with no menstrual return (less than 3 months) 6. Recent (less than 3 months) abortion 7. Ongoing or recent (less than 3 months) infection of the genital tract 8. Sexually transmitted disease during the last 12 months (except bacterial vaginitis, repeats herpes infection, Hepatitis B) 9. Pelvic inflammatory disease. 10. Uterine malformation (congenital or acquired) 11. Allergy to copper 12. Known pelvic tuberculosis 13. Benign and Malignant trophoblast disease 14. Distorted uterine cavity 15. Acute purulent discharge 16. Vesicovaginal fistula 17. Third degree uterine prolapse 18. Systemic Lupus Erythematosus with sever thrombocytopenia 19. Ovarian cancer 20. High individual risk of chlamydia and gonococcal infection (partner has current purulent discharge or STI) 21. Heavy/Prolonged or painful menstrual bleeding, endometriosis, severe dysmenorrhea 22. AIDS, without antiretroviral therapy nor access to care
	No reference cited.	**REFERENCES** 1 Birgisson, N.E. et al. (2015) 'Preventing Unintended Pregnancy: The Contraceptive CHOICE project in Review', Journal of Women's Health, 24(5), pp. 349–353. Available at: https://doi.org/10.1089/jwh.2015.5191. 2 Peipert JF, Zhao Q, Allsworth JE, Petrosky E, Madden T, Eisenberg D, Secura G. Continuation

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			and satisfaction of reversible contraception. Obstet Gynecol. 2011 May;117(5):1105-1113. doi: 10.1097/AOG.0b013e31821188ad. PMID: 21508749; PMCID: PMC3548669. 3 Brockmeyer, A., Kishen, M. and Webb, A. (2008) 'Experience of IUD/IUS insertions and clinical performance in nulliparous women–a pilot study', The European Journal of Contraception & reproductive Health Care, 13(3), pp. 248–254. Available at: https://doi.org/10.1080/02699200802253706. 4 Hubacher D, Reyes V, Lillo S, Zepeda A, Chen PL, Croxatto H. Pain from copper intrauterine device insertion: randomized trial of prophylactic ibuprofen.. Am J Obstet Gynecol. 2006 Nov;195(5):1272-7. doi: 10.1016/j.ajog.2006.08.022. PMID: 17074548. 5 Black, K.I. et al. (2013) 'Global survey of healthcare practitioners beliefs and practices around intrauterine contraceptive method use in nulliparous women', Contraception, 88(5), pp. 650–656. Available at: https://doi.org/10.1016/j.contraception.2013.06.005. 6 Brima, N. et al. (2015) 'A comparison of the expected and actual pain experienced by women during insertion of an intrauterine contraceptive device', Open Access Journal of Contraception, 6, pp. 21–26. Available at: https://doi.org/10.2147/OAJC.S74624. 7 Dermish, A.I. et al. (2013) 'Failed IUD insertions in community practices: an under-recognized problems?', Contraception, 87(2), pp. 182–186. Available at: https://doi.org/10.1016/j.contraception.2012.06.015. 8 Faúndes, D. et al. (1997) 'No relationship between the IUD position evaluated by ultrasound and complaints of bleeding and pain', Contraception, 56(1), pp. 43–47. Available at: https://doi.org/10.1016/S0010-7824(97)00072-3. 9 Gemzell-Danielsson, K. et al. (2019) 'Interventions for the prevention of pain associated with the placement of intrauterine contraceptives: An updated review', Acta Obstetricia et Gynecologica Scandinavica, 98(12), pp. 1500–1513. Available at: https://doi.org/10.1111/aogs.13662. 10 Harrison-Woolrych, M., Ashton, J. and Coulter, D. (2003) 'Uterine perforation on intrauterine device insertion: is the incidence higher than previously reported?', Contraception, 67(1), pp. 53–

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		56. Available at: https://doi.org/10.1016/S0010-7824(02)00417-1. 11 Heinemann, K. et al. (2015) 'Risk of uterine perforation with levonorgestrel-releasing and copper intrauterine devices in the European Active Surveillance Study on Intrauterine Devices', Contraception, 91(4), pp. 274–279. Available at: https://doi.org/10.1016/j.contraception.2015.01.007

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer: Provisionally approved
EC Decision: Approved

Ref. code: 121st ECM IIA/P6

14. Clarification of research proposal entitled "***Efficacy and safety of Tyrosine Kinase inhibitors in downstaging and palliation in patients with advanced papillary thyroid cancer-A Multicenter study***" submitted by Dr. Pooja Ramakant, Additional Professor, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/2023/133 dated 29th March, 2023.

Previous EC Comment	PI response
Approximate Number of subjects is not mentioned.	30, has been added in the relevant column. Similar numbers are expected from other two centers.
Duration of subject participation is greater that duration of study? Explain.	This is a retrospective study, where we will collect 5 years data retrospectively and then analyze the data and write it up for manuscript submission over 1 year.
The proposal has been written in past tense? Has the research already been conducted and is ethical clearance been asked later?	Apologies for the grammatical errors. Relevant changes made in the 'methods' section.
How can one calculate accurate sample size in a retrospective study?	As reported in the study conducted by Kloos R et. al (2009) entitled 'Phase-II trial of Sorafenib in metastatic thyroid cancer', 15% of the patients showed partial response to the treatment. Taking 95% confidence interval, 9% absolute Precision and assuming that at-least 15% will show partial response to Tyrosine Kinase inhibitors, the minimum sample required to be included in the study using single Proportion test is: 61*. *Dhand, N. K., & Khatkar, M. S. (2014). Statulator: An online statistical calculator. Sample Size Calculator for Estimating a Single proportion. Accessed 25 March 2023 at http://statulator.com/SampleSize/ss1P.htm This number has been calculated to get

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	statistically significant results.
What are appropriate statistical tests?	Statistical analysis will be done on Statistical package for social sciences, version 26 IBM, Chicago, USA. Descriptive data will be represented as frequency percentage, mean SD or proportion. Probability (p) will be calculated to test for statistical significance at the 5% level of significance. Progression free time will be reported in the form of mean ± SD as well as median (IQR). Association between categorical variables will be tested using the Chi-Square test; in case, the expected frequency, found to be less than 5 in any particular cell, Fischer Exact test will be used. A minimum 95% confidence interval or p value <0.05 will be considered as statistically significant. Multivariate analysis using logistic regression will be performed for all the variable found significant in univariate analysis. A p-value of 0.05 will be taken as statistically significant.
How will data of different endpoints be calculated from in-patient records? Most patients don't need admission at every point of contact.	Patients receiving TKIs are admitted at every cycle of treatment and only after clinical history, examination and relevant investigations the next dose of medicines is given to the patient. Hence, data of most endpoints will be available from in-patient records.
How will the safety Profile of TKIs be assessed?	Based on the history, examination findings and relevant investigations like complete blood counts, liver and kidney function test, ECG and ECHO reports, which are done before starting every cycle of TKI.
Which version of RECIST will be used?	RESCIST 1.1, Correction done in the 'methods' section
Define lost to follow up (as mentioned in exclusion criteria)	Those who have defaulted treatment and have not been reachable via telephone despite 2-3 attempts.
Residents cannot be included as co-PIs.	Necessary changes made for residents of KGMU, however similar changes cannot be applied for resident doctors of other institutes. Dr. Ranjith Cheriyan Philip is a resident doctor working in CMC, Vellore and his name will be added in the study as per their wish.

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer: Provisionally approved
EC Decision: Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

Ref. code: 121st ECM IIA/P10

15. Clarification of research proposal entitled "***Morphogenic and Morphometric study of coronary sinus in cadaveric heart***" submitted by Mr. Rakesh Mishra, Ph.D. Scholar under the guidance Prof. Rakesh Kumar Diwan, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 01/ANAT/23 dated 1st April, 2023.

Previous EC Comment	PI response
Justification of sample size needs to be added.	• We are using 50 cadaveric hearts as a sample size which gives statically significant result. • From Previous articles, related to our study, used 50 cadaveric hearts which gives statically significant result. **Bcegum Zabina etal |2017| (14**
Innumerate the parameters to be studied and their anticipated statistical analysis.	**Parameters;** 1. To observe Presence or absence of coronary sinus 2. To observe the Location of coronary sinus in relation to left posterior atrioventricular sulcus 3. To observe Shape of coronary sinus either funnel or tubular 4. To measure Length of coronary sinus: External and Internal both 5. To measure Width of coronary sinus at its beginning, at the point of entry of middle cardiac vein and at its termination 6. To observe the Length of coronary sinus covered by muscles of left atrium 7. Correlate Length and Width of heart with length of coronary sinus 8. To measure the length of left posterior atrioventricular sulcus 9. Relationship between Length of coronary' sinus and length of left posterior atrioventricular sulcus.

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer: Provisionally approved
EC Decision: Approved

Ref. code: 121st ECM II B-Ph.D/P2

16. Clarification of research proposal entitled "***Role of stromal-epithelial interaction in breast cancer progression and efficacy of withania sommifera as an antimetastatic and repurposed agent***" submitted by Ms. Aditi Srivastava, Ph.D. Scholar under the guidance Dr. Rumana Ahmad, Department of Biochemistry, Era's Lucknow Medical College &

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Hospital, Era University, Lucknow & Co-Guide Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/650/23 dated 10th April, 2023.

Previous EC Comment	PI response
Principal Investigator is a Ph.D. student from an outside Institution.	Yes, the Principal Investigator (PI) is a Ph.D. student enrolled in Era University. The study had been designed as a collaborative Project with KGMU with which a Memorandum of Understanding (MoU) has been signed. As the breast cancer samples (Invasive Ductal Carcinoma, IDC) for the co-culture experiments would be obtained from Surgical Oncology Department, KGMU. Therefore, Dr. Vijay Kumar, Prof. and Head, the Department of Surgical Oncology, KGMU has been included in the study as a co-guide (photocopy of synopsis defended letter attached as Annexure 1 for ready reference).
It is mentioned that the *Withania somnifera* plant will be verified and reference specimens will be deposited at Integral University, Lucknow, however, there is no involvement of Integral University in the project (no Co-Guide has been included from there).	The present study is an in silico and in vitro study (preclinical) where the efficacy of WS plant extract would be determined in vitro on cancer cell lines. Before in vitro analysis, the plant needs to be verified by a competent taxonomist from any institute. Integral University, Lucknow providers a paid-basis service where they identify and verify the plant specimen and save the deposited specimen for future reference. Therefore, there is no need for the assignment of a co-guide from Integral University. Additionally, the authors have verified the plant specimen and obtained the certificate for the same (photocopy of the certificate of plant identification attached as Annexure 2 for ready reference).
Dose of *Withania somnifera* not mentioned.	As suggested by the ethical committee Members, the PI has included the effective dose range at which the study would be performed (photocopy of PhD proposed performa is attached as Annexure 3 for ready reference).
Patient to be included in the study are not described and no inclusion or exclusion criteria are mentioned.	The present study is an in silico and in vitro pre-clinical study with no involvement of studies on patients. However, for in vitro co- culture experiments, IDC samples would be needed to isolate Cancer-Associated Fibroblasts (CAFs). For this, the authors have added the inclusion and exclusion criteria in the proposal as directed by the ethical committee members (photocopy of PhD proposal performa is attached as Annexure 3 for ready reference).

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer: Provisionally approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

	EC Decision: Approved ***Ref. code: 121stECM II B-Ph.D/P4***
17.	Clarification of research protocol no. RVP-30-001 RECOVER entitled "***Brilaroxazine (RP5063), phase 3, randomized, 28 days, double-blind, placebo-controlled, multicenter study to assess the safety and efficacy of brillaroxzine (RP5063) in subjects with an acute exacerbation of schizophrenia, followed by a 52-week open-label extension***" sponsored by M/s Revive Pharmaceuticals Holdings. Inc. submitted by Prof. Adarsh Tripathi, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1785/Psy/2022 dated 1st December, 2022. ***Previous EC Comment:*** • Sample will be sent abroad–Clearance obtained-written in SOP–Checklist, but document for this is not attached. ***The above Comment forwarded to PI was reviewed by Primary reviewer:-*** ***Recommendation of Primary reviewer:*** Provisionally approved ***The following documents were reviewed in the Meeting:-*** 1-Protocol RVP-30-001 v4.0, Amendment 3 dated 29-Mar-2022 2-RP5063 Investigator's Brochure (IB) Edition 09 dated 15-Dec-2021 3-IB Addendum – Reference Safety Information (RSI) dated 27-Jan-2022 4.Informed Consent Forms:- 1. Main ICF:- a. RVP-30-001_India_Main ICF_Site 205_V2.0_Dr. Adarsh Tripathi_11Oct2022_English b. RVP-30-001_India_Main ICF_Site 205_V2.0_Dr. Adarsh Tripathi_11Oct2022_Hindi including Back translation & Translation certificate 2. Caregiver ICF:- a. RVP-30-001_India_Caregiver ICF_Site 205_V2.0_Dr. Adarsh Tripathi_11Oct2022_English b. RVP-30-001_India_Caregiver ICF_Site 205_V2.0_Dr. Adarsh Tripathi_11Oct2022_Hindi including Back translation & Translation Certificate 3. Pregnant Partner ICF:- a- RVP-30-001_India_PP ICF_Site 205_V2.0_Dr. Adarsh b.Tripathi_11Oct2022_English 5. Patient Materials:- 1. Subject card a. RVP-30-001_Master_Subject Card_V1_11Oct2021_English b. RVP-30-001_Master_Subject Card_V1_11Oct2021_Hindi & Translation Certificate 2. Abnormal Involuntary Movement Scale (AIMS) a. AIMS_en_US_v1.0_13 Jul 2019 b. AIMS_hi_IN_v1.0_07 Jan 2022 & Translation Certificate 3. Barnes Akathisia Rating Scale (BARS) a. BARS_en_US_v1.0_04 Apr 2018 b. BARS_hi_IN_v1.0_21 Jan 2022 & Translation Certificate 4. Caregiver Global Impression of Change (CaGI-C) a. CaGI-C_en_US_v1.0_07 Sep 2021 b. CaGI-C_hi_IN_v1.0_07 Jan 2022 & Translation Certificate

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

5. Clinical Global Impression: Severity of Illness (CGI-S) (Schizophrenia)
   a. CGI-S SCH_en_US_v1.0_24 Aug 2021
   b. CGI-S SCH_hi_IN_v1.0_07 Jan 2022 & Translation Certificate
6. Changes in Sexual Functioning Questionnaire (female) (CSFQ-F-C)
   a. CSFQ-SF 14 (female)_en_US_v1.0_10 Feb 2020
   b. CSFQ-SF 14 (female)_hi_IN_v1.0_21 Jan 2022 & Translation Certificate
7. Changes in Sexual Functioning Questionnaire (male) (CSFQ-M-C)
   a. CSFQ-SF 14 (male)_en_US_v1.0_10 Feb 2020
   b. CSFQ-SF 14 (male)_hi_IN_v1.0_21 Jan 2022 & Translation Certificate
8. Columbia-Suicide Severity Rating Scale (C-SSRS) Baseline/Screening (BS-Life-6mo-1yr)
   a. C-SSRS BS Life-6mo-1yr_en_US_v1.0_10 Jan 2019
   b. C-SSRS BS Life-6mo-1yr_hi_IN_21 Jan 2022 & Translation Certificate
9. Columbia-Suicide Severity Rating Scale (C-SSRS) Since Last Visit
   a. C-SSRS SLV_en_US_v1.0_21 Feb 2019
   b. C-SSRS SLV_hi_IN_v1.0_21 Jan 2022 & Translation Certificate
10. Fägerstrom Test for Nicotine Dependence (FTND)
    a. FTND_en_US_v1.0_17 Dec 2019
    b. FTND_hi_IN_v1.0_07 Jan 2022 & Translation Certificate
11. Mini International Neuropsychiatric Interview 7.0.2 Psychotic Version
    a. M.I.N.I. 7.0.2 Psychotic Disorders_en_US_v1.0_03 Jun 2019
    b. M.I.N.I. 7.0.2 Psychotic Disorders_hi_IN_v1.0_31 Mar 2022 & Translation Certificate
12. Modified Simpson-Angus Scale (MSAS)
    a. mSAS_en_US_v1.0_31 Jul 2019
    b. mSAS_hi_IN_v1.0_07 Jan 2022 & Translation Certificate
13. PANSS Informant Checklist
    a. PANSS Informant Checklist_en_US_v1.0_15 Feb 2019
    b. PANSS Informant Checklist_hi_IN_v1.0_07 Jan 2022 & Translation Certificate
14. Personal and Social Performance Scale (PSP) (Past Month)
    a. PSP (Past Month)_en_US_v1.0_18 Aug 2021
    b. PSP (Past Month)_hi_IN_v1.0_07 Jan 2022 & Translation Certificate
15. Personal and Social Performance Scale (PSP) (Past Week)
    a. PSP (Past Week)_en_US_v1.0_18 Aug 2021
    b. PSP (Past Week)_hi_IN_v1.0_07 Jan 2022 & Translation Certificate
16. Readiness for Discharge Questionnaire
    a. RDQ_en_US_v1.0_07 Sep 2021
    b. RDQ_hi_IN_v1.0_07 Jan 2022 & Translation Certificate
17. Structured Clinical Interview - Positive and Negative Syndrome Scale (SCI-PANSS)
    a. SCI-PANSS_en_US_v1.0_07 Sep 2021
    b. SCI-PANSS_hi_IN_v1.0_21 Jan 2022
18. Trail Making Test A&B Instructions
    a. TMT Form 1 (Parts A & B) Instructions_en_US_v1.0_15 Nov 2019
    b. TMT Form 1 (Parts A & B)_hi_IN_v1.0_07 Jan 2022 & Translation Certificate
19. Trail Making Test A&B Supplemental Pages
    a. TMT Form 1 (Parts A & B) Supplemental Pages_en_US_v1.0_15 Nov 2019

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

	b. TMT Form 1 (Parts A & B) Supplemental Pages_hi_IN_v1.0_07 Jan 2022 & Translation Certificate 20. WAIS IV Coding a. WAIS IV Coding Form_en_US_v1.0_17 Dec 2020 b. WAIS-IV Coding Form_hi_IN_v1.0_21 Jan 2022 & Translation Certificate 21. Brochure a. RVP-30-001_RECOVER_Brochure_US_English_Master_V1_10JAN2022 b. RVP-30-001_RECOVER_Brochure_US_English_Master_V1.0_10JAN2022_Hindi (India)_07FEB2022 & Translation Certificate 22. Flipbook a. RVP-30-001_RECOVER_ICF_Flipbook_USEnglish_ Master_V1.0_10JAN2022 b. RVP-30-001_RECOVER_ICF_Flipbook_USEnglish_Master_V1.0_10JAN2022_Hindi (India)_07FEB2022 & Translation Certificate 23. Poster a. RVP-30-001_RECOVER_Study_Poster_US_English_Master_V1.0_10JAN2022 b. RVP-30-001_RECOVER_Study_Poster_US_English_Master_V1.0_10JAN2022_Hindi (India)_07FEB2022 & Translation Certificate 24. Actigraphy Participant Guide a. AG_Reviva_RVP-30-001_RECOVER_CPIW_ParticipantGuide_03022022_Ver2.0_FINAL b. AG_Reviva_RVP-30-001_RECOVER_CPIW_ParticipantGuide_03022022_Ver2.0_FINAL_Hindi & Translation Certificate 25. Actigraphy Site Guide a. AG_Reviva_RVP-30-001_RECOVER_CPIW_SiteGuide_03022022_Ver2.0_FINAL 26. CaGi-C Screenshots a. Reviva RVP-30-001_CaGI-C_en_US v1.0_Screenshots_27 Sep 2021 b. Reviva RVP-30-001_CaGI-C_hi_IN_v1.0_Screenshots_02 Mar 2022 & Translation Certificate 27. CSFQ-SF 14 (female) Screenshots a. Reviva RVP-30-001_CSFQ-SF 14 (female)_en_US_v1.0_Screenshots_27 May 2020 b. Reviva RVP-30-001_CSFQ-SF 14 (female)_hi_IN_v1.0_Screenshots_24 May 2022 & Translation Certificate 28. CSFQ-SF 14 (male) Screenshots a. Reviva RVP-30-001_CSFQ-SF 14 (male)_en_US_v1.0_Screenshots_19 May 2020 b. Reviva RVP-30-001_CSFQ-SF 14 (male)_hi_IN_v1.0_Screenshots_23 May 2022 & Translation Certificate 29. FTND Screenshots a. Reviva RVP-30-001_FTND_en_US_ v1.0_Screenshots_31 Jul 2020 b. Reviva RVP-30-001_FTND_hi_IN_v1.0_Screenshots_24 May 2022 & Translation Certificate 30. Participant Training Module Screenshots a. Reviva RVP-30-001_Participant Training Module I_en_US_v2.0_Screenshots_13 Jul 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

b. Reviva RVP-30-001_Participant Training Module I_hi_IN_v2.0_Screenshots_22 Feb 2022 & Translation Certificate

31. Tablet UI Screens Screenshots
    a. Reviva RVP-30-001_Tablet UI Screens_en_US_v1.0_Screenshots_01 Sep 2020
    b. Reviva RVP-30-001_Tablet UI Screens_hi_IN_v1.0_Screenshots_10 Apr 2022 & Translation Certificate

6.5906-0001 Annotated CRF_ 06Jul2022
7.Protocol#RVP-30-001_ICON#59060001_DCGISubmission acknowledgement_21 Jul 2022
8.Protocol # RVP-30-001_India_DCGI Approval Letter dated 11Oct2022
9.Protocol # RVP-30-001_India_IMP Import License Approval Letter dated 11Oct2022
10. CTRI Registration number - CTRI/2022/11/047063
11.1. CV_PI_Dr. Adarsh Tripathi
Medical Registration Certificate_PI_Dr. Adarsh Tripathi
3. GCP Training Certificate_PI_Dr. Adarsh Tripathi_27Mar2023
12.Investigator Undertaking dated 07 Jul 2022
13.Insurance Certificate dated 04 Jul 2022

EC Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 121stECMIIC/P1

18. Clarification of research Protocol no. DRL-IND-NDA01-DXMF/2019 entitled "***A prospective, multicenter, randomized, open label, active controlled, phase II study to evaluate the efficacy, safety, and tolerability of fixed dose combination (FDC) of doxycycline hyclate and metformin hydrochloride (10%W/W+1%W/W)gel in the treatment of adults with periodontitis***" sponsored by M/s Dr. Reddy's Laboratories Ltd submitted by Prof. Umesh Pratap Verma, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. PD/CT/02/23 dated 22nd March, 2023.

Previous EC Comment	PI response
Sections on vulnerable and special groups have both been ticked. Please explain.	In the Annexure 07 section on vulnerable is ticked inadvertently, only special age group 18 to 65 years subjects are enrolled in the study. After the correction Annexure 07 copy is attached for your reference.
ICF does not have details of the PI.	Sponsor does not use the site specific ICF in this study. Study coordinators complete the PI and Institutional EC details by hand written during the ICF Consenting processes. ICF English and Hindi Version copy is attached with the PI and EC details
Details regarding Previous use of Metformin in gel form for treatment of periodontitis are lacking.	• Efficacy and Safety of Metformin in Gel formulation in several reported studies.[1,2,3,4] • In all studies shown above, local administration of Metformin following Scaling and Root Planning resulted in

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	better clinical (in terms of gain in Clinical attachment loss, Reduction in Probing Depth) and radiographic parameters (Reduction in Intrabony defects) compared to Scaling and Root Planning alone According to results obtained in the study by Pradeep et al., 1% MF is the optimal concentration in the management of periodontitis.
Please clarify if Metformin's clinical use as gel in adults with periodontitis is established or not.	Safety and Efficacy of Metformin gel is well established in clinical trials[1,2,3,4] and Preclinical studies.[5,6] Topical Product Doxycycline gel 10% was already approved for periodontitis by USFDA. However to evaluate detailed efficacy of metformin in combination with Doxycycline, Dr. Reddy's have come up with said Phase II clinical trial of Doxycycline + Metformin Gel.

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer: Provisionally approved
The following documents were reviewed in the Meeting:-

S. No.	Study Documents	Version No.	Date
1.	Clinical Trial Protocol	Version 3.0	10 Feb 2022
2.	Investigator's Brochure	Version 3.0	21 Dec 2022
3.	Case Report Form	Version 3.0	17 Feb 2022
4.	Subject Informed Consent Document (English)	Version 3.0	14 Feb 2022
5.	Subject Informed Consent Document (Hindi) (Translated from English to Hindi on 05 Dec 2022)	Version 3.0	14 Feb 2022
6.	Back Translated Subject Informed Consent Document Hindi to English (translated on 05 Dec 2022)	Version 3.0	14 Feb 2022
7.	Translation certificates of Informed Consent Documents	NA	05 Dec 2022
8.	Back translation certificates of Informed	NA	10 Dec 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Consent Documents		
	9.	Insurance Policy	NA	Policy Period: 01 Mar 2022 to 28 Feb 2023
	10.	DCGI Approval for Clinical Trial Conduct (CT-06)	NA	14 Sep 2020, 27 May 2022
	11.	Investigator's Undertaking	NA	26 Dec 2022
	12.	Protocol Signature Page	NA	26 Dec 2022
	13.	Principal Investigator's Curriculum Vitae	NA	20 Dec 2022
	14.	Principal Investigator's MRC	NA	-

EC Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 121stECMIIC/P5

19. Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 10th February, 2023 from 01.30 PM. ***virtual.***

The following Members were present in the Meeting:

- Dr. Alok Dhawan -Chairman
- Mrs. Akansha Dubey -Member
- Mrs. Vasundhara Kumari -Member
- Mr. Ujjawal Krishna -Member
- Dr. Rajendra Nath -Member
- Dr. D.N. Upadhyaya -Member
- Dr. Shally Awasthi -Member-Secretary, IEC

19.a **DCGI**

I- ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no.576Neuro/22 dated 22nd November, 2022.

Patient ID & age and gender: S-45-3-307/59 years/Male
Patient Diagnosis: Right Ganglio-capsular intracranial bleed with mass effect with IVE Hypertension.

Patient enrollment date: 18.11.2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Patient follow up under study-Expired on 21-11-2022 during hospital stay.
Follow up visit completed-Expired
Planning on visit- 6th Month
SAE detected on date: 21-11-2022
Follow up visit remaining: Expired
24 hours, notified to EC, Sponsor-Yes
14 days analysis report submitted to EC-NA
Subject History:

Subject S.P.M.59 years/Male, known case of CAD post PTCA and Hypertension, admitted on 18th November, 2022 in the Emergency medical ward with c/o left hemiparesis and altered sensorium with GCS score of 7 and diagnosed to have right intracerebral (Gangliocapsular) bleed, volume approximately 50.9 ml. Since, he was fulfilling inclusion criteria so he was recruited after written informed consent from family and randomized to experimental arm and received tranexamic acid (2 gm 1/V bolus). He was kept in emergency medical ward ICU had received treatment with parenteral antihypertensive to lower blood pressure, decongestive therapy (Inj Mannitol) and intravenous fluids but his GCS score dropped to 4 at about 2 pm so he underwent elective intubation and repeat NCCT head which showed haematoma expansion(volume approx, 64.4 ml). Subsequently, he was on ventilator support and neurosurgery opinion was taken who advised for surgery, but family members gave negative consent. So, he was continued on medical treatment. His deteriorating condition was related with haematoma expansion and treatment options and prognosis were discussed with the family members. He continued same state and by next day his GCS score dropped further to 3. The NCCT head at 24 hours after admission showed further expansion of haematoma volume (67.5 ml). Further, His blood pressure started falling so mannitol was stopped and he was put on initially single and later double ionotropic support due to falling blood pressure. He suffered a cardiac arrest, was given CPR but could not be revived and declared dead at 2.01 pm on 21.11.2022. The immediate cause of death was supposed to be large intracerebral bleed and its complications only.

Recommendation of Primary reviewer:

- The subject was enrolled on 18th November, 2022 when the subject was brought to the hospital with intra-cerebral bleed.
- SAE occurred on 21st November, 2022 during the same admission as recruitment due to expansion of intra-cerebral hematoma and non-consent of LAR to allow surgery.

SAE doesn't appear to be related to the study but due to the expanding intra-cerebral hematoma perse.

ADR sub Committee Comment:

- No casual association & no compensation requird.

ADR sub Committee Decision: Noted

Ref. code: 115 ECM IIA/P5

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

2-	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Shukla, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter nos. 535/Neuro/22 dated 22nd October, 2022 & 550/Neuro/22 dated 2nd November, 2022. **Patient ID & age and gender:** S-45-3-121/40 years/Male **Patient Diagnosis:** Left Ganglio-capsular intracranial bleed with mass effect with IVE Hypertension. **Patient enrollment date:** 07.10.2022 **Patient enrollment date-**Intervention **Patient follow up under study-**Yes **Follow up visit completed-**No **Planning on visit-** Yes **SAE detected on date:** 20-10-2022 **Follow up visit remaining:** Yes (90) **24 hours, notified to EC, Sponsor-**Yes **14 days analysis report submitted to EC-**No**Subject History:** Subject A.G.40 yrs/Male, know case of Diabetes Mellitus Type-2, Hypertension, admitted on 07.10.2022 in the Emergency medical ward with c/o right hemiparesis and altered sensorium diagnosed to have right intracerebral (Gangliocapsular) bleed, volume approximately 50 ml. He was randomized to experimentalarm and received tranexamic acid (2 gm 1/V bolus). He was transferred to Neurology stroke ward on 08.10.2022 and received treatment with Inj. Mannitol, Intravenous Fluids, Inj Piperacillin+tazobactam (due to raised counts on CBC) and Insulin for blood sugar management. He gradually improved and started accepting orally continued to have motor aphasia. The nasoganstric tube and indwelling catheter were removed on eighth day of admission and he was discharged on 10th day (17.10.2022). As per the family members he remained fine for one day at home subsequently from 19.10.2022 his oral intake started decreasing and he became drowsy, his urine output also decreased, and he became developed anuria next day, so we were contacted by the family members so, Patienwas called for readmission. Now, he has been diagnosed as sepsis with shock with acute renal injury. He is currently under treatment. ***Recommendation of Primary reviewer:*** • SAE (Hospitalization due to drowsiness and anuria and sepsis) is likely due to disease outcome (Left Ganglio-capsular intracranial bleed with hypertension and T2DM) and not due to intervention (inj. Tranexamic acid ,IV ,bolus) as patient was randomized in treatment arm on 07-10-2022 and SAE occurred on 19-10-2022,almost 10 days have elapsed after taking intervention, therefore SAE seems not to be related to intervention.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Causal relationship can not be established and no compensation is required as patient was properly treated in hospital and discharged on 01-11-2022 in improved state with the instructions to come to OPD after 2 weeks for review. • (Document /Email regarding, notification to EC within 24 hrs. is not attached). **ADR sub Committee Comment:** • Causal relationship can not be established and no compensation is required as patient was properly treated in hospital and discharged on 01-11-2022 in improved state with the instructions to come to OPD after 2 weeks for review. **ADR sub Committee Decision:** Noted ***Ref. code: 115 ECM IIA/P5***
3.	ADR of research proposal entitled ***"Comparision of the efficacy of a 7 day versus a 14 day course of Intravenous antibiotics in the treatment of uncomplicated neonatal bacterial sepsis: a randomized controlled non inferiority trial"*** submitted by Prof. Mala Kumar, Department of Paediatrics, K.G's Medical University, U.P., Lucknow vide letter no. 2787/Ped/22 dated 10th November, 2022 preliminary email dated 11th Oct, 2022 at 2:14 PM.. **Patient ID & age and gender:** 0621/1 month and 1 day/male **Patient Diagnosis:** 28-30 week premature very low birth weight (VLBW0 baby with respiratory distress syndrome (RDS) and early onset sepsis (EOS) **Patient enrollment date:** 08-10-2022 **Patient enrollment in arm-**14 day trial arm **Patient follow up under study-**35 days **Follow up visit completed-**19-11-2022 **Planning on visit-** Still hospitalized **SAE detected on date:** 23-10-2022 **Follow up visit remaining:** 17 days **24 hours, notified to EC, Sponsor-**29-10-2022 **14 days analysis report submitted to EC-**09-11-2022 **Subject History:** The neonate was 28:30 weeks premature appropriate for gestational age with very low birth weight (1200gm). Baby was suspected of respiratory distress syndrome (RDS) with early onset sepsis (EDS), Baby was started on bubble CPAP and given surfactant. Antibiotics Ampicillin BD and Gentamysin OD were started from 8th October to 10 October and then from 10 October onwards on Amikacin OD (after blood culture sensitivety was available). After completion of 7 days of sensitive antibiotic administration baby was well and then we randomized. Randomization came to be in 14 day trial arm. The last dose of Amikacin was given on 22nd October, 2022. The next day baby became lethargic and had gastric haemorrhage. Sepsis screen was sent on 23rd

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	October, 2022 which turned out to be negative (CRP = 0.59), blood culture sample was misplaced and CSF examination was normal. Piptaz was started from 23rd October, 2022 but condition did not improve. Hemoglobin (Hb) also dipped to 8.8 g/dL so PRBC transfusion was done on 24 October after which Hb improved to 13.2g/d/L. Repeat CRP was sent on 26th October, 2022 which turned out positive with value of 13.32. Blood culture sample was sent on 27th October which came sterile on 30th October, 2022. One more transfusion of PRBC was done on 28th October. However due to clinical deteoration in the form of Respiratory distress from 27th October, 2022 antibiotics were upgraded to Meropenem and the next day Vancomycin was also added. Baby was put on NIV mode of ventilation on 28th October, 2022. On 2 November, 2022 repeat CSF examination was normal and CSF culture came sterile on 4 November, 2022. Baby gradually improved and at present is stable on room air and mother's breast feed (MBF) with ongoing antibiotics. ***Recommendation of Primary reviewer:*** • SAE (continued hospitalization due to lethargy and gastric hemorrhage) is likely due to disease outcome (LBW with Sepsis and Respiratory distress syndrome) and not due to intervention (parenteral antibiotics) as patient was enrolled on 08-10-2022 and randomized in 14 day trial arm and after 7 days of parenteral antibiotics baby was well. SAE was detected on 23-10-2022 after completion of parenteral antibiotic (Amikacin) course (i.e. on 22-10-2022).Patient has received transfusion of PRBC two times (on 24th and 28th October) due to low Hb levels .Patient is still in hospital and under treatment due to deterioration of his clinical condition ,which is now stable. • Causal relationship can not be established and as patient is still in hospital at the site and getting proper management and is gradually improving and presently is stable on room air and mother's breast feed, so no compensation is required. • (Document/Email regarding, notification to EC within 24 hrs. is not attached). **ADR sub Committee Comment:** • Causal relationship can not be established and as patient is still in hospital at the site and getting proper management and is gradually improving and presently is stable on room air and mother's breast feed, so no compensation is required. **ADR sub Committee Decision:** Noted ***Ref. code: 100 ECM IIA/P6***
4.	ADR of research proposal entitled ***"A multicenter, single arm, open label,phase 4 study to evaluate the safety and efficacy of Vedolizumab in Indian patients with Ulcerative Colitis and Crohn's disease"*** submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, K.G's Medical University, U.P., Lucknow vide letter no. 2214/Med/22 dated 26th November, 2022. **Patient ID & age and gender:** TAK-23-182 **Patient Diagnosis:** UC

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Patient enrollment date: 30-08-2022 **Patient enrollment in arm-**Vedolizumab 4020 **Follow up visit completed-**No **Planning on visit-** No **SAE detected on date:** 21-11-2022 **Follow up visit remaining:** 05, V-6,7,8,9,10 **24 hours, notified to EC, Sponsor-**Yes **14 days analysis report submitted to EC-**No (Initial report submitted) **Subject History:** The subject TAK-23-182 screened on 18th July, 2022 and enrolled on date 30th August, 2022. Subject was a known case of ulcerative colitis with pseudopolyposis for 5 years. She attended visit 5 here with loose stools. Sigmoidoscopy showed mucosal healing but pseudo-polyps persisting. Histopathological examination from rectal pseudopolyp showed adenocarcinoma. ***Recommendation of Primary reviewer:*** • SAE (permanent disability in the form of detection of Adenocarcinoma rectum) detected (on 21-11-2022) is likely due to disease progression (Ulcerative colitis with Pseudopolyposis ,rectum) and is unrelated to intervention (Vedolizumab) as patient was enrolled on 30-08-2022 and more than two and a half month has elapsed in treatment arm and Pt. completed 4th successful visit before detection of SAE on 5th visit ,when patient complains of loose stools and on sigmoidoscopy and histopathological examination, adenocarcinoma was detected. • Causal relationship can not be established and as SAE is most likely due to disease progression instead of intervention, therefore no compensation is required. • (Document /Email regarding , notification to EC within 24 hrs. is not attached) **ADR sub Committee Comment:** • Causal relationship can not be established and as SAE is most likely due to disease progression instead of intervention, therefore no compensation is required. **ADR sub Committee Decision:** Noted ***Ref. code: 114thECMIIC/P1***
5-	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 445/Neuro/22 dated 14th December, 2022 & 607/Neuro/22 dated 15th December, 2022. **Patient ID & age and gender:** S-45-3-421(RS)/50 years/Male

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Patient Diagnosis: Left basal ganglia bleed with hypertension.

Patient enrollment date: 05-12-2022

Patient enrollment arm-Intervention arm
Patient follow up under study-Yes.
Follow up visit completed-No
Planning on visit- Yes
SAE detected on date: 12-12-2022
Follow up visit remaining: Yes (90 days)
24 hours, notified to EC, Sponsor-Yes
14 days analysis report submitted to EC-NA

Subject History:

A letter was received in the office of the Ethics Committee on 15th December, 2022 vide letter no.445/Neuro/22 dated 14th December, 2022 by PI, the subject RS, 50 years/Male, known case of hypertension, dyslipidemia not on medication presented with complaint of slurring of speech as well as right upper and lower limb weakness. System onset was at 11.00 AM on 5th December, 2022 and the patient was admitted at 12:41 PM in neurology emergency. At presentation, the heart rate was 65 BMP, BP was 191/122 and GCS was 15 and diagnosed to have left basal ganglia bleed with a volume of approximately 5.09 ml. Since he was fulfilling inclusion criteria so he was recruited after written informed consent from family and randomized to the intervention arm received tranexamic acid (2gm 1/V bolus). He was kept in neurology and received treatment with antihypertensive to lower blood pressure. **He was discharged on the 6th day (10/12/2022).** As per family members. He remained fine for one day at home later the patient developed chest pain and pain radiating to left forearm since one hour. ECG suggestive of Inferior wall MI associated with Right ventricle infarction. Patient was admitted immediately to Cardiology ICU on 12th December, 2022. Conservative management was followed and patient is stabilized on 12th December, 2022. He is currently under treatment.

Also, A letter was was received in the office of the Ethics Committee on 15th December, 2022 vide letter no.607/Neuro/22 dated 15th December, 2022, which in mention by the PI the subject was recovered completely from the event which had been reported to you and he is being discharged on 14th December, 2022. His discharged summary and a copy of the resolution are attached with this letter.

After that, A letter was received in the office of the Ethics Committee on 3rd January, 2023 vide letter no.01/Neuro/23 dated 3rd January, 2023 by PI. The subject was discharged from the PI side on 10th December, 2022 and his further follow-up is due on

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	5th March, 2023 (90th day visit). As per his proxy on today (27-12-2022) his mRS& GCS is 3 and 15 respectively with distal weakness of right upper limb and able to walk without assistance. On 12th December, 2022, patient developed chest pain, ECG suggestive of inferior wall MI associated with right ventricle infarction for which the PI had reported to EC. On today's follow-up he has been advised to continue medication. The PI shall update the EC further about his health after following him up on the above said date. ***Recommendation of PR:-*** SAE (Hospitalization due to chest pain) is likely due to disease outcome (CVA Hemorrhage with Rt. Sided hemiparesis with Inferior wall / Rt. Ventricular / Posterior wall MI) and not due to intervention (inj. Tranexamic acid ,IV ,bolus) as patient was randomized in treatment arm on 05-12-2022 and SAE occurred after one day i.e. on 12-12-2022. Causal relationship can not be established. SAE is unlikely related to Intervention as Pt was discharged just one day back (10-12-2022) after getting treatment for Left basal ganglia bleed and was again admitted in hospital (12-12-2022). As he was given proper treatment after admission and was discharged on 14th December after complete recovery ,therefore no compensation is required . (Document /Email regarding , notification to EC within 24 hrs. is not attached) **ADR sub Committee Comment:** • Causal association not established no compensation required. **ADR sub Committee Decision:** Noted ***Ref. code: 115 ECM IIA/P5***
6.	ADR of research proposal entitled ***"Comparision of the efficacy of a 7 day versus a 14 day course of Intravenous antibiotics in the treatment of uncomplicated neonatal bacterial sepsis: a randomized controlled non inferiority trial"*** submitted by Prof. Mala Kumar, Department of Paediatrics, K.G's Medical University, U.P., Lucknow vide letter no. 3190/Ped/2022 dated 23rd December, 2022. **Patient ID & age and gender:** 0621-132/1 year and 2 month/Male **Patient Diagnosis:** Prematurity with appropriate for gestational age with low birth weight with respiratory distress syndrome with perinatal asphyxia with neonatal hyperbilirubinemia with early onset sepsis. **Patient enrollment date:** 25 September 2021 **Patient enrollment in arm**-7 Day trial Arm **Patient follow up under study**-35 days

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Follow up visit completed-11-11-2021
Planning on visit- Discharged
SAE detected on date: 17-10-2021
Follow up visit remaining: 0 days
24 hours, notified to EC, Sponsor-30-11-2022
14 days analysis report submitted to EC-30-11-2022
SAE initials: B/O SS
SAE term: Sepsis (Pneumonia)
Course of event: Randomization in NICU
Causality: No
Outcome: Discharged

Subject History:

A letter was received in the office of the Ethics Committee on 23rd December, 2022 vide letter no.3190/Ped/2022 dated 23rd December, 2022. The PI informed to the EC that the baby was admitted with above mentioned complaints. Patient was managed with ventilator support, warmer care, vital monitoring, iv antibiotics and ionotropes. Patients were intubated 1/v/o low GC, bradycardia and poor respiratory efforts. Relevant investigations were sent. First sepsis screen came out to be negative but 1/v/0 clinical deterioration repeat sepsis screen was done which came out to be positive. Blood culture was sterile; iv antibiotics were added and upgraded a/t culture sensitivity. Swab for respiratory viruses were sent which was positive for RSV. During the course of hospital stay patient condition improved and ventilator support was gradually weaned off. Currently baby is hemodynamically stable, maintaining saturation on room air, taking MBF well, passing stool and urine normally, antibiotic course has been completed, therefore being discharged with advise to follow up in pediatric OPD on Wednesday after taking prior appointment on ors.gov.in

Recommendation of PR:-

SAE (hospitalization) is likely due to disease outcome (LBW with Sepsis and Respiratory distress syndrome) and not due to intervention (parenteral antibiotics) as patient was enrolled on 08-10-2022 and randomized in 14 day trial arm and completed follow up visit ,after 14 days of parenteral antibiotics baby was well. SAE was detected on 23-10-2022 after completion of parenteral antibiotic course(i.e. on22-10-2022). Patient is now hemodynamically stable , maintaining saturation on room air and antibiotic course has been completed ,therefore being discharged with advice to follow up in pediatric OPD.
Causal relationship can not be established and as patient was given proper management

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	and was gradually recovered and was stable on room air and mother's breast feed and therefore being discharged ,so no compensation is required . (Document /Email regarding , notification to EC within 24 hrs. is not attached) **ADR sub Committee Comment:** • Causal relationship can not be established and as patient was given proper management and was gradually recovered and was stable on room air and mother's breast feed and therefore being discharged, so no compensation is required . **ADR sub Committee Decision:** Noted ***Ref. code: 100 ECM IIA/P6***
7	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Shukla, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 4414/ neuro/ 22 dated 14-12-2022 & 651/Neuro/22 dated 30th December, 2022. **Patient ID & age and gender:** S-45-3-376(VK)/45 years/Male **Patient Diagnosis:** Left basal ganglia bleed with intraventricular extension with hypertension. **Patient enrollment date:** 26-11-2022 **Patient enrollment arm**-Control arm **Patient follow up under study**-Yes. **Follow up visit completed**-No **Planning on visit-** Yes **SAE detected on date:** 09-12-2022 **Follow up visit remaining:** Yes **24 hours, notified to EC, Sponsor**-Yes **14 days analysis report submitted to EC**-NA **Subject History:** A letter from the PI of the project was received in the office of the Ethics Committee on 15th December, 2022 vide letter no. 444/Neuro/22 dated 14th December, 2022. It was revealed that the subject VK, 45 years/Male, a known case of hypertension, was on irregular medication and presented with a complaint of weakness of the right upper & right lower limb and sudden onset altered sensorium admitted on 26th November, 2022 in the Emergency medical ward with GCS score of 14. He was diagnosed to have a left basal ganglia bleed with an intraventricular extension volume of approximately 16.84 ml. Since he was fulfilling inclusion criteria so recruited after obtaining written informed

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	consent from the family and randomized to the control arm. He was kept in the emergency medical ward ICU had received treatment with parenteral antihypertensive to lower blood pressure, later the patient was diagnosed with Hepatitis B via HbsAg surface antigen test on ELIZA. This infection is unrelated to treatment protocol and the patient wasn't previously aware of his status. On admission, routine labs reported hepatitis B rapid antigen test positive. Since the sensitivity and specificity of this test is low, hence ELIZA testing was done. The report arrived on 9th December, 2022. Gastroenterology and medicine reference have been done. Antiviral therapy has been initiated. After that, a letter was received in this office on 30th December, 2022 vide 651/Neuro/22 dated 30th December, 2022. It was informed by the PI that subject VK was discharged from his side on 10th December, 2022 and his further follow-up is due on 5th March, 2023 (90th day visit). As per his proxy on today (27th December, 2022), It is observed that his mRS & GCS is 4 and 15 (E4V5M6) respectively with residual right hemiparesis and unable to walk and attend to his own bodily needs without assistance. This patient was diagnosed with hepatitis B positive on 9th December, 2022 for which PI had reported to EC. On today's follow-up, he has been advised to continue follow-up and treatment for hepatitis B at medical gastroenterology. The PI shall update you further about his health after following up on the above-said date. ***Recommendation of PR:-*** SAE (Hospitalization) is likely due to disease outcome (Left basal ganglia bleed with IVE hypertension) and Hepatitis B infection and not due to intervention, as patient was enrolled in control arm on 26-11-2022. Causal relationship can not be established and no compensation is required as patient was properly treated in hospital for complication and Hepatitis B infection which was detected on 09-12-2022 and was unrelated to protocol. He has been advised to continue follow up. (Document /Email regarding , notification to EC within 24 hrs. is not attached) **ADR sub Committee Comment:** • Causal relationship can not be established and no compensation is required as patient was properly treated in hospital for complication and Hepatitis B infection which was detected on 09-12-2022 and was unrelated to protocol. He has been advised to continue follow up. **ADR sub Committee Decision:** Noted ***Ref. code: 115 ECM IIA/P5***
19.b.1	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Committee" held on 10th February, 2023 from 01.30 PM. ***virtual.*** ***The following Members were present in the Meeting:*** • Dr. Alok Dhawan -Chairman • Mrs. Akansha Dubey -Member • Mrs. Vasundhara Kumari -Member • Mr. Ujjawal Krishna -Member • Dr. Rajendra Nath -Member • Dr. D.N. Upadhyaya -Member • Dr. Shally Awasthi -Member-Secretary, IEC
	Non-DCGI
1-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized-placebo controlled trial*** submitted by Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 354/Cardio/Res/22 dated 14th October, 2022 preliminary email dated 4th October, 2022 at 5:0 PM. **Subject ID: 008** **Subject initial: S-D** **Patient diagnosis:** RHD/Sev-MS/MVA 0.8 cm **Patient enrollment date**-29-04-2022 **Patient enrollment in arm**- Digoxin **Patient follow up under study**-6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit**- 6th Month **SAE detected on date:** 03.10.2022 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor**-04-10-2022 **14 days analysis report submitted to EC**-14-10-2022 **Subject History:** A letter was received in the office of the Ethics Committee on 15/10/2022. Patient was admitted i/v/o Echymotic patches over body with deranged INR and severe Anaemia. During hospital stay 3 unit of PRBC and 4 unit of FFP were given and now

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	patient is being discharged in hemodynamically stable condition ***Recommendation of Primary reviewer:*** • The subject was enrolled on 29th February, 2022. 1 month follow-up was completed. Awaiting 6 months follow-up. • SAE detected on 3rd October, 2022. Hospitalization from 3rd October, 2022 to 6th October, 2022. Patient presented with breathlessness, weakness and ecchymosis. INR was 16. Patient was managed with 3 units PRBC and 4 units FFP. • Patient is on Digoxin which can be a rare cause of drug-induced immune-thrombocytopenia. The subject needs to be investigated, monitored and explanation for the same sought form the PI. No reason for the elevated INR has been furnished by the PI. **ADR sub Committee Comment:** • No reason for the elevated INR has been furnished by the PI. **ADR sub Committee Decision:** Noted ***Ref. code: 102nd ECM IIA/P24***
2-	ADR of research proposal entitled ***"International study of comparative health effectiveness with Medical and Invasive approaches"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter nos.433/Cardio/Res/22 dated 23rd November, 2022 preliminary email dated 11th November, 2022 at 1:26 PM. **Death** **Subject Initial:** S N Y **Subject no.:** 091019-156 **Subject gender:** Male **Patient diagnosis:** Coronary Artery Disease/Chronic Stable Angina **Patient enrollment date**-27-01-2017 **Patient follow up under study**-Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic Follow up till 5 year. **Follow up visit completed**- Randomization visit, Month 1.5, Month 3, Month, 6, Month 12, Month 18. **Planning on visit**- Telephonic Follow-up visit of month of November, 2022 **SAE detected on date:** 11-11-2022 **Follow up visit remaining:** Telephonic visits (Every Month) till 2025 **24 hours, notified to EC, Sponsor by Email**- 11-Nov-2022 **14 days analysis report submitted to EC**-23-11-2022 **Subject History:** A letter was received in the office of the Ethics Committee on 24/112022. The Principal-Investigator informed that subject was randomized in Conservative Arm of the study.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The site person have made a scheduled monthly follow up call to subject on 11th November, 2022 at 11:00 hrs. Subject's LAR informed him that subject passed away on 25th October, 2022 at around 08:00 hrs. LAR informed that subject was feeling down from last few days and had no other major symptoms, on 24th October, 2022 at 21:00 hr. He had taken medicine, skipped his dinner and then slept. Subject did not awaken after that and in morning he found dead. As he was not admitted anywhere, no documents are available and No autopsy was done. ***Recommendation of Primary reviewer:*** • The subject was enrolled on 18th November, 2022 when the subject was brought to the hospital with intra-cerebral bleed. • SAE occurred on 21st November, 2022 during the same admission as recruitment due to expansion of intra-cerebral hematoma and non-consent of LAR to allow surgery. • SAE dose'nt appear to be related to the study but due to the expanding intra-cerebral hematoma parse. **ADR sub Committee Comment:** • SAE dose'nt appear to be related to the study but due to the expanding intra-cerebral hematoma parse. **ADR sub Committee Decision:** Noted ***Ref. code: 60th ECM IIA/P13***
3-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 556/Cardio/Res/2023 dated 12th January, 2023 & preliminary email dated 3rd January, 2023 at 1:47 PM. **Patient ID & age and gender:** 064/52 year/Female **Patient Diagnosis:** RHD/Mod-MS/MVA 1.3 cm. **Patient enrollment date:** 21-04-2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit**- 6th M **SAE detected on date:** 30-12-2022 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor**-3rd January, 2023 **14 days analysis report submitted to EC**-12-01-2023

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Subject History:

A letter was received in the office of the Ethics Committee on 12th January, 2023 by PI, the subject LAR informed to PI that the subject passed away on 31st December 2022 at 3:00 PM. The subject had complaints of breathlessness and discomfort since the last few days she collapsed at home. Local practitioner was called and he confirmed subject's death. No hospital records are available and no autopsy was done as she expired at home. The PI does not have the exact records to ascertain the cause of death.

Recommendation of PR:-

Enrolment date 21-04-2022. 6th month follow up was due in October which was missed. SAE occurred on 31-12-2022 and was reported on 03-01-2023.(late) Clarification may be sought on why the 6 month follow up was skipped and why was the SAE reported late if it was detected on 31-12-2022.

ADR sub Committee Comment:

- Why was 6 month follow-up missed?
- Why SAE reported late?

ADR sub Committee Decision: Noted

Ref. code: 102nd ECM IIA/P24

4- ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Praveen Kumar Shukla, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 555/Cardio/Res/2023 dated 12th January, 2023 & preliminary email dated 31st December, 2022 at 12:30 PM.

Patient ID & age and gender: 003/42 year/Female
Patient Diagnosis: RHD/Mod-MS/MVA 1.3 cm.

Patient enrollment date: 21-04-2022

Patient enrollment arm-Digoxin
Patient follow up under study-6th M,12th M, 18th M, 24th M, 30th M, 36th M.
Follow up visit completed-Enrolment & Baseline Follow-up
Planning on visit- 6th M
SAE detected on date: 30-12-2022
Follow up visit remaining: 6th M,12th M, 18th M, 24th M, 30th M, 36th M
24 hours, notified to EC, Sponsor-31st December, 2022
14 days analysis report submitted to EC-12-01-2023

Subject History:

A letter was received in the office of the Ethics Committee on 12th January, 2023 by PI, The PI made many follow-up calls to the patient for a 6 months actual follow-up visit at the site, but the call was not answered as informed by the PI, the subject's LAR came

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	with the patient on 30th December, 2022 with complaints of breathlessness and dyspnoea. The PI also informed to the patient was admitted in the emergency department for stabilization. The patient is currently under observation for the same and there is no definite diagnosis made yet. So, PI is not sure that patient comes under SAE or AE. The PI had informed to the EC that he will provide his detail for the same within 14 days of the window period. ***Recommendation of PR:-*** • Randomized date 21-04-2022. SAE date 29.12.2022. SAE detected on 30-12-2022. Reported on 31-12-2022. • Date on SAE Narrative (report) is 12-10-2023-it may be corrected. • Subject has skipped the 6 month follow up and reported with SAE on 30-12-2022. • Subject was admitted for treatment and later discharged in a stable condition as per the PI. • SAE doesn't appear to be related to the drug. Clarification/corrections as noted above may be sought. **ADR sub Committee Comment:** • Why was 6 month follow-up missed? • There is a typing error on date, Kindly get it corrected. **ADR sub Committee Decision:** Noted ***Ref. code: 102nd ECM IIA/P24***
19.b2	**Non-DCGI**
	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 19th April, 2023 from 12.30 PM. ***virtual.*** **(Non-DCGI)** ***The following Members were present in the Meeting:*** 1. Dr. Alok Dhawan -Chairman 2. Mrs. Akansha Dubey -Member 3. Mrs. Vasundhara Kumari -Member 4. Mr. Ujjawal Krishna -Member 5. Dr. Rajendra Nath -Member 6. Dr. D.N. Upadhyaya -Member 7. Dr. Nisha Mani Pandey -Member 8. Dr. Shally Awasthi -Member-Secretary, IEC
I-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial"*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 629/Cardio/Res/2023 dated 17th February, 2023 & preliminary email dated 2nd February, 2023 at 1:00 PM.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Patient ID & age and gender: S012/ 33 years/Female **Patient Diagnosis:** RHD/Sev-MS/MVA 0.8 cm. **Patient enrollment date:** 04-05-2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit-** 6th M **SAE detected on date:** 30-12-2022 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor**-3rd February, 2023 **14 days analysis report submitted to EC**-17th February, 2023 **Subject History:** A letter was received in the office of the Ethics Committee on 20th February, 2023 by PI, the subject LAR informed to PI on 2nd February 2023 that the subject was having a complaint of breathlessness and dyspnoea since 20th January, 2023, for which she was hospitalized on 24th January, 2023. The patient was admitted for stabilization and had to undergo surgery, but due to some technical issue the Surgery could not be done and the patient was discharged on 30th January 2023 after being managed conservatively. ***Recommendation of PR:*** a- Enrolment date 04-05-2022. 6th month follow up was due in November which was missed. SAE occurred on 20-01-2023, patient was admitted on 24th January, 2023 and discharged on 30th January, 2023. The SAEwas repored on 3rd February, 2023 (Late). Clarification may be sought on why the 6th month follow up was skipped and why was the SAE reported late if it occurred on 20-01-2023 and patient was admitted on 24th January, 2023. b- In the summary SAE detection date is mentioned 30-12-2023 at one place and 20-01-2023 at another place. If SAE was detected on 20-01-2023, why was it reported on 03-02-2023? **ADR sub Committee Comment:** As above **ADR sub Committee Decision:** Revise & Re-submit ***Ref. code: 102nd ECM IIA/P24***
II-	ADR of research protocol no. PreQuest-01 entitled "***Prospective, multi-centric, single arm post marketing surveillance of PRISTINE, everolimus eluting cobalt chromium coronary stent system to assess its continued safety and efficacy***" sponsored by M/s Relisys Medicine Devices Ltd. submitted by Prof. Pravesh Vishwakarma, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 661/Cardio/Res/23 dated 6th March, 2022 & ***preliminary email dated 1st March, 2023 at 2:07 PM.*** **Hospitalization:-** **Patient ID & age and gender: 103/70 year/Male**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Subject initial: MT **Patient Diagnosis:** F/U/C AWMI/TLT/P/PCI→LAD (11/06/22) **Patient enrollment date:** 14-02-2023 **Patient enrollment Arm:** Pristine Registry **Patient follow up under study-** 1st Month, 6th Month, 9th Month, 12th Month **Follow up visit completed**-Enrolment & Screening & Baseline Visit **Planning on visit:** 1st Month **SAE detected on date:** 21-02-2023 **Follow up visit remaining:** 1st Month, 6th Month, 9th Month, 12th Month **24 hours, notified to EC, Sponsor**-01-03-2023 **14 days analysis report submitted to EC**-15-03-2023 **Subject History:-** A letter was received in the Office of the Ethics Committee on 9th March, 2023. Subject's LAR informed telephonically on 28th February, 2023 that the subject was having a complaint of breathlessness and cough since 21st February, 2023. The patient was admitted on 21st February, 2023 for stabilization and the patient got discharged on 24th February, 2023. ***Recommendation of Primary reviewer:-*** • Enrolment date 14th February, 2023. SAE date-21-02-2023 to 24-02-2023. Reported to PI 28-02-2023. PI reported to IEC-01-03-2023. • Patient was admitted to department of General Medicine, KGMU with cough and sputum and breathlessness and responded to conservative management. SAE doesn't appear to be related to the TRIAL. **ADR sub Committee Decision:** Noted ***Ref.code:110th ECMIIC/P1***
2.	ADR of research protocol no. CKJX839B12302 entitled "***A randomized, double-blind, placebo-controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT)***" sponsored by M/s Novartis Healthcare Pvt. Ltd submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.671/Cardio/Res/23 dated 11th March, 2023 & ***preliminary email dated 27th February, 2023 at 4:35 PM & 28th February, 2023 at 11:14 AM.*** **Hospitalization:-** **Patient ID & age and gender: 1014042 year/Male** **Subject initial:** K **Patient Diagnosis:** Hospitalization for stroke CVA **Patient follow up under study-** Randomization (Day 1), Month 3, Month 9, Month 15, Month 21, Month 27, Month 33, Month 39, Month-45, Month-51, Month 57, Month 69. **Follow up visit completed**-Randomization (Day-1) **Planning on visit:** Month 9 (16 Jul 2023) **SAE detected on date:** 13-01-2023

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Follow up visit remaining: Month 9th, Month 15th to Month 69th **24 hours, notified to EC, Sponsor**-27-02-2023 **14 days analysis report submitted to EC**-27-02-2023 **Subject History:-** A letter was received in the Office of the Ethics Committee on 13th March, 2023. The PI's staff made a scheduled visit of the Month for 3rd call to the subject on 27th February, 2023 around 11:30, Subject's family member told on 13th January, 2023 that the subject had Paralysis Attack for which subject was treated locally nearby hospital. There his CT Brain and other blood investigational done and subject was diagnosed with CVA infarct. Subject came to the PI's site on 1st March, 2023 for follow-up visit with a diagnosis of CVA (On 13th January, 2023) and after the evaluation. CVA was diagnosed and confirmed by CT. Subject was referred to Neurology department for further evaluation. MRI was advised, there but subject denied for that and went back to home. *Recommendation of Primary reviewer:-* • Enrolment date-29-09-2022. SAE date 13-01-2023 to 14-01-2023. SAE detected on 27-02-2023 during routine cal to the patient. SAE notification-28-02-2023. • Patient was admitted to local hospital with a diagnosis of stroke (CVA). During his follow-up on 01-03-2023, patient was evaluated again and advised further Investigations/treatment by department of Neurology which he refused. • SAE doesn't appear to be related to the TRIAL. **ADR sub Committee Decision:** Noted ***Ref. code: 114th ECMIIC/P4***
	Death
1-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 678/Cardio/Res/2023 dated 15th March, 2023 & preliminary email dated 1st March, 2023 at 2:00 PM. **Patient ID & age and gender:** 006/65 year/Female **Patient Diagnosis:** RHD/Mod-MS/MVA 1.6 cm **Patient enrollment date:** 26th April, 2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**- Enrolment & Baseline Follow-up **Planning on visit**- 6th Month **SAE detected on date:** 28th February, 2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	36th Month. **24 hours, notified to EC, Sponsor-** 1st March, 2023 **14 days analysis report submitted to EC-** 15th March, 2023 **Subject History:** A letter was received in the Office of the Ethics Committee on 13th March, 2023. The Subject's LAR informed that she was having complains of seizures, vomiting, frequent stools and urination, for which she was hospitalized on 28th February, 2023. The patient was admitted and was under treatment for drug (Warf) induced intracranial bleeding. The patient **passed away in the hospital on 1st March, 2023** at 9:47 PM due to intracranial bleeding, septicemic shock and aspiration pneumonia. **The causality reported is not related to the study drug.** **ADR sub Committee Decision:** Noted ***Ref. code: 102nd ECM IIA/P24***
IB	**Expedited review**
1-	Expedited review of the research proposal entitled ***"Global cohort study: Hernias, pathway and planetary outcomes for inguinal hernia surgery"*** submitted by Dr. Manish Kumar Agrawal, Associate Professional, Department of General-Surgery, King George's Medical University, U.P., Lucknow vide letter no. 695 dated 15th March, 2023. ***The above Comment forwarded to PI was reviewed by Primary reviewer:-*** ***Recommendation of Primary reviewer:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 123rd ECMIB/P1***
2-	Expedited review of the research proposal entitled ***"An assessment of living status, health issues with special reference to mental health, well-being and satisfaction of residents living in old age homes of Uttar Pradesh-A Pilot study"*** submitted by Dr. Nisha Mani Pandey, Prof. Junior. Grade, Department of G.M.H., King George's Medical University, U.P., Lucknow vide letter no. vide letter no.150/DGMH dated 11th April, 2023. ***The above Proposal forwarded to two reviewers for review:-*** ***Recommendation of First Primary reviewer:*** • English version of the protocol not submitted-PI is requested to submit the English version for better understanding of the study. • Sample size –not given –written as Pilot study (A Preliminary study) but PI is requested to give approximate number of subjects to be recruited in this study. • (Sample size calculation is not needed as it is a Pilot study.) • In Tools- ICMR-NCTB questionnaire –attached ,but details of ICMR-NCTB proforma are missing and permission to use it is also missing.-PI to clarify ***Recommendation of secondary reviewers:*** • Does the study cover all the old age homes of Uttar Pradesh? • The sampling frame (list) of old age homes is required. • If the study is planned for whole of Uttar Pradesh, then why a Pilot Study? • Was the instrument checked for internal consistency? • How was reliability calculated?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• How was validity estimated? • Is it easy to score the instrument? ***The above Comment forwarded to PI was reviewed by both Primary reviewers:-*** ***Recommendation of both Primary reviewers:-*** Provisionally approved **EC Decision:** Approved ***Dr. Nisha Mani Pandey did not take part in the discussion and making decision.*** ***Ref. code: 123rd ECMIB/P2***
3-	Expedited review of the research proposal entitled ***"To study the effectiveness of trauma quality improvement programs(TQIP's) in improving trauma care outcomes at tertiary care hospital in India"*** submitted by Prof. Sandeep Tiwari, Head, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. vide letter no. vide letter no.TS/265/2023 dated 12th April, 2023. ***The above proposal forwarded to two reviewers for review:-*** ***Recommendation of First Primary reviewer:*** • There is no project proposal in Dr. Sandeep Tewari's documents. ***Recommendation of Secondary reviewer:*** • PI has not submitted the protocol of the Research Study (Aims ,Objectives, Study design, Inclusion /Exclusion criteria, sample size, Methodology–not mentioned) • In SOP-Checklist –Section 6-Confidential handling of data–not ticked as Yes (please revise) • ICF (E/H)-attached, but Human Subject Review Waiver Form is also attached. (indicating that it is not Research but disease control activity)-PI to clarify that why he has attached both. • Title is different in Scientific Review Committee document-PI to justify • Letter of Sponsorship/Grant from ICMR is missing. ***The above Comment forwarded to PI was reviewed by both Primary reviewers:-*** ***Recommendation of both Primary reviewers:-*** Provisionally approved **EC Decision:** Approved ***Ref. code: 123rd ECMIB/P3***
4-	Expedited review of the research proposal entitled ***"Evaluation of operating room turnover time by process mapping and time stamping"*** submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. vide letter no. vide letter no. SONC/596/23 dated 31st March, 2023. ***The above proposal forwarded to two reviewers for review:-*** ***Recommendation of First Primary reviewer:*** Approved

Recommendation of Secondary reviewer	**PI response**
Letter of sponsor/Collaboration from Terna Medical College & Hospital/BARC Hospital, HBNI University, Mumbai-not attached.	It has been attached now.
Please attach the list of Centers/Hospital across	Presently 3 centers have received ethical clearance

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	India where this study will be performed.	where the study has started. 1. Terna Medical College and Hospital, New Mumbai 2. Manipal Hospital, Delhi 3. Maulana Azad Medical College, New Delhi
	Inclusion criteria-Age specificity of Patients operated upon not given.	Patients of 18 years and above will be included. We are not collecting any patient related data, it's just an OT process observational study. So, it qualifies for a consent waiver.
	Sample size-PI written, Total number of cases performed daily in selected OTs at each of the collaborating secondary & Tertiary Health care centers in India, but in SOP-Checklist-Total no. of subjects given is-500 from which 50 cases at Surgical Oncology Department, KGMU-Please clarify whether it is a Pilot study and if not then give Sample size calculation.	It is a pilot study; therefore no formal sample size calculation is required. We aim to recruit approximately 50 patients during the study period from the 2 OTs of the Department of Surgical Oncology.
	ICF regular attached- If all age patients operated upon will be taken then Guardian consent/Child Assent form should also be attached.	We are not collecting any patient related data, it's just an OT process observational study. So, it qualifies for a consent waiver. However, in our department we only operate Adult Cancer Patients. So only patients above 18 years will be included.

The above Comment forwarded to PI was reviewed by secondary reviewer:-
Recommendation of Secondary reviewer:-

- Letter of sponsor/Collaboration from Terna Medical College & Hospital/BARC Hospital, HBNI University, Mumbai still not given by PI (He instead attached the IEC letter send to Dr. Bhakti Sarang by IEC, Terna Medical College) PI is requested to attach the said document.

The above Comment forwarded to PI:-Reply pending by PI.
EC Decision: Reminder will be sent to the Principal-Investigator

Ref. code: 123rd ECMIB/P4

II-A	**New proposals**
1.	Research proposal entitled ***"Biomarkers for chemoresistance in oral squamous cell carcinoma (OSCC)"*** submitted by Prof. Seema Gupta, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 248/RT/23 dated 15th March, 2023. ***Recommendation of primary reviewer:*** • In the Materials and methods section the name of the candidate gene Primer is not mentioned. • Sample size calculation not given. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 123rdECM IIA/P1***
2.	Research proposal entitled "*A salivary metagenomic analysis of microbial diversity in*

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	children with severe early childhood caries" sponsored by CST UP submitted by Dr. Vijay Kumar Shakya, Additional Professor, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 631/Cons & Endo/23 dated 27th March, 2023. ***Recommendation of primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 123rd ECM IIA/P2***
3.	Research proposal entitled **"*Effect of prospective bilateral superficial cervical plexus nerve block on post-thyroidectomy headache and cervical pain: A randomised controlled trial*"** submitted by Dr. Pooja Ramakant, Prof. Junior Grade, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/2023/21 dated 13th January, 2023. ***Recommendation of primary reviewer:*** • Compensation for injury: What if someone has allergic reaction to drug? • Objectives: Very vague-What if someone has allergic reaction to drug? • Elements of RCT need to be mentioned. • Data analysis: What tests? • Implications: accurate dosage…Dosage is not being studied. • Why subject participation for 4 months? **EC Comment:** • Senior Resident cannot be Co-Principal-Investigator. • Objectives very vague-What is the measure of efficacy? **EC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: 123rd ECM IIA/P3***
4.	Research proposal entitled **"*Evaluation of high risk proteins involved in breast cancer and their correlation with tumor aggressiveness and chemotherapy response: A retrospective study*"** sponsored by CSIR-CDRI submitted by Dr. Sumaira Qayoon, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 396/23 dated 31st March, 2023. **EC Comment:** • Annexure one needs to be filled up such as for 'risk and benefit', ' data monitoring ' , 'compensation for injury' etc. • It is indicated by astrix that written consent will be taken. Kindly clarify since consent waiver form is also attached. • Kindly indicate other centers involved in this multicenter study . • The first objective indicates that metanalysis will be undertaken to shortlist six high risk genes while budget indicates that immunohistochemistry will be undertaken from the very beginning of the study. Have those six genes been identified? If yes, then kindly mention them and if not then the budget quoted may change depending upon the antibody cost of specific gene that needs to be assessed. Kindly clarify. • Regarding the third objective to correlate protein expression with chemotherapeutic response, kindly mention the clinical parameters that need to be recorded and the RCB scoring. In addition also attach the data-sheet-proforma that will be used to record the various observations.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

	• The second objective states a comparison between TNBC versus non-TNBC patients. What would be the sample size of each group- 100 or 200? Kindly state. • Also mention clearly in methodology section as how will you approach each objective clearly. • What are the chronic immunological disorders that need to be excluded ? Kindly state. • It is stated in hypothesis section that "in a related study m-RNA expression will be analyzed in fresh biopsy tissue sample" Is this ethically approved or will it be submitted? Since this seems to be a prospective study, the current submission being retrospective (based on blocks) seems different. Kindly clarify. • Kindly attach pre-designed proforma as indicated in data management section. • Briefly mention the summary of anticipated statistical analysis **EC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: 123rdECM IIA/P4***
5.	Research proposal entitled "***Comparative study between the outcome of endoscopic type I tympanoplasty (Double Door Technique) and microscopic type I tympanoplasty (Interlay Technique)***" submitted by Dr. Rajat Jain, Assistant Professor, Department of Otorhinolaryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1156/ENT/23 dated 16th March, 2023. **EC Decision:** Approved ***Ref. code: 123rdECM IIA/P5***
II-B	**New Ph. D. proposal**
1.	Research proposal entitled "***Role of neuroinflammation in the progression of neurodegenerative disorders and identification of novel drug targets***" submitted by Dr. Saniya Ansari, Ph.D Scholar under the guidance Prof. Shailendra Kumar Saxena, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/1080/23 dated 28th February, 2023. ***Recommendation of Primary reviewer:*** • Details of sample size calculation shall be provided. • Age of the subjects to be included in the study not mentioned. • It is not clear from the contents if CSF samples will also be collected from the controls too? • Inclusion and exclusion criteria for the controls not given. • Prof. Hardeep Singh is mentioned as an Expert and he will also be participating in the study by recruiting patients. How can an expert participate in the study? **EC Comment:** As above **EC Decision:** Revise & re-submit. Give changes done in a tabular form ***Ref. code: 123rdECMIIB-Ph.D/P1***
2.	Research proposal entitled "***Deciphering the role of novel metastatic genes in epithelial to mesenchymal transition of oral squamous cell carcinoma cell (OSCC)***" submitted by Mr. Dharmendra Kumar, Ph.D. Scholar Batch 2020 under the guidance Dr. Satyendra Kumar Singh, Additional Professor, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/1088/23 dated 13th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	March, 2023. **EC Decision:** Approved ***Ref. code: 123rd ECMIIB-Ph.D/P2***
II-B	**Women Scientist**
1.	Research proposal entitled "***Role of nasal douching technique in the management of allergic rhinitis***" sponsored by DHR submitted by Dr. Shruti Agnihotri through her Mentor Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 260/ResMed/23 dated 3rd March, 2023. ***Recommendation of Primary reviewer:*** • The objective indicates nasal douching only while methodology also includes Pranayam (yoga). Kindly clarify. • The second objective estimates the effect of anti-allergic medication while case study form does not record any institution of medication. Kindly rectify • Similarly the fourth objective estimates effect on quality of life but no such recording is shown in case study form. • Kindly clarify first two points of inclusion criteria. It seems that patients of allergy rhinitis with or without asthma both will be included. Mention clear-cut the diagnostic criteria. • Kindly show the steps of sample size calculation to make it more clear • In data management and analysis kindly mention 'all the parameters' and "different types of intervention at different times". • The technique of nasal douche used in the study may be briefly described in methodology section. • As per the section on "benefit and significance of study" will a 30 minute yoga practice be done in every patient- If yes, then include this in methodology before also. • What would be included in the standard medical treatment? kindly brief. **EC Comment:** As above **EC Decision:** Revise & re-submit. Give changes done in a tabular form ***Ref. code: 123rd ECMIIB-WS/P1***
II-C	**Review of New Drug Trial**
1.	Research protocol no.RCLS-CIP-01 entitled "***A prospective open-level, single arm, interventional, multicentric, pilot study to evaluate the safety and effectiveness of OZYN-D, a novel intraosseous device for delivery of medications and fluids***" sponsored by M/s Rcupe Life Sciences Pvt. Ltd. submitted by Prof. Sandeep Tiwari, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow, vide letter no. TS/188/2023 dated 13th March, 2023. ***Recommendation of Primary reviewer:-*** • In SOP-Checklist-point-3–Clinical Trials–(ii)-is this device approved and marketed in India–PI mentioned-NA–PI is required to clarify • Point -6- Confidential handling of data – not ticked YES • Insurance to be renewed (it is upto-21-04-2023) • DCGI acknowledgment and permission letter awaited (if required)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

	• CTRI document to be send after registry **EC Comment:** • As above **EC Decision:** Revise & re-submit. Give changes done in a tabular form ***Ref. code: 123rdECMIIC/P1***
2.	Research protocol no. HBI-8000-303 entitled "***A multicenter, randomized, double-blind phase 3 study of HBI-8000 combined with nivolumab versus placebo with nivolumab in patients with unresectable or metastatic melanoma not previously treated with PD-1 or PD-L1 inhibitors***" sponsored by M/s Huyabio International, LLC submitted by Dr. Shiv Rajan, Associate Prof. Department of Surgical Oncology, King George's Medical University, U.P., Lucknow, vide letter no. SONC/590/2023 dated 31st March, 2023. ***Recommendation of Primary reviewer:*** • Budget not mentioned in CTA document. **EC Comment:** • As above **EC Decision:** Approval subject to modification ***Ref. code: 123rdECMIIC/P2***
3.	Research protocol no. CKJX839D12302 entitled "***A randomized, double-blind, placebo-controlled multicenter study to evaluate the effect of inclisitan on preventing major adverse cardiovascular events in high-risk primary prevention patients (VICTORION-1 PREVENT)***" sponsored by M/s Novartis Healthcare Private Limited submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 723/Cardio/Res/23 dated 31st March, 2023. ***Recommendation of Primary reviewer:*** Approved ***The following documents were reviewed in the Meeting:***

Sr. No.	Title
1.	Clinical Trial Protocol Version 00 (Original Protocol) dated 12-Dec-2022
2.	Investigator's Brochure KJX839/Inclisiran edition 16 dated 30-Nov-2022
3.	Case Report Form 0.16_CKJX839D12302_17Jan2023(UAT) Unique
4.	Insurance Certificate for period of 1st January 2023 to 31st December 2023
5.	SUSAR Line listings: CKJX839 (L1) SUSAR(s) 01APR2022 30SEP2022 BLINDED ALL Arms (CT)
6.	Audio Visual Consent Form V1.0 dated 01/Apr/2021 in English
7.	Audio Visual Consent Form V1.0 dated 01/Apr/2021 translated from English to Hindi on 23 June 2021

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

8.	Informed Consent Form: Core ICF V1.0 dated 22 Dec 2022 back translated from Hindi to English 20 Jan 2023
9.	Translation and Back translation certificate: Core ICF V1.0 dated 22 Dec 2022 • Hindi
10.	Informed Consent Form: Optional Genetics ICF V1.0 dated 22 Dec 2022 in English
11.	Informed Consent Form: Optional Genetics ICF V1.0 dated 22 Dec 2022 translated from English to Hindi on 13 Jan 2023
12.	Informed Consent Form: Optional Genetics ICF V1.0 dated 22 Dec 2022 back translated from Hindi to English 18 Jan 2023
13.	Translation and Back translation certificate: Informed Consent Form: Optional Genetics ICF V1.0 dated 22 Dec 2022 • Hindi
14.	Informed Consent Form: Pregnant participants ICF V1.0 dated 22 Dec 2022 in English
15.	Informed Consent Form: Pregnant participants ICF V1.0 dated 22 Dec 2022 translated from English to Hindi on 13 Jan 2023
16.	Informed Consent Form: Pregnant participants ICF V1.0 dated 22 Dec 2022 back translated from Hindi to English 20 Jan 2023
17.	Informed Consent Form: Core ICF V1.0 dated 22 Dec 2022 back translated from Hindi to English 20 Jan 2023
18.	Translation and Back translation certificate: Core ICF V1.0 dated 22 Dec 2022 • Hindi
19.	Informed Consent Form: Optional Genetics ICF V1.0 dated 22 Dec 2022 in English
20.	Informed Consent Form: Optional Genetics ICF V1.0 dated 22 Dec 2022 translated from English to Hindi on 13 Jan 2023
21.	Translation and Back translation certificate: Informed Consent Form: Pregnant participants ICF V1.0 dated 22 Dec 2022 • Hindi

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

	22.	Patient Card V3.0 in English
	23.	Patient Card V3.0 translated from English to Hindi on 10 June 2021
	24.	Patient Card V3.0 back translated from Hindi to English 15 June 2021
	25.	Translation and Back translation certificate: Patient Card V3.0 • Hindi
	26.	Thank you Letter_End of the study_Version 2.0 dated 16 Nov 2021 in English
	27.	Thank you Letter_End of the study_Version 2.0 dated 16 Nov 2021 translated from English to Hindi on 27 Jan 2023
	28.	Thank you Letter_End of the study_Version 2.0 dated 16 Nov 2021 back translated from Hindi to English 30 Jan 2023
	29.	Translation and Back translation certificate: Thank you Letter_End of the study_Version 2.0 dated 16 Nov 2021 • Hindi
	30.	VICTORION-1 PREVENT_Poster_V1 10Jan23_English
	31.	VICTORION-1 PREVENT_Patient information brochure_V1_10Jan23_English
	32.	VICTORION-1 PREVENT_Study visit guide_V1_10Jan23_English
	33.	VICTORION-1 PREVENT_Patient ID_V1_10Jan23_English
	34.	CKJX839 (L1) SUSAR(s) 01OCT2021 31MAR2022 BLINDED ALL Arms (CT)
	35.	CTRI
	36.	Global template for Clinical Trial Agreement
	EC Decision: Approval subject to fulfillment & Administrative formalities ***Ref. code: 123rd ECMIIC/P3***	
4.	Research protocol no. NN9838-4942 entitled "***Re-REDEFINE 3: The cardiovascular safety of cagrilintide 2.4 mg.s.c. in combination with semaglutide 2.4 mg s.c. (CagriSema 2.4 mg/2.4 mg.s.c.) once-weekly in participants with obesity and established cardiovascular disease***" sponsored by M/s Novo Nordisk India Private Limited submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 722/Cardio/Res/23 dated 31st March, 2023. ***Recommendation of Primary reviewer:*** • Section on subject selection has been left blank including of subjects/Vulnerable	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	and special group subjects and type of subjects. • Section on Use of Biological Materials mentions that blood samples will be sent abroad but details of laboratory and reason thereof are not given. **EC Comment:** • As above **EC Decision:** Approval subject to modification. ***Ref. code: 123rdECMIIC/P4***
III-A	**Additional Document**
1.	Additional of research protocol no. EX6018-4758 entitled "**ZEUS-** ***effects of ziltivekimab versus placebo on cardiovascular outcomes in participants with established atherosclerotic cardiovascular disease, chronic kidney disease and systemic inflammation***" sponsored by M/s Novo Nordisk India Private Ltd. submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 704/Cardio/Res/23 dated 28th March, 2023. ***Recommendation of Primary reviewer:*** Approved ***The following documents were reviewed in the Meeting:-***

S.No.	Documents
1.	**1.1** Protocol Version 5.0 dated 17-Feb-2022 **1.2** Protocol v2 to v5 track changes **1.3** Protocol attachment 1 edition 3.0
2.	**2.1** Subject Information/Informed Consent Form Version 3.0 IN_EN dated 01 Mar 2022 Status: Final **2.2** Subject Information/Informed Consent Form Version 3.0 IN_HI dated 04 Mar 2022 Status: Final **2.3** Subject Information/Informed Consent Form Version 3.0 IN_HI_BT dated 04 Mar 2022 Status: Final
3.	**3.1** Subject Information/Informed Consent Form for Optional Pre-screening Version 4.0 IN_EN dated 01 Mar 2022 Status: Final **3.2** Subject Information/Informed Consent Form for Optional Pre-screening Version 4.0 IN_HI dated 04 Mar 2022 Status: Final **3.3** Subject Information/Informed Consent Form for Optional Pre-screening

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Version 4.0 IN_HI_BT dated 04 Mar 2022 Status: Final
	4.	Inclusion exclusion criteria version v2.0 dated 14 Feb 2022
	5.	Protocol general guidance on TB risk v2.0 dated 11 Feb 2022
	6.	Event adjudication committee charter v2.0 dated 16 Feb 2022
	7.	ZEUS Study App Amendment 1 dated 15 Feb 2022
	8.	**8.1** Other info to Subjects 4758 Health tracker outline v1.0 dated 19-Apr-2021 **8.2** Other info to subjects 4758 Health tracker sample report master
	9.	**3.1** Subject Information/Informed Consent Form for Optional Pre-screening Version 4.0 IN_EN dated 01 Mar 2022 Status: Final **3.2** Subject Information/Informed Consent Form for Optional Pre-screening Version 4.0 IN_HI dated 04 Mar 2022 Status: Final **3.3** Subject Information/Informed Consent Form for Optional Pre-screening Version 4.0 IN_HI_BT dated 04 Mar 2022 Status: Final
	EC Decision: Approved ***Ref. code: 116th ECMIIC/P1***	
III-B	**Modification**	
1.	Modification of research protocol no. EX9536-4773 entitled "***Effect of semaglutide 2.4 mg once-weekly on function and symptoms in subjects with obesityrelated heart failure with preserved ejection fraction, and type 2 diabetes***" sponsored by M/s Novo Nordisk India Pvt. Ltd. submitted by Dr. Pravesh Vishwakarma, Prof. Junior Grade, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 660/Cardio/Res/23 dated 4th March, 2023. ***Recommendation of Primary reviewer:*** Approved ***The following documents were reviewed in the Meeting:-*** 1. Summary of changes table. 2. Protocol v7.0 dated 09 Sep 2022 3. Six minute Walk Test, v2.0, IN_EN, dated 26 July-2022 4. Six minute Walk Test, v2.0, IN_HI, dated 26 Sep-2022 5. Translation certificate-IN_HI 6. Six minute Walk Test, v2.0, IN_HI_BT, Dated 26 Sep-2022 7. Translation certificate-IN_HI_BT **EC Decision:** Approved ***Ref. code: 113th ECMIIC/P4***	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

IV	Other Matter with the permission of Chair
1.	Principal-Investigator wants to correct her title because she spelled it wrong in the proposal which was approved by the 120th EC Meeting held on 21st December, 2022, submitted by Prof. Anjoo Agarwal, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/39/23 dated 5th April, 2023. Previous title *"Maternal near miss review (MNM-R) and corrective measures at selected tertiary hospitals in India"*. Correct title *"Indian Near Miss Registry: Incidence of Late Maternal Death & Non-communicable disease following potential life-threatening event during pregnancy and child birth: A cohort study"*. **EC Decision:** Kindly submit the full proposal for review ***Ref. code: 120th ECM IIA/P9***
V	**Brought to Ethics Committee after XVII-PGTSC held on 26th May, 2023.**
	Minutes of XVII-PG Thesis sub Committee of "Institutional Ethics Committee" Meeting held on 12th April, 2023 from 3:00 PM *virtual.* ***The following Members were present in the Meeting:-*** 1. Dr. G.G. Agarwal -Member 2. Dr. A.A. Mahdi -Member 3. Dr. Rajendra Nath -Member 4. Dr. D.N. Upadhyaya -Member 5. Dr. Nisha Mani Pandey -Member 6. Dr. Shally Awasthi -Convener ***The following Member was not present in the Meeting:-*** 1-Dr. Anita Rani was not presents in the Meeting-Send her written comment
I-A	**Action taken**
1-	Clarification of research proposal entitled *"Morphological and morphometric analysis of right atrium and interatrial septum-a human autopsy study"* submitted by Dr. P. Yeshwanthi, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 665/ANAT/23 dated 10th March, 2023. ***Previous EC Comment:*** • Consent form needs to be corrected. It is an autopsy study so the consent cannot be in the first person. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIII-PGTSC-IIA/P12***
2-	Clarification of research proposal entitled *"A study of Cardiometabolic risk factors in non alcoholic steatohepatitis patients"* submitted by Dr. Shalini Suri, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

426/PHY/23 dated 14th March, 2023.

Previous PGTSC Comment	PI response
The "Study hypothesis" and "Aims & Objectives" do not match.	Attached separately
After identifying the study variables and study parameters, the objective should be converted into research hypothesis in terms of the study parameters.	Attached separately
The sample size calculation is arbitrary. It should be specific to the research hypothesis.	Attached separately
Statistical analysis section is missing.	Attached separately

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XIV-PGTSC-IIA/P15

3- Clarification of research proposal entitled ***"Effect of red blood cell storage duration on cerebral blood oxygenation in elective cranial surgery: A prospective randomized controlled study"*** submitted by Dr. Anjali Kumari, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/230/23 dated 6th March, 2023.

Previous PGTSC Comment	PI response
In Scientific Review Committee –one Co-guide's (Dr. Hemlata) name is there- please justify.	We are thankful to reviewer for paying attention towards this inconsistency. Now as per suggestion, modification has been made to scientific review committee.
Departmental names against two Co-guides (Prof. B K Ojha and Prof. Tulika Chandra) are wrongly mentioned in Investigator detail page- please corrects.	We are thankful to reviewer for paying attention towards this inconsistency. Departmental names have been corrected: Prof. B K Ojha- Department of Neurosurgery Prof. Tulika Chandra- Department of Transfusion Medicine

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

As this is Randomized Controlled study, therefore Flow chart of methodology should be included.	We are thankful to reviewer for paying attention towards this inconsistency. Now as per suggestion, flow chart of methodology has been added.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XIV-PGTSC-IIA/P29

4- Clarification of research proposal entitled ***"Comparision between video laryngoscopy and direct laryngoscopy for tracheal intubation in Pediatrics patients with hydrocephalus: A randomized control study"*** submitted by Dr. Mona Nayak, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/231/23 dated 6th March, 2023.

Previous PGTSC Comment	PI response
PI sheet not related to study –should be revised	Attached separately
As this is Randomized control study, PI should submit flow chart.	CONSORT flow chart attached separately
	ICF consent form attached separately
Assessment scales not attached	Attached separately

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XIV-PGTSC-IIA/P30

5. Clarification of research proposal entitled ***"Sonographic predictors of adverse outcome in pregnancy complicated by hyperglycemia in pregnancy"*** submitted by Dr. Aayushi Saini, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/210/23 dated 16th March, 2023.

Previous PGTSC Comment:

- Questionnaire not attached
- Case record form–not given

The above Comment forwarded to PI was reviewed by PR:-

Second recommendation of PR:	PI response
PI may kindly be advised to look in her methodology section of her proforma- that reviewer is quoting "Information on age, education, parity, occupation, income and obstetrics history was	This study prospective observational study not required questionnaires in this study. Only using a case record proforma.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	obtained from mother using a questionnaire. |
	The above Comment forwarded to PI was reviewed by PR:- ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P36***
6-	Clarification of research proposal entitled ***"Efficacy of transdermal buprenorphine in management of pain in children with cancer: A prospective observational study"*** submitted by Dr. Simran Kapoor, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 885/Ped/23 dated 16th March, 2023.

Previous PGTSC Comment	PI response
Guardian consent form –E/H not similar–should be revised.	Attached separately
Separate Child Assent Form should also be submitted.	Attached separately

	The above Comment forwarded to PI was reviewed by PR:- ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P42***
7-	Clarification of research proposal entitled ***"To compare efficacy between I/V pentaglobin and I/V vitamin C in sepsis of burn patients: A prospective randomized study"*** submitted by Dr. Naveen Kumar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 1532/Anaes/23 dated 15th March, 2023. **Previous PGTSC Comment:-** Consent form needs correction as it is mentioned that informed consent will be taken from the patient. When the patient will be on a ventilator then how can that be done? ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P85***
8-	Clarification of research proposal entitled ***"Comparing the efficacy of sphenopalatine ganglion block with palatal block for analgesia in children with cleft palate undergoing palatoplasty under general anesthesia: A randomized control study"*** submitted by Dr. Priya Tiwari, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/232/23 dated 6th March, 2023. **Previous PGTSC Comment:** • References mentioned in the text are not given in the bibliography and those in the bibliography are not cited in the text. ***The above Comment forwarded to PI was reviewed by PR:-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of PR: Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P93***
9-	Clarification of research proposal entitled ***"Study of menstrual irregularities and disorders and its impact on quality of life (QOL) in medical undergraduates"*** submitted by Dr. Deepa Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/01/23 dated 1st April, 2023. **Previous PGTSC Comment:** • The study is on the evaluation of Quality of Life (QOL) instrument. • There is checklist for evaluating such scales. • Where the items come from? Were they assessed for (i) comprehension, (ii) lack of ambiguity? • Was the scale checked for internal consistency: Does it have good test-retest reliability? • Has the instrument been checked for any kind of validity? • The sample size calculation is arbitrary. It should be based on reliability coefficient. ***The above Comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XV-PGTSC-IIA/P2***
10-	Clarification of research proposal entitled ***"Evaluation of plasma OREXIN-A, inflammatory cytokines and reductive stress in patients with idiopathic and atypical parkinsonism"*** submitted by Dr. Prashant Pandey, JRI, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/1164/23 dated 16th March, 2023.

Previous PGTSC Comment	PI response
This is prospective cohort study.	This is a comparative cross-sectional study. Neither the patients nor the controls will be followed-up. The controls are solely for the purpose of comparison.
Define the two cohorts exclusively.	This is a comparative cross-sectional study with two groups: a. patients with idiopathic/atypical parkinsonism b. healthy controls
Identify one primary objective and classify the rest into secondary objectives.	Changes have been made accordingly in the attached copy of thesis proforma.
Convert the primary objective into research hypothesis in terms of study parameters.	Research hypothesis has been added in the attached copy of thesis proforma (on page 19)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Sample size calculation and statistical analysis should be in coherence with the research hypothesis.	Sample size calculation and statistical analysis is updated and is in coherence with the research hypothesis.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P5

11- Clarification of research proposal entitled ***"Combination therapy of standard antidepressant with oral ketamine as first-line therapy in late-life depression: A open-label trial"*** submitted by Dr. Shubha Joshi, SRI, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 107/DGMH/23 dated 16th March, 2023.

Previous PGTSC Comment	PI response
Sampling technique (purposive sampling) is not correct.	**The study objectives have been revised.** Objectives of the study: 1) To assess and compare the safety and efficacy of combination therapy of a standard anti-depressant and oral ketamine with the standard anti-depressant therapy alone in late-life depression. 2) To assess the association between depressive symptoms and/or treatment response and blood biomarkers in the active group and control group. **For Clarification** [Sample calculation has been done using the G-power. Considering the methodology of the protocol the test family assumed to be used is taken as F-test with repeat measure ANOVA (within–between interaction). The effect size of 0.25 and power of 0.95 is kept with a 95% confidence interval. For the two groups assessed **for 4 observations**, a total sample size of 36 is calculated (at least 18 in each group). Accordingly, considering the drop rate of 20%, the total number of patients proposed to be recruited would be 44 (22 in each group).
Sample size calculation is inconsistent to the objective of the study.	Consecutive sampling will be used.
Sample size calculation and statistical analysis should be in coherence with the research hypothesis.	The study objectives have been revised. For clarification: The sample size calculation is mentioned above.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Since we are assessing and comparing the safety and efficacy **Safety:** A side effect checklist will be applied in the active and control groups. (already mentioned in the assessment schedule) **Efficacy:** Decline in the severity rating scale for depression: HAM-D Score and GDS score. Baseline group differences will be assessed by the Independent t-test. Change in severity Scores over time will be assessed by Repeat Measure ANOVA.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P8

12- Clarification of research proposal entitled ***"Effect of black coffee and green tea on plasma C-peptide level and fasting blood glucose level in apparently Healthy adults"*** submitted by Dr. Anupam Mittal, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3028/PHY/2023 dated 28th March, 2023.

Previous PGTSC Comment:-

- This seems to be a comparative study between two groups.
- These two groups are not mentioned anywhere in "aim and objectives".
- Identify these two groups exclusively.
- Define aims and objectives, research hypothesis, study design etc. after identifying these comparative groups.
- Sample size calculation and statistical analysis should be in coherence with the research hypothesis.

P ***The above Comment forwarded to PI was reviewed by PR:-***
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P10

13- Clarification of research proposal entitled ***"Randomised, single blind, control trial of transcranial direct current stimulation in adolescents with major depressive disorder as early augmentation"*** submitted by Dr. Saumya Upadhyay, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 519/Psy/23 dated 28th March, 2023.

Previous PGTSC Comment	PI response

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

How will consent be taken, if patient is blind? Please clarify.	Consent will be taken from the guardian and assent from the patient for enrollment of the patient in either of the study groups, i.e. test arm or control arm. However, the patient will not be aware of the category of their group, hence ensuring blinding.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P13

14- Clarification of research proposal entitled ***"A comparative analysis of extra hepatic biliary system anatomy during laparoscopic cholecystectomy with and with and without biliary mapping using methylene blue"*** submitted by Dr. Ravendra Kumar, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3604/ 23 dated 31st March, 2023.

Previous PGTSC Comment	PI response
Is use of Methyline blue a standard procedure for intra operative	Methylene blue(MB) is a diaminophenothiazine with a long history of clinical use due to its minimal side effect profiles. MB currently is used for treatment of methemoglobinemia, carbon monoxide poisoning, and vasoplegic syndrome as well as for surgical staining. MB could diffuse rapidly into brain and accumulate in the cytoplasm and mitochondria of neurons. In recent years its role as a mitochondrial protective agent has elicited much of its renewed interest, especially, studies have shown that MB has established its neuroprotective effects against ischemic stroke, post-chemotherapy-induced Encephalopathy and neurodegenerative diseases caused by Alzheimer's disease(AD) and psychoses. To date, there is no trials have examined the role of intraoperative MB administration in prevention of POD and POCD in elderly patients undergoing non-cardiac surgery, who have preoperative normal neurocognitive function. It 's an entirely novel therapy for postoperative neurocognitive disorders and will have high clinical translatable value if this intervention is found to be beneficial.
The review of literature mentions that in difficult laparoscopic cases methyene tracking of EBA is helpful with positive outcome. Kindly justify the need of study.	Attached separately

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Kindly clarify the number of participants: 200 or 50, the steps of calculation are not complete.	Total 200 cases included in the study sample size attached.
	Provide Details of surgical procedure.	Attached separately
	ICF: Please explain study procedure to patient in easy language.	Attached separately

Previous PGTSC Comment:-
The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P14

15- Clarification of research proposal entitled ***"Role of endocrine disrupting chemical (BISPHENOLA) in the etiopathogenesis of PCOS"*** submitted by Dr. Smriti Yadav, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/5228/2023 dated 29th March, 2023.

Recommendation of Primary reviewer:

- ICF: Kindly explain the procedure to the study participants.

Previous PGTSC Comment:-
The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P16

16- Clarification of research proposal entitled ***"Relationship between hand dexterity function and brain regional volumetry in patients of cognitive impairment-A cross sectional study"*** submitted by Dr. Roshni Basu Roy, SRI, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 100/DGMH/23 dated 13th March, 2023.

Previous PGTSC Comment	PI response
Is functional MRI in respect to treatment decision or prognosis, beneficial for the patient having cognitive impairment? If not, then the patient must be informed that this investigation is not a routine process and he/she has to express the willingness to participate in the study.	There is no mention of Functional MRI in this study protocol. In this study we will do Structural MRI Brain which is much beneficial for treatment decision and assessing prognosis of the patients of cognitive impairment .
Please mention clearly that what is the cost of investigation and who will bear it? Patient or	Structural MRI Brain done in Radiology Department of KGMU costs Rs 3500 per subject. This investigation is commonly done in our

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

investigator. It should be clearly mentioned in the ICF.	Department in the management of patients of cognitive decline. In view of this if the patient agrees to bear the cost for this investigation for his/her treatment benefits then he/she will bear the cost, otherwise the investigator will bear the cost of this investigation. This point is included in the ICF.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P20

17- Clarification of research proposal entitled ***"To evaluate the predictors of extent and pattern of response to neoadjuvant chemotherapy in breast cancer with emphasis on MAGEE3 equation"*** submitted by Dr. Shehla Fayyaz, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 297/23 dated 13th March, 2023.

Previous PGTSC Comment	PI response
Design of study is mentioned as retrospective in the cover letter and retrospective ad prospective in the Material and Methods section. Please clarify.	The error has been rectified in the cover letter and the study would be retrospective and prospective observational study .
Sample size is mentioned as 200 at one place and 125 at another.	This has been a typographical error and it has been rectified in annexure I. Sample size is 125
PI has asked for consent waiver but the design of study is prospective with consent and collection of date being done in prospective manner.	The study would be retrospective and prospective so waiver of consent has been requested for retrospective cases and consent will be taken in prospective cases.
The PI has also included a consent form in the proforma.	As the study would be retrospective and prospective, the consent form has been included for prospective cases.
Consent cannot be waived if patients are involved in the study.	Patients won't be involved directly. The slides which have been already prepared from paraffin blocks for routine reporting will be reviewed. We will ensure that the slides will be coded and anonymity of data is maintained and can't be linked, relinked to the identifiable human

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

		subject. The cases will be observed by the PI and Co-PI only.

The above Comment forwarded to PI was reviewed by PR:-
Second recommendation of PR:

- The study cannot be BOTH retrospective & prospective. Please choose one design of study.
- Since patient tissue is being used it will require patient consent whether prospective or retrospective. Consent CANNOT be waived unless the study is on anonymized data.

The above Comment forwarded to PI:- Reply pending by PI
PGTSC Decision: Reminder forward to PI.

Ref. code: XV-PGTSC-IIA/P21

18- Clarification of research proposal entitled ***"Quantification of level of endotoxins and lipoteichoic acid (LTA) after photodynamic therapy (PDT) in teeth with secondary endodontic infection: A clinical study"*** submitted by Dr. Dhaniba. K.C, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.05/Coms & Endo/23 dated 5th April, 2023.

Previous PGTSC Comment	PI response
The study has six investigators from the same department, including the PI, with overlapping roles. Please reduce the number of Co-PIs or define their individual roles.	Defined the individual role of Co-PIs and copy attached.
The IEC form is incompletely filled.	The IEC form filled completely and copy attached.
Please fill the form properly and re-submit.	Form filled and copy attached.
Consent form does not have contact details/phone number of PI/Co-PI.	Contact details/phone number of PI added and copy attached.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P22

19. Clarification of research proposal entitled ***"Outcome analysis of pituitary adenoma patients: a retrospective study of last 5 years at a tertiary care centre"*** submitted by Dr. Sanjeev Kumar, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/586 dated 27th March, 2023.

Previous PGTSC Comment	PI response
Design of the study is mentioned as retrospective but data is also being collected prospectively from patients.	Yes, this study is a retrospective study (duration-2018-2023) All patients diagnosed with pituitary

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	adenoma and treated surgically in last 5 years at our centre will be included. If follow up data of these patients are not available in our records, then follow up data and current status will be completed by calling them.
No sample size is mentioned in the study.	All cases will be included in study, which were treated for pituitary SOL at KGMU during last five years. A sample size of even 50 patients will be enough for meaningful results.
Patients are being subjected to repeat scanning on follow-up for the study. Who will bear the cost of the scans if the scan is not part of the standard follow-up protocol?	Repeated scanning is part of standard follow up protocol for Pituitary patients and cost will be born by patient themselves.
Vulnerable subjects' section has to be filled in by the PI.	No vulnerable subjects are included in the study. New IEC form (filled) attached separately.

The above Comment forwarded to PI was reviewed by PR:-

Recommendation of PR:

- No sample size is mentioned.
- No sample size calculation has been done.
- PI has mentioned no vulnerable subject are being used, however, the IEC form has different vulnerable subjects ticked in it. Please clarify.

The above Comment forwarded to PI:- Reply pending by PI

PGTSC Decision: Reminder forward to PI.

Ref. code: XV-PGTSC-IIA/P23

20- Clarification of research proposal entitled ***"Effects of equiosmolar 3% hypertonic saline, 8.4% sodium bicarbonate and 20% mannitol on intracranial pressure and metabolic changes in patients undergoing supratentorial craniotomy & tumors excision: A prospective, randomized controlled study"*** submitted by Dr. L.P. Huimila, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1402/23 dated 1st April, 2023.

Previous PGTSC Comment	PI response
Number of subjects not mentioned in the IEC form.	As per your advice new IEC form attached separately.
Section on vulnerable subjects, special group subjects and biological and hazardous material not filled.	As per your advice new IEC form attached separately.
Sample size mentioned as 9(30x3) but sample size calculation has not been done.	Sample size calculation attached separately.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P25

21- Clarification of research proposal entitled ***"Outcome analysis of adult patients with tubercular meningitis and sequale managed medically and surgically: A prospective study"*** submitted by Dr. Bishal Paul, SR, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/585 dated 27th March, 2023.

Previous PGTSC Comment	PI response
The project has 6 Investigators form one department and three from other making a total of nine.	The Investigator list has been revised. Two authors have been removed. The list is Attached separately.
The Secretary IEC kindly takes a call on this.	Attached separately
Sample size calculation is 139.	Corrections done in the IEC form attached separately.
How many subjects will be recruited for the study has not been mentioned in the IEC form.	Yes, Attached separately.
Section on 'Use of Biological material' has been incompletely/incorrectly filled as CSF samples/sputum samples are being collected.	Corrections done in the IEC form attached separately.
Recruitment form both sexes has been marked as 'No'. Will only males or females be recruited for the study?	Corrections done in the IEC form attached separately.

The above Comment forwarded to PI was reviewed by PR:-
Third recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P27

22- Clarification of research proposal entitled ***"Cross sectional study of intraoperative monitoring of evoked potentials during elective neurosurgeries"*** submitted by Dr. Deep Shikha, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3051/PHY/23 dated 6th April, 2023.

Previous PGTSC Comment:

- Sample size is given as 100 but sample size calculation has not been done.
- For patients above 2 years and below age of maturity, Assent form is required.

The above Comment forwarded to PI was reviewed by PR:-
Third recommendation of PR: Approved
PGTSC Decision: Approval ratified

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

Ref. code: XV-PGTSC-IIA/P28

23- Clarification of research proposal entitled ***"Association between exercise capacity and health markers in adolescents"*** submitted by Dr. Chandra Mani, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 687/PHY/23 dated 14th March, 2023.

Previous PGTSC Comment:

- Since the study is on subject with an age range of 12-18 years and Assent form for children must be included in the proforma.

The above Comment forwarded to PI was reviewed by PR:-

Third recommendation of PR: Approved

PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P29

24- Clarification of research proposal entitled ***"Nerve conduction velocity of sural nerve in type 2 diabetic patients"*** submitted by Dr. Lavkush Maurya, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 510/PHY/23 dated 15th March, 2023.

Previous PGTSC Comment	PI response
Special group subjects are ticked but details are not given in the IEC form.	New IEC form attached separately.
Direct identifiers are being used with confidential handling of data.	Attached separately.
Sections on Consent and Risks and Benefits are incompletely filled.	Attached separately.
Sample size calculation has not been done.	Attached separately.

The above Comment forwarded to PI was reviewed by PR:-

Third recommendation of PR: Approved

PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P30

25- Clarification of research proposal entitled ***"Effect of lemon TEA and Black coffee on heart rate variability and blood pressure recovery time of the moderate exercise"*** submitted by Dr. Pradeep Kumar Chauhan, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3038/PHY/23 dated 1st April, 2023.

Previous PGTSC Comment:-

- Objectives of the study not written properly – need to be revised.
- Subjects to be included in the study not defined.
- Inclusion and exclusion criteria for recruitment of subjects not given.
- Sample size calculation not included.
- No references included or listed.
- Consent form to be specific for the study.

The above Comment forwarded to PI was reviewed by PR:-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

Recommendation of PR:

- There are many problems with the proposal.
- In the material and methods section the duration of giving beverages (tea/coffee) to the volunteers is not mentioned.
- References given in bibliography are not mentioned anywhere in the text (in introduction/ review of literature etc.). Some references given in text are not listed in bibliography (Gonzaga et al. 2017, Niranjan et al. 2008 and Clark et al. 2020).
- Sample size calculation is not given.

PGTSC Decision: Approval subject to modification. Give changes done in a tabular form.

Ref. code: XV-PGTSC-IIA/P31

26- Clarification of research proposal entitled ***"Blood stream associated Hospital acquired infection in a Paediatrics population: A tertiary care hospital experience"*** submitted by Dr. Mohd Junaid Khan, JR, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1682/23 dated 13th March, 2023.

Previous PGTSC Comment	PI response
No references included or listed.	References have been added.
Consent form needs to be corrected. It shall be from the parent or legal guardian of the child.	New consent form attached.

The above Comment forwarded to PI was reviewed by PR:-
Third recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P32

27- Clarification of research proposal entitled ***"Assessment of Psychological Health of Women with gynaecological cancers"*** submitted by Dr. Zaheen Fatima, JR, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. 2020/OB/23 dated 27th March, 2023.

Recommendation of Primary reviewer:

- References not as per any pattern (e.g. Vancouver style etc.)

The above Comment forwarded to PI was reviewed by PR:-
Third recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P33

28- Clarification of research proposal entitled ***"Gender differences in clinical spectrum of spondyloarthritis patients: A clinical observational study in a tertiary health care centre"*** submitted by Dr. Parag Vijayvergia, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/210/23 dated 6th March, 2023.

Previous PGTSC Comment:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

- It is mentioned that the study will be started w.e.f. January 2023. Has the candidate started work without ethical clearance??
- Rest fine, may be approved.

The above Comment forwarded to PI was reviewed by PR:-
Third recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P34

29- Clarification of research proposal entitled ***"Utility of infrared thermoscopy in assessing synovitis in rheumatoid arthritis patients: an observational study"*** submitted by Dr. Nidhish Chandra M, SR, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/207/23 dated 6th March, 2023.

Previous PGTSC Comment	PI response
Under whom Investigations (including biochemical parameters) will be carried out?	No extra investigations will be carried out. Only the biochemical parameters that are routinely done for follow up of Rheumatoid arthritis patients will be collected for the study.
Improper exclusion criteria. Needs to be rechecked.	Made corrections in the exclusion criteria.
It is mentioned that the study will be started w.e.f. January 2023. Has the candidate started work without ethical clearance?	Study will be started after obtaining ethical clearance from the Institute Ethical Committee. Thesis work has not been started till now.

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P35

30- Clarification of research proposal entitled ***"Study of prevalence, progression and response to therapy in connective tissue disease associated disease associated pulmonary artery hypertension"*** submitted by Dr. Lily Kumari, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/208/22 dated 6th March, 2023.

Previous PGTSC Comment	PI response
Please recheck the title	The title will be named as "STUDY OF PREVALENCE, PROGRESSION AND RESPONSE TO IMMUNOSUPPRESSIVE THERAPY IN CONNECTIVE TISSUE DISEASE ASSOCIATED PULMONARY ARTERY HYPERTENSION"
Sample size calculation not included.	It is included in the protocol and will be again highlighted in the attached proforma

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Why is consent not from the patient?	Consent form is already attached in the proforma and will be taken by patients.
It is mentioned that the study will be started w.e.f. December 2022. Has the candidate started work without ethical clearance?	Study will be started after obtaining ethical clearance from the Institute Ethical Committee. Thesis work has not been started till now.

The above Comment forwarded to PI was reviewed by PR:-
Third recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P37

31- Clarification of research proposal entitled ***"Effect of cyclophosphamide on ovarian function in systemic lupus erythematous and comparison with other immunosuppressant-azathioprine and mycophenolate mofetil"*** submitted by Dr. Shweta Bhardwaj, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/209/23 dated 6th March, 2023.

Previous PGTSC Comment	PI response
Sample size calculation not mentioned.	We have planned to include 25 patients receiving cyclophosphamide and 25 patients on azathioprine or mycophenolate mofetil and conduct it as a pilot study.
If the candidate is not sure of getting sufficient number of subjects then make it a pilot study.	Has changed the study design into a pilot study?

The above Comment forwarded to PI was reviewed by PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P38

32- Clarification of research proposal entitled ***"Comparative study of role of hyperbaric oxygen therapy versus traditional modalities for anti-aging therapy"*** submitted by Dr. Mehvesh Khan, SR, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 390/23 dated 17th March, 2023.

Previous PGTSC Comment	PI response
It is mentioned that the study will be started w.e.f. November 2022. Has the candidate started work without ethical clearance?	No, ethical clearance awaited, work has not been started yet.
Sample size calculation not included.	Assuming a pooled standard deviation of 4.31 units, the study would require a sample size of: 8 .For each group (i.e., a total sample size

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

		of 24, assuming equal group sizes), to achieve a power of 90% and a level of significance of 5% (two sided), for detecting a true difference in means between the test and the reference group of 7.31 (i.e. 14.25 - 6.94) units.

The above Comment forwarded to PI was reviewed by PR:-
Third recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P39

33- Clarification of research proposal entitled ***"Institutional experience in liquid based cytology (LBC) in thyroid nodules: comparative analysis with conventional fine needle aspiration smears and evaluation of BRAF V600E and TERT promoter expression By immunocytochemistry in malignant lesions"*** submitted by Dr. Garima Yadav, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 418/23 dated 5th April, 2023.

Previous PGTSC Comment:

- Materials and methods incomplete.

The above Comment forwarded to PI was reviewed by PR:-
Third recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P39

34. Clarification of research proposal entitled ***"Ascitic calprotectin levels in ascetic fluid and its role in diagnosis of spontaneous bacterial peritonitis in adult patients"*** submitted by Dr. Sushil Mishra, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1737/23 dated 27th March, 2023.

Previous PGTSC Comment:

- Although it is mentioned that the study will be conducted in collaboration with the department of Medicine but no Co-PI has been included from that department. Similarly, Surgical Gastro person is there as a Co-PI but the name of that department is missing from study settings.

The above Comment forwarded to PI was reviewed by PR:-
Third recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P42

35. Clarification of research proposal entitled ***"A study of adverse drug effect/adverse drug reactions in patients with obsessive compulsive disorder"*** submitted by Dr. Shivukumar Naik H, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 166/Pharma/23 dated 1st April, 2023.

Previous PGTSC Comment:

- Tools not attached-Please attach mentioned tools

The above Comment forwarded to PI was reviewed by PR:-
Third recommendation of PR: Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P57

36- Clarification of research proposal entitled ***"Clinico-radiological correlation of preoperative high resolution computed tomography temporal bone with per operative findings in chronic otitis media squamosal type"*** submitted by Dr. Srishti Khera, JRI, Department of Otorhinolaryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1532/23 dated 29th March, 2023.

Previous PGTSC Comment	PI response
In Inclusion criteria age specificity has not been mentioned	All patients, who were diagnosed with Chronic Otitis Media Squamosal Type, with or without complications age group of 8-60 years, will be enrolled in the study.
ICF-H/E –Attached but if all age gp pts are to be included then Guardian consent and Child Assent form are also to be submitted -PI to clarify	Assent form attached separately.

The above Comment forwarded to PI was reviewed by PR:-
Third recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P66

37- Clarification of research proposal entitled ***"Study of microvascular density and expression of vascular endothelial growth factor in eyelid and ocular surface tumors"*** submitted by Dr. Priyanka, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 1969/OPH/23 dated 3rd April, 2023.

Previous PGTSC Comment:

- Section on type of subjects/vulnerable subjects/consent is left unfilled.

The above Comment forwarded to PI was reviewed by PR:-
Third recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P71

II-A New Thesis-Resident

1. Research proposal entitled ***"Endocapsular multi-chop vs standard four quadrant chop: per-randomized controlled trial comparing per-operative ultrasound energy used, per-operative complications and postoperative corneal parameters"*** submitted by Dr. Tapan, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 1501/OP/23 dated 15th February, 2023.

Recommendation of PR:

- The fundamentals of performing RCT are not completely Specified:
- Method of randomization , follow-up, outcome event efficacy or effectiveness trial not clear
- Statistical and methodological issues in RCT missing.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

	• Sample size calculation is not clear. It should be done after properly defining the research hypothesis in term of the study population parameter. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XVII-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Role of diet and lifestyle in colorectal cancer (CRC)-A case control study in Lucknow"*** submitted by Dr. Christopher James, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1314/CM/23 dated 9th March, 2023. ***Recommendation of PR:*** • Identify one primary objective, the rest should be put into secondary objectives. • Convert the primary objectives into a proper research hypothesis using the parameters of the study population. • The sample size is arbitrary. Mention the formula used. • How the cases will be matched with controls? • What will be the ratio of matching (1:1 or 1:K)? • The statistical analysis will be for matched study **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XVII-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Randomised controlled trial comparing standard treatment of obstructive sleep apnoea to add-on acetazolamide treatment"*** submitted by Dr. Anurag Ambika Prasad Tripathi, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 551/PCCM/2023 dated 15th March, 2023. ***Recommendation of PR:*** • The fundamentals of performing RCT are not completely Specified. • Random allocation to treatment not given. • Method of randomization not given. • Blinding or masking not given. • Blind assessment of outcome not given. • Loss to follow-up data. How it will be done. • Efficacy or effectiveness trial. Please clarify. • Statistical and methodological issues in RCT. • Sample size calculation is not clear. It should be done after properly defining the research hypothesis in term of the study population parameter. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

	Ref. code: XVII-PGTSC-IIA/P3
4.	Research proposal entitled ***"Predictors of successful weaning and extubation of critically-ill patients on invasive mechanical ventilator"*** submitted by Dr. Mrityunjaya Singh, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 552/PCCM/2023 dated 15th March, 2023. ***Recommendation of PR:*** • Identify one primary objective, and the rest should be grouped into secondary objectives. • Convert the primary hypothesis into a proper research hypothesis in terms of the study population parameters. • This study seems to be developing a "predictor" model. • There are certain guidelines for developing such model. You should cite those here. • The sample size calculation is missing. There is a proper formula for this. Presently it is very arbitrary. • Statistical analysis should be given in detail for developing prediction model. • In Study period (Patient enrolment: 1.5 minimum tentative) is not clear. Kindly explain. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form.
	Ref. code: XVII-PGTSC-IIA/P4
5.	Research proposal entitled ***"Histological evaluation of pulpal response at varying remaining dentin thickness in teeth restored with various restorative materials: An ex vivo study"*** submitted by Dr. Ankita Agarwal, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 614/Cons & Endo/2023 dated 17th March, 2023. ***Recommendation of PR:*** • Identify one primary objective. • In the present form objectives are ambiguous. The outcome event for evaluation of the pulp dentin complex should be clearly identified. • The primary objective should be converted into proper research hypothesis in terms of the study population parameters. • Sample size calculation and statistical analysis section are missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form.
	Ref. code: XVII-PGTSC-IIA/P5
6.	Research proposal entitled ***"Role of amitriptyline versus propranolol in treatment of migraine with calcified neurocysticercosis-an open label randomized controlled trial"*** submitted by Dr. Preeti Gupta, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 126/Neuro/2023 dated 22th March, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th April, 2023

	Recommendation of PR: Approved **PGTSC Decision:** As above ***Ref. code: XVII-PGTSC-IIA/P6***
7.	Research proposal entitled ***"Immediate vs delayed rehabilitation of maxillofacial trauma patient with dental implants- A randomized control trial"*** submitted by Dr. Poonam, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 353/OMSD/2023 dated 18th March, 2023. *Recommendation of PR:* Approved **PGTSC Decision:** As above ***Ref. code: XVII-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Assessment of bone mineral density and stone composition in patients with urolithiasis: A prospective study"*** submitted by Dr. Abhijeet Kumar, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 248/URO/2023 dated 22nd March, 2023. *Recommendation of PR:* • A reference for the stone analysis method shall be provided along with the lab in which it will be carried out. ▪ In the Hindi consent form the name of the institution needs to be corrected, instead of King George's Medical University, "George Medical University" is given. ▪ It is mentioned at many places that the work will start in December 2022, how without ethical clearance study was undertaken. A clarification is needed. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XVII-PGTSC-IIA/P8***
9.	Research proposal entitled ***"Surgical outcome assessment of addition of rivaroxaban in peripherial infrapopliteal arterial occlusion diseases-A prospective cross-sectional study"*** submitted by Dr. Gaurav Joshi, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 386/2023 dated 2nd March, 2023. *Recommendation of PR:* • Sample size calculation formula is given but how many subjects will be recruited is not mentioned. • Hindi consent form needs to be corrected especially the words "damni roda rogon" for arterial occlusion diseases should be changed in easy language. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XVII-PGTSC-IIA/P9
10.	Research proposal entitled ***"Evaluation of etiopathogenesis and outcomes of pleural empyema in tertiary care centre: A prospective observational study"*** submitted by Dr. Sahil Kumar, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 385/2023 dated 3rd March, 2023. ***Recommendation of PR:*** • It is proposed to recruit 150 cases but the basis on which this number has been taken is not mentioned. Sample size calculation shall be included. • It is not clear as to how the outcome of various procedures performed is going to be assessed. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XVII-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Evaluation of drug induced peripheral neuropathy in patients with drug susceptible and drug resistant pulmonary tuberculosis"*** submitted by Dr. Ravikant Sharma, JR, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 132/Neuro/2023 dated 22nd March, 2023. ***Recommendation of PR:*** • Approved **PGTSC Decision:** As above ***Ref. code: XVII-PGTSC-IIA/P11***
12.	Research proposal entitled ***"A study on maternal and perinatal outcome in late term pregnancies"*** submitted by Dr. Preeti Yadav, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/5041/2023 dated 3rd March, 2023. ***Recommendation of PR:*** • Approved **PGTSC Decision:** As above ***Ref. code: XVII-PGTSC-IIA/P12***
13.	Research proposal entitled ***"Prospective randomized control trial to compare the efficacy of decompressive craniectomy with suture duroplasty to non suture duroplasty using oxidized regenerated cellulose in traumatic brain injury"*** submitted by Dr. Samir Kumar Madhukar, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. N/S/45/2023 dated 2nd March, 2023. ***Recommendation of PR:*** • Suggest modification of 'randomized control trial' to randomized controlled study' since 'trial' would require CTRI registration. • Vulnerable subject has been ticked as 'Any other'. **PGTSC Comment:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XVII-PGTSC-IIA/P13***
14.	Research proposal entitled ***"Limbus-insertion distance (LID) of horizontal recti on anterior segment optical coherence tomography (ASOCT) and it's correlation with comitant horizontal strabismus-A pilot study"*** submitted by Dr. Ankita, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 1534/23 dated 2nd March, 2023. ***Recommendation of PR:*** • Assent form required for Children **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XVII-PGTSC-IIA/P14***
15.	Research proposal entitled ***"Evaluation of serum estrogen and serum testosterone levels in patients of primary open angle glaucoma and its correlation with nerve fibre layer thickness"*** submitted by Dr. Divyanshi, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 1538/23 dated 1st March, 2023. ***Recommendation of PR:*** • Sample size calculation has not done. • Proforma appears incomplete. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XVII-PGTSC-IIA/P15***
16.	Research proposal entitled ***"Evaluation of serum pro-brain natriuretic peptide as biomolecular marker for macular and optic disc vascularity and ellipsoid zone integrity in diabetic retinopathy"*** submitted by Dr. Shivani Chaturvedi, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 1540/23 dated 2nd March, 2023. ***Recommendation of PR:*** Approved **PGTSC Decision:** ***Ref. code: XVII-PGTSC-IIA/P16***
17.	Research proposal entitled ***"To assess the role of urinary protein as a risk factor and prognostic marker in patients of acute ischemic stroke at a tertiary care center in northern India"*** submitted by Dr. Akashdeep Sharma, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2067/23 dated 3rd March, 2023. ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XVII-PGTSC-IIA/P17***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

18.	Research proposal entitled ***"A study of clinic-biochemical parameters as prognostic markers in elderly hospitalized patients with sepsis"*** submitted by Dr. Pooja Chaurasiya, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2061/23 dated 3rd March, 2023. ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XVII-PGTSC-IIA/P18***
19.	Research proposal entitled ***"To assess the role of serum vitamin B12 as a risk factor and prognostic marker in patients of acute ischemic stroke at a tertiary care centre in northern India"*** submitted by Dr. Sagar, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2068/23 dated 2nd March, 2023. ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XVII-PGTSC-IIA/P19***
20.	Research proposal entitled ***"To compare between CTP/MELD NA/MELD HDLC/RDW/RDW to platelet ratio as a predictor of short term (30 Day) mortality in cirrhosis of liver"*** submitted by Dr. Shambhavi Sinha, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2066/23 dated 3rd March, 2023. ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XVII-PGTSC-IIA/P20***
21.	Research proposal entitled ***"A study of clinic-biochemical and cardiac profile in snake bite at a tertiary care centre in northern India"*** submitted by Dr. Tarun Pal, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2070/23 dated 3rd March, 2023. ***Recommendation of PR:*** • ICF-H/E–Attached-but as the patients of age group more than 13 yrs. are to be recruited, therefore PI has to submit Child Assent Form in addition to regular ICF. • CRF not attached–Please attach **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XVII-PGTSC-IIA/P21***
22.	Research proposal entitled ***"Clinical and neuroimaging predictors of the occurrence of seizure in patients with SSPE"*** submitted by Dr. Ajeet Kumar Jaiswal, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 2070/23 dated 3rd April, 2023. ***Recommendation of PR:*** • Gone through the proposal. Overall it is fine, however, as many biochemical/pathological

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	investigations, including CSF examination, are part of the project so one person from the Department of Pathology may be included as a Co-PI to supervise the investigative part. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XVII-PGTSC-IIA/P22***
II-B	**Research proposal for STS grant**
1.	Research proposal entitled "***Association of academic stress with memory and attention among medical undergraduates in India: A survey based correlation study***" sponsored by ICMR, New Delhi submitted by Mr. Abhinav Shukla, MBBS 2020 Batch through his Mentor Prof. Bandana Gupta, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 454/Psy/23 dated 22nd March, 2023. ***Recommendation of PR:*** • In SOP-Checklist- serial no. 8 – Written informed consent columns not ticked- Please revise it. • According to the letter (no-45/Ethics/2023 dated 05-04-2023) received through Institutional Ethics Committee, some modifications regarding sample size from 382 to 1000 is requested from PI, but he did not revised the calculation. Therefore, revised sample size calculation for increased in sample size is needed. • Letter of ICMR–STS-grant indicating the name of concerned researcher-not given, please attach or send the approval letter to IEC as soon as PI receive it. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XVII-PGTSC-IIB-STS/P1***
2.	Research proposal entitled "***Radiographic evaluation of root canal filling material and its relationship with periapical status in Indian subpopulation***" sponsored by ICMR, New Delhi submitted by Ms. Nandini Garg, BDS 3rd year student through her Mentor Dr. Vijay Kumar Shakya, Additional Professor, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 630/Cons&Endo/23 dated 25th March, 2023. ***Recommendation of PR:*** • Study design clarification from PI is needed that whether this is Retrospective or Prospective Cross sectional study (as PI mentioned the duration of study in Protocol is from January 2022 to Dec. 2022) • PI to submit the approval letter of STS grant from ICMR, New Delhi or send to IEC as soon as he receives the ICMR-grant letter. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	form. ***Ref. code: XVII-PGTSC-IIB-STS/P2***
3-	Research proposal entitled ***"Development of cost effective methods for molecular detection of human immunodeficiency virus, hepatitis B C virus"*** sponsored by ICMR, New Delhi submitted by Mr. Rishabh Agarwal, MBBS student through his Mentor Dr. Shivanjali Raghuvanshi, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 364 dated 28th March, 2023. ***Recommendation of PR:*** • Sample size clarification is needed as PI mentioned in Inclusion criteria that 120 Blood units reactive to Viruses (HIV, HBV and HCV) + 120 non reactive blood units will be taken, but in sample size given in Protocol, total 220 blood units are mentioned and In SOP-Checklist -120 subjects are mentioned. • Moreover, sample size calculation not done. Please give calculated sample size. • PI is requested to give flow chart of the study. • Patient information sheet attached but not related to study • ICMR- STS-Grant letter to be attached or send to IEC as soon PI receive the approval. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XVII-PGTSC-IIB-STS/P3***
II-B	**MHA**
1.	Research proposal entitled ***"To study the operations and utilization of laundry and linen linen services in a tertiary care Government Teaching Hospital, Lucknow"*** submitted by Dr. Shifa Kausar under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/096/23 dated 1st March, 2023. ***Recommendation of PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XVII-PGTSC-II B-MHA/P1***
III	**Modification**
1.	Modification of research proposal entitled ***"Effect of nurse led education programme on knowledge & expressed practice regarding rheumatoid arthritis and its self-care among patients in Rheumatology Department in KGMU, Lucknow, U.P."*** submitted by Ms. Akshita Awasthi through her guide Mr. Rohitash Kumar, Assistant Professor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no. 339/2023 dated 6th March, 2023. ***Recommendation of PR:*** • Change of Title • Inclusion of Prof. Urmila Dhakad, HOD and Dr. Puneet Kumar, Associate.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Professor, Department of Rheumatology, KGMU as Co-guide. **PGTSC Decision:** Approved ***Ref. code: XIV-PGTSC-IIB/P10***
IV	**Other Matter**
1.	Principal Investigator wants to correct her title because she spelled it wrong in the proposal which was approved by the XIV-PGTSC Committee in the 14th December, 2022 submitted by Dr. Shalini Yadav, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/13/23 dated 1st April, 2023. Previous title ***"Maternal plasma soluble neurolipon 1 in fetal growth restriction versus appropriate for age fetus: A prospective case control study".*** Correct title ***"Maternal plasma soluble neuropilon 1(NRP) in fetal growth restriction versus appropriate for age fetus: A prospective case control study".*** **PGTSC Decision:** Approved ***Ref. code: XIV-PGTSC-IIA/P101***

The next Meeting has been scheduled for 19th June, 2023 from 3.00 PM

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University U.P.,
Institutional Ethics Committee
Lucknow - 226003 (UP) India

Prof. Shally Awasthi
Member Secretary, IEC

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

No. 506 **/Ethics/2023**
Dated: 08/06/2023

To,

Dr. Alok Dhawan,
Chairman, IEC &
Director,
Centre of Biomedical Research (CBMR),
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Raebareli Road,
Lucknow, U.P.226014

Sub.: Reg. Minutes of 123rd Institutional Ethics Committee Meeting held on 19th April, 2023.

Dear Sir,

Please find enclosed herewith the Minutes of 123rd Institutional Ethics Committee Meeting held on 19th April, 2023, for your kind signature.

Thanking you,
With regards

Encl: As above

Yours Sincerely

(Shally Awasthi)
Member Secretary, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 124th IEC Meeting held on 19th June, 2023

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of 124th "Institutional Ethics Committee" Meeting held on 19th June, 2023 from 3.00 P.M. ***virtual.***

The following Members were present in the Meeting:-

1.	Dr. Alok Dhawan	-Chairman
2.	Dr. G.G. Agarwal	-Member
3.	Dr. Akash Agarwal	-Member
4.	Mrs. Vasundhara Kumari	-Member
5.	Mr. Ujjawal Krishna	-Member
6.	Mrs. Akansha Dubey	-Member
7.	Dr. A.A. Mahdi	-Member
8.	Dr. Anupam Mishra	-Member
9.	Dr. Rajendra Nath	-Member
10.	Dr. Nisha Mani Pandey	-Member
11.	Dr. Shally Awasthi	-Member-Secretary, IEC

The following members were not Present in the Meeting:-

1.	Dr. Shubha Phadke	- She has given his written comment
2.	Dr. Anita Rani	- She has given his written comment
3.	Dr. K.K. Yadav	-He has given his written comment
4.	Dr. D.N. Upadhyaya	- He has given his written comment

IA	Action Taken
1-	Clarification of research proposal entitled "***Environmental exposure to toxins and their role in inducing hypothyroidism and infertility in women: A case control study***" sponsored by DHR-HRD, New Delhi submitted by Dr. Saima Amjad under the guidance Prof. A.A Mahdi, Head, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no.nil dated 10th May, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous EC Decision: Approved with partial modification to Change the topic to **"toxicants"** ***The above comment forwarded to the P.I., Reply given by P.I. was reviewed by the Primary reviewer.*** Modified title: ***"Environmental exposure to toxicants and their role in inducing hypothyroidism and infertility in women: A case control study"*** ***Recommendation of Primary reviewer:*** **Decision:** Provisionally approved **EC Decision:** Approved ***Ref. code: 113th ECM II B-YS/P1***
2-	Clarification of research proposal entitled ***"Premature greying of hair in children and adolescents-a case control study analysis of nutritional and biochemical parameters"*** submitted by Dr. Parul Verma, Associate Professor, Department of Dermatology Venerology & Leprosy, King George's Medical University, U.P., Lucknow vide letter no. 98/23 dated 23rd May, 2023. ***Recommendation of Primary reviewer:*** • Patient information sheet to be attached as per SOP • Sample size calculation need to be elaborated step by step • The prospective outcome variables should be briefly mentioned and categorized as continuous and categorical before detailing the analytical method. • Does counting of hairs via hand lens constitute an accepted method (mention reference) or an indigenous way adopted by the investigator? • Since the ICF has to be signed by the parents only, the language has to be modified somewhat. ***The above comment forwarded to the P.I. but reply awaited for.*** Kindly submit the Patient Information Sheet as per SOP 2019. **EC Decision:** Reminder forwarded to PI. ***Ref. code: 117th ECM IIA/P20***
3-	Clarification of research proposal entitled ***"Prospective study on Spectrum of Inhalation burn injury at a tertiary care center and role of prognostic factors and severity predictors in its management"*** submitted by Dr. Sandhya Pandey, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 546/23 dated 6th May, 2023.

Previous EC Comments	PI response
Which inflammatory marker will be assessed and where they will be assessed by which	Hematological inflammatory markers will be assessed like ESR, reactive protein and Procalcitonin. They will be assessed in

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	method	biochemistry or pathology lab, KGMU by routine blood investigation. (Added in methodology section and shaded yellow)
	Although there are multiple Co-PIs none is from an investigating department.	Since these blood investigations are being done on routine basis for all admitted patients, we are just analyzing them in relation to inhalational burn, hence investigating department was not approached.
	Where the biological parameters like carboxy hemoglobin, and cyanide level will be assessed	Carboxyhemoglobin and levels will be assessed by Arterial blood gas (ABG) analysis in trauma or Gandhi ward. (Added in methodology section and shaded yellow)

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer:
Provisionally Approved
EC Decision: Approved

Ref. code: 117th ECM IIA/P33

4- Clarification of research proposal entitled ***"Use of HBOT for Limb salvageability and limiting the amputation level in electric burn injuries"*** submitted by Dr. Sandhya Pandey, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 552/23 dated 8th May, 2023.

Previous EC Comment:

- Sample size and study duration not clear.

The above Comment forwarded to PI was reviewed by Primary reviewer:-
Recommendation of Primary reviewer:
Provisionally Approved
EC Decision: Approved

Ref. code: 117th ECM IIA/P34

5- Clarification of research proposal entitled ***"To establish the molecular axis of inflammatory cytokines, circadian genes and their association with notch-1 signaling pathway in the pathogenesis of chronic myeloid leukemia"*** submitted by Ms. Nimra Habib under the guidance Dr. Ranjana Singh, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/2023/169 dated 18th May, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comments	PI response
Budget not mentioned	Rs. 30,55,500 rupees
No Co-PIs from collaborating (Deptt. of Clinical Hematology) has been included -please justify or include the Co-PI from respective department.	Dr S.P Verma from Clinical Haematology Department.
Inclusion criteria -Age and sex specificity – not mentioned.	Inclusion criteria: Patient both male and female within 18 to 70 years with chronic phase CML will be included in the study and a written consent form will be taken from all the patients.
If control patients will be taken then what will be the Inclusion and exclusion criteria. (In SOP form the PI mentioned that from total 60 pts -30 will be of CML cases and 30 as control)	For healthy Control (30 samples) □ Exclusion criteria: Volunteers with any type of malignancy and disorders will be excluded from the study. □ Inclusion criteria: Healthy volunteers who are willing to give consent from both the sexes within 18 to 70 years of age group will be considered in the study.
Study design not mentioned in Protocol.	STUDY DESIGN: 4 ml blood collection in EDTA vials from Patients of CML and control. Kept in -20°C until further processing of Molecular analysis. Estimation of biochemical parameters and inflammatory cytokines. Cell culture and cell transfection technique. Expression analysis of genes by qRT-PCR. Protein by Western Blot Analysis. Statistical Analysis.
Methodology part not explained well (how grouping will be done) –PI should attach the Flow chart of methodology.	Mentioned in summary and flowchart attached.
Approval letter of Fellowship and information about budget -may be attached.	Attached in the documents.

The above Comment forwarded to PI was reviewed by Primary reviewer:-

Recommendation of Primary reviewer:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Provisionally Approved

EC Decision: Approved

Ref. code: 117thECM II B-WS/P1

6- Clarification of research proposal entitled ***"Etiology of anemia among critically ill obstetric patients admitted to intensive care unit of a tertiary care center"*** submitted by Dr. Armin Ahmed, Associate Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/2023/1434 dated 10th April, 2023.

Previous EC Comment	Previous EC Decision
Hindi translation of the title needs improvement to make it understandable easily.	Hindi title changed in PID and consent forms.
The PID should be for guardian as well as some patients being very seriously ill may not be able to give the consent.	Guardian information sheet added in Hindi and English both.

The reply from PI to the above Comments was forwarded to Primary reviewer:-

Recommendation of Primary reviewer: Provisionally approved

EC Decision: Approved

Ref. code: 118thECM IIA/P23

7- Clarification of research proposal entitled ***"FOxTROT 2 India: pilot randomised trial evaluating neoadjuvant chemotherapy in older and/or frail patients with locally advanced but operable colon cancer"*** submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/685/23 dated 11th April, 2023.

Previous EC Comment	Previous EC Decision
Multicentric drug trial.	Yes, it is a Multicentric trial from India.
IEC approval of other centers should be provided. At least the main coordinating centre.	IEC approvals have been attached from AIIMS Rishikesh and CMC Ludhiana.
The drug trial is on old and frail patients but under subject selection–the Vulnerable subject is ticked as 'NO'. They will be enrolling old and frail patients.	Updated revised proforma has been attached.
See pages 28 and 29 for frailty score. It also includes cognitive domain of course the inclusion criteria mentions. Patient able and willing to provide written informed consent for the study'.	Yes, this is correct that the score has been explained on page no. 28 and 29, and this includes cut off for inclusion for cognitive domain based on EORTC-QLQ-C3O questionnaire.
Please take opinion from some expert	The Department of Surgical Oncology,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	about the drugs in trial.	KGMU is providing chemotherapy for cancer patients including colon cancer for last 25 years. We have all the expertise to administer the chemotherapy drugs to the patients for this study.
	The safety and efficacy of NAC in the fit colon cancer population has been established in the FoXTROT 1 study. However, benefits have not been proven in frail or older patients, not significantly represented in that trial. Two important findings suggest that this group should be studied. Firstly, major postoperative complications were reduced in patients who had received NAC, and secondly that subgroup analysis shows evidence of a comparable benefit in older and frail patients. We hypothesise that this population may gain most from a NAC approach. These benefits may be enhanced in the Indian subcontinent, where more patients present with locally advanced disease.	Yes this is the background and rationale for this study which is rightly pointed out by the EC reviewer.
	Patient information brochure is comprehensive but too big. Need to be reduced, otherwise no-one will read.	Yes, we agree that patient information brochure is comprehensive. Every effort has been made to explain each and every aspect of the study to the patient for their complete understanding and trial transparency. This will ensure that patients get detailed information without missing out anything.
	Optional video/audio may be needed.	The chemotherapy treatment used in this trial is well established for this cancer and is being used world-wide. As per the NDCT 2019 guidelines, Audio-video is required for the New Chemical Entity. Therefore this is not applicable for this study.
	Kindly provide Patient information sheet.	Attached

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The reply from PI to the above Comments was forwarded to Primary reviewer:- *Recommendation of Primary reviewer:* • Point 6 on page 17, Hindi consent mentions about CMC Ludhiana and not KGMU [Copy paste effect]. Same issue in English consent. • They should check carefully to confirm if the consent is tailored for KGMU. • Who will pay for the chemotherapy, surgery and complications, if they are there? • What about the issue of compensation? • These two issues and use of previously used drugs in different protocol - Expert in drug trial need to be consulted. • The IEC of CMC, Ludhiana [list of documents is mentioned in the approval letter but it is not attached] and AIIMS, Rishikesh have approved the trial. • The font of consent should be 14 and the line spacing should be more [1.5 at least]. **EC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: 119th ECM IIA/P10***
8-	Clarification of research proposal entitled "***An Indo-German approach to identify universal and specific molecular targets in breast cancer prevention: impact of environmental disruptors, diet and lifestyle on sex hormone levels and cellular consequences thereof in human breast tissues***" sponsored by ICMR-DFG submitted by Prof Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/12/23 dated 12th April, 2023. *Previous EC Comment:-* • Kindly rectify the Hindi version of ICF. It should be same as in English. *The reply from PI to the above Comments was forwarded to Primary reviewer:-* *Recommendation of Primary reviewer:* Provisionally approved **EC Decision:** Approved ***Ref. code: 120th ECM II A/P22***
9-	Clarification of research proposal entitled "***A multicenter cross-sectional study to evaluate the clinical, immunological, and radiological profile of allergic bronchopulmonary aspergillosis (ABPA registry)***" submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 457/23 dated 20th April, 2023. *Previous EC Comment:-* • ICF in some different format other than SOP of EC KGMU, kindly provide the name of investigator is clearly mentioned, therein, Morever the opinion of Chairman Ethics Committee & the Member-Secretry is necessary to override the existing protocol. *The reply from PI to the above Comments was forwarded to Primary reviewer:-* *Recommendation of Primary reviewer:* Provisionally approved **EC Decision:** Approved ***Ref. code: 120th ECM II A/P28***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

10- Clarification of research proposal entitled "***Efficacy of grid-based dental rubrics as an effective assessment tool when compared to traditional assessment methods for undergraduate students managing a class II carious defect***" submitted by Dr. Rhythm, Prof. Junior Grade, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 80/Coms&Endo/23 dated 18th May, 2023.

Previous EC Comment	Previous EC Decision
The title of study does not match with objectives.	1. The title of the study has been modified. 2. Primary and secondary objectives are modified. Marked in red on page 1&2.
Study design	1. The study design has been modified. Marked in red on page 4 & 5
Outcomes measures	1. Modified marked in red on page 5

The reply from PI to the above Comments was forwarded to Primary reviewer:-
Recommendation of Primary reviewer:

- Printing is very light and parts of the manuscript are not readable. Please re-submit clear copy.

EC Decision: Re-submit

Ref. code: 120th ECM II A/P31

11- Clarification of research proposal entitled "***Role of DNA methylation and autophagy regulator genes in prognosis of non-muscle invasive bladder cancer***" sponsored by CST-UP submitted by Mr. Anil Kumar, Ph.D Scholar under the guidance Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 374/URO/ dated 2nd May, 2023.

Previous EC Comment	Previous EC Decision
Comment 1: Title and objectives don't match:	**Reply:** We appreciate the reviewer's perspective and view. We have revised the title of study and the objectives. The revised title is "Role of DNA methylation and autophagy regulator genes in progression of non-muscle invasive bladder cancer,". The term "progression" has replaced the term "prognosis" as it was in earlier submission. The updated title implies how promoter methylation,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		altered gene expression (FGFR3 and TP53) as well as the level of autophagy regulator genes explain/reveal the progression of NMIBC. As a result of completing objectives 1 and 2, we will be able to establish a link between the aforementioned genes and the clinical profile (objective 3) of research subjects. The objectives are rephrased as follows: **Objective 1.** To identify methylation pattern at promoter site of FGFR3 and TP53, and their expression in non muscle invasive bladder cancer. **Objective 2.** To assess gene expression of autophagy regulators (mTOR, ULK1, Beclin1, and LC3) in non muscle invasive bladder cancer **Objective 3.** To correlate clinical profiles of non muscle invasive bladder cancer patients with DNA methylation & expression of autophagy regulator genes.
	Comment 2: Why will pre-existing tissue samples be used?	In the research procedure, we erratically check the box Yes instead of No ('Yes'> 'No'). As a result, we are avoiding using previously collected samples in the present study.
	Comment 3: From where will pre-existing blood samples be collected?	We inadvertently tick the box Yes instead of No ('Yes'> 'No') in the research protocol. This has been rectified, we do not intend to collect samples for future research/bio-banking. The fresh samples collected only for this study will be used.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Comment 4: Where is the consent for bio banking?	We inadvertently tick the box Yes instead of No ('Yes'> 'No') in the research protocol. This has been rectified, we do not intend to collect samples for future research/bio-banking. The fresh samples collected only for this study will be used.
Comment 5: What is the direct benefit to patients?	The study emphasises to establish the role of DNA methylation and altered genes in the progression of the NMIBC. The validation of identified pathways with significant outcome in this particular subset of patients definitely will directly help in managing and taking further decisions.
Comment 6: Outcome measures not mentioned.	1. Methylation status at the promoter site of FGFR3 and TP53 by using methylation specific Real Time PCR. 2. Mean fold expression change in the mRNA levels of FGFR3, TP53, mTOR, ULK1, Beclin1, and LC3. 3. Clinicopathological attributes such as tumor size, histopathological grading, TNM staging, lymph node involvement etc.
Comment 7: Statistical methodology not mentioned.	Statistical analysis was performed using SPSS v. 24.0 (SPSS, Inc., Chicago, IL, USA). Data will be entered in the excel sheet and exported to SPSS. Normal distribution of data will be assessed by Shaprio-Wilk test. Depending the distribution of the data parametric or non-parametric tests will be applied. To compare the mean difference in the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		methylation and gene expression levels between low grade to high grade tumors Student's t-test or Mann–Whitney U test will be used. Spearman's correlation tests will be performed to correlate gene expression levels with the clinicohistopathological variables of patients.
	Comment 8: 51 samples will not be enough to either prognosticate or profile bladder cancer.	**Reply:** We are thankful for the suggestion and updated the sample size with detailed calculation as below: **Study Size:** Based on the correlation between molecular markers methylation and expression levels with clinical profile (disease progression). The expected correlation coefficient is 0.30 for methylation and autophagy markers in non-muscle invasion bladder cancer. **The sample size** $N= [(Z\alpha + Z\beta)/C]^2 + 3$ Considering, Threshold probability for rejecting the null hypothesis i.e. Type I error rate(two-tailed) $\alpha= 0.05$. Probability of failing to reject the null hypothesis under the alternative hypothesis i.e. Type II error rate (β)= 0.10 The expected correlation coefficient (r)= 0.3

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		The standard normal deviate for $\alpha = Z_\alpha = 1.9600$ The standard normal deviate for $\beta = Z_\beta = 0.84$ $C = 0.5 * \ln[(1+r)/(1-r)] = 0.3095$ **Total sample size = 85** Group-1= non-muscle invasion bladder cancer(n=85) Group-2= control group (n=85) **Reference** 1. Hulley SB, Cummings SR, Browner WS, Grady D, Newman TB. Designing clinical research: an epidemiologic approach. 4th ed. Philadelphia, PA: Lippincott Williams &Wilkins; 2013. Appendix 6C, page 79.

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of Primary reviewer:

- Is this a PhD thesis?
- The project does not make great sense still. The title has been altered, but the problems remain the same.
- Title objectives and study plan don't match.
- The study design is not mentioned.
- Review of literature/background/references has not been mentioned.
- There is no mention of how sample size was calculated? Will there be a control group. If yes, what will be that?
- What is progression? How is it defined?
- What is the time cut off to label as non progressive?
- What clinical measures will be correlated, and how?
- First page of IEC form, consents, PIS, missing.
- Very poorly written proposal, especially from a PhD student.

EC Decision: Revise & Re-submit. Give changes done in a tabular form.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: 120th ECM II B-Ph.D./P1

12- Clarification of research proposal entitled "***To elucidate MAP kinase activation role in the hypertensive placenta***" sponsored by Department of Health Research, Ministry of Health & Family Welfare, Government of India, New Delhi submitted by Prof. Shyam Pyari Jaiswar, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/312/23 dated 6th May, 2023.

Previous EC Comment	Previous EC Decision
Discrepancy in the title of project	The title of the project has been corrected all the places as '**To elucidate atypical kinases activation in the placental dysfunction'.**
Patient information sheet: Kindly explain to the patient: why she has been selected, instead of saying that she fulfils inclusion criteria	The patient information sheet has been corrected according to the EC comments and has been attached for further reference.
ICF: Kindly explain the study procedure that her placental tissue will be utilized for study and will be kept in deep freezer.	Study procedure has been explained in the consent form according to the EC comments as 'The biopsies, etc. of the placental tissues after the scheduled delivery of the patient/ participant will be utilized for the study and will be kept in deep freezer for the downstream analysis. The blood sampling (3-5ml) will be done after 20th week of the confirmed pregnancy in the preeclampsia or normal pregnancy cases.' and the file has been attached for further reference.

. ***The reply from PI to the above Comments was forwarded to PR:-***
Recommendation of Primary reviewer: Provisionally approved
EC Decision: Approved

Ref. code: 121st ECM IIA/P7

13- Clarification of research proposal entitled "***Systematic assessment of neurodegenerative disorders by video-oculography- A prospective exploratory study***" sponsored by UPCST, Lucknow submitted by Prof. Hardeep Singh Malhotra, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 204/Neuro/23 dated 17th May, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comment	Previous EC Decision
According to PI, VNG machine is available in the ENT department and one Co PI will be from ENT department but the list is not expressing the same. Kindly add one CO PI from ENT department.	We regret the incorrect statement that got carried over from our previous collaboration with the ENT department. The infrastructure for the assessment of patients in the form of Video-Oculography (VOG) machine is now available in the department of Neurology and shall be utilized for the conduct of the study. We had, therefore, not included a Co-PI. We have corrected the statement on page 11 in this regard.
ICF: Study Procedure states Standard Guidelines. It has been assumed that patient is aware of Standard Guidelines. Kindly explain the whole procedure in simple words.	We regret the deficiency. The ICF has been modified (both English and Hindi) with a simple introduction and the detail of the procedure has been provided in the Patient Information Sheet (both English and Hindi).
Patient Information Sheet: is not attached.	We apologize for the inadvertent miss. Both English and Hindi sheets have been attached in the revised proposal.

The reply from PI to the above Comments was forwarded to Primary reviewer:-
Recommendation of Primary reviewer: Provisionally approved
EC Decision: Approved

Ref. code: 121st ECM IIA/P8

14- Clarification of research protocol no. DEN302 entitled "***A randomized, double-blind, placebo-controlled, phase 3 trial to investigate the safety and immunogenicity of a dengue tetravalent vaccine (Live Attenuated) (TDV) administered subcutaneously to healthy subjects aged 4 to 60 years in India***" sponsored by M/s Takeda Vaccines, Inc. submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/12/2023 dated 18th May, 2023.

Previous EC Comment	Previous EC Decision
Permission for sending samples abroad–	The permission letter will be come along

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

In SOP-Checklist–ticked yes, but document missing.	with DCGI approval letter.
DCGI Permission letter–awaited	As per the DCGI subject expert committee at CDSCO requested to sponsor for the conditional EC approval letter from the site EC, Which may require presenting toDCGI for the DCGI NOC. Sponsor communication with DCGI mail copy is attached for your reference.

The reply from PI to the above Comments was forwarded to Primary reviewer:-
Recommendation of Primary reviewer:

- Permission for sending samples abroad and the DCGI Approval letter have still not been given.

The above comment forwarded to PI but reply pending.

EC Decision: Reminder forwarded to PI

Ref. code: 121st ECMIIC/P2

15- Clarification of research protocol no. 20210025 Romosozumab (EVENITY®) entitled "***An open-label, single-arm, multicenter phase 4 study to evaluate safety and tolerability of romosozumab (EVENITY®) in postmenopausal women in India with osteoporosis and a high risk of fracture***" sponsored by M/s One Amgen Center Drive Thousand Oaks submitted by Prof. Ashish Kumar, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. CT/OS/03/2023 dated 29th April, 2023.

Previous EC Comment	Previous EC Decision
Budget in CTA documents is missing.	As per your valuable comment budget copy is provided by the sponsor and attached for your reference.

The reply from PI to the above Comments was forwarded to Primary reviewer:-
Recommendation of Primary reviewer: Provisionally approved
The following documents were reviewed in Its Meeting:-

1. Protocol_ Superseding Original Protocol Version dated 19 September 2022.
2. Investigator's Brochure _ Version 14.1 Dated 01October 2021 **(Controlled Copy_ AMG _Romozosumab_ IB v14.1_Copy#030 to Copy#034)**
3. 20210025_eCRF Specification_ Dated 20 Oct2022.
4. Ind_2.0_Main Informed Consent Form dated _24Oct2022_Based on Global Informed Consent Form version number 2 Dated 13 October 2022_Language_ English
5. Ind_2.0_Main Informed Consent Form dated_ 24Oct2022_Based on Global Informed Consent

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Form version number 2 Dated 13 October 2022 _Translated to Hindi 6. Ind_2.0_Main Informed Consent Form dated_ 24Oct2022_Based on Global Informed Consent Form version number 2 Dated 13 October 2022_Back translation to English from Hindi. 7. Informed consent forms Translation certificate_ Dated 09 Nov2022. 8. Romosozumab (EVENITY®)_20210025__India_Subject Card English Effective Date: 14 Mar 2022, Version:1.0 9. Romosozumab (EVENITY®)_20210025__India_Subject Card English Effective Date: 14 Mar 2022, Version:1.0_Translated in Hindi. 10. Romozosumab (EVENITY®)_20210025__India_Subject Card English Effective Date: 14 Mar 2022, Version:1.0 _ Back translation to English from Hindi. 11. Translation Certificate of Subject Card Version 1.0 dated 14Mar2022_Dated 10Nov2022 12. Draft Clinical Trial Agreement Order 13. Draft Clinical Trial Agreement 14. 20210025_Investigator undertaking_ Dr. Ashish Kumar _signed dated 11 Oct 2022 15. 20210025_ Curriculum Vitae _Principal Investigator_ Dr. Ashish Kumar_ Signed dated 24 Nov 2022 16. 20210025_Medical Registration Certificate_ Principal Investigator _Dr. Ashish Kumar_ Signed dated 24 Nov 2022 17. 20210025_ Curriculum Vitae _Sub Investigator_ Dr. Deepali Shrivastava_ Signed dated 23 Nov 2022 18. 20210025_Medical Registration Certificate_ Sub Investigator_ Dr. Deepali Shrivastava_ Signed dated 23 Nov 2022 19. Two CD containing soft copy of the above-mentioned documents. 20. Study Insurance No 48/2023/7747 Letter dated 16- Dec-2022. 21. DCGI Submission Letter dated 09-Nov-2022 22. DCGI Approval Letter Dated 29-Dec-2022. **EC Decision:** Approval subject to fulfillment & Administrative formalities. ***Ref. code: 121st ECMIIC/P3***
16-	Clarification of research proposal entitled "***Morphpmetric, morphological and histological study of placenta, in still births, intra uterine deaths and live births***" submitted by Dr. Mah Paiker, Ph.D. Scholar under the guidance Prof. Mahboobul Haque, Head, Department of Anatomy, IIMS&R, Lucknow through Prof. S.P. Jaiswar, Co-guide, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/519/23 dated 22nd May, 2023. ***Recommendation of Primary reviewer:*** • Identify one primary objective, and the rest should be clubbed into secondary objectives. • Identify the study variables and population parameters. • Convert the primary objective into a proper research hypothesis. • Sample size is given to be 90. There is no formula given. • Everything including sample size calculation, statistical analysis etc. should be in accordance with the research hypothesis. In the present form it is very arbitrary. ***The reply from PI to the above Comments was forwarded to Primary reviewer:-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: Provisionally approved **EC Decision:** Approved ***Ref. code: 122nd ECMIIB-Ph.D/P1***
17-	Clarification of research proposal entitled "***Exploring the role of miRNAs in oral cancer***" submitted by Mrs. Pooja Nayak, Ph.D. Scholar under the guidance Dr. Mohammad Kaleem Ahmad, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/2023/168 dated 18th April, 2023. ***Previous EC Comments:-*** • Identify one primary objective, and the rest should be clubbed into secondary objectives. • Identify the study variables and population parameters. • Convert the primary objective into a proper research hypothesis. • The sample size calculation is arbitrary. • Everything including sample size calculation, statistical analysis etc. should be in accordance with the research hypothesis. ***The reply from PI to the above Comments was forwarded to Primary reviewer:-*** ***Recommendation of Primary reviewer:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 122nd ECMIIB-Ph.D/P2***
18-	Clarification of research protocol no. TILD-19-07 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF experienced subjects with active psoriatic arthritis I (INSPIRE 1)***" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/54/23 dated 3rd June, 2023. **Previous EC Decision:** • DCGI application does not mention KGMU site/KGMU PI. • DCGI application attached but no approval is attached. • Clinical Trail Agreement is only a format without any details like KGMU site/Budgetary allocation. ***The reply from PI to the above Comments was forwarded to Primary reviewer:-*** ***Recommendation of Primary reviewer:*** 1-No point-by-point clarification has been submitted. 2-Following points need to be addressed:- a- DCGI application has been submitted mentioning KGMU site/KGMU PI, but no approval is attached. b- Clinical trial agreement is only an edited format with track changes on without any details like KGMU site/Budgetary allocation. 3-Please submit DCGI approval of KGMU site and signed CTA without track changes preferably flagged on relevant areas like signature and budget allocation. ***Reply received by PI according to above comments which was forwarded to Primary reviewer.***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Recommendation of Primary reviewer:- Provisionally Approved

The following documents were reviewed in Its Meeting:-

Sl. No.	Documents	Version number/ Date
1a	Protocol	Amendment 1.2 (India) dated 25 Nov 2022
1b	Protocol Signature Page Amendment 1.2 (India)-25 Nov 2022	Signed Dated 17 Dec 2022
2	Investigator Brochure	V 12, 12 Jan 2022, Release date 18 Jan 2022
3	Inform Consent Form (ICF)	
3a	English	Subject Information Sheet and Consent Form in English, Version 2 for India dated 24-Jan-2023 adapted from the Master Subject Information Sheet, Version 7.0 dated 17 Nov 2022 Protocol TILD-19-07, Sun Pharmaceutical Industries Limited
3b	**List of Changes for PIS/ICF** /Assent form/AV-ICF/Consent for pregnancy Testing and Appropriate Follow-up	**Reference Document,**Subject Information Sheet and Consent Form in English, Version 2 for India dated 24-Jan-2023 adapted from the Master Subject Information Sheet, Version 7.0 dated 17 Nov 2022 Protocol TILD-19-07, Sun Pharmaceutical Industries Limited signed on dated 27 Jan 2023
4	Informed Consent Form (Translation)	
a	English to Hindi	Subject Information Sheet and Consent Form in English,Version 2 for India dated 24-Jan-2023 adapted from the MasterSubject Information Sheet, Version 7.0 dated 17 Nov 2022, Protocol TILD-19-07, Sun Pharmaceutical Industries Limited. Translation date: - 06 Feb 2023

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

5	Informed Consent Form (Back Translation)	
a	Hindi to English	Subject Information Sheet and Consent Form in English,Version 2 for India dated 24-Jan-2023 adapted from the MasterSubject Information Sheet, Version 7.0 dated 17 Nov 2022, Translation from English to Hindi: 06 Feb 2023, Protocol TILD-19-07, Sun Pharmaceutical Industries Limited. Back Translation date 10 Feb 2023
6	ICF (Translation) Certificates	
A	English to Hindi	06 Feb 2023
B	Hindi to English	10 Feb 2023
7	Insurance Certificate No	4067-TILD-19-07-22-23 Valid from 1 Jul 2022 to 30 Jun 2023
8	DCGI submission Letter	Dated 02 Aug 2022
9	Clinical Trial Agreement	Draft
10	Investigator Undertaking	Document Signed Dated 15 Dec 2022
11a	Curriculum Vitae	Dated 17 Dec 2022
A	English to Hindi	06 Feb 2023
A	English to Hindi	06 Feb 2023
B	Hindi to English	10 Feb 2023
12	Medical Registration Certificate	Dated 17 Dec 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

13	FDA1572	Dated 17 Dec 2022
14	FDF 3455	Dated 20 Feb 2023
15	**Scales (Patient Facing)- English**	
a	PtGA pain VAS (The Assessment of Pain: Arthritis)	v3.0 – 13 January 2021
b	HAQ-DI (Health Assessment Questionnaire)	STANFORD-RA (MAY99 – Phase 31) – English, USA
c	BASDAI (The Bath Ankylosing Spondylitis Disease Activity Index)	v3.0 – 13 January 2021
d	FACIT-F (Fatigue Scale version 4)	TILD-19-07 (Inspire 1) FACIT-Fatigue v1.0 15Jun2020, English (Universal), Copyright 1987, 1997, 16 November 2007
d i	FACIT- (Fatigue Scale (Version 4)) Hindi	8 Jul 2012
d ii	Translation Certificate English to Hindi	8 Jul 2012
e	VAS for PtGA of disease activity (Patient's Global Assessment of Disease Activity)	HAQ-Patient Global VAS – United States/English – MAPI Institute. HAQ-PatientGlobalVAS_TS2.0_eng-Usori.doc TILD-19-07 (Inspire 1) PtGA disease activity VAS
f	SF-36v2® Health Survey □ 1992,	V1.1 6 May 2016

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		2004, 2010 Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-36® is a registered trademark of Medical Outcomes Trust. (SF-36v2® Health Survey Acute, India (English)	
	f i	English Translation Certificate	6 May 2016
	f ii	SF-36v2® Health Survey □ 2004, 2010 Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-36® is a registered trademark of Medical Outcomes Trust. (SF-36v2® Health Survey Acute, India (Hindi)	V1.1 Rev 19 Jul 2018
	f iii	Hindi Translation Certificate	19 Jul 2018
	g	English for US – WPAI:PsA (Work Productivity and Activity Impairment Questionnaire: Psoriatic Arthritis)	V2.0 – 26/JUN/2013 TILD-19-07 (Inspire 1)
	16	**Scales (Investigator/Joint assessor assessment)-English**	
	a	TILD-19-07 (Inspire 1) tender & swollen joints count 68/66 (Tender and swollen measurement)	v2.0 15Jun2020
	b	TILD-19-07 (Inspire 1) LDI_LEI (LEEDS DACTYLITIS INDEX)	v2.0 15Jun2020
	c	TILD-19-07 (Inspire 1) PASI (Psoriasis Area And Severity	v2.0 15Jun2020

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Index worksheet)	
d	TILD-19-07 (Inspire 1) NAPSI (NAIL PSORIASIS SEVERITY INDEX)	v2.0 15Jun2020
e	TILD-19-07 (Inspire 1) PGA-PSO (Physician's Global Assessment of Skin (Whole Body))	v2.0 15Jun2020
f	TILD-19-07 (Inspire 1) PGA-DA (Physician's global assessment of disease activity)	v3.0 03Jan2021
g	C-SSRS Baseline – India/English - Version of 09 Nov 2021 - ICON. ID02505-TR-0335 / C-SSRS-Baseline_AU5.1_eng-IN.doc	Version 14 January 2009
h	C-SSRS Since Last Visit - India/English - Version of 07 Apr 14 - Mapi. ID7651 / C-SSRS-SinceLastVisit_AU5.1_eng-IN.doc	Version 14 January 2009
I	C-SSRS - Baseline - India/Hindi - Version of 28 Feb 2018 - Mapi. ID5061378 / C-SSRS-Baseline_AU5.1_hin-IN.doc	Version 14 January 2009
II	C-SSRS Since Last Visit - India/Hindi - Version of 14 Apr 14 - Mapi. ID7651 / C-SSRS-SinceLastVisit_AU5.1_hin-IN.doc	Version 14 January 2009
17	Laboratory Manual's	
a i	ACM Global Laboratories Manual	Version 1.0, 23 Sep 2020
a ii	ACM Global Laboratories MEMO – Correction to ESR tube size indicated in Lab Manual Version 1	dated 13 Oct 2020
a iii	ACM Global Laboratories QuantiFERON Gold Plus Sample	10 Aug 2020

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Processing Memo	
	b	Labcorp Central Laboratory Service Manual (TILD-19-07)APAC, Manual created on 10 Nov 20	v2.1.0, 25MAR2022
	c	Bioclinica - Procedure Manual for Radiographic Examinations of the Hands/Wrist and Feet	Version 1.0, 4 Jun 2020
	d	ERT Study manual Cardiac Safety for Trial TILD-19-07 (Inspire 1) &TILD-19-19 (Inspire 2)	Version 3.0, 30 Apr 2020
	e	ERT Cardiac_ECG Quick Guide Sun Pharma TILD-19-07 (Inspire 1) & TILD-19-19 (Inspire 2)	Version 3.0, 30 Apr 2020
	f	Cardiac Safety Memo (TILD-19-07/ TILD-19-19)	29 Apr 2020
	18	AnnotatedCRF MZA56173	Version 1.0 dated 05 Nov 2021
	19	DCGI Covering letter for Application No	GCT/CT04/FF/2022/33217 (GCT/68/22) dated 27 Dec 2022 -for File No. CT//22/000068
	20	DCGI Permission Letter for File No. CT/68/22-DCG(I)	CT-06 PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUGdated 27 Dec 2022
	21	DCGI Import License Number	TL/CT/22/000338 dated 27 Dec 2022
	EC Decision: Approval subject to fulfillment & Administrative formalities. ***Ref. code: 122nd ECMIIC/P5***		
19-	Clarification of research protocol no. TILD-19-19 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to***		

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

tildrakizumab in Anti-TNF naive subjects with active psoriatic arthritis II (INSPIRE 2)" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/53/23 dated 3rd June, 2023.

Previous EC Decision:

- DCGI application does not mention KGMU site/KGMU PI.
- DCGI application attached but no approval is attached.
- Clinical Trail Agreement is only a format without any details like KGMU site/Budgetary allocation.

The reply from PI to the above Comments was forwarded to Primary reviewer:-

Recommendation of Primary reviewer:

1-No point-by-point clarification has been submitted.

2-No response to the following queried raised in the last review:-

a- DCGI application does not mention KGMU site/KGMU PI

b- DCGI application attached but no approval is attached.

c- Clinical Trial agreement is only a format without any details like KGMU site/Budgetary allocation.

Reply received by PI according to above comments which was forwarded to Primary reviewer.

Recommendation of Primary reviewer:- Provisionally Approved

The following documents were reviewed in Its Meeting:-

Sl. No.	Documents	Version number/ Date
1a	Protocol	Amendment 1.1, 04 Jul 2022
1b	Protocol Signature Page Amendment 1.1, 04 Jul 2022	Signed Dated 18 Jan 2023
2	Investigator Brochure	V 12, 12 Jan 2022, Release date 18 Jan 2022
3	Inform Consent Form (ICF)	
3a	English	Subject Information Sheet and Consent Form in English, Version 2 for India dated 24-Jan-2023 adapted from the Master Subject Information Sheet, Version 7.0 dated 17 Nov 2022 Protocol TILD-19-19, Sun

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			Pharmaceutical Industries Limited
	3b	List of Changes for PIS/ICF /Assent form/AV-ICF/Consent for pregnancy Testing and Appropriate Follow-up	Subject Information Sheet and Consent Form in English, Version 2 for India dated 24-Jan-2023 adapted from the Master Subject Information Sheet, Version 7.0 dated 17 Nov 2022 Protocol TILD-19-19, Sun Pharmaceutical Industries Limited signed on 27 Jan 2023
	4	Informed Consent Form (Translation)	
	a	English To Hindi	Subject Information Sheet and Consent Form in English, Version 2 for India dated 24-Jan-2023 adapted from the Master Subject Information Sheet, Version 7.0 dated 17 Nov 2022 Protocol TILD-19-19, Sun Pharmaceutical Industries Limited English To Hindi Translated on 06 Feb 2023
	5	Informed Consent Form (Back Translation)	
	a	Hindi to English	Subject Information Sheet and Consent Form in English, Version 2 for India dated 24-Jan-2023 adapted from the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			Master Subject Information Sheet, Version 7.0 dated 17 Nov 2022 Translation from English to Hindi: 06 Feb 2023 Protocol TILD-19-19, Sun Pharmaceutical Industries Limited Hindi to English Back Translated on 10 Feb 2023
	6	ICF (Translation) Certificates	
	a	English To Hindi	06 Feb 2023
	b	Hindi to English	10 Feb 2023
	7	Insurance Certificate No	4067- TILD_19_19-22-23 valid from 01 July 2022 to 30 June 2023
	8	DCGI submission Letter	Dated 02 Aug 2022
	9	Clinical Trial Agreement	Draft CTA
	10	Investigator Undertaking	Document Signed Dated 18 Jan 2023
	11a	Curriculum Vitae	Dated 17 Dec 2022
	11 b	Good Clinical Practice Certificate	Dated 03 Jan 2022
	12	MRC	Dated 17 Dec 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

13	FDA1572	Dated 17 Dec 2022
14	FDF 3455	Dated 20 Feb 2023
15	**Scales (Patient Facing)- English**	
a	PtGA pain VAS (The Assessment of Pain: Arthritis)	v3.0 – 13 January 2021
b	HAQ-DI - United States/English - Mapi. HAQ-DI_AU1.0-eng-USori.doc Stanford University (Health AssessmentQuestionnaire)	STANFORD-RA (MAY99 – Phase 31) – English, USA
c	BASDAI, Andrei Calin, 1994 (The Bath Ankylosing Spondylitis Disease Activity Index)	v3.0 – 13 January 2021
d	TILD-19-19 (Inspire 2) FACIT-Fatigue (Fatigue Scale (Version 4))	v1.0 15Jun2020
e	FACIT- (Fatigue Scale (Version 4)) Hindi	8 Jul 2012
e1	Translation Certificate English to Hindi	8 Jul 2012
f	HAQ- Patient Global VAS - United States/English - MAPI Institute. TILD-19-19 (Inspire 2) (Patient's Global Assessment of Disease Activity)	PtGA disease activity VAS HAQ-PatientGlobalVAS_TS2.0_eng-USori.doc
g	SF-36v2® Health Survey □ 1992, 2004, 2010 Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-36® is a registered trademark of Medical Outcomes Trust. (SF-36v2® Health Survey Acute, India (English)	V1.1 6 May 2016
g1	English) Translation Certificate	6 May 2016

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	h	SF-36v2® Health Survey □ 2004, 2010 Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-36® is a registered trademark of Medical Outcomes Trust. (SF-36v2® Health Survey Acute, India (Hindi))	V1.1 Rev 19 Jul 2018
	h1	Hindi Translation Certificate	19 Jul 2018
	I	WPAI-SHP (Work Productivity and Activity Impairment Questionnaire: Psoriatic Arthritis (WPAI:PsA))-TILD-19-19 (Inspire 2)	English for US – WPAI:PsA V2.0 – 26/JUN/2013
	16	**Scales (Investigator/Joint assessor assessment)**	
	a	TILD-19-19 (Inspire 2) tender & swollen joints count 68/66 (Tender & Swollen Measurements)	v2.0 15Jun2020
	b	TILD-19-19 (Inspire 2) LDI_LEI (LEEDS DACTYLITIS INDEX (LDI))	v2.0 15Jun2020
	c	TILD-19-19 (Inspire 2) PASI (Psoriasis Area And Severity Index work sheet)	v2.0 15Jun2020
	d	TILD-19-19 (Inspire 2) NAPSI (NAIL PSORIASIS SEVERITY INDEX)	v2.0 15Jun2020
	e	TILD-19-19 (Inspire 2) PGA-PSO Physician's Global Assessment of Skin (Whole Body)	v2.0 15Jun2020
	f	TILD-19-19 (Inspire 2) PGA-DA (Physician's global assessment of disease activity)	v3.0 03Jan2021
	g	C-SSRS Baseline – India/English - Version of 09 Nov 2021 - ICON. ID02505-TR-0335 / C-SSRS-Baseline_AU5.1_eng-IN.doc	Version 14 January 2009

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	g1	C-SSRS Since Last Visit - India/English - Version of 07 Apr 14 - Mapi. ID7651 / C-SSRS-SinceLastVisit_AU5.1_eng-IN.doc	Version 14 January 2009
	h	C-SSRS - Baseline - India/Hindi - Version of 28 Feb 2018 - Mapi. ID5061378 / C-SSRS-Baseline_AU5.1_hin-IN.doc	Version 14 January 2009
	17	Laboratory Manual's	
	a i	ACM Global Laboratories Manual	1.0 , 23 Sep 2020
	a ii	ACM Global Laboratories QuantiFERON Gold Plus Sample Processing Memo	10 Aug 2020
	b	Labcorp Central Laboratory Service Manual (TILD-19-19)APAC, Manual created on: 10 Nov 2020	v2.1.0 Manual revised: 23 Mar 2022
	c	ERT Study manual Cardiac Safety for Trial TILD-19-07 (Inspire 1) &TILD-19-19 (Inspire 2)	Version 3.0,30 Apr 2020
	d	ERT Cardiac_ECG machine Quick Guide: Sun Pharma TILD-19-07 (Inspire 1) & TILD-19-19 (Inspire 2)	Version 3.0,30 Apr 2020
	e	Cardiac Safety Memo for TILD-19-07 (Inspire 1) & TILD-19-19 (Inspire 2)	29 Apr 2020
	f	Sun PharmaGlobal FZETILD-19-19 Bioclinica (Procedure Manual for Radiographic Examinations	Version 1.0 25 Jun-2020

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		of the Hands/Wrist and Feet)	
	18	Annotated Study Book (eCRF) RZA35078	V1.0 17 Mar 2022
	19	DCGI Covering letter for Application No	GCT/CT04/FF/2022/33255 (GCT/67/22) dated 03 Jan 2023 - for File No. CT/22/000067 signed on 03 Jan 2023
	20	DCGI Permission Letter for File No. CT/67/22-DCG(I)	CT/67/22-DCG(I) CT-06 PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG signed on 03 Jan 2023
	21	DCGI Import License Number	TL/CT/22/000344 signed on 03 Jan 2023

EC Decision: Approval subject to fulfillment & Administrative formalities.

Ref. code: 122nd ECMIIC/P6

20. Clarification of research proposal entitled "***Role of nasal douching technique in the management of allergic rhinitis***" sponsored by DHR submitted by Dr. Shruti Agnihotri through her Mentor Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 576/ResMed/23 dated 5th June, 2023.

Recommendation of Primary reviewer:

- The objective indicates nasal douching only while methodology also includes Pranayam (yoga). Kindly clarify.
- The second objective estimates the effect of anti-allergic medication while case study form does not record any institution of medication. Kindly rectify
- Similarly the fourth objective estimates effect on quality of life but no such recording is shown in case study form.
- Kindly clarify first two points of inclusion criteria. It seems that patients of allergy rhinitis with or without asthma both will be included. Mention clear-cut the diagnostic criteria.
- Kindly show the steps of sample size calculation to make it more clear
- In data management and analysis kindly mention 'all the parameters' and "different types of intervention at different times".

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The technique of nasal douche used in the study may be briefly described in methodology section. • As per the section on "benefit and significance of study" will a 30 minute yoga practice be done in every patient- If yes, then include this in methodology before also. • What would be included in the standard medical treatment? kindly brief. ***The reply from PI to the above Comments was forwarded to Primary reviewer:-*** ***Recommendation of Primary reviewer:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 123rdECMIIB-WS/P1***
21-	Clarification of research protocol no.RCLS-CIP-01 entitled "***A prospective open-level, single arm, interventional, multicentric, pilot study to evaluate the safety and effectiveness of OZYN-D, a novel intraosseous device for delivery of medications and fluids***" sponsored by M/s Rcupe Life Sciences Pvt. Ltd. submitted by Prof. Sandeep Tiwari, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow, vide letter no. TS/3172023 dated 17th May, 2023. ***Previous EC Comments:-*** • In SOP-Checklist-point-3–Clinical Trials–(ii)-is this device approved and marketed in India–PI mentioned-NA–PI is required to clarify • Point -6- Confidential handling of data – not ticked YES • Insurance to be renewed (it is up to-21-04-2023) • DCGI acknowledgment and permission letter awaited (if required) • CTRI document to be send after registry ***The reply from PI to the above Comments was forwarded to Primary reviewer:-*** ***Recommendation of Primary reviewer:*** Provisionally approved ***The following documents were reviewed in Its Meeting:-***

S.no	Name of documents	Version/reference no.	Date
01.	Clinical Investigational Plan	RCLS-CIP-01 version 02	08/March/2022
02.	Investigator's brochure	RCLS-IB-01 version 01	16/February/2022
03.	Patient Information sheet(English – Master Copy)	RCLS-ICF-01 Version 02	31/May/2022
04.	Informed Consent Form (English – Master Copy)	RCLS-ICF-01 Version 02	31/May/2022
05.	Informed Consent Form(Hindi Copy and Back Translation from Hindi to English)	RCLS-ICF-01 Version 02	31/May/2022 Translated on 4/November/2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

06.	Patient Information Sheet (Hindi Copy and Back Translation from Hindi to English)	RCLS-ICF-01 Version 02	31/May/2022 Translated on 5/November/2022
07.	Case Reports From	RCLS-CRF-01 Version01	8/March/2022
08.	Instructions For Use (IFU)	RCLS-IO-PV-01 Rev.7/20-12-2021	20/December/2021
09.	ISO 13485:2016 Certificate	Unique ID 170756621	Valid until-16/July/2023
10.	CE Certificate	Unique ID 170756622	Valid until-26/May/2024
11.	Investigator Undertaking as per Medical Device Rules, Investigator CV, and MRC and Co-Investigator CV, and MRC	---	23/February/2023
12.	Publication	---	---
13.	Draft Clinical Trial Agreement	---	---
14.	IEC Approval from other investigator site(s)	Letter from MSRMH, Bangalore	22/June/2023
15.	Consent Letter/Letter of undertaking from other Investigator	---	23/February/2023
16.	Ethics Committee Review Payment	---	
17.	Insurance	---	22/April/2022 To 21/April/2023
18.	DCGI Acknowledge letter	---	08/December/2022
19.	CSA	---	Draft

EC Decision: Approval subject to fulfillment & Administrative formalities.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: 123rd ECMIIC/P1

22- Clarification of research protocol no. NN9838-4942 entitled ***"Re-REDEFINE 3: The cardiovascular safety of cagrilintide 2.4 mg.s.c. in combination with semaglutide 2.4 mg s.c. (CagriSema 2.4 mg/2.4 mg.s.c.) once-weekly in participants with obesity and established cardiovascular disease"*** sponsored by M/s Novo Nordisk India Private Limited submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 111/Cardio/Res/23 dated 25th May, 2023.

Recommendation of Primary reviewer:

- Section on subject selection has been left blank including of subjects/Vulnerable and special group subjects and type of subjects.
- Section on Use of Biological Materials mentions that blood samples will be sent abroad but details of laboratory and reason thereof are not given.

The reply from PI to the above Comments was forwarded to Primary reviewer:-

Recommendation of Primary reviewer: Provisionally approved`

The following documents were reviewed in Its Meeting:-

Section No.	Documents
	Protocol
1.	a-Protocol Version 1.0 dated 22 Aug 2022 b-Protocol attachment 1: Global list of key staff and relevant departments and suppliers of clinical relevance version 2.0 dated 07 Nov 2022 c- Protocol attachment 2: Country list of key staff and relevant departments version 1.0 dated 05 Jan 2023 d-Agreement on Protocol signed by Dr. S K Dwivedi on 22 Nov 2022
	INVESTIGATOR BROCHURE
2.	a- Investigator's Brochure Cagrilintide (NNC0174-0833), CagriSema, edition 8 version 1.0 dated 08 Dec 2022 b-Investigator's Brochure Cagrilintide (NNC0174-0833), CagriSema, edition 8 version 1.0 dated 08 Dec 2022 receipt form c-Investigator's Brochure Semaglutide s.c. edition 8 version 1.0 dated 30 Jun 2022 d-Investigator's Brochure Semaglutide s.c. edition 8 version 1.0 dated 30 Jun 2022 receipt form
	SIIC – MAIN
3.	a-NN9838-4942, Subject Information/Informed Consent Form – Main Version 1.0_IN_EN Dated 10 Nov 2022, Status: Final b-NN9838-4942, Subject Information/Informed Consent Form – Main Version 1.0_IN_HI Dated 01 Dec 2022, Status: Final c-NN9838-4942, Subject Information/Informed Consent Form – Main Version 1.0_IN_HI_BT Dated 01 Dec 2022, Status: Final d-Translation certificate 1.0_IN_HI e-Translation certificate 1.0_IN_HI_BT

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	SIIC – MALE PARTNER OF A FEMALE PARTICIPANT
4.	a. NN9838-4942, Subject Information/Informed Consent Form - Male Partner of Female Participant Version 1.0_IN_EN Dated 17 Nov 2022, Status: Final b. NN9838-4942, Subject Information/Informed Consent Form – Male Partner of Female Participant Version 1.0_IN_HI Dated 12 Dec 2022, Status: Final c. NN9838-4942, Subject Information/Informed Consent Form – Male Partner of Female Participant Version 1.0_IN_HI_BT Dated 12 Dec 2022, Status: Final d. Translation certificate 1.0_IN_HI e. Translation certificate 1.0_IN_HI_BT
	SIIC – FUTURE RESEARCH
5.	a. NN9838-4942, Subject Information/Informed Consent Form – Future Research Version 1.0_IN_EN Dated 17 Nov 2022, Status: Final b. NN9838-4942, Subject Information/Informed Consent Form – Future Research Version 1.0_IN_HI Dated 12 Dec 2022, Status: Final c. NN9838-4942, Subject Information/Informed Consent Form – Future Research Version 1.0_IN_HI_BT Dated 12 Dec 2022, Status: Final d. Translation certificate 1.0_IN_HI e. Translation certificate 1.0_IN_HI_BT
	SIIC – GENOTYPING
6.	a. NN9838-4942, Subject Information/Informed Consent Form – Genotyping Version 1.0_IN_EN Dated 17 Nov 2022, Status: Final b. NN9838-4942, Subject Information/Informed Consent Form – Genotyping Version 1.0_IN_HI Dated 12 Dec 2022, Status: Final c. NN9838-4942, Subject Information/Informed Consent Form – Genotyping Version 1.0_IN_HI_BT Dated 12 Dec 2022, Status: Final d. Translation certificate 1.0_IN_HI e. Translation certificate 1.0_IN_HI_BT
	SIIC – DIRECT TO PATIENT
7.	a. NN9838-4942, Subject Information/Informed Consent Form – Direct to Patient Version 1.0_IN_EN Dated 22 Nov 2022, Status: Final

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		b. NN9838-4942, Subject Information/Informed Consent Form – Direct to Patient Version 1.0_IN_HI Dated 12 Dec 2022, Status: Final c. NN9838-4942, Subject Information/Informed Consent Form – Direct to Patient Version 1.0_IN_HI_BT Dated 12 Dec 2022, Status: Final d. Translation certificate 1.0_IN_HI e. Translation certificate 1.0_IN_HI_BT
		DIRECTION FOR USE
	8.	a. Direction for Use for CagriSema 1.0 (1,0) mg/ml + 0.5 (0,5) mg/ml; CagriSema 2.0 (2,0) mg/ml + 1.0 (1,0) mg/ml; CagriSema 9.6 (9,6) mg/ml + 4.8 (4,8) mg/ml; CagriSema 6.8 (6,8) mg/ml + 3.4 (3,4) mg/ml; CagriSema 4.0 (4,0) mg/ml + 2.0 (2,0) mg/ml; Placebo DFU_DV3384SDD_A_v.1.0_IN(EN) PC000210440 b. Direction for Use for CagriSema 1.0 (1,0) mg/ml + 0.5 (0,5) mg/ml; CagriSema 2.0 (2,0) mg/ml + 1.0 (1,0) mg/ml; CagriSema 9.6 (9,6) mg/ml + 4.8 (4,8) mg/ml; CagriSema 6.8 (6,8) mg/ml + 3.4 (3,4) mg/ml; CagriSema 4.0 (4,0) mg/ml + 2.0 (2,0) mg/ml; Placebo DFU_DV3384SDD_A_v.1.0_IN(HI) PC000210442
		CRF DOCUMENTS
	9.	• Sample CRF Additional Pages version 1.0 including the following documents - a) Adverse Event (AE) form and Instruction pages for the adverse event form b) Safety Information Form (SIF) and Instruction pages to the Safety Information Form c) Technical Complaint form for Clinical Study and Instruction page d) Maternal Form 1A (before pregnancy outcome) e) Maternal Form 1B (after pregnancy outcome) f) Maternal Form 2 (abnormal pregnancy outcome) g) Paternal Form (abnormal pregnancy outcome) h) Instruction pages for pregnancy forms • Annotated Study Book for Study Design: NN9838-4942 CVOT dated 06 Aug 2022
		LAB DOCUMENTS
	10.	• Q2 Solutions Laboratory Manual Asia Region V01 dated 07-Aug-2022
		SUBJECT RECRUITMENT RETENTION MATERIALS – ENGLISH
	11.	a. Other Info to Subjects Certificate of achievement EN v1.0 dated 07 Jul 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		b. Other Info to Subjects Contact Person Checklist EN v1.0 c. Other Info to Subjects Dose Reminder Tips Card EN v1.0 dated 08 Jul 2022 d. Other Info to Subjects Exercise Videos Storyboard v1.0 dated 08 Jul 2022 e. Other Info to Subjects Food and Nutrition CKD EN v2.0 dated 23 Sep 2022 f. Other Info to Subjects Health Tracker Booklet EN v1.0 dated 09 Aug 2022 g. Other Info to Subjects Health tracker sample report v1.0 dated 09 Aug 2022 h. Other Info to Subjects Healthy Eating for your Cardiovascular System EN v1.0 dated 14 Jul 2022 i. Other Info to Subjects Healthy Eating T2D EN v1.0 dated 14 Jul 2022 j. Other Info to Subjects Managing Stress Leaflet EN v1.0 dated 07 Jul 2022 k. Other Info to Subjects Participant Booklet Master EN v2.0 dated 23 Sep 2022 l. Other Info to Subjects Patient Letter – Your Contribution EN v1.0 m. Other Info to Subjects Treatment Action Plan EN v1.0 dated 04 Jul 2022 n. Other Info to Subjects Visit & Dose Reminder Card EN v1.0 dated 08 Jul 2022 o. Other Info to Subjects Visit Overview EN v1.0 p. Other Info to Subjects Welcome Letter EN v1.0 dated 09 Aug 2022 q. Other Info to Subjects What is Hypoglycaemia EN v1.0 dated 09 Aug 2022 r. Subject Card Participant ID Card EN v2.0 dated 22 Aug 2022 s. Other Info to Subjects Health Tracker Outline v2.0 dated 09 Nov 2022 t. Other Info to Subjects Recruitment poster EN u. Other Info to Subjects Participant ICF Guide Master EN v2 dated 14 Nov 2022 v. IP Instructions Pharmacy Instructions for DTP EN v1.0 dated 23 Sep 2022
		SUBJECT RECRUITMENT RETENTION MATERIALS – HINDI
	12.	a. Other Info to Subjects Certificate of achievement HI v1.0 dated 07 Jul 2022 b. Other Info to Subjects Dose Reminder Tips Card HI v1.0 dated 08 Jul 2022 c. Other Info to Subjects Food and Nutrition CKD HI v2.0, 2022 d. Other Info to Subjects Health Tracker Booklet HI v1.0 dated 09 Aug 2022 e. Other Info to Subjects Healthy Eating for your Cardiovascular System HI v1.0

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		f. Other Info to Subjects Healthy Eating T2D HI v1.0 dated 14 Jul 2022 g. Other Info to Subjects Managing Stress Leaflet HI v1.0 dated 07 Jul 2022 h. Other Info to Subjects Participant Booklet Master HI v2.0 dated 23 Sep 2022 i. Other Info to Subjects Patient Letter - Your Contribution v1.0 HI j. Other Info to Subjects Treatment Action Plan HI v1.0 k. Other Info to Subjects Visit & Dose Reminder Card HI v1.0 dated 08 Jul 2022 l. Other Info to Subjects Visit Overview HI v1.0 m. Other Info to Subjects Welcome Letter HI v1.0 dated 09 Aug 2022 n. Other Info to Subjects What is Hypoglycemia HI v1.0 dated 09 Aug 2022 o. Subject Card Participant ID Card HI v2.0 dated 22 Aug 2022 p. Other Info to Subjects Recruitment poster HI q. Other Info to Subjects Participant ICF Guide HI v2 dated 16 Jan 2023
		SUBJECT QUESTIONNAIRE – ENGLISH
	13.	a. Subject Questionnaire DN4 EN b. Subject Questionnaire MNSI EN Patient Version c. Subject Questionnaire MNSI scoring EN (Site-facing) d. Subject Questionnaire PSQI EN Version of 03 Oct 05 – Mapi e. Subject Questionnaire SF-36v2 Health Survey Single-Item Presentation Text Acute, EN f. Subject Questionnaire Subject facing screen report v3 dated 25 Oct 2022 g. Subject Questionnaire Site facing screen report v1 dated 25 Oct 2022 h. Subject Questionnaire_How to Use the Michigan Neuropathy Screening Instrument EN (Site-facing) i. Subject Questionnaire PSQI scoring instructions EN (Site-facing)
		SUBJECT QUESTIONNAIRE – HINDI
	14.	a. Subject Questionnaire DN4 India/Hindi – Version of 07 Jul 14 – Mapi b. Subject Questionnaire MNSI HI draft TFT Subject facing c. Subject Questionnaire PSQI – India/Hindi – Version of 12 Sep 09 – Mapi d. Subject Questionnaire SF-36v2 Health Survey Single-Item Presentation Text Acute, India

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		(Hindi)
		SUBJECT DIARIES – ENGLISH
	15.	a. Subject Dosing Diary Visit 2 to Visit 6 v1.0_IN_EN_11 Jan 2023 b. Subject Dosing Diary Visit 7 to Visit 12, Visit 19 and Visit 20 v1.0_IN_EN_11 Jan 2023 c. Subject Dosing Diary Visit 13 to Visit 18 v1.0_IN_EN_11 Jan 2023 d. Subject Numeric Rating Scale Diary (NRS) v1.0_IN_EN_11 Jan 2023
		SUBJECT DIARIES – HINDI
	16.	a. Subject Dosing Diary Visit 2 to Visit 6 v1.0_IN_HI_16 Jan 2023 b. Subject Dosing Diary Visit 7 to Visit 12, Visit 19 and Visit 20 v1.0_IN_HI_16 Jan 2023 c. Subject Dosing Diary Visit 13 to Visit 18 v1.0_IN_HI_16 Jan 2023 d. Subject Numeric Rating Scale Diary (NRS) v1.0_IN_HI_16 Jan 2023
		PATIENT RETENTION ITEM
		Other Info to Subjects Retention Catalogue EN v1.0 24 Aug 2022
		INSURANCE CERTIFICATS
	18.	a. Global Insurance Policy Number 390–08654942-30078, Expiry date 30 Apr 2023 b. Local Insurance Policy Number P0023200001/9999/100060, Expiry date 30 Apr 2023
		CV, GCP, MRC, IU OF PRINCIPAL INVESTIGATOR
	19.	a. CV of the PI b. GCP Certificate of PI c. MRC of the PI d. Investigator Undertaking of PI signed on 29 Nov 2022
		CTRI, CTA & DCGI SUBMISSION LETTER
	20.	a. CTRI document (attached in soft copy of dossier) Reference Number REF/2023/01/062274 b. Draft Clinical Trial Agreement

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	c. DCGI Submission Letter dated 20 Dec 2022 **EC Decision:** Approval subject to fulfillment & Administrative formalities. ***Ref. code: 123rd ECMIIC/P4***
23-	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 19th June, 2023 from 02.45 PM. ***virtual.*** ***The following Members were present in the Meeting:*** 1. Dr. Alok Dhawan -Chairman 2. Mrs. Akansha Dubey -Member 3. Mrs. Vasundhara Kumari -Member 4. Mr. Ujjawal Krishna -Member 5. Dr. Rajendra Nath -Member 6. Dr. Nisha Mani Pandey -Member 7. Dr. Shally Awasthi -Member-Secretary, IEC ***The following Member was not present in the Meeting:*** 1. Dr. D.N. Upadhyaya -He has given his written comment
	DCGI
I-	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 187/Neuro/23 dated 18th April, 2023. **Patient ID & age and gender:** S-45-3-1193/35 years/Male **Subject initial:** A-S **Patient Diagnosis:** Left Gangio-capsular intracranial bleed with midline shift and IVH **Patient enrollment date:** 11-04-2023 **Patient enrollment Arm:** Control **Patient follow up under study**-Expired on 16-04-2023 during hospital stay. **Follow up visit completed**-Expired **SAE detected on date:** 12-04-2023 **Follow up visit remaining:** Expired **24 hours, notified to EC, Sponsor**-Yes **14 days analysis report submitted to EC**-NA **Subject History:** A letter was received in the Office of the Ethics Committee on 25th April, 2023. Subject A-S 45-3-1193-35 years/Male was admitted on 11th April, 2023 in the Emergency Medical ward with c/o sudden weakness of right side of the body diagnosed to have right

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	intracerebral (Ganglio-capsular) bleed, volume approximately 28.94 ml. He was randomized to the control arm, transferred to Neurology stroke ward on the same day (11-04-2023) and received standard treatment. The next morning (12.04.2023) around 10:30 AM, the patient developed labored breathing and poor GCS. Blood pressure could not be controlled by increasing labetalo infusion. The patient was immediately intubated and placed on a mechanical ventilator. NCCT Head was repeated and hematoma expansion was noted. The patient's condition deteriorated further during his stay in the hospital. On 16th April, 2023 at 19:15 PM, the patient developed sudden arrest and despite all methods of CPR, he could not be revived. The patient was declared dead and LAR / relatives was/were informed. *Recommendation of Primary reviewer:-* • SAE (Intubation & mechanical ventilation during hospital stay) is likely due to disease outcome (Raised intracranial pressure with Left Gangliocapsular bleed secondary to systemic hypertension) and not due to intervention as patient was randomized in control arm on 11-04-2023. On 12-04-2023 around 10:30 AM, the patient developed labored breathing and poor GCS. His BP could not be controlled by giving increasing dose of Labetalol. The Patient was immediately intubated and placed on mechanical ventilator (SAE). The patient's condition deteriorated further and on 16 th April ,2023 at 19:15 PM he developed sudden cardio-respiratory arrest and despite all methods of CPR ,he could not be revived. • Causal relationship can not be established and no compensation is required as patient was enrolled in control arm (11-04-2023) and was properly treated in hospital and SAE happened due to his deteriorating condition on next day (12-04-2023) of enrollment. **ADR sub Committee Comment:** • As above **ADR sub Committee Decision:** Noted ***Ref.code:115th ECMIIA/P5***
	Non-DCGI
	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 19th June, 2023 from 02.45 PM. ***virtual.*** ***The following Members were present in the Meeting:*** 1. Dr. Alok Dhawan -Chairman 2. Mrs. Akansha Dubey -Member 3. Mrs. Vasundhara Kumari -Member 4. Mr. Ujjawal Krishna -Member 5. Dr. Rajendra Nath -Member

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	6. Dr. Nisha Mani Pandey -Member 7. Dr. Shally Awasthi -Member-Secretary, IEC ***The following Member was not present in the Meeting:*** 1. Dr. D.N. Upadhyaya -He has given his written comment
I-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 12/Cardio/Res/2023 dated 20th April, 2023 & preliminary email dated 3rd April, 2023 at 1:00 PM. **Patient ID & age and gender:** 033/37 Y/Female **Patient Diagnosis:** RHD/Sev-MS/MVA 1.5 cm. **Patient enrollment date:** 21-07-2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit-** 6th M **SAE detected on date:** 03-04-2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor**-3rd April, 2023 **14 days analysis report submitted to EC**-18th April, 2023 **Subject History:** A letter was received in the Office of the Ethics Committee on 20th April, 2023 by PI. It was revealed by the PI that the subject's LAR informed him that the subject was having complaint of breathlessness for which she was hospitalized on 23rd March, 2023 and **passed away** on the same day. It might be considered as a case of new onset or worsening of HF as informed by the subject's LAR via telephonic conservation. Despite multiple reminders, the subject's LAR was unable to provide any documents supporting the hospitalization or **death** of the patient. ***Recommendation of Primary reviewer:-*** • Enrolment date 21st July, 2022, SAE date 23rd March, 2023. Principal Investigator reported to IEC 3rd April, 2023. • Patient was not in follow-up. Skipped the 6-month follow-up also, SAE occurred on 23rd March, 2023, but was detected on 3rd April, 2023. Why was the patient not on follow-up?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• No mention is made of which hospital was the patient admitted to for her complaints on 23rd March, 2023. Was it KGMU? • Was an autopsy done? No mention is made of these details. These clarifications may be asked for from the Principal-Investigator. • In the SAE narrative start day and time of the drugs is given as 23rd March, 2023 (Is it a misprint?) **ADR sub Committee Comment:** • As above **ADR sub Committee Decision:** Noted ***Ref. code: 102nd ECM IIA/P24***
24-	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 19th April, 2023 from 12.30 PM. ***virtual.*** ***The following Members were present in the Meeting:*** 1.Dr. Alok Dhawan -Chairman 2.Mrs. Akansha Dubey -Member 3.Mrs. Vasundhara Kumari -Member 4.Mr. Ujjawal Krishna -Member 5.Dr. Rajendra Nath -Member 6.Dr. D.N. Upadhyaya -Member 7.Dr. Nisha Mani Pandey - Member Dr. Shally Awasthi -Member-Secretary, IEC
1-	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 36/Neuro/23 dated 25th January, 2023 & ***preliminary email dated 24th January, 2023 at 1:41 PM.*** **Patient ID & age and gender:** S-45-3-634/65 years/Male **Subject initial:** MIA **Patient Diagnosis:** Right cortical bleed **Patient enrollment date:** 02-01-2023 **Patient enrollment Arm:** Control arm **Patient follow up under study**-Expired on 23-01-2023 during hospital stay. **Follow up visit completed**-Expired **SAE detected on date:** 24-01-2023 **Follow up visit remaining:** Expired **24 hours, notified to EC, Sponsor**-Yes **14 days analysis report submitted to EC**-NA **Subject History:-** A letter was received in the Office of the Ethics Committee on 20th January, 2023. Subject MIA 65 years/Male was admitted on 2nd January, 2023 in the Emergency Medical ward with c/o left hemiparesis and altered sensorium with GCS score of 14 and diagnosed to have right

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	intracerebral (cortical) bleed, volume approximately 14.17 ml. Since he was fulfilling inclusion criteria so he was recruited after written informed consent from family and randomized to control arm. He was kept in emergency medical ward ICU had received treatment with parenteral antihypertensive to lower blood pressure (Amlong, Arkamin). He was sent to Neurology stroke ward on 3rd January, 2023 and received treatment with calcium channel blocker for blood pressure management. He gradually improved and discharged on 6th day (07-01-2023). As per family member he remained fine at home. On 23rd January, 2023 the patient presented with a complaint of breathlessness of 2 hrs. The patient was assessed promptly on arrival. Bedside ultrasound revealed b/l pleural effusion. NCCT head was repeated and did not show any new ischemic/hemorrhagic stroke. Vitals on admission-HR-86/min, SpO2-90% on room air. E4V5M6 on GCS, Blood pressure was 110/70 mmHg. Chest Xray revealed B/L perihilar nonhomogenous opacities. On auscullation course crepitations were present all over the lungfields. Patient was provided oxygen support and broad-spectrum antibiotics after about 14 hours of admission the patient experienced sudden cardiac arrest in ward of emergency medicine. No return of spontaneous circulation seen after advanced cardiac life support was provided to the patient. The patient was declared dead at 16:29 hours on 23rd January, 2023. ***Recommendation of Primary reviewer:*** • SAE (Death) is likely due to disease outcome (Rt. Cortical bleed) and not due to intervention as patient was randomized in control arm on 02-01-2023. He gradually improved and discharged on 07-01-2023. Pt again admitted due to breathlessness, USG of lungs was done showed B/L pleural effusion. SAE occurred on 23-01-2022, almost 10 days after randomization. As Pt was randomized in control arm therefore SAE is most likely due to disease outcome. • Causal relationship can not be established and no compensation is required as patient was properly treated in hospital and SAE occurred after 10 days due to disease progression and sudden cardiac arrest. **ADR sub Committee Decision:** Noted ***Ref.code:115th ECMIIA/P5***
II-	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 37/Neuro/23 dated 28th January, 2023. **Patient ID & age and gender:** S-45-3-759/40 years/Male **Subject initial:** A-O-K **Patient Diagnosis:** Left Basal ganglia bleed **Patient enrollment date:** 22-01-2023 **Patient enrollment Arm:** Control arm **Patient follow up under study**-Expired on 25-01-2023 **Follow up visit completed**-Expired **Planning on visit-** Expired **SAE detected on date:** 25 -01-2023 **Follow up visit remaining:** Expired

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	24 hours, notified to EC, Sponsor-Yes **14 days analysis report submitted to EC**-NA **Subject History:** A letter was received in the Office of the Ethics Committee on 28th January, 2023. Subject AOK 40 years/Male was admitted on 22nd January, 2023 the patient was admitted in the Emergency medical ward with c/o weakness on right upper & lower limb with shivering. K/C/O acute pancreatitis (3 rears back) with GCS score of 15 and diagnosed to have left intracerebral (Basal ganglia) bleed, volume approximately 12.44 ml. Since he was fulfilling inclusion criteria so he was recruited after getting written informed consent from the family and randomized to the control arm. He was kept in the emergency medical ICU had received treatment with parenteral antihypertensive to lower blood pressure (Labetalol-infusion). He was sent to Neurology stroke ward on 23rd January, 203 and received treatment with Nieardipin. Arkamin, Telmistran, Amlong for blood pressure management. On 24th January, 2023 the patient GCS deteriorated to 1E2V2M5 & repeat NCCT was done which revealed an increase in the size of the bleed (vol.74.0) and midline shift. On 25 January 2023 at about 7 AM the GCS declined to E1V1M1. By 10 AM patient developed a labored breathing pattern & pulse was not recordable. CPR was started as per ACLS protocol. After 45 minutes, no return of spontaneous circulation was noted. Patient could not be revived and was declared dead at 10:40 AM. *Recommendation of Primary reviewer:* • SAE (Death) is likely due to disease outcome (Left Basal ganglia bleed)) and not due to intervention as patient was randomized in control arm on 22-10-2023 and SAE occurred on 25-01-2023 , 3 days after intervention which was due to sudden deterioration in GCS (Glasgow coma scale), NCCT (non contrast CT scan) reveled increased size of previous bleed (due to raised intracranial pressure with left putamen bleed with midline shift with mass effect) resulted in labored breathing, pt can not be revived by CPR. History shows that Pt was also chronic alcohol abuser and having systemic hypertension. • Causal relationship can not be established and no compensation is required as patient was properly treated in hospital after randomization in control arm and death occurred was most likely due to disease progression (reveled from increased size of previous bleed) **ADR sub Committee Decision:** Noted ***Ref.code:115th ECMIIA/P5***
III-	ADR of research proposal entitled ***"PRISTENE Registry "Prospective, multi/centric, singlearm post marketing surveillance of PRISTINE, everolimus cobaltchromium coronary stent system to assess its continued safety and efficacy"*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

University, U.P., Lucknow vide letter no. 93/Neuro/23 dated 27th February, 2023 & 128/Neuro/23 Dated 27th March, 2023.

Patient ID & age and gender: S-45-3-376-45 Years and 1 Month 1 day/Male
Subject initial: VAK
Patient Diagnosis: Right hemiparesis

Patient enrollment date: 26-11-2022
Patient enrollment Arm: Control Arm
Patient follow-up under the study: Yes
Planning on visit- No
Follow up visit completed- Yes (17-02-2023)
SAE detected on date: 09/12/2022
Follow up visit remaining: No
24 hours, notified to EC, Sponsor-Yes
14 days analysis report submitted to EC-Yes
Subject History:-

A letter was received in the Office of the Ethics Committee on 1st March, 2023. Subject VAK 45 years 1 month 1 day/Male was discharged on 10th December, 2022 and his 90th day follow-up was done on 17th February, 2023. As per his proxy on 17th February, 2023 his mRS & GCS was 4 and 15 respectively with residual right hemiparesis and unable to walk and attend to own bodily needs without assistance. This patient was diagnosed hepatitis B positive on 09-12-2022 for which PI had reported to EC. On that day's follow-up he has been advised to continue medication at gastroenterology.

Recommendation of Primary reviewer:-

- SAE (Hospitalization and detection of Hepatitis B infection) is likely due to disease outcome (Left Gangliocapsular bleed) and accidental detection of Hepatitis B infection during hospital stay and not due to intervention as patient was randomized in control arm on 26-11-2022. He gradually improved and discharged on 10-12-2022. On his 90th day follow up done on 17-02-2023, he has residual hemiparesis and unable to walk. According to PI during his hospital stay he was diagnosed with Hepatitis B infection on 09-12-2022 and for which he has taken treatment from Gastroenterology Department, KGMU.

- Causal relationship can not be established and no compensation is required as patient was properly treated in hospital and SAE occurred after 13 days due to disease progression and accidental detection of Hepatitis B infection which is unrelated to intervention and for which Patient was advised to continue treatment from Department of Gastroenterology.

ADR sub Committee Decision: Noted
EC Decision: Noted

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref.code:115th ECMIIA/P5
IB	**Expedited review**
1-	Expedited review of the research proposal entitled ***"Effect of COVID-19 vaccine on thrombotic events among 18-45 year old population in Indian, 2022, Multicentric hospital-based matched case control study"*** submitted by Dr. Ambuj Yadav, Assistant Professor, Department of Medicine, K.G's Medical University, U.P., Lucknow vide letter no.817/Med/23 dated 8th April, 2023. ***The above Proposal forwarded to two reviewers, for review:-*** ***Recommendation of First Primary reviewer:-*** Provisionally approved ***Recommendation of Secondary reviewer:-*** Provisionally approved **EC Decision:** Approved ***Ref. code: 124th ECMIB/P1***
2-	Expedited review of the research proposal entitled ***"Factors associated with sudden deaths among adults aged 18-45 years, India: Multicentric matched case-control study"*** submitted by Dr. Ambuj Yadav, Assistant Professor, Department of Medicine, K.G's Medical University, U.P., Lucknow vide letter no.976/Med/23 dated 18th April, 2023. ***The above Proposal forwarded to two reviewers, for review:-*** ***Recommendation of First Primary reviewer:-*** • The title/objective should be more specific. What aspects of death shall be investigated? • There are certain guidelines for multicenter studies. These must be followed. Only a list of potential sites is given. The name of participating centres is required. • What will be the common protocol? • Which will be a coordinating center to collect, process and analyze the data? • The number of field sites varies greatly across studies according to their size, complexity and purpose. How will this be handled? • Sample size calculation is arbitrary. This is due to the fact that the aim/objective is not clearly defined. The outcome event should be clearly defined. The primary objective should be converted into a proper research hypothesis in terms of the study variables and parameters. • Sample size calculation will be based on the research hypothesis. • Data analysis plan is very general. It should be specific to the research hypothesis. ***Recommendation of Secondary reviewer:-*** • Detailed sample size calculation is missing. • Informed consent forms are given-As this seems to be a Retrospective case-control study of subjects/patient seen during 1st October, 2021 to 31st December, 2022), how will PI take the Informed consent of Cases/control?-whether indirectly from hospital record or by some other way-PI to clarify. • Letter of Approval of grant from ICMR-National Institute of Epidemiology not attached, only signed agreement from PI is given and not from counterpart

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	(ICMR-NIE) please clarify or attach the required documents. **The above comments forwarded to Principal-Investigator but reply was pending.** **EC Decision:** Send reminder to PI ***Ref. code: 124th ECMIB/P2***
3-	Expedited review of the research proposal entitled ***"Understanding the effect of single-dose intravenous ferric carboxy-maltose in improving hemoglobin levels among postpartum women with moderate or severe Anemia in selected hospitals in Lucknow Uttar Pradesh"*** submitted by Prof. Shyam Pyari Jaiswar, Head, Department Obst. & Gynaecology, K.G's Medical University, U.P., Lucknow vide letter no.OG/653A/23 dated 5th June, 2023. ***The above Proposal forwarded to two reviewers, for review:-*** ***Recommendation of First Primary reviewer:-*** • Title should be: "On the effectiveness of single-dose……". • This is repeated trial longitudinal study. • The research hypothesis should be formulated accordingly using the study variables and population parameters. • In the absence of proper research hypothesis, sample size calculation has no meaning. • The sample size is said to be 200 without any justification. • Statistical analysis section is for paired observation. It should be for repeated trials (At the start, 4 weeks and 8 weeks.). There shall be three observations on each subject. • Since this is multi-center study. • There are certain guidelines for multi-center studies. These must be followed. Only a list of potential sites is given. • What will be the common protocol? • Which will be a coordinating center to collect process and analyze the data? • The number of field sites varies greatly across studies according to their size, complexity and purpose. How will this be handled? **The above comments forwarded to PI was reviewed by *Primary reviewer:-*** Provisionally approved ***Recommendation of Secondary reviewer:-*** Provisionally approved **EC Decision:** Approved ***Ref. code: 124th ECMIB/P3***
II-A	**New Proposal**
1.	Research proposal entitled ***"To study the impact of micro RNAs and their genetic variants on gall bladder cancer"*** submitted by Prof. M.L.B. Bhatt, Head, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	343/RT/23 dated 31st March, 2023. *Recommendation of Primary reviewer:* • Sample size calculation not provided. • Methodology and references page missing • Name of micro RNA genes not mentioned. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P1***
2.	Research proposal entitled ***"Bone marrow metastasis in non-hematological malignancies: A study from tertiary care centre"*** submitted by Prof. Rashmi Kushwaha, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 82/23 dated 5th April, 2023. *Recommendation of Primary reviewer:* • Objectives of the study are not provided **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P2***
3.	Research proposal entitled ***"Plasma metabolomics profiling of dengue and chikungunya patients: A case-control study"*** submitted by Dr. Ashutosh Shrivastava, Additional Professor, Department of Centre For Advanced Research, King George's Medical University, U.P., Lucknow vide letter no. 2018/CFAR/23 dated 31st March, 2023. *Recommendation of Primary reviewer:* Approved **EC Decision:** As above ***Ref. code: 124th ECM IIA/P3***
4.	Research proposal entitled ***"Analysis of expression and polymorphism in miRNA target gene associated with gall bladder cancers (GBC)"*** submitted by Prof. M.L.B. Bhatt, Head, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 365/RT/23 dated 13th April, 2023. *Recommendation of Primary reviewer:* • Objective of the study are not clear. • Sample size calculation not provided. • Methodology not clear defined. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P4***
5.	Research proposal entitled ***"Effect of low-level laser therapy during regenerative***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	endodontic procedure in necrotic immature young teeth-clinical and molecular perspectives" submitted by Dr. Pragya Pandey, Associate Professor, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 17/Coms&Endo/23 dated 12th April, 2023. *Recommendation of* ***Primary reviewer:*** • Techniques for biomarker estimation not provided. The paper which has been cited does not cover all the parameters to be investigated. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P5***
6.	Research proposal entitled ***"Morphological and morphometric analysis of cadaveric lung in North Indian population"*** submitted by Dr. Arvind Kumar Pankaj, Additional Professor, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 56/ANAT/23 dated 28th April, 2023. *Recommendation of* ***Primary reviewer:*** • Title says North Indian Population. What is the target population? What is the sampling frame? • The objective should specify: How the morphological and morphometric analysis shall be used? • There is no sample size calculation. • Methodology is incomplete. • There is no statistical analysis section. • There is no informed consent form (Hindi and English). **EC Comment:** As above **EC Decision:** Revise and Re-submit. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P6***
7.	Research proposal entitled ***"Randomized control trial of direct pulp capping using laser"*** submitted by Prof. Rakesh Kumar Yadav, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 589/Coms&Endo/23 dated 2nd March, 2023. *Recommendation of* ***Primary reviewer:*** • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • There seems to be three groups for comparison.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The sample size calculation is arbitrary. It is for two group's comparison. It is due to absence of proper research hypothesis. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **EC Comment:** As above **EC Decision:** Revise and Re-submit. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P7***
8.	Research proposal entitled "***Introducing the professionalism mini-evaluation exercise (P-MEX) in undergraduate medical training in India: A validity and feasibility study***" submitted by Dr. Sarika Gupta, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1080/Ped/23 dated 12th April, 2023. *Recommendation of **Primary reviewer:*** • There are certain guidelines for multicenter studies. These must be followed. It only says that the study will be conducted in 13 medical colleges. The name of participating centres is required. • What will be the common protocol? • Which will be a coordinating center to collect, process and analyze the data? • The number of field sites varies greatly across studies according to their size, complexity and purpose. How will this be handled? • Sample size calculation is not given. • Sample size calculation will be based on the research hypothesis. • Data analysis plan is very general. It should be specific to the research hypothesis. **EC Comment:** As above **EC Decision:** Revise and Re-submit. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P8***
9.	Research proposal entitled "***Relationship between implementation of evidence-based and supportive ICU care and outcomes of patients with acute respiratory distress syndrome (The ICU Liberation Study)***" submitted by Dr. Saumitra Misra, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1455/23 dated 28th April, 2023. *Recommendation of **Primary reviewer:*** • Sample size calculations are not clear. There are too many numbers. Where are they coming from? Sample size formula is required. • There are too many objectives. • One primary objective should be sorted out and the rest should be put into secondary objectives.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The primary objective should be converted into a proper research hypothesis in terms of study variables and population parameters. Sample size should be done for this hypothesis. • Statistical analysis section is missing **EC Comment:** As above **EC Decision:** Revise and Re-submit. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P9***
10.	Research proposal entitled "***External limiting membrane and ellipsoid zone restoration-based grading system for successful macular hole surgery***" submitted by Prof. Sandeep Saxena, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 115/Oph/23 dated 12th April, 2023. *Recommendation of* ***Primary reviewer:*** • How the novel ELM and EZ restoration-based grading system will be develop? An outline is required. • Study duration says: April 2022- March 2023. It is already over. • Sample size calculation is arbitrary. It is for prevalence study. • Statistical analysis section is very general. It should be specific to the objectives of the study. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P10***
11.	Research proposal entitled "***Creation of gold standard medical imaging datasets of dural based lesions treated with primary gamma knife radiosurgery or microsurgery for developing arificial intelligence tools***" sponsored by ICMR, New Delhi submitted by Dr. Ankur Bajaj, Additional Professor, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/764/23 dated 3rd May, 2023. *Recommendation of* ***Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 124th ECM IIA/P11***
12.	Research proposal entitled "***To evaluate polymorphism in CYP2C19 gene and its impact on clinical outcome in patients of coronary artery disease (CAD) treated with combined clopiogrel and aspirin therapy***" sponsored by Council of Science & Technolohu, UP (UPCST) submitted by Dr. Akshyaya Pradhan, Prodessor Jr Grade, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 733/Cardio/Res/23 dated 5th April, 2023. *Recommendation of* ***Primary reviewer:*** • Please fill the Patient Information sheet. ONLY GUIDELINES ARE ATTACHED. ICF: please explain the study procedure to the patient in simple and understandable language.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P12***
13.	Research proposal entitled "***Evaluation of neutrophils as a immunosuppressive lineage, biomarker and therapeutic target in tobacco induced oral cancer***" sponsored by SERB under POWER Research Grant Scheme submitted by Dr. Sameer Gupta, Additional Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/765/23 dated 8th May, 2023. *Recommendation of* ***Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 124th ECM IIA/P13***
14.	Research proposal entitled "***ASIAN bipolar genetics network (A-BIG-NET0 study***" sponsored by National Institute of Mental Health & Neuro Sciences submitted by Prof. Adarsh Tripathi, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 628/PSY/23 dated 17th April, 2023. *Recommendation of* ***Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 124th ECM IIA/P14***
15.	Research proposal entitled "***Long term course and outcome and co-morbidity in patients with bipolar disorder: A multicentric study***" submitted by Prof. Adarsh Tripathi, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 482/PSY/23 dated 23rd March, 2023. *Recommendation of* ***Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 124th ECM IIA/P15***
16.	Research proposal entitled "***Epidemiology, patterns and mechanisms of injury in pediatric trauma patients in a level 1 trauma centre of Northern India***" submitted by Dr. Yadavendra Dheer, Associate Professor, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. TS/246/23 dated 5th April, 2023. *Recommendation of* ***Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 124th ECM IIA/P16***
17.	Research proposal entitled "***Identification of plasma micro RNAs biomarker in severe traumatic brain injury patients: a case-control study***" submitted by Dr. Anshu Priya, Assistant Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 146/FMT/23 dated 15th May, 2023. *Recommendation of* ***Primary reviewer:*** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: As above ***Ref. code: 124th ECM IIA/P17***
18.	Research proposal entitled "***Practice pattern of intraoperative fluid therapy in elective major gastrointestinal cancer surgeries in India (I-INFUSE)- A multicentre observational study***" submitted by Dr. Hemlata, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/540/23 dated 16th May, 2023. *Recommendation of* ***Primary reviewer:*** The following sections are missing:- • Methodology • Inclusion criteria/Exclusion Criteria • Outcome Measures • Sponsorship information • Number of patients to be enrolled • Statistical plan **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P18***
19.	Research proposal entitled "***Objective determination of amount of glue injected in gastric varices for good clinical and technical outcome: A proof of concept study from a tertiary care Hospital of North India***" submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1098/MED/23 dated 12th May, 2023. *Recommendation of* ***Primary reviewer:*** • In brief description objective of the study is not mentioned. • Study setting is not mentioned. • If data is to be retrieved from case records there is no need information sheet and consent form as PI already declares that laboratory data of interventional cases will be retrieved Jan 2022 to Dec 2022. • Inclusion/ exclusion criteria is not written in the text but mentioned in checklist • Consent form…is it needed as study seems to be retrospective; if yes, there are many terms that needs to be reframed. • In check list no of subjects is written as 6; one year data to be included in the study (as written in description). Statistical analysis of 6 data? **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P19***
20.	Research proposal entitled "***Surveillance of humoral and T-cell immunity for COVID-19 in population of Uttar Pradesh***" sponsored by MHM, UP Government submitted by Dr.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Geeta Yadav, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 520/23 dated 28th April, 2023. ***Recommendation of Primary reviewer:*** • Estimates of antibodies and T cell are to be done in KGMU and data is to be collected from various districts of Uttar Pradesh, what precautionary measures will be taken to maintain quality of the sample and who will be the responsible for it. • For sampling probably 10 districts of the state are to be selected; however, it is not mentioned anywhere that how many districts will be required for data collection. • The checklist indicates that any other will take the consent, which needs to be defined how anyone can take the consent and will any other be able to satisfy the query of the participants. • Will the participant be able to understand the study process as it is written? • Assent is not there. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P20***
21.	Research proposal entitled ***"Development of risk scoring algorithm using clinical, biochemical, ultrasound and molecular markers to predict preeclampsia-A pilot study"*** sponsored by UP-CST submitted by Prof. Amita Pandey, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/271/23 dated 1st May, 2023. ***Recommendation of Primary reviewer:*** • If females with 11-16 wks pregnancy are to be included in the study inclusion criteria should denote the same. • In Hindi consent form, at many places space in between words are missing. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P21***
22.	Research proposal entitled ***"Clinicopathological parameters of hemophilia patients at a tertiary care centre of Northern India"*** submitted by Prof. Rashmi Kushwaha, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 605/23 dated 19th May, 2023. ***Recommendation of Primary reviewer:*** • The research hypothesis is written under the heading of Aims & Objectives. • Expected outcome is written as study objectives. • PI declares that study is not a research activity and is a chart review then there is no need for consent form. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 124th ECM IIA/P22
23.	Research proposal entitled "***Comparative evaluation of Glasgow coma score (GCS) with or without assessment aid among resident physicians and nursing staff in emergency Medicine Department- a randomized control trial***" submitted by Prof. Haider Abbas, Head, Department of Emergency Medicine, King George's Medical University, U.P., Lucknow vide letter no. 155/EM/23 dated 22nd May, 2023. ***Recommendation of Primary reviewer:*** • Study title needs to be modifies as per hypothesis. • The research hypothesis is written under the heading of Aims & Objectives. • The methodology section needs to be written correctly as materials and methods • Study duration is to be checked as in checklist it is written as 4 weeks and in brief description as 2 weeks from data collection to literature preparation. • Inclusion and exclusion criteria • How consent of a Coma patient will be solicited. • Study duration is to be checked as in checklist it is written as 4 weeks and in brief description as 2 weeks from data collection to literature preparation. • Sample size? **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: 124th ECM IIA/P23*** ***(Primary Reviewer: Dr. Nisha Mani Pandey)***
24.	Research proposal entitled "***Indian Near Miss Registry: Incidence of late maternal death & non-communicable disease following potential life-threatening event during pregnancy and child birth: A cohort study***" submitted by Prof. Anjoo Agarwal, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. 481/23 dated 18th May, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Previous Ref. Code: 120th ECM IIA/P9*** ***Current Ref. code: 124th ECM IIA/P24***
II-B	**IMR-Faculty**
1.	Research proposal entitled ***"Study of urinary L1 cell adhesion molecule (L1CAM) as potential biomarker of the renal damage in Indian children with posterior urethral valve"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Dr. Gurmeet Singh, Assistant Professor, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 321/PedSy/23 dated 25th April, 2023. ***Recommendation of Primary reviewer:*** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Decision: As above ***Ref. code: 124th ECM II B-IMR-F/P1***
2.	Research proposal entitled ***"A study to compare diagnostic performance of galectin-3 (a novel biomarker) and NT-proBNP (an established biomarker) for cardiac dysfunction in patients with chronic liver disease"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Dr. Mahak Lamba, Assistant Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1105/MED/23 dated 15th May, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 124th ECM II B-IMR-F/P2***
II-B	**New Ph. D Proposal**
1.	Research proposal entitled ***"Effect of nutraceutical potential of pumpkin seeds on glycaemic and lipid profile in type 2 diabetes mellitus patients"*** sponsored by CST U.P submitted by Miss. Poonam Sahu, Ph.D Scholar under the guidance Prof. Dileep Kumar Verma, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3072/PHY/23 dated 19th April, 2023. ***Recommendation of Primary reviewer:*** • This is a clinical study of herbal remedies. Therefore an Ayurvedic co-investigator can be included. Moreover, kindly clarify if the processes of inclusion as a clinical trial need to be done? • Informed consent form for volunteers (as indicated in annexure 1 that volunteers and patient will be recruited). Study design as indicated in case Control- does Control refer to healthy subjects? • While study design flow chart suggests it to be randomised controlled trial- Kindly clarify. • Patient information sheet to be included in detail both in Hindi and English. • Sample size to be made molecular in respect to primary objective. Elaborate the numbers mentioned in difference in expected means. • The budget indicates 3.9- is it in thousands or lakhs? • Who will fund for pumpkin seed? The CST papers do not indicate anything about pumpkin seed purchase. Also the attached CST sanction letter is for some other project. Kindly explain? • Who will bear the cost of biochemical analysis and how much cost is expected for these tests per case basis. • Summarize the anticipated statistical analysis briefly. • Summarize randomization process. Will this be age and gender matched - kindly brief. **EC Comment:** As above **EC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: 124th ECMIIB-Ph.D/P1***
2.	Research proposal entitled ***"Effectiveness of meta cognitive therapy in patients with***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	obsessive compulsive disorder" submitted by Ms. Ayushi Gaur, Ph.D. Scholar, Amity Institute of Behavioral & Allied Sciences, Amity University Uttar Pradesh, Lucknow under the guidance Dr. Shivali Sharma, Assistant Professor, Amity University Uttar Pradesh, Lucknow, Through Dr. Shweta Singh, Professor Jr. Grade, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 728/Psy/23 dated 8th May, 2023. ***Recommendation of Primary reviewer:*** • No guide/ co-guide from King George medical University has been mentioned on first page of annexure 1 for this Ph.D. project. Kindly indicate who is the chief guide of this PhD work? • Scientific committee report/ approval is not attached. • In hypothesis, 4 points are repeated. Kindly correct. The aims do not indicate meta cognitive therapy, while hypothesis states the same. Kindly resolve the discrepancy. • Kindly elaborate sample size calculation with respect to the aims of the study. • What anticipated appropriate statistical analysis will be undertaken? Kindly brief. • Patient information sheet to be submitted as per standard operating procedures of ethics committee of King George's medical University both in English and Hindi. • Hence the investigator needs to address above issues and resubmit. **EC Comment:** As above **EC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: 124thECMIIB-Ph.D/P2***
3.	Research proposal entitled ***"Elucidate the regulatory role of miRNAs in epithelial to mesenchymal transition in cervical cancer patients"*** submitted by Mr. Praveen Kumar, Ph.D Scholar, under the guidance Dr. Nitu Nigam, Associate Professor, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 74/CFAR/23 dated 15th May, 2023. ***Recommendation of Primary reviewer:*** • The account of budget is not indicated and sponsor is indicated as NA. Kindly specify the total • budget (split up) and kindly specify the source of funding. • Attach the CSIR JRF papers pertaining to the candidate. • Kindly fill up the left blanks in annexure 1. • 'National significance with rationale' indicates the details about prostate cancer (in males) while the project is for cervical cancer in females. • Patient information sheet in Hindi is to be included. • Name and contact of Guide to be included in informed consent form. • All study procedures undertaken on patient's sample need to be briefed in informed consent form to the patient and not labeled as NA. • The second and third aims pertain to the progression of cervical cancer and prognostic aspects of cervical cancer respectively, but there is neither indication of any clinical data

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	been collected nor any follow-up data. Kindly attach a case sheet to record the clinical findings and specify which specific clinical prognostic marker is intended to be correlated with molecular outcomes. • It is indicated that 60 normal cervical samples will be collected. Does it mean from normal subjects? What will be the indication to take samples from normal person?? Kindly specify. • It is further indicated that patients will be included on the basis of well-defined inclusion and exclusion criteria. Those criteria include both cervical cancer and other serious uncontrollable medical conditions, decreasing life expectancy' Please clarify. Inclusion and exclusion criteria may be modified accordingly. • The study design is case control and experimental if any control is included then kindly mention the inclusion criteria and include informed consent form as well as in information sheet for control. • How will clinical validation be done as shown in last flowchart? Also specify some tentative micro RNA and EMT markers **EC Comment:** As above **EC Decision:** Revise and re-submit. Give changes done in a tabular form. ***Ref. code: 124thECMIIB-Ph.D/P3***
4.	Research proposal entitled "***Assessment of Th2 inflammatory mediators and their correlation with clinical parameters in phenotypes of bronchial Asthma***" submitted by Ms. Shreya Tripathi, Ph.D. Scholar, under the guidance Dr. Ajay Kumar Verma, Professor Junior Grade, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 521/23 dated 18th May, 2023. *Recommendation of **Primary reviewer:*** • Patient information sheet to be submitted as per standard operating procedures of ethics, committee of King George medical University, both in English and Hindi. • The left blanks in annexure 1 should be filled. • Methodology indicates that blood sample will be collected but is indicated otherwise in annexure. • Kindly mention inclusion criteria of controls. The criteria of selecting attendants of patients need to be made carefully as attendants of asthmatics may have some genetic predisposition to Influence the markers under study. • It is indicated that age and gender matched controls will be collected. The criteria of selecting control child of 6y age should also be mentioned. • Where will the lab work be done or undertaken? • What would be the total budget of lab investigations? Kindly submit a rough split estimate. • No evidence is enclosed by the sponsor (University grants commission) that is indicated to fund the project. • Informed consent document from healthy subjects (controls) need to indicate that they will not directly be benefited from this 5 ml blood collection. **EC Comment:** As above **EC Decision:** Revise and re-submit. Give changes done in a tabular form.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 124thECMIIB-Ph.D/P4
II-B	**Fellowship**
1.	Research proposal entitled ***"Elucidate the role of miRNA mediating epithelial to mesenchymal transition in chronic myeloid leukemia"*** sponsored by DST Inspire Fellowship submitted by Ms. Surbhi Gupta, under the guidance Dr. Nitu Nigam, Associate Professor, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 53/CFAR/23 dated 2nd May, 2023. ***Recommendation of Primary reviewer:*** • Very poorly written proposal • Title, Outcome measures, Aims/Objectives/methodology are all discordant • Review written in wrong format • Patient Information sheet not proper **EC Comment:** As above **EC Decision:** Revise and re-submit. Give changes done in a tabular form.
	Ref. code: 124thECM II B-FS/P1
II-C	**Review of New Drug Trial**
1.	Research protocol no.CKJX839D12303 entitled ***"A multi-center, randomized, double-blind, placebo-controlled, parallel-group IIIb study evaluating the effect of inclisiran on atherosclerotic plaque progression assessed by coronary computed tomography angiography (CCTA) in participants with a diagnosis of non-obstructive coronary artery disease without previous cardiovascular events (VICTORION-PLAQUE)"*** sponsored by M/s Novartis Healthcare Private Limited submitted by Prof. S. K. Dwivedi, Head, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no. 721/Cardio/Res/2023 dated 31st March, 2023. ***The following documents were reviewed in the Meeting:-***

Sr. No	Title
1.	Clinical Trial Protocol (Version Number: 00; Dated: 08-Jul-2021)
2.	Investigator's Brochure (Edition 16; release date 30 Nov 2022)
3.	eCRF 1.0_06May2022(PROD)- Unique
4.	Patient Information and Informed Consent Form (Version 1.0, Dated 21 Feb 2022)
5.	Patient Information and Informed Consent Form (Version 1.0, Dated 21 Feb 2022) translated from English to Hindi on 2 Mar 2022
6.	Patient Information and Informed Consent Form (Version 1.0, Dated 21 Feb 2022) back

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	translated from Hindi to English on 10 Mar 2022
7.	Translation and back translation certificate for Patient Information and Informed Consent Form (Version 1.0, Dated 21 Feb 2022): • Hindi
8.	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 21 Feb 2022)
9.	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 21 Feb 2022) translated from English to Hindi on 2 Mar 2022
10.	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 21 Feb 2022) back translated from Hindi to English on 10 Mar 2022
11.	Translation and back translation certificates for Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 21 Feb 2022): • Hindi
12.	Informed Consent for Exploratory Genetic Research (Version 1.0, Dated 21 Feb 2022)
13.	Informed Consent for Exploratory Genetic Research (Version 1.0, Dated 21 Feb 2022) translated from English to Hindi on 2 Mar 2022
14.	Informed Consent for Exploratory Genetic Research (Version 1.0, Dated 21 Feb 2022) back translated from Hindi to English on 10 Mar 2022
15.	Translation and back translation certificates for Informed Consent for Exploratory Genetic Research (Version 1.0, Dated 21 Feb 2022): • Hindi
16.	Audio-Video Informed Consent Form (Version 1.0, Dated 1 Apr 2021)
17.	Audio-Video Informed Consent Form (Version 1.0, Dated 1 Apr 2021) translated from English to Hindi on 23 Jun 2021
18.	Audio-Video Informed Consent Form (Version 1.0, Dated 1 Apr 2021) back translated from Hindi to English on 25 Jun 2021
19.	Translation and back translation certificates for Audio-Video Informed Consent Form (Version 1.0, Dated 1 Apr 2021): • Hindi
20.	Patient card_English
21.	Patient card translated to Hindi

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	22.	Patient card back translated from Hindi to english
	23.	Certificate of translation for Patient Card • Hindi
	24.	Participant Thank you Letter
	25.	Participant Thank you Letter_Translated to Hindi
	26.	Participant Thank you Letter_Back translated from Hindi to English
	27.	Certificate of translation for Participant Thank you Letter • Hindi
	28.	Insurance certificate for the period of 2023
	29.	Draft CTA
	30.	CTRI
	31.	CKJX839 (L1) SUSAR for the period- 01 OCT 2021 to 31 MAR 2022 BLINDED ALL Arms (CT)
	32.	CKJX839 (L1) SUSAR(s) 01APR2022 30SEP2022 BLINDED ALL Arms (CT)
	33.	HA CT NOC dated 25 Jul 2022
	34.	CRF Completion Requirements - 18-Apr-2022
	35.	DCGI Acknowledgement of CKJX839D12303-IB ver 16 dated 9 Jan 2022
	36.	CV, GCP , MRC of the PI
	37.	IU

*Recommendation of **Primary reviewer:***

- Budget in CTA document not mentioned

EC Decision: Approval subject to modification & fulfillment of formalities.

Ref. code: 124th ECMIIC/P1

2.	Research protocol no. ITI-007-501 entitled "***A randomized, double-blind, placebo-controlled, multicenter study to assess the efficacy and safety of lumateperone as adjunctive therapy in the treatment of patients with major depressive disorder (MDD)***" sponsored by M/s Intra-Cellular Therapies, Inc. Alexandria Center for Life Science 430 East submitted by Prof. Adarsh Tripathi, Department of Psychiatry, King George's Medical University, U.P., Lucknow, vide letter no. 672/Psy/2023 dated 26th April, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • Approved *The following documents were reviewed in the Meeting:-* 1-I TI-007-501_HAB80868_Protocol Amendment2 dated 20-Aug-2021 1.2 ITI-007-501_HAB80868_Protocol Signature Page dated 08-Sep-2022 of Dr.Adarsh Tripathi for Protocol Amendment 2 dated 20-Aug-2021 2. ITI-007-501_HAB80868_Investigator Brochure Edition 17_ Dated 23-Feb-2023 3. ITI-007-501_eCRF_Final_2.0_14Jan2022 4. ITI-007-501_Justification for the Use of Placebo_17Aug22 5. ITI-007-501_ Data Safety Monitoring Board (DSMB) Statement_17Aug22 6. ITI-007-501 Risk Assessment Justification Letter_17Aug2022 7.1 Main_V1.0IND (en) 2.0(29Mar2023) 7.2 Main_V1.0IND (hi) 2.0(29Mar2023) 7.3 Main_V1.0IND (hi) 2.0(29Mar2023) _Translation certificate dated 04-Apr-2023 7.4 Back Translation of Main_V1.0IND (hi) 2.0(29Mar2023) 7.5 Back Translation of Main_V1.0IND (hi) 2.0(29Mar2023)_Back translation certificate dated 04-Apr-2023 7.6 Summary of changes_ITI-007-501_Main_V1.0IND(en)2.0(29Mar2023) 8.1 Preg_V1.0IND (en) 1.0(20Sep2022) 8.2 Preg_V1.0IND (hi) 1.0(20Sep2022) 8.3 Preg_V1.0IND (hi) 1.0(20Sep2022)_Translation certificate dated 05-Nov-2022 8.4 Back translation of Preg_V1.0IND (hi) 1.0(20Sep2022) 8.5 Back translation of Preg_V1.0IND (hi)1.0(20Sep2022)_Back translation certificate dated 05-Nov-2022 9.1 Other_V8.0IND (en) 1.0(20Sep2022) 9.2 Other_V8.0IND (hi) 1.0(20Sep2022) 9.3 Other_V8.0IND (hi) 1.0(20Sep2022)_Translation certificate dated 05-Nov-2022 9.4 Back translation of Other_V8.0IND (hi) 1.0(20Sep2022) 9.5 Back translation of Other_V8.0IND (hi) 1.0(20Sep2022)_Back translation certificate dated 05-Nov-2022 9.6 (A-V) Recording Declaration_V5.0IND (en) 1.0 dated 20Sep2022 10.1 Subject Database Declaration of Consent for the Processing of Personal Data_V1.0IND (en) 1.0 (16Sep2022) 10.2 Subject Database Declaration of Consent for the Processing of Personal Data_V1.0IND (hi) 1.0 (16Sep2022) 10.3 Subject Database Declaration of Consent for the Processing of Personal Data_V1.0IND (hi) 1.0 (16Sep2022) _Translation certificate_05-Nov-2022 10.4 Back translation of Subject Database Declaration of Consent for the Processing of Personal Data_V1.0IND (hi) 1.0 (16Sep2022) 10.5 Back translation of Subject Database Declaration of Consent for the Processing of Personal

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Data_V1.0IND (hi) 1.0 (16Sep2022)_Back Translation certificate_05-Nov-2022 11.1 Patient Emergency Info Card 24 Jun 2021 [V2.0 IND(en)] 11.2 ITI-007-501Patient Emergency Info Card 24 Jun 2021 [V2.0IND (hi)] 11.3 ITI-007-501Patient Emergency Info Card 24 Jun 2021 [V2.0IND (hi)]_Translation certificate dated 04-Nov-2022 12.1 ITI-007-501_GA D-7_SOURCE_ENGLISH_US_2021_Jun_16 12.2 ITI-007-501_GAD-7_SOURCE_HIN (IND)_2022_Aug_10 12.3 ITI-007-501_GAD-7_SOURCE_HIN (IND)_2022_Aug_10_ Translation certificate dated 10Aug2022 13.1 ITI-007-501_QIDS-SR-16_SOURCE_ENGLISH_US_2021_Jun_16 13.2 ITI-007-501_QIDS-SR-16_SOURCE_hin_IN_2022_Sep_13 13.3 ITI-007-501_QIDS-SR-16_SOURCE_hin_IN_2022_Sep_13 _Translation certificate dated 13Sep2022 14.1 Placebo Questionnaire_22Mar2021 [V1 IND (en)] 14.2 Placebo Questionnaire_22Mar2021 [V1 IND(hi)] 14.3 Placebo Questionnaire_22Mar2021 [V1 IND (hi)]_Translation certificate dated 04-Nov-2022 15.1 Placebo Response Training for Subjects_22 Mar 2021 [V1 IND (en)] 15.2 Placebo Response Training for Subjects_22 Mar 2021 [V1 IND (hi)] 15.3 Placebo Response Training for Subjects_22 Mar 2021 [V1 IND (hi)] - Translation certificate dated 04-Nov-2022 16.1 Patient Brochure, 05 Oct 2022 [V01 Global (English)] 16.2 Patient Brochure, 05 Oct 2022 [V01 IND (Hindi)] 16.3 Translation Certificate dated 13Oct2022 of ITI-007-501_Patient Brochure, 05 Oct 2022 [V01 IND (Hindi)] 17. ITI-007-501_AIMS_SOURCE_ENGLISH_US_2021_Jun_16 18. ITI-007-501_ATRQ_SOURCE_ENGLISH_US_2021_Jun_24 19. ITI-007-501_BARS_SOURCE_ENGLISH_US_2021_Jun_16 20. ITI-007-501_CGI-S_SOURCE_ENGLISH_US_2021_Jun_16 21. ITI-007-501_C-SSRS BL-Screening_SOURCE_ENGLISH_US_2021_Jun_16 22 ITI-007-501_C-SSRS SLV_SOURCE_ENGLISH_US_2021_Jun_25 23. ITI-007-501_MINI_SOURCE_ENGLISH_US_2021_Jun_16 24. ITI-007-501_MINI7.0.2 Standard_AU5.2A_hin-IN_12-dec-2022 25.ITI-007-501_MINI7.0.2 Standard_AU5.2A_hin-IN_12-dec-2022_Translation certificate 12-Dec-2022 26 ITI-007-501_SAS_SOURCE_ENGLISH_US_2021_Jun_25 27 ITI-007-501_SIGMA_SOURCE_ENGLISH_US_2021_Jun_16 28. VCT FAQ India 2021-6-English 29. ITI-007-501_ GP Letter_16 Jun 2021 [V2.0 Global (en)] 30. ITI-007-501 Study Physician Referral Letter, 12 Oct 2022 [V01 Global (en)] 31. ITI-007-501 Chart Review Checklist, 09 Sep 2022 [V01 Global (en)] 32. ITI-007-501 Study Eligibility Criteria Booklet, 23 Sep 2022 [V01 Global (en)] 33. ITI-007-501 Study Investigator Welcome Letter, 30 Sep 2022 [V01 Global (en)] 34. ITI-007-501 India Insurance Policy 2022-L0217475-CLT valid till 13 Oct 2023 35. ITI-007-501_Draft CTA Template. 36.1 ITI-007-501_Site 503_Dr. Adarsh Tripathi _CV _dated 15-Sep-2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	36.2 ITI-007-501_ Site 503_Dr. Adarsh Tripathi _GCP_ Dated 27-Mar-2023 36.3 ITI-007-501_ Site 503_Dr. Adarsh Tripathi_MRC 36.4 ITI-007-501_ Site 503_Dr. Adarsh Tripathi_ Investigator Underaking_23-Feb-2023. 37. DCGI approval letter dated 17-Apr-2023 38. Undertaking from the sponsor for import and export of biological samples dated 12-Apr-2023 39. Licence to import new drug for clinical trial dated 17-Apr-2023 40. ITI-0070501_CTRI_25Apr2023 **EC Decision:** Approval subject fulfillment & Administrative formalities ***Ref. code: 124th ECMIIC/P2***
3.	Research protocol no. ITI-007-503 entitled "***An open-label, multicenter trial to assess the safety and tolerability of lumateperone as adjunctive therapy in the treatment of patients with major depressive disorder***" sponsored by M/s Intra-Cellular Therapies, Inc. Alexandria Center for Life Science submitted by Prof. Adarsh Tripathi, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 671/Psy/2023 dated 26th April, 2023. ***Recommendation of Primary reviewer:*** • Approved ***The following documents were reviewed in the Meeting:-*** 1.1 ITI-007-503_HAB80876_Protocol Amendment1 dated 23-Aug-2021 1.2 ITI-007-503_HAB80876_Protocol signature page dated 28-Oct-2022 of Dr. Adarsh Tripathi for protocol amendment 1 dated 23-Aug-2021 2. ITI-007-503_ HAB80876_Investigator Brochure_ Edition 16_ Dated 02-Jun-2022 3. ITI-007-503_eCRF_Final_3.0_17Jan2022 4. ITI-007-503_ Data Safety Monitoring Board (DSMB) Statement _03Aug2022 5. ITI-007-503_ Risk Assessment Justification Letter _03Aug2022 6.1 Main_V1.0IND(en)1.0(24Jan2023) 6.2 Main_V1.0IND(hi)1.0(24Jan2023) 6.3 Main_V1.0IND(hi)1.0(24Jan2023)_Translation certificate dated 11-Feb-2023 6.4 Back translation of Main_V1.0IND(hi)1.0(24Jan2023) 6.5 Back translation of Main_V1.0IND(hi)1.0(24Jan2023)_Back translation certificate dated 11-Feb-2023 7.1 Preg_V1.0IND(en)1.0(23Sep2022) 7.2 Preg_V 1.0IND(hi)1.0(23Sep2022) 7.3 Preg_V1.0IND(hi)1.0(23Sep2022)_Translation certificate dated 12-Nov-2022 7.4 Back translation of Preg_V 1.0IND(hi)1.0(23Sep2022) 7.5 Back translation of Preg_V 1.0IND(hi)1.0(23Sep2022)_Back translation certificate dated 12-Nov-2022 8.1 PK_V1.0IND(en)1.0(23Sep2022) 8.2 PK_V1.0IND(hi)1.0(23Sep2022) 8.3 PK_V1.0IND(hi)1.0(23Sep2022)_Translation certificate dated 12-Nov-2022 8.4 Back Translation of PK_V1.0IND(hi)1.0(23Sep2022) 8.5 Back Translation of PK_V1.0IND(hi)1.0(23Sep2022)_Back translation certificate dated 12-Nov-2022 9.1 Other_V8.0IND(en)1.0(23Sep2022) 9.2 Other_V8.0IND(hi)1.0(23Sep2022) 9.3 Other_V8.0IND(hi)1.0(23Sep2022)_Translation certificate dated 12-Nov-2022 9.4 Back Translation of Other_V8.0IND(hi)1.0(23Sep2022) 9.5 Back Translation of Other_V8.0IND(hi)1.0(23Sep2022)_Back translation certificate dated 12-Nov-2022 9.6 Audio Visual (A-V) Recording Declaration_V5.0IND(en)1.0(27Jul2022)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	10.1 ITI-007-503 Patient Emergency Info Card 24 Jun 2021 [V1.0 IND(en)] 10.2 ITI-007-503 Patient Emergency Info Card 24 Jun 2021 [V1.0IND(hi)] 10.3 ITI-007-503 Patient Emergency Info Card 24 Jun 2021 [V1.0IND(hi)]_Translation certificate dated 04-Nov-2022 11. ITI-007-503_AIMS_SOURCE_ENGLISH_US_2021_Jul_29 12. ITI-007-503_BARS_SOURCE_ENGLISH_US_2021_Jul_29 13. ITI-007-503_CGI-S_SOURCE_ENGLISH_US_2021_Jul_29 14. ITI-007-503_C-SSRS SLV_SOURCE_ENGLISH_US_2021_Jul_29 15. ITI-007-503_SAS_SOURCE_ENGLISH_US_2021_Jul_29 16. ITI-007-503_SIGMA_SOURCE_ENGLISH_US_2021_Jul_29 17. ITI-007-503 _GP Letter_V 1.0_16-Jun-2021 18.ITI-007-503 Study Eligibility Criteria Booklet, 23 Sep 2022 [V01 Global(en)] 19. ITI-007-503_Patient Appreciation item description document_Master English_V1 20. ITI-007-503 India Insurance Policy 2022-L0217470-CLT Valid till 13 Oct 2023 21. ITI-007-503_Draft CTA Template 22.1 ITI-007-503_Site 503_ Dr. Adarsh Tripathi_CV_15-Sep-2022 22.2 ITI-007-503_ Site 503_ Dr. Adarsh Tripathi _GCP_27-Mar-2023 22.3 ITI-007-503_ Site 503_ Dr. Adarsh Tripathi _ MRC 22.4 ITI-007-503_Site 503_ Dr. Adarsh Tripathi _ Investigator Undertaking_23-Feb-2023 23. DCGI approval letter dated 12-Apr-2023 24. Undertaking from the sponsor for import and export of biological samples dated 12-Apr-2023 25. Licence to import new drug for clinical trial dated 12-Apr-2023 26. ITI-007-503_CTRI_28Apr2023 **EC Decision:** Approval subject fulfillment & Administrative formalities ***Ref. code: 124th ECMIIC/P3***
4.	Research protocol no. ALK28/ENZ130-PER1 entitled "***A prospective, randomized, multicenter, comparative, double-blind, parallel study to evaluate the efficacy, safety, pharmacokinetics, and immunogenicity of biosimilar pertuzumab (ENZENE) with reference pertuzumab (Perjeta®, Genentech. Inc.,) in previously untreated patients with HER2 positive metastatic breast cancer***" sponsored by M/s Enzene Biosciences Ltd submitted by Dr. Naseem Akhtar, Additional Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow, vide letter no. SONC/773/2023 dated 10th May, 2023. ***Recommendation of Primary reviewer:*** • Section on Vulnerable subjects is incorrectly filled since patients with metastatic breast cancer will come under the category of seriously ill/terminally ill/vulnerable patients. • Section on biological/hazardous materials doesn't mention the use of blood investigator/CT Scan which is ionizing radiation. • DCGI'S approval letter doesn't specify sites approved for the study. **EC Decision:** Approval subject to modification & fulfillment of formalities ***Ref. code: 124th ECMIIC/P4***
5.	Research protocol no. BICICH/WBL/P3/2022 entitled "***A multicentric, randomized, open label, parallel group, comparative phase III trial to evaluate the efficacy and safety of***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	fixed dose combination of bisoprolol 10mg and cilnidipine 10mg and chlorthalidone 12.5mg in subjects with uncontrolled essential hypertension and stable coronary artery disease (CAD)" sponsored by M/s Windlas Biotech Limited submitted by Dr. Deepak Bhagchandani, Assistant Professor, Department of Medicine, King George's Medical University, U.P., Lucknow, vide letter no. MED/CT/09/2023 dated 3rd May, 2023. *Recommendation of **Primary reviewer:*** • Section on biological/hazardous material doesn't mention collection of blood for biochemical investigations like KFT, LFT 2 DCGI permission letter doesn't mention KGMU site. **EC Decision:** Approval subject to modification & fulfillment of formalities ***Ref. code: 124thECMIIC/P5***
III A-	**Additional Document**
1.	Additional of research protocol no. TILD-19-07 entitled ***"A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF experienced subjects with active psoriatic arthritis I (INSPIRE 1)"*** sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/32/23 dated 29th March, 2023. *Recommendation of **Primary reviewer:*** • Approved ***The following documents were reviewed in the Meeting:-***

1	**Pain Visual analog scale**	
A	PtGA pain **VAS** (The Assessment of Pain: Arthritis) **English**	PtGAP - India/English - Version of 16 Mar 2023 - ICON. ID0517-TR-0165 / PtGAPain_VAS_v3.0_TS2.0_eng-IN_16MAR2023.docx
A1	PtGA pain **VAS** (The Assessment of Pain: Arthritis) **English** Translation certificate	16 Mar 2023
B	PtGA pain **VAS** (The Assessment of Pain: Arthritis) **Hindi**	PtGAP - India/Hindi - Version of 03 March 2023 - ICON. ID0517-TR-0165 / PtGAPain_VAS_v3.0_TS2.0_hin-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		IN_03MAR2023.docx
4	**B1**	PtGA pain **VAS** (The Assessment of Pain: Arthritis) **Hindi** Translation certificate
B	Health Assessment Questionnaire - Disability Index	
a	HAQ-DI (Health Assessment Questionnaire) English	HAQ – HAQ-DI – India/English – 03 August 2000 – Mapi. ID3753 / HAQ-DI_AU1.0_eng-IN.doc
b	HAQ-DI (Health Assessment Questionnaire) Hindi	HAQ-DI - India/Hindi - 05 May 2008 - Mapi. ID4435 / HAQ-DI_AU1.0-hin-IN1.doc
c	HAQ-DI (Health Assessment Questionnaire) **English and Hindi translation Certificate**	05 Oct2010
C	**BASDAI - The Bath Ankylosing Spondylitis Disease Activity Index**	
A	BASDAI (The Bath Ankylosing Spondylitis Disease Activity Index) **English**	BASDAI © Andrei Calin, 1994. v3.0 - 13 January 2021 BASDAI - India/English - Version of 16 Mar 2023 - ICON. ID0517-TR-0165 / BASDAI_TS9.0_eng-IN_16MAR2023.docx
A1	BASDAI (The Bath Ankylosing Spondylitis	16 Mar 2023

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Disease Activity Index) **English** Translation certificate	
B	BASDAI (The Bath Ankylosing Spondylitis Disease Activity Index) **Hindi**	BASDAI © Andrei Calin, 1994v3.0 - 13 January 2021 BASDAI - India/Hindi - Version of 03 March 2023 - ICON. ID0517-TR-0165 / BASDAI_TS9.0_hin-IN_03MAR2023
B	BASDAI (The Bath Ankylosing Spondylitis Disease Activity Index) **Hindi** Translation certificate	03 Mar 2023
A	FACIT-F (Fatigue Scale version 4) **English**	
A	FACIT-F (Fatigue Scale version 4) **English**	TILD-19-07 (Inspire 1) FACIT-Fatigue v1.0 15Jun2020 English (Universal) 16 November 2007 Copyright 1987, 1997
B	FACIT- (Fatigue Scale (Version 4)) **Hindi**	Hindi 8 July 2012 Copyright 1987, 1997
B1	Translation Certificate English to **Hindi**	08 Jul 2012
E	**HAQ-Patient Global VAS - PsA pain VAS**	
a	PsA pain VAS Indian **English**	HAQ-PatientGlobalVAS - India/English - Version of 22 Jul 11 - Mapi Institute. ID6212 / HAQ-PatientGlobalVAS_TS2.0_eng-IN.doc
b	PsA pain VAS **Hindi**	HAQ-PatientGlobalVAS - India/Hindi - Version of 22 Jul 11 - Mapi Institute. ID6212 / HAQ-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		PatientGlobalVAS_TS2.0_hin-IN.doc
c	PsApainVAS Indian English and Hindi **translation Certificate**	05 Aug2011
F	36-Item Short Form Survey (SF-36)	
A	SF-36v2® Health Survey □ 1992, 2004, 2010 Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-36® is a registered trademark of Medical Outcomes Trust. (SF-36v2® Health Survey Acute, India (English))	6 May 2016 v1.1
A1	English Translation Certificate	06 May 2016
B	SF-36v2® Health Survey □ 2004, 2010 Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-36® is a registered trademark of Medical Outcomes Trust. (SF-36v2® Health Survey Acute, India (Hindi))	Rev. 19 Jul 2018 v1.1
B1	Hindi Translation Certificate	19 Jul 2018
G	Work Productivity and Activity Impairment Questionnaire: Psoriatic Arthritis	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

A	WPAI:PsA (Work Productivity and Activity Impairment Questionnaire: Psoriatic Arthritis) English	English for India
A1	English Translation Certificate	06 Mar 2023
B	Hindi– WPAI:PsA (Work Productivity and Activity Impairment Questionnaire: Psoriatic Arthritis) Hindi	Hindi for India
B1	Hindi Translation Certificate	10 Mar 2023

EC Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 122nd ECMIIC/P5

2. Additional of research protocol no. TILD-19-19 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF naive subjects with active psoriatic arthritis II (INSPIRE 2)***" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/33/23 dated 29th March, 2023.

*Recommendation of **Primary reviewer:***

- Approved

The following documents were reviewed:-

1	**Pain Visual analog scale**
A	PtGA pain VAS (The Assessment of Pain: Arthritis) **English**
A1	PtGA pain VAS (The Assessment of Pain: Arthritis) **English** Translation certificate
B	PtGA pain VAS (The Assessment of Pain: Arthritis) **Hindi**
B1	PtGA pain VAS (The Assessment of Pain: Arthritis) **Hindi** Translation certificate
B	Health Assessment Questionnaire - Disability Index
a	HAQ-DI (Health Assessment Questionnaire) English
b	HAQ-DI

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		(Health Assessment Questionnaire) Hindi
	c	HAQ-DI (HealthAssessment Questionnaire) **English and Hindi translation Certificate**
	C	**BASDAI - The Bath Ankylosing Spondylitis Disease Activity Index**
	A	BASDAI (The Bath Ankylosing Spondylitis Disease Activity Index) **English**
	A1	BASDAI (The Bath Ankylosing Spondylitis Disease Activity Index) **English** Translation certificate
	B	BASDAI (The Bath Ankylosing Spondylitis Disease Activity Index) **Hindi**
	B	BASDAI (The Bath Ankylosing Spondylitis Disease Activity Index) **Hindi** Translation certificate
	D	The **Functional Assessment of Chronic Illness Therapy – Fatigue**
	A	FACIT-F (Fatigue Scale version 4) **English**
	B	FACIT- (Fatigue Scale (Version 4)) **Hindi**
	B1	Translation Certificate English to **Hindi**
	E	**HAQ-Patient Global VAS - PsA pain VAS**
	a	PsA pain VAS Indian **English**
	b	PsA pain VAS **Hindi**
	c	PsApainVAS IndianEnglish and Hindi**translation Certificate**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	F	36-Item Short Form Survey (SF-36)
	A	SF-36v2® Health Survey □ 1992, 2004, 2010 Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-36® is a registered trademark of Medical Outcomes Trust. (SF-36v2® Health Survey Acute, India (English))
	A1	English Translation Certificate
	B	SF-36v2® Health Survey □ 2004, 2010 Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-36® is a registered trademark of Medical Outcomes Trust. (SF-36v2® Health Survey Acute, India (Hindi))
	B1	Hindi Translation Certificate
	G	Work Productivity and Activity Impairment Questionnaire: Psoriatic Arthritis
	A	WPAI:PsA (Work Productivity and Activity Impairment Questionnaire: Psoriatic Arthritis) English
	A1	English Translation Certificate
	B	Hindi– WPAI:PsA (Work Productivity and Activity Impairment Questionnaire: Psoriatic Arthritis) Hindi
	B1	Hindi Translation Certificate

EC Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 122nd ECMIIC/P6

III-B	**Modification**
1.	Modification of research protocol no. Tuxedo-2 entitled "***Ultra-thin strut versus xience in a diabetic population with multi- vessel disease-2 India study***" sponsored by M/s Batra Hospital and Research Centre submitted by Prof. Sharad Chandra, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 52/Cardio/Res/23 dated 6th May, 2023. ***Recommendation of Primary reviewer:*** Approved ***The following documents were reviewed in the Meeting:-***

Sl. No.	Study Document	Version and Date

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

1.	TUXEDO-2 Study Protocol	Version- 1.2, 17 May 2022
2.	TUXEDO-2_Protocol 1.2_Summary of change for Protocol Version 1.2 dated 17 May 2022	NA
3.	TUXEDO-2_ Investigator undertaking for Protocol V 1.2	Sign dated 22 Aug 2022
4.	TUXEDO-2_Protocol Signature Page for Protocol V 1.2	Sign dated 22 Aug 2022
5.	TUXEDO-2_Site specific English ICD adapted from Master English ICD version 1.3 dated 17 May 2022	Version- 1.0 dated 22 Aug 2022
6.	PISICF_TUXEDO-2 English to Hindi Ver 1.3 • Forward • Backward • Final	Version- 1.0 dated 25 Aug 2022
7.	Translation Certificates • Hindi	25 Aug 2022

EC Decision: Approved

Ref. code: 101st ECMIIC/P11

2- Modification of research protocol no. QPT-ORE-006 entitled ***"A Phase2, Double-blind, placebo-controlled, multicenter clinical trial comparing chemo immunotherapy (Paclitaxel-carboplatin-oregovomab) versus chemotherapy (Paclitaxel-carboplatin-Placebo) as neoadjuvant therapy in patients with advanced epithelial ovarian, fallopian tube or peritoneal carcinoma"*** sponsored by M/s Onco Quest Pharmaceuticals Inc submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/759/23 dated 3rd May, 2023.

Recommendation of Primary reviewer:

- Approval from DCGI for protocol amendment 3.0–attached (But there is topographical mistake in the date of approval for amendment which is mentioned as 20-02-2022 instead of 20-02-2023)-corrected letter is requested from DCGI and which is awaited.
- Noted

The following documents were reviewed in the Meeting:-

Sr. No.	Documents	Version	Date
1.	Protocol Amendment 3	3.0	20 Feb 2023
2.	Protocol Signature Page for Protocol Amendment 3, Version 3.0	NA	NA
3.	Investigator Undertaking	NA	NA

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	4.	CTRI Registration Copy (CTRI/2022/10/046210) which was registered on 06 Oct 2022 and updated on 22 Dec 2022 with names of 12 participating investigators	NA	NA
	5.	DCGI approval letter for PA	3.0	05 Apr 2023
	6.	DCGI acknowledgement copy for typo error in protocol amendment 3 dated 20 Feb 2023 approval letter	3.0	12 Apr 2023
	7.	KSGO 2023	NA	NA

EC Decision: Approved

Ref. code: 117thECMIIC/P4

IV **Brought to Ethics Committee after XVIII-PGTSC held on 26th May, 2023.**

Minutes of XVIII-PGTSC of "Institutional Ethics Committee" Meeting held on 26th May, 2023 from 1:30 PM ***virtual.***

The following Members were present in the Meeting:-

1. Dr. G.G. Agarwal -Member
2. Dr. Rajendra Nath -Member
3. Dr. Nisha Mani Pandey -Member
4. Dr. Anita Rani -Member
5. Dr. Shally Awasthi -Convener

The following Members could not attend the Meeting:-

1. Dr. D.N. Upadhyaya -He has given his written comment
2. Dr. A.A. Mahdi - He has given his written comment

IA **Action Taken**

1- Clarification of research proposal entitled ***"Assessment of snakebites reporting to emergency medicine Department"*** submitted by Dr. Utsav Anand Mani, SR, Department of Emergency Medicine, King George's Medical University, U.P., Lucknow vide letter no.140/EM/23 dated 11th May, 2023.

Previous PGTSC Comment:

- This seems to be a prevalence study. The primary objective and corresponding research hypothesis should be written in that light.
- The numerator and denominator should be properly defined.
- The sample size calculation should be done for the prevalence study. Simply giving number 500 is not enough.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• There is variety of "Major objectives". It should be split into primary and secondary objectives. • For achieving some of these objectives, the proper questionnaire would be required. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: IX-PGTSC-IIA/P2***
2-	Clarification of research proposal entitled ***"Sentinel lymph node biopsy in post NACT breast cancer patients using low cost dual dye technique with carbon 12 nano particles and methylene blue dye-a pilot study"*** submitted by Dr. Anirudh Gupta, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 195/SY/23 dated 2nd May, 2023. ***Recommendation of Primary reviewer:*** • The study variables and study parameters should be identified. • The research hypothesis should be properly formulated in terms of study parameters. • This is a pilot study; the sample size calculation is not required. • The study design is not mentioned. It simply says "prospective study". ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P5***
3-	Clarification of research proposal entitled ***"A clinical comparison of efficacy of BASKA mask and LMA blockbuster for patients undergoing laparoscopic cholecystectomy: A prospective randomized comparative clinical study"*** submitted by Dr. Seema Reyaz, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 82/Anaes/23 dated 4th April, 2023. ***Previous PGTSC Comment:-*** • The study variables and study parameters should be identified. • The research hypothesis should be properly formulated in terms of study parameters. • The sample size calculation is not given. It can be done only after defining the research hypothesis. • Statistical Analysis section is very general. It should be done according to the research hypothesis. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P12***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

4-	Clarification of research proposal entitled ***"Comparison of modified thoracolumbar interfascial plane block with erector spinae plane block for postoperative analgesia fillowing lumbar spine surgeries"*** submitted by Dr. Vaishali Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/473/2023 dated 27th April, 2023. ***Previous PGTSC Comments:*** • After identifying the study variables and study parameters, the objective should be converted into research hypothesis in terms of the study parameters • This is comparative study. The study design is not mentioned. • Sample size calculation is not given. • Statistical analysis section should be more specific. It should be planned after defining the proper research hypothesis. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P13***
5-	Clarification of research proposal entitled ***"A study to determine the prevalence of congenital CMV infection in neonates admitted in the NICU of a tertiary care center"*** submitted by Dr. Sujata Kumari, JRI, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 321/Ped/23 dated 13th April, 2023. ***Previous PGTSC Comment:-*** • PI has attached the Child assent form, but the study is of Neonates, therefore Guardian Consent Form in English and Hindi version is needed. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P31***
6-	Clarification of research proposal entitled ***"Role of point of care lung ultrasound in ventilator associated pneumonia in Paediatric population"*** submitted by Dr. Twinkle Yadav, JRI, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1054/Ped/23 dated 11th April, 2023.

Previous PGTSC Comment	PI response
Sample size calculation not done	Sample size attached separately
Guardian consent form submitted but PI Child should also be submit Child Assent form (As children of 1 yr. to 12 yrs. of age will be recruited)	Yes, Assent form attached separately

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approval ratified ***Ref. code: XIV-PGTSC-IIA/P32***
7-	Clarification of research proposal entitled ***"The study of correlation between serum vitamin D3 and HBV DNA levels in hepatitis B virus infected Children: A prospective observational study"*** submitted by Dr. Moses Riamei, JRI, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1208/Ped/23 dated 1st May, 2023. ***Previous PGTSC Comment:-*** • Detailed sample size calculation not done, only reference is given. • Guardian consent and Assessment form are same. PI to submit separate Child Assent form. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P33***
8-	Clarification of research proposal entitled ***"Assessment of growth and complications amongst neonates receiving total parentral nutrition"*** submitted by Dr. Varsha Chaudhary, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 311/Ped/23 dated 12th April, 2023. ***Previous PGTSC Comment:-*** • Regular ICF-H/E –Attached, but PI should submit Guardian consent form. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P52***
9-	Clarification of research proposal entitled ***"Role of neonatal sequential organ failure assessment score (nSOFA) for prediction of mortality among preterm neonates with respiratory distress syndrome"*** submitted by Dr. Vaishali Sahu, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. nil dated nil. ***Previous PGTSC Comment:-*** • Sample size discrepancy in SOP form (53 cases) and protocol (113 cases), please specify the sample size and its calculation. • Revise and submit Guardian consent form (E/H version) ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P53***
10-	Clarification of research proposal entitled ***"A study to assess risk factors associated with febrile seizures in Children under five years of age"*** submitted by Dr. Harikeshwar Mishra, JRI, Department of Paediatrics, King George's Medical University, U.P.,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Lucknow vide letter no. 1190/Ped/23 dated 27th April, 2023. ***Recommendation of Primary reviewer:*** • One of the Co-PIs(Dr. Sciddhartha) has not signed the IEC form. • Sponsor has been mentioned as 'Government' with no details of expenses. • 'Devices' has been ticked in the section on Clinical Trials without details of the device in the synopsis. • Number of subjects has not been mentioned in the IEC form. • Section on biological material doesn't mention blood collection. • Gene sequencing ha not been mentioned in the consent form. • Assent form has not been attached. • In the section on vulnerable subjects, Children have not been ticked. • Section on Compensation has not been completed. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P57***
11-	Clarification of research proposal entitled ***"Association of urinary vitamin D binding protein and neutrophil gelatinase associated lipocalin with steroid responsiveness in idiopathic nephritic syndrome of Childhood"*** submitted by Dr. Tanya Gupta, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1076/Ped/23 dated 12th April, 2023. ***Previous PGTSC Comment:-*** • Sponsor is mentioned as government but no budget is given. • Devices are ticked in the Clinical trials sections without mentioning which device is being tested. • Section on biological/hazardous material doesn't mention the use of bodily fluids. • Section on compensations has been left blank. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P62***
12-	Clarification of research proposal entitled ***"Spectrum of visceral organ injury: management of life threatening haemorrhage with angioembolization and its outcome"*** submitted by Dr. Nitin Bharti, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 80/Radio/23 dated 2nd April, 2023. ***Previous PGTSC Comment:-*** • Please specify who among the investigators, will perform angioembolization? • Explain the procedure in detail in ICF. Specify the outcome parameters. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

PGTSC Decision: Approval ratified

Ref. code: XIV-PGTSC-IIA/P107

13- Clarification of research proposal entitled ***"Role of CT coronary angiography in patients with acute chest pain with normal ECG and TROPONIN levels"*** submitted by Dr. Shakeb Zaidi, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 81/Radio/23 dated 2nd April, 2023.

Previous PGTSC Comment:-

- Sample size calculation has been not provided.

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of PR: Approved

PGTSC Decision: Approval ratified

Ref. code: XIV-PGTSC-IIA/P108

14- Clarification of research proposal entitled ***"A study of maternal liver dysfunction in early pregnancy and its correlation with gestational diabetes mellitus"*** submitted by Dr. Arushi Chaudhary, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. nil dated nil.

Previous PGTSC Comment	PI response
There are too many objectives. There should be one primary objective and the rest should be grouped into secondary objectives.	**Objective** - To assess the role of first trimester deranged liver function test as early predictor of Gestational diabetes mellitus
The primary objective should be converted into proper research hypothesis in terms of study parameters.	**NULL HYPOTHESIS** – Liver Dysfunction in early pregnancy is not an early predictor of Gestational Diabetes Mellitus **ALTERNATE HYPOTHESIS**–Liver Dysfunction in early pregnancy is an early predictor of Gestational Diabetes Mellitus
Sample size calculation and statistical analysis section should be in accordance with the research hypothesis.	**Sample size** We are going to study the correlation of Gestational Diabetes during first trimester with maternal liver dysfunction. In a previous study conducted by Chen et al. (Maternal liver dysfunction in early pregnancy predisposes to gestational diabetes mellitus independent of preconception overweight: A prospective cohort study. BJOG. 2022;129:1695–1703. https://doi.org/10.1111/1471-0528.17117). The incidence of GDM in women with Liver Dysfunction was 24.6%. In present study we also target a similar outcome. The sample size was calculated using the

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		following formula suggested by Charan and Biswas (2013)1 : $n = \frac{\left[Z_{\alpha} \sqrt{\left(1+\frac{1}{m}\right) p^{*}(1-p^{*})} + Z_{\beta} \sqrt{p1(1-p1)/m + p2(1-p2)} \right]^2}{(p_1 - p_2)^2}$ where, n: Sample size r = ratio of cases in each group= 1 p * : Pooled prevalence of the outcome = 60.15%= 0.60 Zα/2 : critical value of z at 95% confidence = 1.96 Zβ: critical value of z at 80% power = 0.84 p1, : proportion of event in group 1= 67.25 =0.672 p2: proportion of event in group 2= (58.67+54.55/2) = 54.55= 0.54 n= 1.96√(1+1/1)*(0.21)*(1-0.21)+ 1.84√[{(0.27)*(0.75)}/{1+(0.17)*(1-0.17)}]^/ (0.25-0.17)^2 = 405 Thus the calculated sample size is 405 for each group. Keeping a provision of data loss @ 10%, the proposed minimum sample size is 445 patients in each group. Statistical analysis The results will be presented in frequencies, percentages and mean±SD. The Chi-square test will be used to compare the categorical variables. The Unpaired t-test will be used to compare the continuous variables. The p-value<0.05 will be considered significant. All the analysis will be carried out on SPSS 21.0 version (Chica/dl go, Inc., USA).
	What are the cohorts in the study design?	**Study Design** - Prospective cohort study **Study Group** –Women with deranged Liver function test in 1st trimester of pregnancy visiting Antenatal care OPD in the Dept of OBS & GYN, KGMU, Lucknow **Control group**- Women with normal Liver function test in 1st trimester of pregnancy visiting Antenatal care OPD in the Dept of OBS & GYN, KGMU, Lucknow

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The reply from PI to the above Comments was forwarded to PR:- *Recommendation of PR:* Approved **PGTSC Decision:** Approval ratified ***Ref. code: XV-PGTSC-IIA/P3***
15-	Clarification of research proposal entitled ***"Assessment of need, acceptance & outcome of menopausal hormone therapy in gynecological cancer cases"*** submitted by Dr. Vaishali Anand, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. 198/23 dated 15th April, 2023. ***Previous PGTSC Comment:-*** • Identify one primary objective and classify the rest into secondary objectives. • Convert the primary objective into research hypothesis in terms of study parameters. • Sample size calculation and statistical analysis should be in coherence with the research hypothesis. *The reply from PI to the above Comments was forwarded to PR:-* *Recommendation of PR:* Approved **PGTSC Decision:** Approval ratified ***Ref. code: XV-PGTSC-IIA/P4***
16-	Clarification of research proposal entitled ***"Study of intraocular pressure variation in subjects with type II diabetes mellitus"*** submitted by Dr. Afreen Saif, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 160/23 dated 10th April, 2023.

Previous PGTSC Comment	PI response
This is prospective cohort comparative study.	I opted for Hospital based cross sectional study because I would take the required data at a snap and I won't be following the patients thereafter.
Define the two cohorts exclusively	Since it's a cross sectional study therefore I have kept two separate groups: **Group 1:** Males and females, age 20 years and above, with Type II diabetes mellitus. **Groups 2 :** Males and females, aged 20 years and above (without Type II DM) apparently healthy individuals
Identify one primary objective and classify the rest into secondary objectives.	**Primary Objectives:** To compare the intraocular pressure in diabetics and non diabetics **Secondary Objective:** To find out the impact of the duration of type II diabetes mellitus on intraocular pressure. To observe the relationship of anthropometric parameters and lipid profile with intraocular pressure.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Convert the primary objective into research hypothesis in terms of study parameters.	**Study Design** - Prospective cohort study **Study Group** –Women with deranged Liver function test in 1st trimester of pregnancy visiting Antenatal care OPD in the Dept of OBS & GYN, KGMU, Lucknow **Control group**- Women with normal Liver function test in 1st trimester of pregnancy visiting Antenatal care OPD in the Dept of OBS & GYN, KGMU, Lucknow
	Sample size calculation is arbitrary.	Type II diabetes mellitus is associated with raised intraocular pressure
	Sample size calculation and statistical analysis should be in coherence with the research hypothesis.	Sample size calculation is done on basis of prevalence of glaucoma among patients with Type II diabetes mellitus (prevalence of diabetes is 12% alone while prevalence of glaucoma in Type II diabetes mellitus ranges between 4.96%-14.6) The above mentioned lines has been quoted from: Dharmadhikari S, Lohiya K, Cheekar V, et al. Magnitude of determinants of glaucoma in Type II diabetics: A hospital based cross sectional study in Maharashtra, India. Oman fournal of ophthalmology 2015;8(1):974-980.
	Sample size calculation and statistical analysis should be in coherence with research hypothesis.	Attached separately

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P6

17- Clarification of research proposal entitled ***"Magnesium and zinc supplementation in the patients of essential hypertension"*** submitted by Dr. Suresh Kumar Singh, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3068/PHY/23 dated 19th April, 2023.

Previous PGTSC Comment:-

- There are too many aim and objectives.
- Identify one primary objective and classify the rest into secondary objectives.
- Convert the primary objective into research hypothesis in terms of study parameters.
- Study design is not clear.
- Sample size calculation is arbitrary.
- Sample size calculation and statistical analysis should be in coherence with the research hypothesis.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P9

18- Clarification of research proposal entitled ***"To evaluate the predictors of extent and pattern of response to neoadjuvant chemotherapy in breast cancer with emphasis on MAGEE3 equation"*** submitted by Dr. Shehla Fayyaz, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 450/23 dated 17th April, 2023.

Previous PGTSC Comment	PI response
The study cannot be BOTH retrospective & prospective. Please choose one design of study.	Kindly note that we have arrived at the sample size by using the prevalence of breast cancer in India as per Globocon data 2022 and keeping confidence level of 90%. I would like to emphasize on the point that in our study we need to have paired samples i.e pretreatment biopsy and post treatment resection samples. As per HBCR data, around 40% patients who get biopsy done in KGMU do not undergo complete treatment here. Hence, getting required paired sample size may be difficult in prospective study only as MD Thesis is strictly time bound. Kindly consider our request to approve the retrospective and prospective type of study.
Since patient tissue is being used it will require patient consent whether prospective or retrospective. Consent CANNOT be waived unless the study is on anonymized data.	Kindly note that data will be completely anonymized. Patients won't be involved directly. The slides which have been already prepared from paraffin blocks for routine reporting will be reviewed. We will ensure that the slides will be coded and anonymity of data is maintained and can't be linked, relinked to the identifiable human subject. The cases will be observed by the PI and Co-PI only. The study is purely observational.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: XV-PGTSC-IIA/P21

19- Clarification of research proposal entitled ***"Outcome analysis of pituitary adenoma patients: a retrospective study of last 5 years at a tertiary care centre"*** submitted by Dr. Sanjeev Kumar, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 192/NS/23 dated 12th April, 2023.

Previous PGTSC Comment	PI response
No sample size is mentioned.	This study is retrospective study. All cases will be enrolled register based data in the department.
No sample size calculation has been done.	Attached separately
PI has mentioned no vulnerable subject are being used, however, the IEC form has different vulnerable subjects ticked in it. Please clarify.	No, vulnerable subjects included in the study New IEC form attached separately.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P23

20- Clarification of research proposal entitled ***"Seroprevalence of hepatitis E (HEV) antibody in pregnant female"*** submitted by Dr. Meghna, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. 2703/OG/23 dated 27th March, 2023.

Previous PGTSC Comment	PI response	Action taken
Sample size is mentioned as 500 at one place and 100 at another.	TYPOGRAPHIC ERROR-	SAMPLE SIZE FOR STUDY
A gastroenterology faculty from another Institution has been included as Co-PI while KGMU itself has a Gastro department.	THE TEST BEING DONE IN THESIS (HEV ANTIBODY) IS NOT AVAILABLE AT OUR CENTRE, ALSO THE COST OF TEST WHICH IS AT RESEARCH MODE IS BEING AFFORD BY THE CO-INVESTIGATOR FROM OTHER INSTITUTION. QUANTITATIVE ASSAY OF ANTIBODIES WHICH IS NO WHERE AVAILABLE IS LIKELY TO BE DONE AT SGPGI, AS AVAILABILITY OF HEPATITIS E KIT IN SGPGI, CO-PI FROM ANOTHER	AS AVAILABILITY OF HEPATITIS E KIT IN SGPGI, CO-PI FROM ANOTHER INSTITUTE INCLUDED.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		INSTITUTE INCLUDED. THAT'S WHY CO PI FROM SGPGI IS CONSIDERED FOR THESIS.	

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P24

21- Clarification of research proposal entitled ***"Effect of lemon TEA and Black coffee on heart rate variability and blood pressure recovery time of the moderate exercise"*** submitted by Dr. Pradeep Kumar Chauhan, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3118/PHY/23 dated 18th May, 2023.

Recommendation of Primary reviewer:

- Objectives of the study not written properly – need to be revised.
- Subjects to be included in the study not defined.
- Inclusion and exclusion criteria for recruitment of subjects not given.
- Sample size calculation not included.
- No references included or listed.
- Consent form to be specific for the study.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P31

22- Clarification of research proposal entitled ***"Expression of RUNX2 and C-MYC in gall bladder carcinoma, correlate with tumour infiltrating lymphocyte and clinicopathological parameters"*** submitted by Dr. Pankaj Gautam, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 446/23 dated 13th April, 2023.

Previous PGTSC Comment	PI response
Methods for estimation of biochemical markers not given	I will be performing immunohistochemistry marker (RUNX2 and C-MYC) on tissue embedded paraffin blocks and interpreting it's expression.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P40

23- Clarification of research proposal entitled ***"A study of structural and resting state functional MRI in child and adolescent with specific learning disorder"*** submitted by Dr. Avneendra Kumar Singh, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 594/Psy/23 dated 11th April, 2023.

Previous PGTSC Comment	PI response

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

There are four Co-PIs with same role –Please justify.	Role of Co-PIs is added in the revised documentattached herein (page-01).
One Co-guide's (Dr. Uttam Kumar) affiliation is different in Undertaking and SOP-IEC Investigator documents –Please correct.	The affiliation of Co-guide (Dr. Uttam Kumar) iscorrected and added in the revised document attached herein (page-02).
PI will do the comparative study taking healthy control and patients, but in methodology grouping has not been explained (whether it is prospective case control study or cross-sectional study-PLEASE CLEAR)- please attach flow chart of the study.	The flow chart has been added in methodology in the revised document attached herein (page 9-10).
The brief description of some tools is given but they are not attached–please attach all concerned tools (including semi-structured proforma)	The concerned tools are added in the revised document attached herein (page 13-20)

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P41

24- Clarification of research proposal entitled ***"A study of comparative efficacy of double lumen tube and EZ blocker for lung Isolation surgeries: A randomized comparative study"*** submitted by Dr. Gaurav Chandela, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/242/23 dated 14th March, 2023.

Previous PGTSC Comment	PI response
In Scientific review committee the name and signature of Guide (Dr. Shefali Gautam, Addl. Prof. Psychiatry) is included–please correct or revise the committee.	Dr. Shefali Gautam Additional Professor, Anaesthesiology, Remove in scientific review committee, New Scientific Review committee Attached separately
Patient information sheet is not related to study-please resubmit.	Attached separately
Sample size and its calculation has not been mentioned in Protocol (Only mentioned in IEC-SOP form)- please include.	CONSORT flow chart Attached separately
Flow chart of methodology giving detailed grouping is required.	Attached separately

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P42

25- Clarification of research ***"Study of single nucleotide polymorphism in foxo3 gene and correlation with prognosis in glioblastoma"*** submitted by Dr. Shamanaz, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 202/23 dated 13th April, 2023.

Previous PGTSC Comment:-

- Methodology and sample size details did not mentioned the grouping for tissue samples taken from cases and control-please give detail.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

<table>
<tr><td></td><td>
• In Inclusion criteria –Age /sex criteria are missing- please include.
The reply from PI to the above Comments was forwarded to PR:-
Second recommendation of PR:
• PI has attached the Child Assent Form (E/H)-but PI should also attach Guardian Consent Form separately apart from the Child Assent form.
The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified
Ref. code: XV-PGTSC-IIA/P44
</td></tr>
<tr><td>26-</td><td>
Clarification of research proposal entitled "A study of untargeted plasma metabolomic profile in children and adolescents with attention deficit hyperactivity disorders" submitted by Dr. Brijesh Kumar Yadav, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 593/Psy/23 dated 11th April, 2023.
<table>
<tr><th>Previous PGTSC Comment</th><th>PI response</th></tr>
<tr><td>All Co-guides and Guide have similar roles–please justify.</td><td>Different roles of Co guide and Guide is added in the revised document attached herein (page 3)</td></tr>
<tr><td>Study design– In setting part of protocol–PI mentioned it as Prospective case control study and in methodology the data of cases and control subjects are given ,it seems that this is prospective case control study-PI should clear the discrepancy of study design and mention it separately in Protocol.</td><td>Study design discrepancy is revised and added in the revised document attached herein (page 7).</td></tr>
<tr><td>In Inclusion criteria –Sex specificity not mentioned.</td><td>In Inclusion criteria both male and female will be included and is added in the revised document attached herein (page 7).</td></tr>
</table>
The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified
Ref. code: XV-PGTSC-IIA/P45
</td></tr>
<tr><td>27-</td><td>
Clarification of research proposal entitled "Psychological stress faced and factors associated with it at workplace and its relation to Mental Health of female healthcare workers of rural Lucknow-A cross-sectional study" submitted by Dr. Akshata M.A., JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 110/CM/MD/23 dated 29th April, 2023.
Previous PGTSC Comment:-
• To achieve the objective of the study, the proper questionnaire is required.
• After this only, the study can be planned.
</td></tr>
</table>

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P4

28- Clarification of research proposal entitled ***"Evaluation of facial and dental aesthetic determinants-A photometric study"*** submitted by Dr. Zainab Bint Shams, JRII, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 345/Ortho/2023 dated 19th April, 2023.

Previous PGTSC Comment	PI response
This is not "Cross-sectional Study" as mentioned in the study design.	The study is a **Prospective Cohort Comparative** study as two groups are being compared for their facial and dental proportions with the golden proportion.
This is prospective cohort comparative study. There are two groups under comparison.	The comment has been revised. Yes The study is a prospective cohort comparative study.
Research hypothesis should be properly formulated after identifying the study variables and study parameters.	**Research hypothesis** has been formulated. **NULL HYPOTHESIS** : Faces considered more beautiful exhibit the same parameters used by the orthodontist to assess the successful results. The more beautiful a face was judged to be by the panel , the less the putative golden proportions would differ from the real golden value (1.618) **ALTERNATE HYPOTHESIS** : Faces considered more beautiful fail to exhibit the same parameters used by the orthodontist to assess the successful results. The more beautiful a face was judged to be by the panel , the more the putative golden proportions would differ from the real golden value (1.618) **STUDY PARAMETERS** ARE

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		• FACIAL AESTHETIC DETERMINANTS : 9 proportions(7 vertical and 2 transverse) of the face . • DENTAL AESTHETIC DETERMINANTS : 7 smile characteristics. • So a total of 16 parameters will be assessed in this study.
	Sample size calculation is arbitrary.	**Sample size calculation done** at 90% power Sample size is calculated on the basis of maximum correlation between Dz and VAS scores using the formula: $$n = d\left[\left(\frac{z_\alpha + z_\beta}{C(r)}\right)^2 + 3\right]$$ Where • $C(r) = \frac{1}{2}\log_e \frac{1+r}{1-r}$ • $r = 0.32$, maximum correlation between Dz and VAS scores (Ref : Kiekens RM, Kuijpers-Jagtman AM, van 't Hof MA, van 't Hof BE, Maltha JC. Putative golden proportions as predictors of facial esthetics in adolescents. Am J Orthod Dentofacial Orthop. 2008 Oct;134(4):480-3.) • $d = 0.5$, the design effect • type I error $\alpha = 5\%$

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		corresponding to 95% confidence level • type II error $\beta = 10\%$ for detecting results with 90% power of study
	Statistical analysis section is missing.	Statistical analysis Section added. **Statistical Analysis :** SPSS latest available version and MS Excel will be used for statistical analysis of the data. Continuous variables conforming to a normal distribution will be expressed as mean ± standard deviation. Counting data will be expressed as number and percentages. The $\chi 2$ test and other appropriate tests will used to compare the proportion data between the groups. Correlation and regression analysis will be applied for finding relationships. Other appropriate statistical tests will be used. In all of the statistical analyses, $P < 0.05$ will be considered to be statistically significant.
	Why is there "Child assent form?"	Child assent form has been removed.
	The study subjects are supposed to be in the age group 18-35 years.	The study subjects are in age group 18-35 years. Hence the child assent form has been removed.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P6

29- Clarification of research proposal entitled ***"Correlation between intraoperative quantitative assessment of parathyroid gland perfusion during total thyroidectomy after gland excision using indocyanine green with post-operative hypocalcemia-a prospective observational study"*** submitted by Dr. Ashwinee Rahalkar, SRII, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

ENDOSURG/23/161 dated 19th April, 2023.

Previous PGTSC Comment	PI response
The title of the study is little confusing. The correlation is measured between two variables. What are these variable?	Fluorescence Assessment Software is an inbuilt software of Stryker spyphi machine which is a fluorescence imaging technology, which helps Quantify the intensity in percentage of the fluorescence signal through relative values (known as IP score). QP score measures vascularity (which would correlate with potential viability of parathyroid gland) will be compared with post-operative Serum parathyroid hormone (PTH) levels and clinical signs and symptoms of post thyroidectomy hypocalcemia. This study aims to study the performance of QP score as a surrogate for post-operative Parathyroid hormone levels for anticipating post thyroidectomy hypoparathyroidism.
What is the outcome measure for assessing parathyroid gland perfusion?	Outcome measure for parathyroid gland perfusion will be post-operative Serum Parathyroid hormone level and serum Calcium level along with signs and symptoms of hypocalcemia.
Sample size calculation and statistical analysis section are missing.	Sample size estimation and statistical analysis section has already been mentioned in the proposal. It has been re-attached for your reference.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P7

30- Clarification of research proposal entitled ***"Phase 2 study of concurrent cisplatin, capecitabine and celecoxib with radiotherapy in patients with carcinoma of the esophagus"*** submitted by Dr. Bushra Khalid, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 364/RT/23 dated 13th April, 2023.

Previous PGTSC Comment :-

- Identify the study variable and study parameters.
- Convert the aim/objective of the hypothesis into research hypothesis in terms of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

the study parameters.

- Sample size calculation and data analysis section are missing.
- DCGI permission will be needed, if it is a Phase 2 trial.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P12

31- Clarification of research proposal entitled ***"Study of impact of oral health education training program on oral health knowledge, attitude, behavior, self care, self efficacy among adolescents- randomised controlled trial"*** submitted by Dr. Akulwar Srushti Jagdish, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/58/23 dated 2nd May, 2023.

Previous PGTSC Comments	PI response
This not an RCT.	Required changes made in Text. The study design is now clarified in Aim and Objectives (Section: Aim and Objectives)
This is prospective cohort study. There are two groups under comparison.	The two groups have been clearly mentioned in the protocol (Section : Materials and Methods)
Identify the study variables and the study parameters.	Required changes made in Text (Section : Procedure)
Convert the primary objective into a research hypothesis in terms of the study parameters.	Required changes made in Text(Section : Objectives)
Sample size calculation can be done only after identifying the research hypothesis.	There was no change.
Statistical analysis section has to be more specific in accordance with the research hypothesis and other objectives of the study.	Required changes made in Text (Section : Data Analysis)

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P15

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

32- Clarification of research proposal entitled ***"Evaluation of dental syringe camouflage technique as a distraction method in paediatric dental patients in dental office"*** submitted by Dr. Oberoi Ashmeetkaur Sukhbirsingh, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/59/23 dated 2nd May, 2023.

Previous PGTSC Comments	PI response
This not an RCT.	Required changes made in Text. The study design is now clarified in Aim and Objectives (Section: Aim and Objectives)
This is prospective cohort study. There are two groups under comparison.	The two groups have been clearly mentioned in the protocol (Section: Methods)
Identify the study variables and the study parameters.	Required changes made in Text (Section: Data Collection)
Convert the primary objective into a research hypothesis in terms of the study parameters.	Required changes made in Text (Section: Objectives)
Sample size calculation can be done only after identifying the research hypothesis.	There was no change.
Statistical analysis section has to be more specific in accordance with the research hypothesis and other objectives of the study.	Required changes made in Text (Section: Data Analysis)

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P16

33- Clarification of research proposal entitled ***"Effects of therapeutic plasma exchange in patients with heavy metal poisoning-A pilot study"*** submitted by Dr. Kislay Mishra, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 87/TM/23 dated 17th May, 2023.

Previous PGTSC Comment:-

- Kindly Attach Patient Information Sheet.
- ICF: Kindly explain the procedure of plasma exchange to the patient.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P23

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

34- Clarification of research proposal entitled ***"A comparative analysis of two different dose fractionation Regimens of high dose rate intracavitary brachytherapy in treatment of locally advanced carcinoma of uterine cervix"*** submitted by Dr. Kopal Jaiswal, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 305/RT/23 dated 6th May, 2023.

Previous PGTSC Comment:-

- Proforma is not written in the proper format.
- Kindly Attach Patient Information Sheet
- ICF: Kindly explain the procedure to the patient [what exactly will be done with him/her] in simple language.

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of PR: Approved

PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P25

35- Clarification of research proposal entitled ***"A clinical audit of anal fistula patients operated in the Department of General Surgery KGMU in last ten years"*** submitted by Dr. Shyama Charan Jha, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 202/Suy/23 dated 10th April, 2023.

Previous PGTSC Comment	PI response
Kindly confirm the sample size: 200/980/80	Total sample size 1960 patients included in the study. Sample size attached separately.
Confirm the study duration of 5 years /10 years. Title says 10 years and in the proforma it is mentioned 5 years.	This study is Retrospective study total duration 10 years.
Clarify the process of recruitment of the study population.	Operation theater list from the department and OPD record register of follow-up patients who come to Department of General Surgery, KGMU, Lucknow.
It appears that the PI wants to assess the outcome of patients, who have undergone anal fistula operations in the department and had been followed up for a minimum of 1 year. If so, there is no need for a written informed consent form to be signed by the patient.	Yes, No need for a written informed consent form and attached waiver form separately.
Therefore, the proforma should be submitted for waiver.	As per your advice waiver form attached separately.

The reply from PI to the above Comments was forwarded to PR:-

Recommendation of PR: Approved

PGTSC Decision: Approval ratified

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

<table>
<tr><td></td><td>Ref. code: XVI-PGTSC-IIA/P29</td></tr>
<tr><td>36-</td><td>Clarification of research proposal entitled "Assessment of survival outcome of operableT4a and T4b oral cancer (8th AJCC)" submitted by Dr. Manpreet Saini, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 202/SY/23 dated 3rd May, 2023.
<table>
<tr><th>Previous PGTSC Comment</th><th>PI response</th></tr>
<tr><td>Title needs rectification. The term operable should be replaced with operated.</td><td>As per your advice title changes "Assessment of survival outcome of operated T4a and T4b oral cancer (8th AJCC)"</td></tr>
<tr><td>Please, clarify the process of enrollment of patients. If it is a hospital record base study, PI may submit for waiver of ethical clearance.</td><td>Waiver form attached separately.</td></tr>
</table>
The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified
Ref. code: XVI-PGTSC-IIA/P31</td></tr>
<tr><td>37-</td><td>Clarification of research proposal entitled "Evaluation of perioperative and quality of life outcomes after laparoscopic orchidopexy in palpable canalicula and non-palpable undescended testis in adolescent and adults" submitted by Dr. Mohammad Nasir Ali Ansari, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1043/Sy/23 dated 10th April, 2023.
Previous PGTSC Comment:-

Please attach validated questionnaire/outcome parameters for analysis of perioperative quality of life.
ICF: Kindly explain the procedure to the patient [what exactly will be done with him/her] in simple language.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified
Ref. code: XVI-PGTSC-IIA/P32</td></tr>
<tr><td>38-</td><td>Clarification of research proposal entitled "To decipher the molecular role of insulin like growth factor in chronic myeloid leukemia" submitted by Dr. Pragati Chauhan, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 480/23 dated 25th April, 2023.
Previous PGTSC Comment:-

Although in the material and methods section it is mentioned that the place of work will also be the Department of Medicine but there is no PI or Co-PI from the said department.
</td></tr>
</table>

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Materials and methods incomplete.
- References are not written in proper format.
- Overall the project is very sketchy, needs to be re-written

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P34

39- Clarification of research proposal entitled ***"To decipher the molecular role of vanin1 in pathogenesis of CML and its diagnostic implications"*** submitted by Dr. Shalini Verma, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 507/23 28th April, 2023.

Previous PGTSC Comment	PI response
Aim of the study is sketchy.	Respective changes have made in attached proforma copy.
Although in the material and methods section it is mentioned that the place of work will also be the Department of Medicine but there is no PI or Co-PI from the said department.	Following changes are made: a) PLACE OF WORK: Department of Pathology in collaboration with Department of Clinical Haematology. King George's Medical University, Lucknow b) STUDY POPULATION: All diagnosed cases of CML of all age groups will be taken. c) DIAGNOSIS WILL BE BASED ON: - 1.Clinical history 2. Complete blood count and PBS evaluation. 3. Bone Marrow Examination and BCR-ABL translocation studies. d) INCLUSION AND EXCLUSION CRITERIA INCLUSION CRITERIA: □ Patients of all age group will be included. □ Peripheral Blood Smear and Bone Marrow findings suggestive of CML, confirmed on BCR-ABL translocation studies.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		EXCLUSION CRITERIA: □ Other Leukemias. The present study will be performed in The Department of Pathology, King George's Medical University, Lucknow. All demographics including age, sex and gender will be recorded for all the 150 cases. □ Medical history –1) Number of cycles of Chemotherapy 2) Parent and sibling history 3) Organomegaly status □ Venous blood will be used for study purpose. □ Routine complete blood counts will be obtained using Five-part automated counter. Peripheral smear stained with Leishman's stain for morphological study. □ Bone marrow aspiration and trephine biopsy shall be done in all cases for diagnosis of CML which shall be confirmed with BCR-ABL translocation studies □ Vanin-1 Immunohistochemical analysis shall be done on trephine section of all confirmed cases of CML.
	Material and method section incomplete.	Respective changes have been made in attached proforma copy.
	The reply from PI to the above Comments was forwarded to PR:- ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P36***	
40-	Research proposal entitled ***"Anthropometric analysis of the-LIP-nose complex in bilateral cleft LIP infants in north Indian population"*** submitted by Dr. Kartikeya Shukla, SRI, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 521/23 dated 25th April, 2023. ***Previous PGTSC Comment:-***	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• It is mentioned that the study will be carried out between November 2022 to December 2023. Has the candidate started work without ethical clearance?? • Rest is fine. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P38***
41-	Clarification of research proposal entitled ***"Study of clinico-microbiological profile of cases of chronic dacryocystitis"*** submitted by Dr. Yuvraj Gupta, JRI, Department of Otorhinolaryngology & Head -Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 220/23 dated 12th April, 2023. ***Previous PGTSC Comment:-*** • The inclusion and exclusion criteria are written in past tense, kindly correct it. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P46***
42-	Clarification of research proposal entitled ***"Chromosomal characteristics and clinical profile in juvenile nasopharyngeal angiofibroma"*** submitted by Dr. Vinod Kumar Patel, JRI, Department of Otorhinolaryngology & Head -Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2580/ENT/23 dated 28-03-2023. ***Previous PGTSC Comment:-*** • SOP-Checklist - not ticked properly (to be revised) • Inclusion criteria –All patients having JNA to be taken (Age/ sex specificity) not mentioned-please clarify • Sample size calculation not done • If all age patients to be taken then Guardian consent/ Child Assent form should be included. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P50***
43-	Clarification of research proposal entitled ***"A prospective clinical study to monitor prescription pattern, therapeutic adherence, quality of life and Pharmacoeconomic analysis among patients suffering with interstitial diseases"*** submitted by Dr. Krishan Kumar Singh, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 280/Phamra/23 dated 6th April, 2023. ***Previous PGTSC Comment:-*** • Title should be corrected, as interstitial disease is not self explanatory, it should be Interstitial Lung Diseases-Please correct.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Tools are not attached -Please attach all mentioned tools. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P52***
44-	Clarification of research proposal entitled ***"A prospective study of monitoring of adverse transfusion reactions occurring in patients administered packed red blood cells (PRBC)/ Fresh frozen plasma (FFP)/ platelets (Random Donor Platelets) in Obstetrics and Gynecology Department"*** submitted by Dr. Pranshu Pandit, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 281/Phamra/23 dated 6th April, 2023.

Previous PGTSC Comment	PI response
In Inclusion criteria-Pregnant /lactating women criteria-not mentioned	Old : 1.All the patients aged 18 years and older admitted to Obstetrics and Gynecology department, KGMU who are administered PRBC/FFP/Platelets(Random Donor Platelets)/combination of 2 or all 3 components for any Obstetric or Gynecological indication. 2.Patients willing to give a written informed consent. New : 1.All the patients aged 18 years and older admitted to Obstetrics and Gynecology department, KGMU who are administered PRBC/FFP/Platelets(Random Donor Platelets)/combination of 2 or all 3 components for any Obstetric or Gynecological indication. 2.Pregnant and Lactating women aged 18 years and older admitted to Obstetrics and Gynecology department, KGMU who are administered PRBC/FFP/Platelets(Random Donor Platelets)/combination of 2 or all 3 components will also be included in the study. 3.Patients willing to give a written informed consent.
Tools are not attached	Attached herewith Tools to be used in the study : Case Report Form for recording

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		sociodemographic and clinical details of the patients designed for the study (Annexure-1) Data will be collected on the basis of Transfusion Reaction Reporting Form forBlood and Blood Components and Plasma products (version -2) as per Hemovigilance Programme of India, National Institute of Biologicals, Ministry of Health and Family Welfare, Govt. of India. (Annexure-2)
	The reply from PI to the above Comments was forwarded to PR:- ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P53***	
45-	Clarification of research proposal entitled ***"To study fetomaternal outcome in women with early onset vs late onset obstetric cholestasis"*** submitted by Dr. Nutan Leyangi, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. 202/OG/23 dated 12th April, 2023. ***Previous PGTSC Comment:-*** • In SRC (scientific review committee) name and signature of two Co-guides are there -Please justify or revise • In Inclusion criteria – Age specificity not mentioned • SOP-Check list should be revised as many alternatives not ticked • Sample size disparity in SOP-Checklist (120 pts) and Protocol (185 pts)=Please clarify and correct. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P55***	
46-	Clarification of research proposal entitled ***"Comparative study of clinicopathological characteristics of carcinoma gall bladder associated with APBDJ vs carcinoma gall bladder not associated with APBDJ"*** submitted by Dr. Ram Raj, SR, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SG/255/23 dated 3rd April, 2023. ***Previous PGTSC Comment:-*** • Aims & objective not mentioned in Protocol • In Title the abbreviated word APBDJ-should be expanded to make it self explanatory • Sample size discrepancy in two gps (in sample size calculation -each gp-mentioned -139 pts and in SOP-Check list total pts mentioned as 139)– please	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	clarify • In Methodology ,please include Flow chart of study ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P60***
47-	Clarification of research proposal entitled ***"Drug utilization study and Pharmacoeconomic analysis of drugs, used in the treatment of obsessive compulsive disorders, in patients attending psychiatry outpatient Department, at tertiary care Hospital in Northern India"*** submitted by Dr. Ajay Kumar A.N, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 296/Pharma/23 dated 11th April, 2023. ***Previous PGTSC Comment:-*** • Tools not included in protocol ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P61***
48.	Clarification of research proposal entitled ***"Comparison of effectiveness and longeivity of three different restorative materials using ART versus conventional restorations with composite resin in class 1 cavities of deciduous teeth: A randomized control trial"*** submitted by Dr. Aishwarya Mukherjee, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/54/23 dated 29th April, 2023. ***Previous PGTSC Comment:-*** • As this is RCT study therefore Flow chart should be included in Methodology • Children/subject recruitment age is between 4-8 yrs. therefore Guardian consent + Child Assent form should be submitted instead of regular ICF ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P63***
49.	Clarification of research proposal entitled ***"Tracking referred asphyxiated neonates delivered in public sector health facilities to generate action points for improving neonatal outcome: an exploratory pilot study from a tertiary care referral"*** submitted by Dr. Deepika Pandey, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 310/Ped/23 dated 12th April, 2023. ***Previous PGTSC Comment:-*** • In ICF-Guardian consent E/H -forms not same -please revise • nSOFA score in tools not attached ***The reply from PI to the above Comments was forwarded to PR:-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of PR: Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P64***
50-	Clarification of research proposal entitled ***"A comparative study of perioperative and quality of life outcomes with its ergonomic characteristics in midine totally extraperitoneal repair versus extended totally extraperitoneal repair in inguinal hernia"*** submitted by Dr. Kushagra Tyagi, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 225/SY/23 dated 16th May, 2023. ***Recommendation of Primary reviewer:-*** • IEC form incompletely filled. Please fill it again and resubmit. • Sample size given different in the IEC form and in the synopsis (70+30 in IEC form and 60 in the synopsis) ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P72***
51-	Clarification of research proposal entitled ***"To elucidate relationship of posterior tibial slope to functional outcome after anterior cruciate ligament reconstruction with hamstring graft"*** submitted by Dr. Mohd. Yoosuf, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 201/Ortho/23 dated 20th April, 2023. ***Previous PGTSC Comment:-*** • There are 9 (nine) Investigators in this project. Please reduce this number or define their unique roles. • IEC form is incompletely filled. Please fill it well and re-submit. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P76***
52-	Clarification of research proposal entitled ***"Anatomical variation of heart in autopsied bodies along with histopathology correlation-An observational study"*** submitted by Dr. Ashutosh Kumar Rao, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 113/FMT/23 dated 6th April, 2023. ***Previous PGTSC Comment:-*** • Sections on Type of subjects, Privacy and Confidentiality etc. are not filled properly. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P77***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th June, 2024

53-	Clarification of research proposal entitled ***"Endocapsular multi-chop vs standard four quadrant chop: randomized controlled trial comparing per-operative ultrasound energy used, per-operative complications and postoperative corneal parameters"*** submitted by Dr. Tapan, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 3072/OPH/23 dated 16th May, 2023. ***Previous PGTSC Comment:-*** • The fundamentals of performing RCT are not completely Specified: • Method of randomization , follow-up, outcome event efficacy or effectiveness trial not clear • Statistical and methodological issues in RCT missing. • Sample size calculation is not clear. It should be done after properly defining the research hypothesis in term of the study population parameter. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVII-PGTSC-IIA/P1***
54-	Clarification of research proposal entitled ***"Randomised controlled trial comparing standard treatment of obstructive sleep apnoea to add-on acetazolamide treatment"*** submitted by Dr. Anurag Ambika Prasad Tripathi, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 621/PCCM/23 dated 2nd May, 2023. ***Previous PGTSC Comment:*** • The fundamentals of performing RCT are not completely Specified. • Random allocation to treatment not given. • Method of randomization not given. • Blinding or masking not given. • Blind assessment of outcome not given. • Loss to follow-up data. How it will be done. • Efficacy or effectiveness trial. Please clarify. • Statistical and methodological issues in RCT. • Sample size calculation is not clear. It should be done after properly defining the research hypothesis in term of the study population parameter. ***The reply from PI to the above Comments was forwarded to PR:-*** ***Recommendation of PR:*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVII-PGTSC-IIA/P3***
55-	Clarification of research proposal entitled ***"Evaluation of etiopathogenesis and outcomes of pleural empyema in tertiary care centre: A prospective observational study"*** submitted by Dr. Sahil Kumar, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 215/SY/23 dated 20th May, 2023. **Previous PGTSC Comment** | **PI response**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	It is proposed to recruit 150 cases but the basis on which this number has been taken is not mentioned. Sample size calculation shall be included.	Proposed sample size is 50 cases included in the study. Sample size calculation attached separately.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVII-PGTSC-IIA/P10

56- Clarification of research proposal entitled ***"Clinical and neuroimaging predictors of the occurrence of seizure in patients with SSPE"*** submitted by Dr. Ajeet Kumar Jaiswal, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 214/23 dated 2nd May, 2023.

Previous PGTSC Comment	PI response
Gone through the proposal. Overall it is fine, however, as many biochemical/pathological investigations, including CSF examination, are part of the project so one person from the Department of Pathology may be included as a Co-PI to supervise the investigative part.	We have included Dr. Preeti Agarwal (M.D.) from the Department of Pathology as Co-PI.

The reply from PI to the above Comments was forwarded to PR:-
Recommendation of PR: Approved
PGTSC Decision: Approval ratified

Ref. code: XVII-PGTSC-IIA/P22

IB **Expedited review**

1- Expedited of research proposal entitled ***"A study on Digital screen exposure, temperament, emotional and behavioural problems in pre-schooler children"*** submitted by Ms. Anjana Palni, M.Phil student through her guide Dr. Pooja Mahour, Additional Professor,, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.632/Psy dated 18th April, 2023.

The above research proposal was forwarded to two reviewers, for review:-
Recommendation of First Primary reviewer:

- Data will be collected from community setting like school. What are these Institutes?
- Sampling frame (List) of these schools is required.
- Title should exclude "preschool children" since the data will be collected from schools. Instead, it should mention the age-group of the subjects.
- Sample size formula is required. The sample size calculation is not clear.
- Nothing is said about the "reliability" and "validity" of the Instruments being used.
- Statistical analysis section be written in detail.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation ofSecondary reviewer: • On the scientific review committee decision statement is not ticked. • The role of investigators is missing. • The type of study is not ticked and the status of the review is not ticked. • The operational definition of the preschooler needs to be mentioned. • In the title preschooler children is written- preschooler itself includes children; the title needs to be modified. • If preschoolers are to be taken which type of schools are to be selected and what will be the selection criteria? • How long they will be able to retain a child for assessment in a school as proforma seems to be very lengthy? *What* **strategy will be adopted?** ***The above comments forwarded to PI was reviewed by PR*** **PGTSC Decision:** Approved ***Ref. code: XVIII-PGTSC-IB-M.Phil/P1***
2-	Expedited of research proposal entitled ***"A study of character strengths, perceived perceived parenting styles and peer relationship in adolescents with obsessive compulsive disorder"*** submitted by Ms. Pratibha Singh Chouhan, M.Phil student, through her guide Dr. Pooja Mahour, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.630/Psy dated 28th April, 2023. ***The above research proposal was forwarded to two reviewers, for review:-*** ***Recommendation of First Primary reviewer:*** • This is a case-control study. Each OCD should be matched with a control (healthy adolescents). • Sampling method is not clear. Different methods of recruitment are given for exposed and control group. • For each recruited OCD, the matched control should be selected at the same time. • Sample size calculation is arbitrary. The sample size formula is required. • Statistical analysis section is very general. It should be in detail and specific to the study objectives. ***Recommendation of Secondary reviewer:*** • On the scientific review committee decision statement is not ticked. • Guide and all co-investigators have almost similar roles and are limited to revising and approving the manuscript. PI is an M.Phil student and will need guidance and support at various steps of her work; which may be mentioned as the role-patient recruitment, supervision, monitoring, publication etc. • Is the PI going to apply interim analysis? • What will be the direct identifiers? • Both objectives seem to be similar. • Study is a broad term, the PI needs to specify that in the topic.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The expected outcome of the study is not mentioned. ***The above comments forwarded to PI were reviewed by the both Primary reviewers.*** ***Recommendation of both Primary reviewers.*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVIII-PGTSC-IB-M.Phil/P2***
3-	Expedited of research proposal entitled ***"A study on effect of social support & resilience on body image and social anxiety on patients with burn undergoing treatment"*** submitted by Ms. Surabhi Das, M.Phil student through her guide Dr. Pooja Mahour, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.631/Psy dated 18th April, 2023. ***The above research proposal was forwarded to two reviewers, for review:-*** ***Recommendation of First Primary reviewer:*** • Exclude the word "purposive sampling". It is misleading. • Mention a few words about the instruments used, their reliability and validity. • Sample size calculation is not clear. Give the formula used. • How the scoring will be done of the different instruments. How the aggregate score will be obtained? • Statistical analysis section is missing. ***Recommendation of Secondary reviewer:*** • On the scientific review committee decision statement is not ticked. • The investigator wants to assess cross-sectionally the effect of social support and resilience on burn patients' facial/ body image and social anxiety_ title should be more specific as per the objective of the study. • Guide and all co-investigators have almost similar roles and are limited to revising and approving the manuscript. PI is an M.Phil student and will need guidance and support at various steps of her work; which may be mentioned as the role- patient recruitment, supervision, monitoring, publication etc. • On type of subject, volunteers and patients both are ticked • The primary objective of the study should be specified followed by secondary objectives. • Is approval taken for applying the tools? ***The above comments forwarded to PI was reviewed by PR*** **PGTSC Decision:** Approved ***Ref. code: XVIII-PGTSC-IB-M.Phil/P3***
4-	Expedited of research proposal entitled ***"A study on effective personality traits, emotional regulation and schema modes in borderline personality disorder"*** submitted by Ms. Rhea Dhir, M.Phil student through her guide Dr. Shweta Singh, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.713/Psy dated 2nd May, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above research proposal was forwarded to two reviewers, for review:- *Recommendation of First Primary reviewer:* • Details regarding inclusion of vulnerable subject are missing. *The above comment was forwarded to PI was reviewed by Dr. D.N. Upadhyaya* *Recommendation of Secondary reviewer:* • Approved **PGTSC Decision:** As above ***Ref. code: XVIII-PGTSC-IB-M.Phil/P4***
5-	Expedited of research proposal entitled ***"A study on parenting style, parental attitude and emotional and behavioural well-being of children and adolescents with borderline Intellectual functioning"*** submitted by Ms. Aradhya Sharma, M.Phil student through her guide Dr. Shweta Singh, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.712/Psy dated 2nd May, 2023. ***The above research proposal was forwarded to two reviewers, for review:-*** ***Recommendations of both reviewers:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVIII-PGTSC-IB-M.Phil/P5***
6-	Expedited of research proposal entitled ***"A study on adverse childhood experiences, reflective functioning, narrative identity and life events in patients with dissociative disorder"*** submitted by Mr. Shikhar Tomar, M.Phil student through her guide Dr. Shweta Singh, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.629/Psy dated 17th April, 2023. ***The above research proposal was forwarded to two reviewers, for review:-*** ***Recommendations of both reviewers:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVIII-PGTSC-IB-M.Phil/P6***
7-	Expedited of research proposal entitled ***"A study on social cognition and alexithymia as psychosocial correlates for self-harm among young adults"*** submitted by Mr. Vikrant Patel, M.Phil student through her guide Dr. Pooja Mahour, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no.640/Psy dated 19th April, 2023. ***The above research proposal was forwarded to two reviewers, for review:-*** ***Recommendations of both reviewers:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVIII-PGTSC-IB-M.Phil/P7***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"Tibial tuberosity-trochlear groove distance in north Indian population"*** submitted by Dr. Amit Kumar, JRI, Department of Orthopaedics Surgery,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	King George's Medical University, U.P., Lucknow vide letter no. 3435/Ortho/23 dated 29th March, 2023. ***Recommendation of Primary reviewer:-*** • What is the purpose of measuring "trochlear groove distance"? Not clear. • The title says "North Indian population". But the subjects will be recruited from KGMU only. • Sample size calculation is arbitrary. What are the different parameters used in the formula? How are the values arrived at? • What is the study variables (Measurements) used in the study? A list should be prepared. • Data analysis section is very general. It should be specific to the hypothesis of the study. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Adapted ERAS protocol versus conventional care in perforation peritonitis patients undergoing emergency laparotomy- A prospective comparative study"*** submitted by Dr. Johny Lalhruaitluanga, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2370/Sy/23 dated 3rd March, 2023. ***Recommendation of Primary reviewer:-*** • Sample size calculation and data analysis sections are missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Role of plasmapheresis in organophosphate poisoning"*** submitted by Dr. Sujeet Kumar, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 753/Med/23 dated 28th March, 2023. ***Recommendation of Primary reviewer:-*** • This is not cross-sectional study. • It seems to be pre & post treatment study. It should be clearly mentioned in the primary objective and accordingly research hypothesis formulated. • Sample size mentioned is 20. How is this figure arrived at? Actually, the sample size calculation can be done only after formulating the hypothesis.This can be a pilot study. • Data analysis section is missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-IIA/P3***
4.	Research proposal entitled ***"A study on adverse drug reactions in type 2 diabetes mellitus***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	patients oral antidiabetic drugs in a tertiary care Hospital in Northern India" submitted by Dr. Neeraj Pathak, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 299/Pharm/23 dated 12th April, 2023. ***Recommendation of Primary reviewer:-*** • Sample size calculation is not clear. What are the different parameters used in the formula? How are the values in the formula arrived at? • Statistical analysis section is very general. It should be specific to the research hypothesis of the study. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-IIA/P4***
5.	Research proposal entitled ***"Evaluation of release of various metal ions during fixed orthodontic treatment and their genotoxicity: An in-vivo study"*** submitted by Dr. Chandana Himanshu, JRII, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 342/Ortho/23 dated 13th April, 2023. ***Recommendation of Primary reviewer:-*** • It is a before and after treatment study. There are two kind of treatments. So basically, there are three groups for comparison. • The study should be planned accordingly, and the hypothesis formulated properly. • Sample size calculation and statistical analysis section shall be done in accordance with the hypothesis formulated. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Clinical, biochemical and neuroimaging parameters of TBM patient after end of one year of antituberculosis"*** submitted by Dr. Praveen Kumar Prince, SRI, Department of Orthodontics Neurology, King George's Medical University, U.P., Lucknow vide letter no. 175/Neuro/23 dated 15th April, 2023. ***Recommendation of Primary reviewer:-*** • Covering letter mentions the project as 'Open label Randomized controlled trial' whereas the synopsis mentions it as being a prospective observational study. • Are any controls being used? • This is not clear from the methodology. • Will the design be altered then? • Section on 'Vulnerable subjects is mentioned as 'Yes' but no details are given. No mention of Special Group subjects in the proforma. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-IIA/P6***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

7.	Research proposal entitled ***"To study time-driven activity-based costing of computed tomography scans in a tertiary care Government teaching Hospital, Lucknow"*** submitted by Dr. Moina Wasi Khan, JRI, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/186/23 dated 29th April, 2023. ***Recommendation of Primary reviewer:-*** • The title of the research project should not have location or Institution specifics. Will suggest removal of the word 'Lucknow' • In the Methodology, no mention is made of what kind of data will be collected to calculate the per unit time cost of CT Scans. • What volume of data will be collected is also not mentioned? How many studies are required to reach a valid conclusion? No data sheet/data collection format is attached to the proforma. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Evaluating the relation between surface characteristics and biofilm adhesion over different archwires and brackets- An in vivo study"*** submitted by Dr. Maheshwar Singh, JRII, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 356/Ortho/23 dated 25th April, 2023. ***Recommendation of Primary reviewer:-*** • Sample size mentioned is 33. However, in the sample size calculation it is mentioned that the sample size is 11 per type of wire. • There are six subgroups (there in each metallic as well as ceramic) • Shouldn't the sample size be 66? **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-IIA/P8***
9.	Research proposal entitled ***"Observation of oral microbiota and their effect on periodontium three months before and after debonding of fixed orthodontic appliance"*** submitted by Dr. Amar Dipika Singh, JRII, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 354/Ortho/23 dated 24th April, 2023. ***Recommendation of Primary reviewer:-*** • Sections on Type of subjects/Vulnerable subjects left blank in the proforma. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Comparative evaluation of maxillofacial morphology in***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	unilateral and bilateral cleft lip and palate subjects: A CBCT study" submitted by Dr. Nainsi Jain, JRII, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 358/Ortho/23 dated 28th April, 2023. ***Recommendation of Primary reviewer:-*** • Will such patients be included into the study who have been already operated for cleft repair or those in which no surgery has been done? • Will the three groups be age and sex matched? • Sample size is mentioned 57 at one place and 60 at one place. • Vulnerable subjects has been ticked as 'No' whereas children are being used as study subjects. • Who will bear the cost of the CBCT? • Is this investigation part of standard treatment protocol? • How much radiation will the children be exposed to? • Will this help in their further treatment? • Why will the controls undergo CBCT and the associated radiation to be a part of the study? **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Neurological involvement in sarcoidosis- An ambispective study"*** submitted by Dr. Nagmani, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 221/Neuro/23 dated 6th May, 2023. ***Recommendation of Primary reviewer:-*** • Exact calculated sample size for Ambispective study not given • ICF-E/H –Attached [whether it is for both type –(Retro/Prospective) of study or if only for Prospective study then PI to clarify that how he will take consent for Retrospective study which will be done on previous 5 yrs. registered pts or PI will attach HSRWF for these pts]-PI to clarify **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-IIA/P11***
12.	Research proposal entitled ***"To study nutritional supplements prescribed in a tertiary care Government Hospital, Lucknow"*** submitted by Dr. Kris Agarwal, JRIII, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/210/23 dated 2nd May, 2023. ***Recommendation of Primary reviewer:-*** • In Inclusion criteria–It is written that checking of Indents of Radiotherapy department for nutritional supplements will be done (But in Objective section of the Protocol-Surgical Oncology Department is also included for checking the indents for nutritional supplements)- PI to clarify. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XVIII-PGTSC-IIA/P12
13.	Research proposal entitled ***"A double blinded randomized controlled trial on the effect of electrostimulation on saliva production in oral cancer patients undergoing radiotherapy"*** submitted by Dr. Ajith Kumar. E, JRI, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 230/OMSR/23 dated 11th May, 2023. ***Recommendation of Primary reviewer:-*** • It is an Academic RCT but PI in SOP –Checklist in section-3- Clinical Trials – mentioned as NA-PI to justify • In Inclusion criteria -Age/Sex specificity not mentioned • Control group-Physiotherapy (as Placebo)-details not given as to what type of Physiotherapy? • Clinical Trial Registry document may be submitted to IEC as soon as registration being done. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form.
	Ref. code: XVIII-PGTSC-IIA/P13
14.	Research proposal entitled ***"Total blinded randomized controlled trial to evaluate the efficacy of melatonin in treatment of tempromandibular disorder"*** submitted by Dr. Bipin Tiwari, JRI, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 229/OMSR/23 dated 11th May, 2023. ***Recommendation of Primary reviewer:-*** • It is an Academic RCT but PI in SOP –Checklist In section-3- Clinical Trials – mentioned as NA- and ticked subsequent subsections -PI to justify • In Inclusion criteria - Age/ sex /Pregnant and lactating women criteria not given • Clinical Trial Registry document may be submitted to IEC as soon as registration being done. • Tools-mentioned above are not submitted **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form.
	Ref. code: XVIII-PGTSC-IIA/P14
15.	Research proposal entitled ***"Salivary insulin like growth factor-1 and osteocalcin as skeletal maturity indicators in cleft lip and palate subjects"*** submitted by Dr. Balaji. R, JRII, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 369/Ortho/23 dated 6th May, 2023. ***Recommendation of Primary reviewer:-*** • In SOP-Checklist-Vulnerability section (5-vi)-ticked –No, but children are to be included-should be corrected and section 7 – vii, viii, ix subsections not ticked properly.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th June, 2024

	PGTSC Comment: As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-IIA/P15***
	IMR- Resident
1-	Research proposal entitled ***"Immunohistochemical expression of minichromosome maintenance complex 3 (MCM3) and transport and golgi organization protein 1 (TANGO1) in different grades of oral squamous cell carcinoma and its validation bt rtpcr"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Saloni Verma, JRI, Through her Mentor Prof. Shaleen Chandra, Head, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, KGMU via letter no. 1295/OP/23 dated 12th April, 2023. ***Recommendation of Primary reviewer:*** • Title not clear • Material and Methods section: What are health patients?? • For RNA extraction it is mentioned that DNA isolation kit will be used. That is incorrect. Everything is written in past tense, as if the work has already been carried out. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVIII-PGTSC-II B IMR-R/P1***
2.	Research proposal entitled ***"Exploration of three proteins panel to predict prognosis in oral squamous cell carcinoma"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Priya Devi, JRI, Through her Mentor Prof. Shalini Gupta, Head, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, KGMU via letter no. 1297/OP/23 dated 15th April, 2023. ***Recommendation of Primary reviewer:-*** • Material and Methods section: What are health patients?? Please provide details as also the inclusion and exclusion criteria for the same. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-II B IMR-R/P2***
3.	Research proposal entitled ***"Efficacy of digital reconstruction at varying trauma: an innovative approach in forensic odontology"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow KGMU, UP, Lucknow submitted by Dr. Ayushi Jain, JRI through her Mentor Prof. Shalini Gupta, Head, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, KGMU vide letter no. 1299/OP/23 dated 15th April, 2023. ***Recommendation of Primary reviewer:-*** • Although consent forms are given but the subjects to be taken for the study are no

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	where defined. What will be the inclusion and exclusion criteria?? **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: XVIII-PGTSC-II B IMR-R/P3***
	M. Phil Course
1.	Research proposal entitled ***"A study on metacognitions, neurocognitive functions and quality of life among older adults with depressive disorder"*** submitted by Ms. Srishti Sahu, IInd Year under the guidance Dr. Shweta Singh, Additional Professor, Department of Psychiatry King George's Medical University, U.P., Lucknow vide letter no. 579/Psy/23 dated 7th April, 2023. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XVIII-PGTSC-II B M.Phil/P1***
	MHA
1.	Research proposal entitled ***"To study the cost associated in managing Bio-Medical waste (BMW) in a tertiary care Government Hospital Lucknow, India"*** submitted by Dr. Mahwish Suhaib, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/193/23 dated 1st May, 2023. ***Recommendation of Primary reviewer:-*** • In all the proposals of the Chief supervisor, co-guide roles are not defined; in the role column, only their sign is present. • In all proposals, the type of data analysis is not mentioned clearly. • This study requires a waiver as it is to assess the cost of BMW in the University, which can be provided. **PGTSC Decision:** Waiver of Ethical approval Granted ***Ref. code: XVIII-PGTSC-II B-MHA/P1***
2.	Research proposal entitled ***"To study COVID-19 vaccination at district level with focus on wastage multiplication factor (WMF)"*** submitted by Dr. Mahwish Suhaib, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/194/23 dated 1st May, 2023. ***Recommendation of Primary reviewer:-*** • In all the proposals of the Chief supervisor, co-guide roles are not defined; in the role column, only their sign is present. • In all proposals, the type of data analysis is not mentioned clearly. • A waiver request is made which can be provided. **PGTSC Comment:** As above **PGTSC Decision:** Waiver of Ethical approval Granted

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th June, 2024

	Ref. code: XVIII-PGTSC-II B-MHA/P2
3.	Research proposal entitled ***"To study nutritional supplements prescribed in a tertiary care Government Hospital Lucknow, India"*** submitted by Dr. Shifa Kausar, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/208/23 dated 2nd May, 2023. ***Recommendation of Primary reviewer:-*** • In all the proposals of the Chief supervisor, co-guide roles are not defined; in the role column, only their sign is present. • In all proposals, the type of data analysis is not mentioned clearly. • This is a pilot study, which is to be carried out in the surgical oncology department only need to be mentioned in the title for clarity. • An information guide for obtaining the data should be prepared and provided to understand the process of the study. **PGTSC Comment:** As above **PGTSC Decision:** Approval for waiver subject to modification.
	Ref. code: XVIII-PGTSC-II B-MHA/P3
4.	Research proposal entitled ***"To assess the lead time of central medical store in a tertiary care Government Hospital Lucknow, India"*** submitted by Dr. Saumya Rawat, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/207/23 dated 2nd May, 2023. ***Recommendation of Primary reviewer:-*** • In all the proposals of the Chief supervisor, co-guide roles are not defined; in the role column, only their sign is present. • In all proposals, the type of data analysis is not mentioned clearly. • Study duration is written as 8 months but the split in the timeline is of 8 weeks. • In data collection, the PI informs that the data has been collected and records maintained. If data is collected waiver is requested for the analysis? • What analysis will be done is not clarified. **PGTSC Comment:** As above **PGTSC Decision:** Approval for waiver subject to modification.
	Ref. code: XVIII-PGTSC-II B-MHA/P4
5.	Research proposal entitled ***"To study cost incurred of compost production, in a tertiary care Government Hospital, Lucknow, India"*** submitted by Dr. Saumya Rawat, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/206/23 dated 2nd May, 2023. ***Recommendation of Primary reviewer:-*** • In all the proposals of the Chief supervisor, co-guide roles are not defined; in the role column, only their sign is present.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• In all proposals, the type of data analysis is not mentioned clearly. **PGTSC Comment:** As above **PGTSC Decision:** Approval for waiver subject to modification. ***Ref. code: XVIII-PGTSC-II B-MHA/P5***
6.	Research proposal entitled ***"A comparative study on Ayushman Bharat Pradhan mantri Jan Arogya Yojana (AB-PMJAY) packages with respect to the cost incurred in Orthopedic Department of a tertiary care Government Hospital, Lucknow"*** submitted by Dr. Nabila Asif, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/217/23 dated 11th May, 2023. ***Recommendation of Primary reviewer:-*** • In all the proposals of the Chief supervisor, co-guide roles are not defined; in the role column, only their sign is present. • In all proposals, the type of data analysis is not mentioned clearly. • In Checklist some of the statements are not filled. • Inclusion/ exclusion criteria show that the investigator wishes to identify and recruit the patients from dept of orthopedics; however, the study title/ parameters indicate it is to be done by observing the records by talking to the record keepers/coordinators. • Kindly ensure that patient's case sheets will be revised and all identifiers anonymized. **PGTSC Comment:** As above **PGTSC Decision** : Approval for waiver subject to modification. ***Ref. code: XVIII-PGTSC-II B-MHA/P6***
	Research proposal for STS grant
1.	Research proposal entitled ***"Association of screen time and heart rate variability in first year Medical students"*** sponsored by ICMR STS submitted by Mr. Mehul Saxena, MBBS through his Mentor Prof. Archna Ghildiyal, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2996/PHY/23 dated 20th March, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVIII-PGTSC-IIB-STS/P1***
2.	Research proposal entitled ***"Effect of alpha sound wave auditory stimulation on anxiety levels in patients undergoing endodontic treatment: A randomized controlled trial"*** sponsored by ICMR STS submitted by Ms. Siddhi Solanki, BDS through his Mentor Prof. Ramesh Bharti, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 22/Coms&Endo/23 dated 13th April, 2023. ***Recommendation of Primary reviewer:-*** • Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th June, 2024

	PGTSC Decision: As above ***Ref. code: XVIII-PGTSC-IIB-STS/P2***
	Research proposal for IMR-Student
1.	Research proposal entitled ***"Evaluation of the clara cell protein in serum of patients of esophageal atresia with trachea-esophageal fistula"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Mr. Pushpendra Yadav, MBBS 2020 through his Mentor Dr. Anand Pandey, Junior Grade, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 336/PedSy/23 dated 28th April, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVIII-PGTSC-IIB-IMR-S/P1***
2.	Research proposal entitled ***"Evaluating the in-vitro efficacy of platelets and plasma after pathogen reduction"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Mr. Rishabh Agarwal, MBBS 2021 through his Mentor Prof. Rashmi Kushwaha, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 479/23 dated 25th April, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVIII-PGTSC-IIB-IMR-S/P2***
3.	Research proposal entitled ***"Prevalence of cracked teeth amongst dental patients of North India visiting tertiary care centre-A prospective cross sectional study"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Ms. Anusha Agarwal, BDS through her Mentor Prof. Ramesh Bharti, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 64/Cons&Endo/23 dated 3rd May, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVIII-PGTSC-IIB-IMR-S/P3***
4.	Research proposal entitled ***"Incidence and prognostic significance of androgen receptors in patients of triple negative breast cancer"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Mr. Pranav Sankhyadhar, MBBS 2020, Through his Mentor Dr. Kushagra Gaurav, Associate Professor, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1216/23 dated 10th May, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XVIII-PGTSC-IIB-IMR-S/P4
5.	Research proposal entitled ***"Long-term outcome of kidney function of patients with renal injuries grade 3 and above"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Mr. Mehul Saxena, MBBS 2021 through his Mentor Dr. Yadvendra Dheer, Associate Professor, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. TS/244/23 dated 5th May, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XVIII-PGTSC-IIB-IMR-S/P5***
III	**Modification**
1.	Modification of research proposal entitled ***"Clinico-radiological characteristics of degenerating and calcified solitary neurocysticercosis with persistent seizure: prospective comparative study"*** submitted by Dr. Aditya Kumar, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 224/Neuro/2023 dated 8th May, 2023. ***Recommendation of Primary reviewer:-*** **PGTSC Decision:** Approved ***Ref. code: XVII-PGTSC-IIA/P23***
IV	**Other Matter**
1-	Reg. request for permission to change the instrument/device, used the thesis in the research proposal entitled ***"Comparative assessment of hand grip exercise and 6-minute walk test in chronic obstructive pulmonary disease patients"*** submitted by Dr. Toyaj Kumar, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3105/PHY/22 dated 13th May, 2023. **PGTSC Decision:** Approved ***Ref. code: XV-PGTSC-IIA/P11***

The next meeting will be held on 1st August, 2023 from 3.00 P.M.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 19th June, 2024

King George's Medical University U.P.,
Institutional Ethics Committee
Lucknow - 226003 (UP) India

Prof. Shally Awasthi
Member Secretary, IEC

(Registration No.:ECR/262/Inst/UP/2013/RR-19)

To,

No. 883 **/Ethics/2023**

Dated: 02/08/2023

Dr. Alok Dhawan,
Director,
Centre of Biomedical Research (CBMR),
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Raebareli Road,
Lucknow, U.P. 226014

Sub.: Reg. Minutes of 124th Institutional Ethics Committee Meeting held on 19th June, 2023.

Dear Sir,

Please find enclosed herewith the Minutes of 124th Institutional Ethics Committee Meeting held on 19th June, 2023, for your kind signature.

Thanking you
With regards

Encl.: As above

Yours Sincerely

01/8/23

(Shally Awasthi)
Member Secretary, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 125th IEC Meeting held on 1st August, 2023

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the 125th Institutional Ethics Committee Meeting *virtually* held on 1st **August, 2023 from 3:00 PM.**

The following Members were present in the Meeting:-

1.	Dr. Alok Dhawan	-Chairman
2.	Dr. Akash Agarwal	-Member
3.	Mrs. Vasundhara Kumari	-Member
4.	Mr. Ujjawal Krishna	-Member
5.	Mrs. Akansha Dubey	-Member
6.	Dr. Anita Rani	- Member
7.	Dr. K.K. Yadav	-Member
8.	Dr. D.N. Upadhyaya	- Member
9.	Dr. A.A. Mahdi	-Member
10.	Dr. Anupam Mishra	-Member
11.	Dr. Rajendra Nath	-Member
12.	Dr. Nisha Mani Pandey	-Member
13.	Dr. Shally Awasthi	-Member-Secretary, IEC

The following members were not Present in the Meeting:-

1.	Dr. Shubha R Phadke	- She has given her written comment
2.	Dr. G.G. Agarwal	-He has given his written comment

IA	Action Taken
1-	Clarification of research proposal entitled ***"Premature greying of hair in children and adolescents-a case control study analysis of nutritional and biochemical parameters"*** submitted by Dr. Parul Verma, Associate Professor, Department of Dermatology Venerology & Leprosy, King George's Medical University, U.P., Lucknow vide letter no. 178/Skin/22 dated 25th July, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous EC Comment / **PI response** Patient information sheet to be attached as per SOP / As per suggestion, now the patient's information sheet has been added. ***The above comment forwarded to PI was reviewed by:-*** ***Recommendation of Primary reviewer:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 117th ECM IIA/P20***
2-	Clarification of research Protocol no. QPT-ORE-006 entitled ***"A Phase2, Double-blind, placebo-controlled, multicenter clinical trial comparing chemoimmunotherapy (Paclitaxel-carboplatin-oregovomab) versus chemotherapy (Paclitaxel-carboplatin-Placebo) as neoadjuvant therapy in patients with advanced epithelial ovarian, fallopian tube or peritoneal carcinoma"*** sponsored by M/s Onco Quest Pharmaceuticals Inc submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/1165/2023 dated 13th July, 2023. **Previous EC Comment** / **PI response** Approval from DCGI for protocol amendment 3.0–attached (But there is topographical mistake in the date of approval for amendment which is mentioned as 20-02-2022 instead of 20-02-2023)-corrected letter is requested from DCGI and which is awaited / DCGI acknowledgment copy and DCGI clarification has been attached for the same ***The above comment forwarded to PI was reviewed by:-*** ***Recommendation of Primary reviewer:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 117th ECM IIC/P4***
3-	Clarification of research proposal entitled ***"Efficacy of grid-based dental rubrics as an effective assessment tool when compared to traditional assessment methods for undergraduate students managing a class II carious defect"*** submitted by Dr. Rhythm, Professor Junior Grade, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 160/Coms & Endo/22 dated 3rd July, 2023. ***The above comment forwarded to PI was reviewed by PR:-*** ***Recommendation of Primary reviewer:*** • Rubric is not attached • What is the type of variable of outcome? **EC Comment:** As above **EC Decision:** Approval subject to modification

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: 120th ECM IIA/P31

4- Clarification of research proposal entitled "***Role of FGFR3 and TP53 gene methylation and their correlation with autophagy regulator gene expression in the progression of non-muscle invasive bladder cancer***" sponsored by UPCST, Lucknow submitted by Mr. Anil Kumar, Ph.D Scholar under the guidance Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 608/URO/ dated 19th July, 2023.

Previous EC Comment	PI response
Comment 1: Is this a PhD thesis?	Reply: Yes, this proposal is for PhD thesis.
Comment 2: The project does not make great sense still. The title has been altered, but the problem remains the same.	Reply: This study will shed light on methylation-mediated regulatory responses in the progression of non-muscle invasive bladder cancer. This study is a novel study to explore the unexplored genes expression and DNA methylation pattern in NMIBC. The study will focus on the following points. Epigenetic Analysis: The study focuses on the epigenetic modifications of FGFR3 and TP53 genes by examining the methylation patterns at their promoter sites. Epigenetic alterations play a crucial role in cancer development and progression, and specifically studying these modifications in bladder cancer adds to the current knowledge base. Autophagy Regulators: Investigating the expression of autophagy regulators, such as mTOR, ULK1, Beclin1, and LC3, in non-muscle invasive bladder cancer adds a novel aspect to the study. Autophagy is a cellular process with diverse roles in cancer, and understanding its involvement in bladder cancer may provide valuable insights into potential therapeutic strategies. Correlation Analysis: The study aims to correlate the methylation and expression

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		patterns of FGFR3 and TP53 genes with the expression levels of autophagy regulators. This correlation analysis can uncover potential interactions and relationships between these molecular factors, contributing to a more comprehensive understanding of their collective impact on bladder cancer progression. Clinical Relevance: Investigating the role of the methylation and expression patterns of FGFR3 and TP53 genes in the Progression of non-muscle invasive bladder cancer has significant clinical relevance. Identifying potential biomarkers or therapeutic targets associated with these genes can aid in Prognosis, treatment decision-making, and the development of personalized approaches for patients with bladder cancer.
	Comment 3: Title objectives and study plan don't match.	Reply: The study plan is revised and it is mentioned in Figure 1, in the summary of proposal.
	Comment 4: The study design is not mentioned.	Reply: This is a cohort study. It is mentioned in the corrected version of summary.
	Comment 5: Review of literature/background/references has not been mentioned.	Reply: The review of literature/background and references are attached herewith.
	Comment 6: There is no mention of how the sample size was calculated? Will there be a control group. If yes, what will be that?	Reply: Samples size was calculated by using formula of correlation between expression of markers and DNA methylation, we use r = 0.30, (minimum correlation between markers) where, r is the correlation coefficient that shows Positive correlation between tested markers and clinical parameters (progression, tumour stage, and grade). The value of r ranged from 0 to 1, and

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			classified into following ranges. r = 0 (means, there is no correlation) r = 0.30-0.50, weak correlation r = 0.50-0.70, moderate correlation r = 0.70-0.90, strong correlation and r = 1 (means, perfect correlation). The expected correlation coefficient is 0.30 for mentioned markers in non muscle invasive bladder cancer. The formula used for sample size calculation is The sample size N= [(Z α +Zβ)/C] 2 +3 Where, α= 0.05, ( )= 0.20, The expected correlation coefficient (r)= 0.30 The standard normal deviate for α = Z α = 1.96 The standard normal deviate for β = Z β = 0.84 C = 0.5 * ln[(1+r)/(1-r)] = 0.3095 C = 0.5* ln [(1+0.30)/ (1-0.30)] C = 0.5* ln (1.857) C = 0.3095 Calculation: N= [(1.96+0.84)/C] 2 +3 N= [2.8/0.3095] 2 +3 N= (9.04 x 9.04) +3 N = 84.83 N= Total 85 samples Total sample size = 85= Group-1= non-muscle invasion bladder cancer(n=85) Group-2= normal bladder mucosal tissue will be taken from the patients of benign prostate hyperplasia (BPH) by cup shaped biopsy technique considered as control group. reference no.2.	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Reference 1. Hulley SB, Cummings SR, Browner WS, Grady D, Newman TB. Designing clinical research: an epidemiologic approach. 4th ed. Philadelphia, PA: Lippincott Williams &Wilkins; 2013. Appendix 6C, page 79. 2. Tripathi, K., et al. (2021). "Promoter hypomethylation as potential confounder of Ras gene overexpression and their clinical significance in subsets of urothelial carcinoma of bladder. & quot; Mol Biol Rep 48(3): 2183-2199.
	Comment 7: What is progression how is it defined?	Reply: Progression means the increase in stage and grade of tumour. The most commonly used definition for non muscle invasive bladder cancer progression is proposed by the International bladder cancer group (IBCG). The proposed definition of cancer progression is an increase in T stage from CIS or Ta to T1 (lamina propria invasion), development of T2 or greater or lymph node (N+) disease or distant metastasis (M1), or an increase in grade from low to high. Reference: 1. Lamm D, Persad R, Brausi M, Buckley R, Witjes JA, Palou J, Böhle A, Kamat AM, Colombel M, Soloway M. Defining progression in nonmuscle invasive bladder cancer: it is time for a new, standard definition. J Urol. 2014Jan;191(1):20-7.doi: 0.1016/j.juro.2013.07.102. Epub 2013 Aug 22. PMID: 23973937.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Comment 8: What is the time cut off to label as non progressive?	Reply: The time cut off for non progressive bladder cancer varies, depending on specific clinical guidelines and criteria used in a study design or clinical setting and individual patient's characteristics. However, in this study protocol, 12 months of follow-up period will be taken to assess recurrence and progression of tumour through cystoscopic examination at every 3, 6, 9 and 12 months after initial TRUBT. CECT will be done if needed. This protocol is similar to EORTC guidelines. □ If no evidence of tumour recurrence or disease progression observed during the period of 12 months, the tumours will be classified as non-progressive. □ If the tumour recurs during the 12-month follow-up period on cystoscopic examination, a tumour biopsy (TURBT) is, taken for histopathological examination to assess the grade and T-stage of carcinoma. The tumour size, number, grade, and stage, and lymph node on CECT will be collectively analysed to label as progression. Reference: Sylvester, R. J., et al. (2006). &q uot; Predicting recurrence and p progression in individual patients with stage Ta T1 bladder cancer using EORTC risk tables: a combined analysis of 2596 patients from seven EORTC trials & quot; Eur Urol 49(3): 466-465; discussion 475-467.
	Comment 9: What clinical measures will be correlated and how?	Reply: In the proposed study we will be correlate promoter methylation of mentioned gene and their expression with clinical characteristics of patients such as symptoms, tumor grade, stage, number of tumours, shape, recurrence and

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Progression of the tumor following TURBT (Histopathology report). The study will correlate these parameters by statistical analysis with Spearman or Pearson correlation methods through SPSS software.
	Comment 10: First page of IEC form, consents, PIS, missing.	Reply: First page of IEC form, consent form and PIS have been attached. In the earlier proposal also these forms were submitted.
	Comment 11: Very Sketchy proposal, especially form a PhD student.	Reply: The aim of this study is to investigate the role of FGFR3 and TP53 gene methylation and their correlation with autophagy regulator gene expression in the progression of non- muscle invasive bladder cancer. Due to the recurrent nature of NMIBC and the ability to progress from low-grade to high- grade tumors, constant surveillance is required. Low grade NMIBC tend to be associated with FGFR3 whereas high grade NMIBC shows loss function of TP53 gene, which suggests progression of tumor by distinct molecular pathways. The efforts have been made to define the pathway behind NMIBC progression, and attempts to identify biomarkers that can help to manage and treat the disease. This study will provide insight on the following points; Information about the epigenetic modifications occurring in proposed genes in relation to bladder cancer. Help to understand the activity and regulation of genes in the context of bladder cancer. This will provide insights into the involvement of autophagy in bladder cancer progression. The study will determine if there are any

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			associations or correlations between the epigenetic modifications of FGFR3, TP53 and the regulation of autophagy regulators. This will provide insights into the potential role of these genes in the development and progression of bladder cancer and may contribute to the understanding of potential therapeutic targets or prognostic markers.

The above comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
In section 5(vi) vulnerable subjects
Study design?
The above comments forwarded to the Chairman, IEC was reviewd & approved.
EC Decision: Approved

Ref. code: 120th ECM II B-Ph.D./P1

5- Clarification of research proposal entitled ***"Elucidating mechanisms underlying increased expression and activity of oncogenic kinases and their downstream targets regulating metastasis in breast cancer"*** sponsored by CSIR, New Delhi submitted by Prof. M.L.B. Bhatt, Head, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no.405/RT/23 dated 11th May, 2023.

Previous EC Comment	PI response
Identify the study variables and population parameters	Population parameters: Set of population that will be incorporated in the current study include: Women belonging to both rural and urban areas. Women with variable educational background (uneducated, primary education and secondary/higher education will be included). Women patients diagnosed with breast cancer of age 30- 55 years. Study variables: Patients diagnosed with and without cancer (i.e., normal samples) in biopsy. Patients with and without relapse after standard chemotherapy.
Specify one primary objective and club	Primary objective:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	rest into secondary objectives.	To identify the mechanisms underlying aberrant expression/function of regulatory factors involved in cancer progression and drug resistance.The mechanisms behind PIM1-mediated increased oncogenic activities are known, what and how does PIM itself is regulated in these cancers is poorly known. Here we propose to identify E3s and DUBs which may positively regulate stability of oncogenic kinases including PIM1 and thereby enhance their oncogenic kinase activity which may implications in increased cancer stemness and metastasis via regulating CD44. As a result, we aim to determine how PIM1 and its regulatory protein(s) are expressed in healthy individuals and breast cancer patients (primary and metastasized sample). We would also check for PIM1, regulatory E3s/DUBs and CD44 expression in both chemotherapy-treated individuals who experienced relapse and those who did not. Secondary objectives: 1. To elucidate mechanisms underlying regulation of increased expression/activity of PIM1, CD44 and USP10 in breast cancer. 2. To screen E3s/DUBs through immunoblotting for their ability to regulate factors (e.g., PIM, USP10, CD44 etc.) involved in cancer progression/drug resistance. 3. To decipher mechanism of PIM1 and CD44 regulation by identified E3s and DUBs. 4. Evaluate levels of identified E3s/DUBs and PIM1 in primary human samples of breast cancer.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		5. Elucidating the underlying mechanism of increased stemness and metastasis in breast cancer by oncogenic kinases such asPIM1.
	Convert primary objective into research hypothesis using study variables and population parameters	Primary objective: To identify the mechanisms underlying aberrant expression/function of regulatory factors involved in cancer progression and drug resistance. The mechanisms behind PIM1-mediated increased oncogenic activities are known, what and how does PIM itself is regulated in these cancers is poorly known. Here we propose to identify E3s and DUBs which may positively regulate stability of oncogenic kinases including PIM1 and thereby enhance their oncogenic kinase activity which may implications in increased cancer stemness and metastasis via regulating CD44. As a result, we aim to determine how PIM1 and its regulatory protein(s) are expressed in healthy individuals and breast cancer patients (primary and metastasized sample). We would also check for PIM1, regulatory E3s/DUBs and CD44 expression in both chemotherapy-treated individuals who experienced relapse and those who did not. This study will include: Population parameters: Set of population that will be incorporated in the current study include: Women belonging to both rural and urban areas. Women with variable educational background (uneducated, primary education and secondary/higher education will be included). Women patients diagnosed with breast

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		cancer of age 30- 55 years. Study variables: Patients diagnosed with and without cancer (i.e., normal samples) in biopsy. Patients with and without relapse after standard chemotherapy.
	What is the study design?	Study Design: The aim is to elucidate the mechanism underlying increased expression and activity of PIM1, CD44 etc. and their regulation by E3s and DUBs in breast cancer patients. For this, patient samples will be obtained either in formalin or DMEM (Dulbecco's Modified Eagle Medium) cell culture media for IHC and cell culture-based experiments respectively. PIM1 has been reported to be upregulated in breast cancer. In order to identify the expression of PIM1 and its target gene/protein in cancerous condition, immunohistochemistry (IHC) results from the tissue sections of breast cancer will be compared to the control group i.e., (samples not diagnosed with breast cancer during biopsy). Since PIM1 is also involved in the development of drug resistance, IHC results from patients with tumor relapse will be compared to the group that does not show any relapse after chemotherapy. The findings in the above experimental conditions will be further extended in ex-vivo study using patient samples where following methods/techniques will be used – Protein isolation and western blotting. RNA isolation and determination of RNA levels in the given experimental conditions.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Cell biology assays (Colony formation assay and mammoshpere assay) Study type: Analytical study Population parameters: Set of population that will be incorporated in the current study include: Women belonging to both rural and urban areas. Women with variable educational background (uneducated, primary education and secondary/higher education will be included). Women patients diagnosed with breast cancer of age 30- 55 years. Study variables: Patients diagnosed with and without cancer (i.e., normal samples) in biopsy. Patients with and without relapse after standard chemotherapy. Expected outcome: We anticipate that USP10 (a deubiquitinase), which has been linked to an oncogenic role in breast cancer, may control PIM1 kinase expression by stabilizing its protein, further fostering the growth and progression of breast cancer. As PIM1 has been discovered to be significantly expressed in cancer stem cells, we are further speculating on the significance of the USP10-PIM1- CD44 axis in enabling cancer cell migration by increasing stemness property in them.
	Sample size calculation is missing.	The sample size calculation is attached herewith as Annexure I.
	Data management and statistical analysis details are not given.	Data Management and analysis: Samples will be collected at KGMU and the processing of samples and experimentation work shall be performed at CSIR- CDRI as described in the methodology section. In order to compare

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		the mean expression between two groups, the student's test will be used. To compare the variance in the expression of two or more groups, the ANOVA test will be used. Benjamini- Hochberg procedure will be used to avoid Type I error (false positives).TheBenjamini–Hochberg method will be used to control the False Discovery Rate (FDR) using sequential modified Bonferroni correction for multiple hypothesis testing. The statistical analyses will be done using GraphPad prism v8. To analyse the IHC data, including diagnostic value of certain molecular expression and prognostic relationship of the biomarkers, results of the IHC will also be statistically analysed.
	Processing of samples and experimentation shall be done at CSIR-CDRI. It is not mentioned in the role of co-investigators.	Dr. Arun Kumar Trivedi, (Ph.D.) (Sr. Principal Scientist, CSIR-CDRI, Lucknow) 1. Conceptualization and designing of studies. 2. Supervision of sample processing and experimentation. 3. Data interpretation and its analysis Role of PIs attached herewith as Annexure II.

The above comment forwarded to PI was reviewed by PR:
Recommendation of PR:
Provisionally Approved
EC Decision: Approved

Ref. code: 121st ECM IIA/P1

6- Clarification of research proposal entitled ***"Prevalence and determinants of hepatitis B & Hepatitis C among pregnant women in Lucknow district"*** submitted by Mr. Abhishek Yadav, Ph.D. Scholar 2019 under the guidance Prof. Monika Agarwal, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 329//CM/23 dated 10th June, 2023.

Previous EC Comment	PI response
First page of Annexure 1 is missing.	It is being attached with the letter. Annexure 1
Patient information sheet both in English	It is being attached with the letter.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

and Hindi needs to be submitted.	Annexure 2
Anticipated statistical Analysis needs to be submitted.	Data will be entered in Microsoft excel sheet. Confidentiality of each study participant will be maintained throughout the study. The data will be analysed using SPSS version 24.0. Descriptive summary using frequencies, percentages, graphs, mean, standard deviation, median and IQR will be used to present study results.Categorical variable will be analysed using chi square test. Continuous variable will be tested using independent t test. Regression analysis will be done to establish association between independent and dependent variables. P-value of 0.05 will be considered significant.
The semi structured questionnaire needs to be submitted that will be used to assess the risk factor and determinants amongst pregnant women.	It is being attached with the letter. Annexure 3
Set Performa for follow-up also needs to be submitted.	It is being attached with the letter. Annexure 4
Also Submit the pretested structured questionnaire and indicate where this pretesting has been done with its pre testing out come.	Pretesting of the questionnaire was conducted in PHC Sarojini Nagar of District Lucknow. Chronbach's Alpha is a way to measure the internal consistency of a questionnaire or survey. Reliability Statistics for Risk Factor-Cronbach's Alpha ranges between 0 and 1, which is 0.8444 for risk factors, so the questionnaire (Question no 43 to Question no 72) is reliable. Average inter item covariance: 0.029518 Number of items in the scale: 27 Scale reliability coefficient: 0.8444 Reliability Statistics for knowledge about

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		hepatitis- Cronbach's Alpha ranges between 0 and 1, which is 0.9926 for the knowledge about hepatitis, so the questionnaire (Question no 73 to Question no 89) is reliable. Average inter item covariance: 0.222115Number of items in the scale: 17 Scale reliability coefficient: 0.9926 Annexure 5

The above comments forwarded to PI was reviewed by PR:-
Recommendation of PR:

- Provisionally approved

EC Decision: Approved

Ref. code: 121st ECM II B-Ph.D/P1

7- Clarification of research proposal entitled "***Evaluation of high risk proteins involved in breast cancer and their correlation with tumor aggressiveness and chemotherapy response: A retrospective study***" sponsored by CSIR-CDRI submitted by Dr. Sumaira Qayoon, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 890/23 dated 8th July, 2023.

Previous EC Comment	PI response
Annexure 1 needs to be filled up for 'risk and benefits', 'data monitoring', 'compensation for injury' etc.	The necessary changes have been done
It is indicated by astrix that written consent will be taken. Kindly clarify since consent waiver form is also attached.	Written consent from patients will not be necessary as this is a retrospective study and we will be using archived samples for which the waiver of consent form has been submitted.
Kindly indicate other centres involved in this multicentre study.	The centres involved in this multicentre study include Department of Pathology, KGMU, Lucknow and CSIR-Central Drug Research Institute, Lucknow.
The first objective indicates that meta-analysis will be undertaken to shortlist six high risk genes while budget indicates that immunohistochemistry will be undertaken from the very beginning of the study. Have those six genes been identified? If yes, then kindly mention	Yes, the six genes have been identified by meta-analysis study. The genes are BCL11A, IMPA2, LAMP3, HORMAD1, B3GNT5 and PDL1. The antibodies required for IHC studies will roughly cost Rs50,000/- each for a 100µL vial. We are anticipating the need for 2 vials for

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	them and if not then the budget quoted may change depending upon the antibody cost of specific genes that needs to be assessed. Kindly clarify.	antibodies every year since the number of samples is high. Therefore, a budget of 5 lakhs/yr and total of Rs15 lakhs for 3 years has been budgeted for antibodies, since they are the primary requirement for IHC studies.
	Regarding third objective to correlate protein expression with chemotherapeutic response, kindly mention the clinical parameters that need to be recorded and the RCB scoring. In addition also attach the data-sheet-proforma that will be used to record the various observations.	Response to chemotherapy will be assessed in terms of Residual Cancer Burden (RCB) and details have been added in material and methods section. Data sheet has been attached
	The second objective states a comparison between TNBC versus non-TNBC patients. What would be the sample size of each group- 100 or 200? Kindly state.	The sample size of TNBC and other subtypes i.e luminal A, Luminal B and Her2/Neu and Normal will be 64 samples for each group.
	Also mention clearly in methodology section as how will you approach each objective clearly.	The first objective of identifying the high-risk proteins through meta-analysis approach, has been completed. The second objective of analysing the expression of high-risk proteins in non-TNBC and TNBC groups will be done by using standard protocol of Immuno-histochemistry (IHC). The third objective of correlating the status of high-risk proteins with response to chemotherapy will be done by evaluating response of tumor to neoadjuvant chemotherapy. This will be assessed in terms of Residual Cancer Burden (RCB) and details have been added in material and methods section.
	What are the chronic immunological disorders that need to be excluded? Kindly state.	This point has been eliminated from the exclusion criteria.
	It is stated in hypothesis section that "in a related study m-RNA expression will be analysed in fresh biopsy tissue sample".	The hypothesis section that declares that "in a related study mRNA expression will be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Is this ethically approved or will it be submitted? Since this seems to be a prospective study, the current submission being retrospective (based on blocks) seems different. Kindly clarify.	analysed in fresh biopsy tissue sample", is a different ongoing project. This project has obtained ethical clearance earlier (Ref code: 93rd ECM IIA/P5). So this has been deleted from hypothesis section of the current submission.
	Briefly mention the summary of anticipated statistical analysis.	Statistical analysis will be done using the following formula: • Assessments – Primary outcome variable will be at least a 2 folds change in gene expression of high-risk proteins between TNBC and other subgroups of breast cancer patients. – Secondary outcome variables- will be change in expression profile of high-risk proteins between same patient or same group "before" and "after" chemotherapy. Reference variable used for sample size collection is the formula: Number of samples (n) = [2 x (Z (1-α/2) + Z β) x σ 2]/Δ 2 , where Z P (Z (1- α/2) +Z β) = points on normal distribution to give required power and significance, α = significance level, β = power of the study, σ = standard deviation = [2 x (1.96+1.28) 2 x0.721 2]/0.5 2 = 64 of each group. • Total number of samples needed was calculated as follows: 64 patients belonging to one subgroup x 5 groups (TNBC, Luminal A, Luminal B, Her2,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Normal) = 320 samples total. • The project has received conditional approval from CSIR-CDRI (Annexure-II).

EC Comment:

- Please submit the revised protocol which has incorporated all suggestions.

EC Decision: Approval subject to modification

Ref. code: 123rd ECM IIA/P4

8- Clarification of research proposal entitled ***"Role of neuroinflammation in the progression of neurodegenerative disorders and identification of novel drug targets"*** submitted by Dr. Saniya Ansari, Ph.D. Scholar under the guidance Prof. Shailendra Kumar Saxena, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/107/23 dated 15th June, 2023.

Previous EC Comment	PI response
Details of sample size calculation shall be Provided	Sample size calculation has been added as suggested.
Age of the subjects to be included in the study not mentioned	Age of the subjects has been added as suggested.
It is not clear from the contents if CSF samples will also be collected from the controls too?	CSF will be taken from normal pressure hydrocephalus (NPH) patients admitted in Department of Neurosurgery, KGMU, in which CSF is routinely taken out for diagnostic purpose and the leftover samples will be used as the control for this study.
Inclusion and exclusion criteria for the controls not given	We have added inclusion and exclusion criteria for the control patients as suggested.
Prof. Hardeep Singh is mentioned as an expert and he will also be participating in the study by recruiting patients. How can an expert participate in the study?	Prof. Hardeep Singh is participating as an internal expert in doctoral committee (nominated by Hon'ble VC, KGMU), but his role in the project is as clinician for the recruitment of the patients and successful implementation of the project at clinical level.
Revise and Re-submit, Give a tabular Format	Proposal re-submitted for consideration with corrections.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comments forwarded to PI was reviewed by PR: ***Recommendation of PR:*** Provisionally Approved **EC Decision:** Approved ***Ref. code: 123rd ECMIIB-Ph.D/P1***
9-	Clarification of research proposal entitled "***Bone marrow metastasis in non-hematological malignancies: A study from tertiary care centre***" submitted by Prof. Rashmi Kushwaha, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 889/23 dated 10th July, 2023. **Previous EC Comment** / **PI response** Objectives of the study are not provided / To assess the hemato-morphological features in cases of Non-hematological malignancies with bone marrow metastasis ***The above comment forwarded to PI was reviewed by PR:*** ***Recommendation of PR:*** Provisionally Approved **EC Decision:** Approved ***Ref. code: 124th ECM IIA/P2***
10-	Clarification of research proposal entitled "***Effect of low-level laser therapy during regenerative endodontic procedure in necrotic immature young teeth-clinical and molecular perspectives***" submitted by Dr. Pragya Pandey, Associate Professor, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 189/Coms&Endo/23 dated 20th July, 2023. ***The above comment forwarded to PI was reviewed by PR:*** ***Recommendation of PR:*** Provisionally Approved **EC Decision:** Approved ***Ref. code: 124th ECM IIA/P5***
11-	Clarification of research proposal entitled "***Introducing the professionalism mini-evaluation exercise (P-MEX) in undergraduate medical training in India: A validity and feasibility study***" submitted by Dr. Sarika Gupta, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1604/Ped/23 dated 6th July, 2023. ***The above comment forwarded to PI was reviewed by PR:*** ***Recommendation of PR:*** Provisionally Approved **EC Decision:** Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 124th ECM IIA/P8
12-	Clarification of research proposal entitled "***External limiting membrane and ellipsoid zone restoration-based grading system for successful macular hole surgery***" submitted by Prof. Sandeep Saxena, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 6055/OPH/23 dated 6th July, 2023. ***The above comment forwarded to PI was reviewed by PR.*** ***Recommendation of PR:*** Provisionally Approved **EC Decision:** Approved
	Ref. code: 124th ECM IIA/P10
13-	Clarification of research proposal entitled "***Practice pattern of intraoperative fluid therapy in elective major gastrointestinal cancer surgeries in India (I-INFUSE)- A multicentre observational study***" submitted by Dr. Hemlata, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/854/23 dated 24th July, 2023. ***The above comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** • Ethics form is not attached • What constitutes intraoperative fluid is not defined • What is the definition of massive blood loss? • Radical/revision cholecystectomy for cancer needs liver resection: can't be included in inclusion criteria. **EC Comment:** As above **EC Decision:** Approval subject to clarification. Give changes done in tabular format.
	Ref. code: 124th ECM IIA/P18
14-	Clarification of research proposal entitled "***Surveillance of humoral and T-cell immunity for COVID-19 in population of Uttar Pradesh***" sponsored by MHM, UP Government submitted by Dr. Geeta Yadav, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 938/23 dated 17th July, 2023.

Previous EC Comment	PI response
Estimate of the antibodies and T cell are to be done in KGMU and data to be collected from various districts. what precautions will be taken to maintain the samples and who will be responsible for it.	The lab technician at each PSU will collect the sample and medical officers will be responsible for overall sample adequacy, representativeness, monitoring and transport of samples. Training of all concerned staff will be done before collection of samples.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Samples will be transported in upright position in ice box. Details have been addedstudy procedure section of revised proposal.
For sampling 10 districts of the state are to be selected. However, it is not.mentioned anywhere how many districts. Will be required for data collection?	The samples will be collected from 10 district subdivided in 290 PSU (primary sampling units). The details are mentioned in sample size section of the revised proposal.
The checklist indicates that any other will take the consent, which needs to be defined how anyone can take the consent and will any other be able to satisfy the query of the participants.	The laboratory Technician will take the consent of participant or parents (in case of children). Training of all the staff involved will be done about the study.
Will the participants be able to understand the study process as it is written?	The study process is mentioned in both Hindi and English languages and the community mobilisers and lab technician will help participants to understand the study process in case of any query.
Assent is not there	Assent has been attached with revised proposal.

The above comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally Approved
EC Decision: Approved

Ref. code: 124th ECM IIA/P20

15- Clarification of research research proposal entitled "***Clinicopathological parameters of hemophilia patients at a tertiary care centre of Northern India***" submitted by Prof. Rashmi Kushwaha, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 888/23 dated 10th July, 2023.

Previous EC Comment	PI response
The research hypothesis is written under the heading of Aims and Objectives	**Hypothesis** : This study is to fill the information gap by evaluating the clinicopathological profile of hemophilia in patients who were presented to this tertiary care institution at the time of diagnosis. **Aim** – To assess the Clinicopathological

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	parameters of hemophilia patients
Expected outcome is written as study objectives	**Study Objectives** 1. To evaluate hemato-morphological features in cases of non-haematological malignancies infiltrating marrow. 2. To determine the incidence of anaemia, bicytopenia and pancytopenia in cases of non-haematological malignancies infiltrating marrow. 3. To determine the differences between the hemato-morphological feature in cases of non-haematological malignancies with or without bone marrow metastasis.
PI declares that study is not a research activity and is a chart review then there is no need for consent form	Yes, this work is Retrospective study, no need of consent form is required

The above comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally Approved
EC Decision: Approved

Ref. code: 124th ECM IIA/P22

16- Clarification of research proposal entitled "***Comparative evaluation of Glasgow coma score (GCS) with or without assessment aid among resident physicians and nursing staff in emergency Medicine Department- a randomized control trial***" submitted by Prof. Haider Abbas, Head, Department of Emergency Medicine, King George's Medical University, U.P., Lucknow vide letter no. 190/EMD/23 dated 22nd May, 2023.

Previous EC Comment	PI response
Study title needs to be modified as per hypothesis	Effect of Assessment Aids on Inter-Observer Variability in Glasgow Coma Score (GCS) Evaluation: A Randomized Controlled Study among Resident Physicians and Nursing Staff in the Emergency Medicine Department.
The research hypothesis is written under	Mentioned separately. Refer to copy of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

the heading of aims & objectives.	literature attached.
Study duration is to be checked as in checklist it is written as 4 weeks and in brief description as 2 weeks from data collection to literature preparation.	Rectified and mentioned properly. Refer to copy of literature attached.
Inclusion and exclusion criteria	Mentioned clearly. Refer to copy of literature attached.
How consent of a coma patient will be solicited?	By the attendant of the patient by making him understand what exactly the purpose of study is. Refer to copy of literature attached.
Study duration is to be checked as in checklist it is written as 4 weeks and in brief description as 2 weeks from data collection to literature preparation.	Rectified and mentioned properly. Refer to copy of literature attached.
Sample size	As mentioned earlier, sample size calculated was 140 (70 in both the groups). Refer to copy of literature attached.

The above comment forwarded to PI was reviewed by PR:-

Recommendation of PR:
Provisionally Approved
EC Decision: Approved

Ref. code: 124th ECM IIA/P23

17- Clarification of research proposal entitled ***"Elucidate the role of miRNA mediating epithelial to mesenchymal transition in chronic myeloid leukemia"*** sponsored by DST Inspire Fellowship submitted by Ms. Surbhi Gupta under the guidance Dr. Nitu Nigam, Associate Professor, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 126/CFAR/23 dated 6th July, 2023.

Previous EC Comment	PI response
Proposal / Synopsis need to be written properly	Rationale of the proposed study updated Outcome revised Methodology rewritten
Review literature in synopsis to be updated in correct format	National and International status segregated and incorporated latest research details
Patient information sheet need to appropriate	Patient information sheet changes implemented as recommended

The above comment forwarded to PI was reviewed by PR:-

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of PR: • The Objectives are unclear, vague. • What is the primary objective? • Sample size calculation is based on which objective? • Sample size of 30, appears to be too little for this type of research. **EC Comment:** As above **EC Decision:** Approval subject to modification. ***Ref. code: 124th ECM II B-FS/P1***
18-	Clarification of research protocol no.CKJX839D12303 entitled "***A multi-center, randomized, double-blind, placebo-controlled, parallel-group IIIb study evaluating the effect of inclisiran on atherosclerotic plaque progression assessed by coronary computed tomography angiography (CCTA) in participants with a diagnosis of non-obstructive coronary artery disease without previous cardiovascular events (VICTORION-PLAQUE)***" sponsored by M/s Novartis Healthcare Private Limited submitted by Prof. S. K. Dwivedi, Head, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 191/Cardio/Res/2023 dated 3rd July, 2023. ***The above comment forwarded to PI was reviewed by PR:-*** ***Recommendation of PR:*** Provisionally Approved *The following documents were reviewed in the Meeting:-*

Sr. No	Title
1-	Clinical Trial Protocol (Version Number: 00; Dated: 08-Jul-2021)
2-	Investigator's Brochure (Edition 16; release date 30 Nov 2022)
3-	eCRF 1.0_06May2022(PROD)- Unique
4-	Patient Information and Informed Consent Form (Version 1.0, Dated 21 Feb 2022)
5-	Patient Information and Informed Consent Form (Version 1.0, Dated 21 Feb 2022) translated from English to Hindi on 2 Mar 2022
6-	Patient Information and Informed Consent Form (Version 1.0, Dated 21 Feb 2022) back translated from Hindi to English on 10 Mar 2022
7-	Translation and back translation certificate for Patient Information and Informed Consent Form (Version 1.0, Dated 21 Feb 2022): Hindi
8-	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 21 Feb 2022)
9-	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 21 Feb 2022) translated from English to Hindi on 2 Mar 2022
10.	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants (Version 1.0, Dated 21 Feb 2022) back translated from Hindi to English on 10 Mar 2022
11.	Translation and back translation certificates for Informed Consent Form: Pregnancy Follow-up

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	for Pregnant Participants (Version 1.0, Dated 21 Feb 2022): Hindi
12.	Informed Consent for Exploratory Genetic Research (Version 1.0, Dated 21 Feb 2022)
13.	Informed Consent for Exploratory Genetic Research (Version 1.0, Dated 21 Feb 2022) translated from English to Hindi on 2 Mar 2022
14.	Informed Consent for Exploratory Genetic Research (Version 1.0, Dated 21 Feb 2022) back translated from Hindi to English on 10 Mar 2022
15.	Translation and back translation certificates for Informed Consent for Exploratory Genetic Research (Version 1.0, Dated 21 Feb 2022): Hindi
16.	Audio-Video Informed Consent Form (Version 1.0, Dated 1 Apr 2021)
17.	Audio-Video Informed Consent Form (Version 1.0, Dated 1 Apr 2021) translated from English to Hindi on 23 Jun 2021
18.	Audio-Video Informed Consent Form (Version 1.0, Dated 1 Apr 2021) back translated from Hindi to English on 25 Jun 2021
19.	Translation and back translation certificates for Audio-Video Informed Consent Form (Version 1.0, Dated 1 Apr 2021):Hindi
20.	Patient card_English
21.	Patient card translated to Hindi
22.	Patient card back translated from Hindi to english
23.	Certificate of translation for Patient Card Hindi
24.	Participant Thank you Letter
25.	Participant Thank you Letter_Translated to Hindi
26.	Participant Thank you Letter_Back translated from Hindi to English
27.	Certificate of translation for Participant Thank you Letter Hindi
28.	Insurance certificate for the period of 2023
29.	Draft CTA
30.	CTRI
31.	CKJX839 (L1) SUSAR for the period- 01 OCT 2021 to 31 MAR 2022 BLINDED ALL Arms

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		(CT)
	32.	CKJX839 (L1) SUSAR(s) 01APR2022 30SEP2022 BLINDED ALL Arms (CT)
	33.	HA CT NOC dated 25 Jul 2022
	34.	CRF Completion Requirements - 18-Apr-2022
	35.	DCGI Acknowledgement of CKJX839D12303-IB ver 16 dated 9 Jan 2022
	36.	CV, GCP , MRC of the PI
	37.	IU

EC Decision: Approval subject to fulfillment & Administrative formalites

Ref. code: 124th ECMIIC/P1

19- Clarification of research protocol no. ALK28/ENZ130-PER1 entitled "***A prospective, randomized, multicenter, comparative, double-blind, parallel study to evaluate the efficacy, safety, pharmacokinetics, and immunogenicity of biosimilar pertuzumab (ENZENE) with reference pertuzumab (Perjeta®, Genentech. Inc.,) in previously untreated patients with HER2 positive metastatic breast cancer***" sponsored by M/s Enzene Biosciences Ltd. submitted by Dr. Naseem Akhtar, Additional Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow, vide letter no. SONC/1146/2023 dated 12th July, 2023.

Previous EC Comment	PI response
Section Vulnerable subjects is incorrectly filled since patients with metastatic breast cancer will come under the category of seriously ill/terminally ill/vulnerable patients.	Revised annexure has been attached with the correction as suggested.
Section on biological/hazardous materials doesn't mention the use of blood investigation/CT Scan which is ionizing radiation.	Revised annexure has been attached with the correction as suggested. The CT scan which will be performed as a part of the protocol is used only for diagnosing purpose and will help the PI to better understand the disease and its spread, which is as per the routine standard practice. The exposure and the risk with the ionizing radiation that will be used in the CT scan will have the higher benefit to risk ratio.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

DCGI approval letter doesn't specify sites approved for the study.	DCGI approval letter has been attached mentioning the name of the participating sites also the additional site notification to the DCGI through SUGAM portal has been attached along with it. been attached along with it.

The above comment forwarded to PI was reviewed by PR:-

Recommendation of PR:

Provisionally Approved

The following documents were reviewd in the Meeting:-

Sl. no.		Title	Version	Date
1		Clinical Trial Protocol	1.0	25-July-2022
2		Investigator's Brochure (IB)	1.0	27-July-2022
3		Case Report Form (CRF)	1.0	03-Aug-2022
4		Informed Consent Form (ICF) – English	2.0	10-Feb-2023
	4.01	ICF - Hindi translated on 27-Feb-2023	2.0	10-Feb-2023
	4.02	ICF - Hindi back-translated on 27-Feb-2023	2.0	10-Feb-2023
	4.03	ICF - Translation & BT certificates	2.0	27-Feb-2023
5		Patient Diary - English	1.0	27-July-2022
	4.01	ICF - Hindi translated on 27-Feb-2023	2.0	10-Feb-2023
5		Patient Diary - English	1.0	27-July-2022
	5.01	Patient Diary – Hindi translated on 22-Feb-2023	1.0	27-July-2022
	5.02	Patient Diary – Hindi Back translated on 22-Feb-2023	1.0	27-July-2022
	5.03	Patient Diary – Translation & BT certificates	1.0	22-Feb-2023
6		Curriculum Vitae (CV) & MRC of Principal Investigator	-	27-Sep-2022
7		Investigator's Undertaking	-	17-Feb-2023
8		Protocol Signature Page	1.0	25-July-2022
9		Clinical Trial Agreement (CTA) – Draft	-	-
10		CLA Submission Letter	-	19-Sep-2022
11		DCGI (CLA) Approval Letter	-	10-April-2023
12		Insurance Quotation and Insurance Policy	- -	08-Feb-2023 Policy No.: 240400492310000005 Policy validity: 1/6/2023 to 31/05/2023

EC Decision: Approval subject to fulfillment & Adminstrative formalities

Ref. code: 124th ECMIIC/P4

20- Clarification of research proposal entitled "*Evaluation of operating room turnover time*

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

by process mapping and time stamping" submitted by Dr. Shiv Rajan, Surgical Oncology, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1226/23 dated 21st July, 2023.

Previous EC Comment	PI response
Letter of Sponsor/Collaboration from Terna Medical College & Hospital/BARCk Hospital, HBNI University, Mumbai stilkl not given by PI (He instead attached the IEC letter sent to Dr. Bhakti Sarang by IEC, Terna Medical College). PI is requested to attaché the sdaid documents.	Memorandum of Understanding and Data Sharing Agreement of collaborating Institute has been attached.

The above comment forwarded to PI was reviewed by PR:-
Recommendation of PR:
Provisionally Approved
EC Decision: Approved

Ref. code: 123rd ECMIB/P4

21- **ADR sub Committee**

Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 1st August, 2023 from 02.45 PM. *virtual.*

The following Members were present in the Meeting:

- Dr. Alok Dhawan -Chairman
- Mrs. Akansha Dubey -Member
- Mrs. Vasundhara Kumari -Member
- Mr. Ujjawal Krishna -Member
- Dr. Rajendra Nath -Member
- Dr. D.N. Upadhyaya -Member
- Dr. Nisha Mani Pandey -Member
- Dr. Shally Awasthi -Member-Secretary, IEC

DCGI

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ia- ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral Hemorrhage (INTRINSIC TRIAL)"*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 258/Neuro/23 dated 13th June, 2023.

Patient ID & age and gender: S-45-3-1439(MML)/65 years/Female
Patient Diagnosis: Right intracranial (Basal ganglia) bleed with midline shift.

Patient enrollment date: 27-05-2023
Patient enrollment Arm: Control
Patient follow up under study- No
Follow up visit completed- No
Planning on visit: Expired on 9th June, 2023
SAE detected on date: 28-05-2023
Follow up visit remaining: No
24 hrs. Notified to EC, Sponsor-Yes
14 days analysis report submitted to EC-No

Subject History:

A letter of PI was received in the Office of the Ethics Committee on 16th June, 2023, The Patient MML with subject Id-S-45-3-1439(MML)/65 years/Female was admitted on 27-05-2023 in the neurology emergency with c/o left side body weakness. She was a known case of hypertension on regular medication. Her GCS was 11 at the time of admission and she was diagnosed to have right intracerebral (basal ganglia) bleed with volume of approximately 47.0 ml with midline shift. Since she was fulfilling inclusion criteria, she was recruited after obtaining written informed consent from the family and randomized to the control arm. During the hospital stay she developed tachypnea and altered sensorium at 15:30 hrs. on 28th May, 2023. Respiratory rate was 30/min and saturation 88% on room air. The patient was placed on oxygen at 10 liters with non-re-breathable mask. Chest x-ray showed diffuse bilateral infiltrates in both lung fields suggestive of aspiration pneumonia. Further, she went into sepsis and AKI afterwards for which opinions from pulmonary medicine and nephrology were taken and treated accordingly with IV antibiotics, IVF, ANF, and diuretics and shifted to neurology ICU. Initially the patient showed some improvement as her chest x-ray and renal functions became better but later her further and breathing worsened, so she was intubated and put on mechanical ventilation. She suffered a cardiac arrest at 11:00 PM on 9th June, 2023. Two cycles of CPR were given as per ACLS protocol, but the patient couldn't be revived and declared clinically dead on 9th June, 2023 at 23:28 hrs.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of PR: SAE (Aspiration pneumonia needed Intubation & mechanical ventilation during hospital stay resulting in death) is likely due to disease outcome (Right intracranial bleed with midline shift along with systemic hypertension) and not due to intervention as patient was randomized in control arm on 27-05-2023. Causal relationship can not be established and no compensation is required as the patient was properly treated in hospital and SAE happened due to her deteriorating condition on next day (28-05-2023) of enrollment, due to which she remained hospitalized and finally died due to cardiac arrest on 09th June, 2023. **ADR sub Committee Decision:** Noted as above ***Ref. Code:115th ECM IIA/P5***
Ib	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral Hemorrhage (INTRINSIC TRIAL)"*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 239/Neuro/23 dated 23rd May, 2023 & vide letter no. 255 /Neuro/23 dated 23rd May, 2023. **Patient ID & age and gender:** S-45-3-1368(AGA)/62 years/Female **Patient Diagnosis:** Left intracranial thalamic bleed with hydrocephalus and IVH. **Patient enrollment date:** 10-05-2023 **Patient enrollment Arm:** Intervention **Patient follow up under study-** Still admitted **Follow up visit completed-** NA **Planning on visit-** NA **SAE detected on date:** 18-05-2023 **Follow up visit remaining:** Yes **Notified to EC, Sponsor-**Yes **14 days analysis report submitted to EC-** NA **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 26th May, 2023. The Patient, **AGA"** 62 years/Female with subject Id - S-45-3-1368, has been admitted on 10-05-2023 in the neurology emergency with c/o sudden onset unconsciousness. She is a known case of hypertension on regular medication. Her GCS was 11 at the time of admission and she has been diagnosed to have left intracerebral (thalamic) bleed with volume of approximately 8.7 ml with IV extensions with mild hydrocephalus. Since she was fulfilling inclusion criteria, she was recruited after obtaining written informed consent from the family and randomized to the intervention arm. She has been gradually improving so was shifted to the neurology ward on 13-05-2023. The patient developed

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	breathlessness and tachypnea at 9 am on 18-05-23. RR was 32/min, spo2 89% on room air. The patient was shifted back to neurology emergency for close monitoring. Currently, she is maintaining saturation on NRM with Oxygen supplementation 12 L /min. Her chest x-ray suggestive of aspiration pneumonitis and all the necessary measures are being taken to treat it. After that a letter was received in the Office office of the Ethics Committee dated 16th June, 2023 that AGA was discharged from the PI's side on 25th May, 2023 and her 90th day follow-up is due on 10th August, 2023. She had aspiration pneumonia on 18th May, 2023 and was managed with IV antibiotics and O2 support. Currently, she is recovering and her condition has been improved. The PI said in the letter that he will update to the Ethics Committee further about her health after following him up on the above said date. ***Recommendation of PR:*** SAE (Hospitalization due to aspiration pneumonia) on 18-05-2023 is most likely due to disease outcome (Left intracranial thalamic bleed with hydrocephalus and IVH) and not due to intervention (Tranexamic acid) as patient was randomized in intervention arm on 10-05-2023.She was gradually improving so was shifted to neurology ward. Subject was discharged on 25-06-2023. Currently she is recovering and her condition has been improved, Her follow up is due on 10th August, 2023 and PI will update to EC further about her health. **Causal relationship can not be established and no compensation is required** as patient was enrolled in intervention arm (10-05-2023) and SAE happened on 18-05-2023 due to aspiration pneumonia for which she was properly treated and was discharged on 25-05-2023 after recovery. **ADR sub Committee Decision:** Noted as above ***Ref. Code:115th ECM IIA/P5***
Ic-	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral Hemorrhage (INTRINSIC TRIAL)"*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 248/Neuro/23 dated 30th May, 2023. **Patient ID & age and gender:** S-45-3-1439(MML)/65 years/Female **Subject initial:** A-S **Patient Diagnosis:** Right intracranial (Basal ganglia) bleed with midline shift. **Patient enrollment date:** 27-05-2023 **Patient enrollment Arm:** Control **Patient follow up under study-** Still admitted **Follow up visit completed-** NA **Planning of visit:** NA **SAE detected on date:** 28-05-2023 **Follow up visit remaining:** Yes **24 hrs. Notified to EC, Sponsor-**Yes

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	14 days analysis report submitted to EC-NA **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 1st June, 2023. The Patient "MML" with subject Id-S-45-3-1439(MML)/65 years/Female has been admitted on 27-05-2023 in the neurology emergency with c/o left side body weakness. She is a known case of hypertension on regular medication. Her GCS was 11 at the time of admission and she has been diagnosed to have right intracerebral (basal ganglia) bleed with volume of approximately 47.0 ml with midline shift. Since she was fulfilling inclusion criteria, she was recruited after obtaining written informed consent from the family and randomized to the control arm. The patient developed tachypnea and altered sensorium at 15:30 hrs on 28-05-2023. Respiratory rate was 30/min and saturation 88% on room air. The patient was placed on oxygen at 10 liters with Non re-breathable mask. Chest x-ray was suggestive of diffuse bilateral infiltrates in both lung fields suggestive of aspiration pneumonia. ***Recommendation of PR:*** SAE (aspiration pneumonia during hospitalization) on 28-05-2023 is likely due to disease outcome [Right intracranial (Basal ganglia) bleed with midline shift along with systemic hypertension] and not due to intervention as patient was randomized in control arm on 27-05-2023 chest X-ray was suggestive of aspiration pneumonia. She is still admitted and treatment is continuing. **Causal relationship can not be established and no compensation is required** as patient was enrolled in control arm (27-05-2023) and SAE (Aspiration pneumonia) happened on 28-05-2023, for which she was given proper treatment and is still admitted in hospital for further management. (Present record that Patient is still admitted are missing–PI to provide the latest development for this patient) **ADR sub Committee Decision:** Noted as above ***Ref. Code:115th ECM IIA/P5***
Id-	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral Hemorrhage (INTRINSIC TRIAL)"*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 287/Neuro/23 dated 27th June, 2023. **Patient ID & age and gender:** S-45-3-1597(AJH)/55 years/Male **Subject initial:** A-S **Patient Diagnosis:** Left Thalamic bleed with IV extension. **Patient enrollment date:** 19-06-2023 **Patient enrollment Arm:** Control **Patient follow up under study-** Expired on 27-06-2023 during hospital stay **Follow up visit completed-** Expired **Planning on visit-** Expired **SAE detected on date:** 27-06-2023

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Follow up visit remaining: Expired **24 hrs. Notified to EC, Sponsor-**Yes **14 days analysis report submitted to EC-**NA **Subject History:** A letter received in the Office of the Ethics Committee on 28th June, 2023. The Patient "AJH" with subject Id - S-45-3-1597(MML)/55 years/Male, admitted on 19-06-2023 in the neurology stroke ward with c/o sudden weakness right side of the body diagnosed to have left thalamic bleed, volume approximately 3.78 ml. He was randomized to the control arm and received stander treatment. The patient developed sudden onset breathlessness at 11 AM on 26-06-2023. He was tachypneic with Respiratory rate of 34/min and saturation was 92% at 10-12 of supplemental oxygen. His blood pressure was 100/80 mm HG. Upon CT Pulomonery angiography done around 6 pm. it was noted that the patient had acute thrombus in the pulmonary artery at its bifurcation extending into its Right and left branches. He was started on anticoagulation and this event was reported as SAE to the INTRAINSIC Trial coordinator thrombectomy by an intervention radiology in KGMU after getting informed consent at around 12.30 am 27.06.2023. He was also found to have a floating thrombus in the right femoral vein on venous Doppler of the right femoral vein. He Suffered cardiac arrest during the procedure. CPR was done as per standard protocol but could not be revived and was declared dead at 03:10 am on 27.06.2023. ***Recommendation of PR:*** SAE (pulmonary embolism during hospitalization) on 27-06-2023 is most likely due to disease outcome (Left Thalamic bleed with IV extension) and not due to intervention as patient was randomized in control arm on 19-06-2023. He developed sudden onset of breathlessness at 11:00 am on 26-06-2023 and on CT Pulmonary angiography a thrombus was found. He was started on anticoagulation, thrombectomy was done after taking his informed consent at around 12:30 am on 27-06-2023. But he suffered cardiac arrest during the procedure, CPR was done, but he could not be revived and declared dead at 03:10 am on 27-06-2023. **Causal relationship can not be established and no compensation is required** as patient was enrolled in control arm (19-06-2023). SAE (pulmonary embolism) happened on 27-06-2023 and for which he was given proper treatment in hospital, but during thrombectomy he died due to cardiac arrest. **ADR sub Committee Decision:** Noted as above ***Ref. Code:115th ECM IIA/P5***
II	ADR of research protocol no.CKJX839B12302 entitled "***A randomized, double-blind,***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	placebo-controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT)*"** sponsored by M/s Novartis Healthcare Pvt. Ltd submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no.119/Cardio/Res/23 dated 26nd May, 2023. **Patient ID & age and gender:** 1014074/ 59/Yrs. Male **Subject diagnosis:** Sudden Cardiac Death **Patient enrollment date:** 19-12-2022 **Patient follow up under study-** Randomization (Day 1), M-3, M-9, M-15, M-21, M-27, M-33,M-39, M-45, M-51, M 57 to M-69 **Planning on visit-** Month 3 (04 Apr 2023) **SAE detected on date:** 09 May 2023 **Follow up visit remaining:** M-3, M-9, M-15 to M-69 **24 hrs.Notified to EC, Sponsor-**13 May 2023 **14 days analysis report submitted to EC-**13 May 2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 26th May, 2023. A follow up scheduled visit M-3 call was made to the Patient on 13th May, 2023 at 12:00 PM. Subject's family member revealed that the subject **expired** on 9th May 2023 around at 16:00 hrs. Patient complaint of breathlessness for which he consulted a local practitioner on 2nd 4th & 6th May 2023 & was relieved of his symptoms. On 9th May 2023 afternoon (around 4 o'clock), he developed uneasiness in chest & collapsed soon after and local practitioners announced him dead. Death Certificate is not available as he expired at home and death certificate from Government Office yet to receive. No changes were made in the cardiovascular medicine. ***Recommendation of PR: SAE (Death) on 09-05-2023 is likely due to disease outcome (Ant. wall MI with acute LVF resulting in sudden cardiac death) and not due to intervention (Inclisiran) as patient was randomized on 05-01-2023 and 4 months has elapsed after intervention when SAE occurred. Therefore **causal relationship can not be established and no compensation is required** as death occurred at home and no autopsy was done. **ADR sub Committee Decision:** Noted as above ***Ref. Code: 114th ECMIIC/P4***
III	ADR of research protocol no. CT/20/000017 entitled "***A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease***" sponsored by M/s Novartis Health Care Pvt. Ltd. submitted by

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Prof. S.K. Dwivedi, Department of Cardiology of this University via letter no. 206/Cardio/Res/23 dated 14th July, 2023.

Patient ID & age and gender: 1178105 & 51 yr/Male

Subject diagnosis: CAD/STEMI

Patient screening date: 14-02-2022

Patient follow up under study- Randomization visit M-1, M-2, M-3, M-4, M-5, M-6, M-9, M-12, M-15, M 18, M-21, M 24, M 27 and every three month Follow up till 4 Year.

Planning on visit- Month 15

SAE detected on date: 30-06-2023

Follow up visit remaining: M-15, M-18, M-21, M-24, M 27 and every three month Follow up till 4 Year.

24 hrs. Notified to EC, Sponsor-30 Jun-2023

14 days analysis report submitted to EC-14 July, 2023

Subject History:

A letter was received in the Office of the Ethics Committee on 14th July, 2023. The PI said that the SAE on 30th June, 2023 around 12:00 Earlier to that, many calls were made to remind the subject about follow up visit, but not answered. On 30-June-2023 subject's son received to the PI's call and informed that Subject expired on 1st April, 2023 He said that subject was having breathlessness when he went to toilet in the morning. He also had uneasiness along with this and suddenly he collapsed at around 07:00 o'clock on the same morning. His LAR called local practitioner where he confirmed that the subject expired. He was not taken to any hospital and expired at home. No autopsy was done. After many reminder calls. Subject's LAR did not provide any records and death certificate to ascertain the cause of death. Most likely it was sudden cardiac death and not related to study drug.

Recommendation of PR:

SAE (Death) on 01-04-2023 is likely due to disease outcome (CAD/STEMI) and not due to intervention (Pelacarsen -TQJ230) as patient was Screened on 14-02-2022 and randomized on 04-03-2022 and completed 12 month visit successfully and more than 1 year has elapsed after starting interventional drug when SAE occurred.

Therefore **causal relationship can not be established and no compensation is required** as death occurred at home and no autopsy was done.

(Death certificate is not available)

ADR sub Committee Decision: Noted as above. To be send to DCGI.

Ref. code: 101stECMIIC/P18

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 1st August, 2023 from 02.45 PM. ***virtual.***

The following Members were present in the Meeting:

- Dr. Alok Dhawan -Chairman
- Mrs. Akansha Dubey -Member
- Mrs. Vasundhara Kumari -Member
- Mr. Ujjawal Krishna -Member
- Dr. Rajendra Nath -Member
- Dr. D.N. Upadhyaya -Member
- Dr. Nisha Mani Pandey -Member
- Dr. Shally Awasthi -Member-Secretary, IEC

IA	Action taken
I-	Clarification of ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial"*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 201/Cardio/Res/2023 dated 17th February, 2023 & preliminary email dated 10th July, 2023. **Patient ID & age and gender:** S012/ 33 years/Female **Patient Diagnosis:** RHD/Sev-MS/MVA 0.8 cm. **Patient enrollment date:** 04-05-2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up Planning on visit- 6th M **SAE detected on date:** 30-12-2022[NP1] **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. Notified to EC, Sponsor-3rd February, 2023 14 days analysis report submitted to EC-17th February, 2023 ***Previous comment of ADR:*** a- Enrolment date 04-05-2022. 6th month follow up was due in November which was missed. SAE occurred on 20-01-2023, patient was admitted on 24th January, 2023 and discharged on 30th

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	January, 2023. The SAE was reported on 3rd February, 2023 (Late). Clarification may be sought on why the 6th month follow up was skipped and why was the SAE reported late if it occurred on 20-01-2023 and patient was admitted on 24th January, 2023. b- In the summary SAE detection date is mentioned 30-12-2023 at one place and 20-01-2023 at another place. If SAE was detected on 20-01-2023, why was it reported on 03-02-2023? ***The above comment forwarded to PI was reviewed by PR.*** **Recommendation of PR:** • The clarification received is satisfactory. The ADR doesn't appear to be related to the study. **ADR sub Committee Decision:** Noted as above ***Ref. code: 102nd ECM IIA/P24***
	Non-DCGI
I-	ADR of research proposal entitled ***"ISCHEMIA Trial Protocol: International Study of comparative Health Effectiveness with Medical and Invasive Approach"*** submitted by Prof S.K Dwivedi, HOD Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no.155/Cardio/Res/23 dated 20th June, 2023. Death **Patient ID & age and gender:** 091019-065, 61 yr/Male **Patient Diagnosis:** Coronary Artery Disease /Non- ST Elevation Myocardial Infarction **Patient enrollment date:** 04/Jan/2017 **Patients follow up under study:** Randomization Visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic follow up till 5 year. **follow up visit completed:** Randomization Visit, Month 1.5, Month 3, Month 6, Month 12, Month 18 **Planning on visit:** Telephonic follow-up visit of month of June 2023 **SAE detected on date:** 07 Jun-2023 at 13:00 hr **Follow up visit remaining:** Telephonic Visit (Every Month) till 2025 **Notified to EC & Sponsor by Email on** - 08/Jun/2023 at 11:16 AM **14 days analysis report submitted to EC**- 20-Jun-2023 **Subject History:** A letter received in the Office of the Ethics Committee on 20th June, 2023, The subject was randomized in Invasive Arm. The PI made a Scheduled monthly follow up call to the subject on 07 Jun-2023 at 13:00 hr. Subject's LAR informed to PI that subject passed away on 09th **May 2023 at around 06:30 hrs**, LAR informed to the PI that the subject was hospitalized in emergency ward with complaints of breathlessness and then after within 20 minutes he collapsed. The PI doing several calls to LAR but LAR has not provided any documents and no autopsy was done.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of PR:- • Date of SAE-09-05-2023. Date of detection of SAE-07-06-2023. Date of enrolment-04-01-2017. • The follow-up mentioned is only till five (5) years which should end in January 2022 but the section on remaining visits mentions the patient was to be followed up till June, 2025. Why? • The SAE (death) doesn't appear to be related to the study. **ADR sub Committee Decision:** Clarify the discrepancy in date. ***Ref. Code:60th ECM IIA/13***
IIa-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 134/Cardio/Res/2023 dated 12th June, 2023 & preliminary email dated 27th May, 2023 at 2:27 PM. Hospitalization **Patient ID & age and gender:** 015/55 year/Male **Patient Diagnosis:** RHD/Sev-MS/MVA 0.8 cm **Patient enrollment date:** 12-05-2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit**- 6th M **SAE detected on date:** 27- May-2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Notified to EC, Sponsor**-27- May-2023 **14 days analysis report submitted to EC**-9th June, 2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 12th June, 2023. The Subject's LAR informed on 27th May, 2023 that the Subject was having complaint of dyspnoea since first week of January for which he consulted the doctor in the CYVS department and got electively hospitalized on 12th January, 2023, where he underwent MVR surgery and got discharged on 28th January, 2023. *Recommendation of PR:-* • Enrolment date-12-05-2022, SAE start date-12-01-2023. Admitted to CTVS.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	MVR done. Discharged on 28-01-2023. SAE detected-27-05-2023. • Six-month and twelve-month follow-ups were skipped and the SAE was detected on 27-05-2023 (One year after enrolment). Reason for the same may be enquired from the PI. • The SAE does't appears to be related to the study. **ADR sub Committee Decision:** Clarify dates of events ***Ref. code: 102nd ECM IIA/P24***
IIb	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 154/Cardio/Res/2023 dated 20th June, 2023 & preliminary email dated 6th June, 2023 at 11:52 AM. Death **Patient ID & age and gender:** 019/48 year/Female **Patient Diagnosis:** RHD/Sev-MS/MVA 0.9.cm **Patient enrollment date:** 03-06-2022 **Patient enrollment arm-**Digoxin **Patient follow up under study-**6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed-**Enrolment & Baseline Follow-up **Planning on visit-** 6th M **SAE detected on date:** 06th June-2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Notified to EC, Sponsor-**06th June-2023 **14 days analysis report submitted to EC-**20th June, 2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 12th June, 2023. The subject's LAR informed to the PI on 5th June 2023 that the subject had complaints of breathlessness and exaggerated dyspnoea since 2 days. The subject was hospitalized in ICU for the same on 5th June, 2023. The subject passed away on 6th June, 2023 at 2:32 AM due to sudden cardiopulmonary arrest. *Recommendation of PR:-* • Enrolment date-03-06-2022. SAE occurred on 06-06-2023. SAE reported on 06-06-2023. • Subject skipped the six-month follow-up and reported with SAE after one year. Explanation for the same may be sought.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• SAE (death) doesn't appear related to the study. **ADR sub Committee Decision:** Clarify dates of events *Ref. code: 102nd ECM IIA/P24*
IIc	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 166/Cardio/Res/2023 dated 22nd June, 2023 & preliminary email dated 9th June, 2023 at 11:39 AM. Death **Patient ID & age and gender:** 122/32year/Female **Patient Diagnosis:** RHD/Sev-MS/MVA 1.8.cm **Patient enrollment date:** 31-May-2023 **Patient enrollment arm-**Digoxin **Patient follow up under study-**6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed-**Enrolment & Baseline Follow-up **Planning on visit-** 6th M **SAE detected on date:** 09th June-2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Notified to EC, Sponsor-**09th June-2023 **14 days analysis report submitted to EC-**23rd June, 2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 22nd June, 2023. The subject's LAR informed that the subject consulted in the emergency department on 7th June, 2023 with complaints of pain and dyspnoea where she was stabilized and managed conservatively. The subject developed pain and uneasiness and suddenly collapsed at her home on 8th June, 2023. She could not be hospitalized anywhere and a local practitioner visited to her place and confirmed subject's death. The PI does not have any exact records to ascertain the cause of death. No autopsy was done. Hence, causality assessment cannot be done. *Recommendation of PR:-* • Enrolment date-31-05-2023 Dated of SAE 08-06-2023. Date of SAE detection 09-06-2023. SAE occurred before first follow-up. SAE (death) doesn't appear related to the drug. **ADR sub Committee Decision:** Noted

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 102nd ECM IIA/P24
IId	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 183/Cardio/Res/2023 dated 24th June, 2023 & preliminary email dated 12th June, 2023 at 2:02 PM. Death **Patient ID & age and gender:** 076/45 year/Female **Patient Diagnosis:** RHD/Sev-MS/MVA 0.8.cm **Patient enrollment date:** 27 Dec-2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit**- 6th M **SAE detected on date:** 12th June-2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Notified to EC, Sponsor**-12th June-2023 **14 days analysis report submitted to EC**-12th June-2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 24th June, 2023. The subject's LAR informed on 11th June, 2023 at 5:00 pm that the subject has developed complaint of dyspnoea, anxiety, pain in chest, cough and vomiting because of which she was was admitted to a nearby hospital on 8th June, 2023. The subject passed away on 10th June, 2023 in the hospital at 3:50 PM due to cardiogenic shock with respiratory failure. *Recommendation of PR:-* • Enrolment date -27-12-2022. Dated of SAE 10-06-2023. SAE detected on-12-06-2023. • SAE occurred before first follow-up. SAE (death) doesn't appear related to the drug. **ADR sub Committee Decision:** Noted *Ref. code: 102nd ECM IIA/P24*

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

IB	Expedited review
1-	Expedited review of the research proposal entitled ***"National Registry on SARS-COV-2 infection among pregnant women and their neonates (Pan in Preg COVID Registry)"*** submitted by Prof. S.P. Jaiswar, Head, Department of Obst. & Gynaecology, K.G's Medical University, U.P., Lucknow vide letter no.OG/777/23 dated 26th June, 2023. ***The above proposal was forwarded to two reviewers, for review:-*** ***Recommendation of First reviewer:-*** Provisionally approved ***Recommendation of secondary reviewer:-*** Provisionally approved **EC Decision:** Approved ***Ref. code: 125th ECMIB/P1***
2-	Expedited review of the research proposal entitled ***"Global Cohort Study: Global evaluation of cholecystectomy knowledge and outcome (GECKO)"*** submitted by Dr. Manish Kumar Agarwal, Assistant Professor, Department of General Surgery, K.G's Medical University, U.P., Lucknow vide letter no.1665 dated 24th June, 2023. ***The above proposal was forwarded to Primary reviewer, for review:-*** ***Recommendation of Primary reviewer:-*** • Principal-Investigator did not submit protocol summary separately-Please submit the protocol. • In SOP Checklist statement of confidentiality (point-6)-not ticked. • In inclusion criteria sex specificity/pregnant and lactatin mother criteria not mentioned. • Letter of inclusion of KGMU as one of the center/site for GECKO is not attached. ***The above comment forwarded to Primary reviewer was reviewed.*** Provisonally approved **EC Decision:** Approved ***Ref. code: 125th ECMIB/P2***
3-	Expedited review of the research proposal entitled ***"Association of aldose reductase activity and aldose reductase (ALR 2) gene polymorphism with Diabetic Neuropathy in patients of type 2 diabetes mellitus: A case control study"*** submitted by Dr. Shivam Verma a post MD-PhD. Scholar under the guidance of Prof. Narsingh Verma, Department of Physiology, K.G's Medical University, U.P., Lucknow vide letter no.3193/PHY/2023 dated 3rd July, 2023. ***The above proposal was forwarded to two reviewer, for review:-*** ***Recommendation of First reviewer:-*** • Dr. Abbas Ali Mahdi is currently on lien… needs justification, how will he be able to guide the student? • Patient will be recruited from family medicine department. Is this department

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	functional? • I suggest recruiting patients from medicine department as the sample size is large. • Give the current designation of Prof. Abbas. As of how there is in Department of Family Medicine from where will the cases be recruited. ***Recommendation of secondary reviewer:-*** Approved **EC Comment:** Give the current designation of Prof. Abbas. As of now, there is no family medicine department. From where will the cases be recruited? **EC Decision** :Approval is subject to modification and clarifications. Give changes done in tabular format. ***Ref. code: 125th ECMIB/P3***
II-A	**New Proposal**
1.	Research proposal entitled "***Difference in the outcome in patients with breast cancer based on age cut off less than and more than 40 Years- A cohort study***" submitted by Dr. Pooja Ramakant, Additional Professor, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. EndoSurg/185/23 dated 8th May, 2023. ***Recommendation of Primary reviewer:*** Approved for waiver **EC Decision:** As above ***Ref. code: 125th ECM IIA/P1***
2.	Research proposal entitled "***Mapping the association between the site, size & severity of lesions of endodontic origin (LEO) and systemic inflammatory & oxidative stress burden: A cross-sectional clinicobiochemical analysis***" submitted by Dr. Rhythm, Prof. Junior Grade, Department of Conservative Dentistry and Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 94/Coms&Endo/23 dated 30th May, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 125th ECM IIA/P2***
3.	Research proposal entitled "***Pulmonary rehabilitation program for patient with chronic Respiratory disease***" submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. KGMU/PRC/08/23 dated 23rd May, 2023. ***Recommendation of Primary reviewer:*** • Kindly provide a properly filled PIS and kindly explain patient about standard procedure instead of writing as per SOP. **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 125th ECM IIA/P3***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

4.	Research proposal entitled "***Prognostic indicators of COVID-19 confirmed cases admitted in KGMU: apelin ACE2 axis fate in hypertension and macrophage syndrome as complications in COVID-19 focus on gender, age and comorbidites***" sponsored by CSIR-CDRI submitted by Prof. Wahid Ali, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 663/23 dated 27th May, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 125th ECM IIA/P4***
5.	Research proposal entitled "***Umbilical artery Doppler indices correlation with placental thickness and fetal growth: an experience from North Indian tertiary care centre***" submitted by Dr. Anil Rawat, Assistant Professor, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 619/RD/23 dated 27th May, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 125th ECM IIA/P5***
6.	Research proposal entitled "***Sentinel surveillance for national one health programme for prevention and control of zoonotic diseases***" sponsored by National Center for Diseases Control, MOHFW, Shamnath Marg, Delhi submitted by Dr. Suruchi Shukla, Assistant Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 91/23 dated 27th April, 2023. ***Recommendation of Primary reviewer*** • Project is very sketchy. • No references cited/listed. • Although they will be collecting biological samples (blood/ urine/ CSF) yet they have applied for a consent waiver. **EC Comment:** As above **EC Decision:** Revise & Re-submit. Give the changes done in a tabular form. ***Ref. code: 125th ECM IIA/P6***
7.	Research proposal entitled "***Integrated transciptomic and metabolmic analysis of metabolic disturbances in hormone receptor positive breast cancer cells***" sponsored by Council of Science & Technology U.P. submitted by Prof. Anand Kumar Mishra, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. EndoSurg/451/23 dated 8th June, 2023. ***Recommendation of Primary reviewer:*** • Project is very sketchy. • Sample size, inclusion, or exclusion of subjects not included. • Matched controls not properly defined. • In objective 2 it is mentioned that expression analysis of corresponding genes will

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	be carried out, but neither any gene has not been mentioned nor methodology for the same provided. • How will Objective 3 be achieved? Which metabolites will be assessed and correlated with patient survival? Not clear!! • How come the Molecular Biology Unit (it is mentioned as a Department) of the University can be the sponsoring Institution? **EC Comment:** As above **EC Decision:** Revise & Re-submit. Give the changes done in tabular form. ***Ref. code: 125th ECM IIA/P7***
8.	Research proposal entitled "***Clinical profile and outcome of patients with cognitive impairment in a tertiary care Hospital: An insightful prospective observational study***" submitted by Dr. Shailendra Mohan Tripathi, Associate Professor, Department of Geriatric & Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 214/DGMH/23 dated 14th June, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 125th ECM IIA/P8***
9.	Research proposal entitled "***Effect of low dose SSRI in cognition and behavior of patients with dementia without depression-A retrospective study***" submitted by Dr. Shailendra Mohan Tripathi, Associate Professor, Department of Geriatric & Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 215/DGMH/23 dated 14th June, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 125th ECM IIA/P9*** ***(Primary Reviewer: Dr. A.A. Mahdi)***
10.	Research proposal entitled "***Research elective under CBME: A teacher's perspective***" submitted by Dr. Sujita Kumar Kar, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 784/Psy/23 dated 19th May, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 125th ECM IIA/P10***
11.	Research proposal entitled "***Longterm single versus dual antiplatelet therapy in patients with ischemic stroke due to intracranial atherosclerotic disease: A randomized trial***"

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 260/Neuro/23 dated 15th June, 2023. ***Recommendation of Primary reviewer:*** • Study variables and study parameters should be exclusively identified. • Research hypothesis should be stated in terms of the study parameters. • The sample size calculation is arbitrary in the absence of proper research hypothesis. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **EC Comment:** As above **EC Decision:** Revise & Re-submit. Give the changes done in a tabular form. *Ref. code: 125th ECM IIA/P11*
12.	Research proposal entitled "***Effect of incentive spirometer exercise on pulmonary function in children with spastic cerebral palsy-A prospective randomized case-control study***" submitted by Dr. Sandeep Kumar Gupt, Assistant Professor, Department of PMR, King George's Medical University, U.P., Lucknow vide letter no. 5309/23 dated 16th June, 2023. ***Recommendation of Primary reviewer:*** • This is a pre-post prospective cohort study, as the same set of children shall be used to evaluate the effect of incentive spirometer exercise. • The study should be planned accordingly. • Study variables and parameters should be identified. • Research hypothesis should be stated in terms of study parameters. • Sample size calculation is incorrect as it is for independent samples. In the present case, samples are dependent (paired). • The statistical analysis section is very general and is for independent samples analysis. It should be rewritten in accordance with research hypothesis. **EC Comment:** As above **EC Decision:** Revise & Re-submit. Give the changes done in a tabular form. *Ref. code: 125th ECM IIA/P12*
13.	Research proposal entitled "***Transfer learning assisted classification of dementia sub-types using voice recordings: a cross-sectional study***" submitted by Dr. Shailendra Mohan Tripathi, Associate Professor, Department of Geriatric & Mental Health, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. 216/DGMH/23 dated 14th June, 2023. ***Recommendation of Primary reviewer:*** • The title should be more specific. The objective of the study is not clear from the title. • It is prospective comparative cohort study. The two groups are being compared. • The sample size calculation is not given. • The statistical analysis section is very general. It should be specific to the research hypothesis. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give the changes done in tabular form. *Ref. code: 125th ECM IIA/P13*
14.	Research proposal entitled "***Effect of combination treatment with escitalopram and risperidone in punding behavior among patients with dementia-a retrospective study***" submitted by Dr. Shailendra Mohan Tripathi, Associate Professor, Department of Geriatric & Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 217/DGMH/23 dated 14th June, 2023. ***Recommendation of Primary reviewer:*** • This is retrospective case-control study. • The cases and controls should be exclusively defined for studying the effectiveness. • Sample size calculation is not given. • In the absence of proper research hypothesis, the statistical analysis section looks arbitrary and incomplete. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give the changes done in tabular form. *Ref. code: 125th ECM IIA/P14*
15.	Research proposal entitled "***Artificial intelligence guided BI-RADS classification for suspected breast mass using mammographic imaging data***" submitted by Dr. Priyanka Yadav, Assistant Professor, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 620/RD/23 dated 27th May, 2023. ***Recommendation of Primary reviewer:*** • This is a diagnostic test study. • Nothing is said about the evaluation of proposed method of classification. • The sensitivity and specificity of the proposed method are not discussed. • The sample size calculation is not given.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• What kind of AI models shall be used? • The statistical analysis section is missing. **EC Comment:** As above **EC Decision:** Revise & Re-submit. Give the changes of done in tabular form. *Ref. code: 125th ECM IIA/P15*
16.	Research proposal entitled "***Atypical presentation of leprosy: A retrospective cross-sectional study***" submitted by Dr. Swastika Suvirya, Additional Professor & Head, Department of Dermatology, Venereology & Leprosy, King George's Medical University, U.P., Lucknow vide letter no. 149/Skin/23 dated 20th June, 2023. **EC Decision:** Waiver of consent may be given. *Ref. code: 125th ECM IIA/P16*
17.	Research proposal entitled "***A prospective observational study to compare the hemodynamic parameters in supine versus prone position in patients of acute respiratory distress syndrome, using transesophageal Doppler and ultrasound guided inferior vena cava distensibility***" submitted by Prof. Haider Abbas, Head, Department of Emergency Medicine, King George's Medical University, U.P., Lucknow vide letter no. 163/EMD/23 dated 9th June, 2023. ***Recommendation of Primary reviewer:*** • Age group needs to be defined • Hindi consent form needs to be written in simple and understandable sentences. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give the changes done in tabular form. *Ref. code: 125th ECM IIA/P17*
18.	Research proposal entitled "***Postmastectomy pain patterns, associated risk factors & its impact on the quality of life of cancer patients in a tertiary health care center of Northern India- A retrospective & cross-sectional study***" submitted by Prof. Anil Kumar Gupta, Head, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. nil dated 16th June, 2023. ***Recommendation of Primary reviewer:*** • The study seems to be a cross sectional study. As postmastectomy patients coming to the PMR or General Surgery or after 3 months of mastectomy patients are to be contacted on the basis of records. The data is to be obtained cross sectionally. Thus, title and study design needs to be modified. • Under the heading **Collection of data** subheading **Subject**: study procedure is written. Is it a mixed study? Will face to face interview and telephonic interview be able to provide similar kind of authentic data? How the telephonic interview be

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	verified (audio/ video call)? What time duration will be there to complete one interview? How the points be drawn/ indicated by the patient on body chart? • Some of the sentences are written in past tense. • Hindi ICF needs to be written in simple and understandable language. **EC Comment:** As above **EC Decision:** Revise & Re-submit. Give the changes done in tabular form. *Ref. code: 125th ECM IIA/P18*

19.	Research proposal entitled "***Management of whole body burns-experience at our center and review of literature***" submitted by Prof. Vijay Kumar, Head, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 862/23 dated 6th July, 2023.
	Recommendation of Primary reviewer:
	• On scientific review sheet
	  • In front of ICF it is written as included which is neither there nor needed, may be written as NA.
	  • None of the decision comments is ticked.
	• The title of the study needs modification. *Management of whole body burns-experience at our center and review of literature…..the word* **our** may be replaced by **a tertiary care** center or Department Name with the Institute Name.
	EC Comment:
	As above
	EC Decision: Approval subject to modification. Give the changes done in tabular form.
	Ref. code: 125th ECM IIA/P19

20.	Research proposal entitled "***Epidemiology of pediatric burn in tertiary care centre of north India-A pilot study***" submitted by Prof. Vijay Kumar, Head, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 863/23 dated 6th July, 2023.
	Recommendation of Primary reviewer:
	• On the scientific review sheet
	  • In front of ICF it is written as included which is neither there nor needed.
	  • None of the decision comments is ticked.
	• During retrospective extraction of data on the study proforma it would be better to retrieve patient's information anonymously by providing unique ID and excluding the name.
	• The study needs a waiver, which may be given.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: As above **EC Decision:** Waiver of consent can be granted after modification. *Ref. code: 125th ECM IIA/P20*
II-B	**IMR-Faculty**
1.	Research proposal entitled ***"Association of advanced glycation end products with microvascular and neurodegenerative changes in diabetic retinopathy"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Dr. Nibha Mishra, Assistant Professor, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 3099/OPH/23 dated 22nd April, 2023. **EC Comment:** • IEC form incomplete **EC Decision:** Approval subject to modification. *Ref. code: 125th ECM II B-IMR-F/P1*
2.	Research proposal entitled ***"DNA methyvlation of brain-derived neurotrophic factor (BDNF) and late-life depression"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Dr. Akanksha Sonal, Assistant Professor, Department of Geriatric & Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 191/DGMH/23 dated 15th May, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above *Ref. code: 125th ECM II B-IMR-F/P2*
3.	Research proposal entitled ***"Impact of awareness of menstrual hygiene and identification of premenstrual dysphoric disorder on quality of life among adolescent Girls in Rural and Urban Area, Lucknow"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Dr. Rashmi P. John, Assistant Professor, Department of College of Nursing, King George's Medical University, U.P., Lucknow vide letter no. 839/PF/23 dated 17th June, 2023. **EC Comment:** • Objectives are not well defined. Objectives should be specific. The reviewer is unable to decide whether you will try to find out level or something else in the awareness of menstrual hygiene. Similarly in the second objective what will be your objective like diagnosis, burden of symptoms for PMS and PMDD is not clear. • Statististical Analysis of various scores/answers/scales are not given. • Since the study population is adolescent girls from the school question number 20 and 21

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	(How satisfied are you with your personal life and How satisfied are you with your sex life) are not permissible school environments. Moreover we need a child's Assent form and parents ICF prior to recruitment in the study. **EC Decision:** Revise & re-submit. ***Ref. code: 125th ECM II B-IMR-F/P3***
II-B	**New Ph. D Proposal**
1.	Research proposal entitled "***Association of serum osteocalcin level and bone gamma-cardoxyglutamate protein gene (BGLAP) polymorphism with type2 diabetes mellitus patients in India***" sponsored by ICMR submitted by Dr. Ritu Tiwari, Ph.D Scholar, under the guidance Prof. Shraddha Singh, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3194/PHY/23 dated 3rd July, 2023. **EC Comment:** **EC Comment:** • Since the study population will be recruited from the Medicine department's OPD as said in the proposal, it would be better if someone from the Medicine department would coordinate the recruitment process from OPD. • Have a Co-PI from the Department of Medicine ***Ref. code: 125th ECMIIB-Ph.D/P1***
2.	Research proposal entitled "***Exploring the role of endocrine disrupting chemicals (EDCs) on the toxicogenomics of non-alcoholic fatty liver disease***" sponsored by ICMR submitted by Ms. Hina Parveen, Ph.D. Scholar under the guidance Dr. Mohammad Kaleem Ahmad, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/364/23 dated 4th July, 2023. **EC Decision:** Provisionally approved provided that the ICMR approves the budget. ***Ref. code: 125th ECMIIB-Ph.D/P2***
II-C	**Review of New Drug Trial**
1.	Research protocol no. BCD-178-2/PREFER entitled "***A double-blind, randomized clinical study of the efficacy and safety of BCD-178 and perjeta® as neoadjuvant therapy of HER2-positive breast cancer***" sponsored by M/s JSC Biocad, Russia submitted by Prof. Abhinav Arun Sonkar, Head, Department of General Surgery, King George's Medical University, U.P., Lucknow, vide letter no. 1400/2023 dated 23rd May, 2023. ***Recommendation of Primary reviewer:*** • Budget in CTA document not mentioned • CTRI document should be submitted to EC office as soon as trial registration occurs. • DCGI Permission letter-awaited

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment: • As above **EC Decision:** Approval subject to modification & fulfillment of Administrative formalities. ***Ref. code: 125th ECMIIC/P1***
2.	Research protocol no. ABX464-105 entitled "***A randomized, double-blind, placebo-controlled, multicenter phase III study to evaluate the efficacy and safety of ABX464 once daily for induction treatment in subjects with moderately to severely active ulcerative colitis***" sponsored by M/s ABIVAX submitted by Prof. Abhijit Chandra, HOD, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow, vide letter no. SGE/CT/06/2023 dated 13th May, 2023. ***Recommendation of Primary reviewer:*** • CTRI document should be submitted to EC office as soon as trial registration occurs. **EC Comment:** • As above **EC Decision:** Approval subject to modification & fulfillment of Administrative formalities. ***Ref. code: 125th ECMIIC/P2***
3.	Research protocol no. ABX464-107 entitled "***A randomized, double-blind, multicenter phase III study to evaluate the long-term efficacy and safety of ABX464 25mg or 50mg once daily as a maintenance therapy in subjects with moderately to severely active ulcerative colitis (Short title: ABTECT-Maintenance)***" sponsored by M/s ABIVAX submitted by Prof. Abhijit Chandra, HOD, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SGE/CT/07/2023 dated 12th May, 2023. ***Recommendation of Primary reviewer:*** • CTRI documents should be submitted to EC office as soon as trial registration occurs. **EC Comment:** • As above **EC Decision:** Approval subject to modification & fulfillment of Administrative formalities. ***Ref. code: 125th ECMIIC/P3***
4.	Research protocol no. PMZ-1620/CT-2.4/2022; CT NOC No. CT/ND/37/2022 entitled "***A multicentre, randomized, double-blind, placebo-controlled, phase-II trial to assess safety, and efficacy of sovateltide in the treatment of hypoxic-ischemic encephalopathy in neonates***" sponsored by M/s Pharmazz India Pvt. Ltd submitted by Prof. S. N. Singh,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Department of Pediatrics, King George's Medical University, U.P., Lucknow, vide letter no. Ped/CT/05/2023 dated 15th June, 2023. ***Recommendation of Primary reviewer:*** • DCGI CT NOC does not mention KGMU site/P1 **EC Comment:** • As above **EC Decision:** Approval subject to modification & fulfillment of Administrative formalities. ***Ref. code: 125th ECMIIC/P4***
III-B	**Modification**

1. Modification of research protocol no. GO42784 entitled ***"A phase III, randomized, open-label, multicenter study evaluating the efficacy and safety of adjuvant giredstrant compared with physician's choice of adjuvant endocrine monotherapy in patients with estrogen receptor-positive, HER2-negative early breast cancer"*** sponsored by M/s F. Hoffmann-La Roche Ltd. Prof. Anand Mishra, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ES/17/23 dated 11th May, 2023.

The following documents were reviewed in the Meeting:-

Sr. No.	Document/Language	Version No. and Date
1.	Protocol No: GO42784_Protocol Version 3.0, 30 Jun 2022	Protocol Version 3.0, 30 Jun 2022 (Controlled Copy No: PPD/ GO42784/ Protocol Version 3.0, 30Jun 2022/ 100-106)
2.	Protocol No: GO42784_Protocol Version 3.0, 30 Jun 2022	Protocol Version 3.0, 30 Jun 2022 track changecopy
3.	Protocol No: GO42784_Protocol Version 3.0, 30 Jun 2022	Protocol Version 3.0, 30 Jun 2022 Summary ofchange
4.	Protocol No: GO42784_Protocol Version 4.0, 21 Dec 2022	Protocol Version 4.0, 21 Dec 2022 (Controlled Copy No: PPD/ GO42784/ Protocol Version 4.0, 21Dec 2022/ 100-106)
5.	Protocol No: GO42784_Protocol Version 4.0, 21 Dec 2022	Protocol Version 4.0, 21 Dec 2022 track changecopy
6.	Protocol No: GO42784_Protocol Version 4.0, 21 Dec 2022	Protocol Version 4.0, 21 Dec 2022 Summary ofchange
7.	Protocol Version 3 datedClarification letter	Version 3 Dated 26 August 2022
8.	Protocol Version 4 Clarification letter dated 08 Feb 2023	Version 4 Dated 08 Feb 2023
9.	DCGI Submission Acknowledgement of PA V3.0 +PA V4.0	Application No. GCT/PostAppr/2023/23899 (CT/21/000087), Cover letter dated 13Feb2023

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	10.	Investigators Brochure: RO7197597 (Giredestrant, GDC-9545)	Investigator's Brochure for RO7197597 (Giredestrant, GDC-9545), version 6, May 2022 (Controlled Copy No: PPD/ Investigator's Brochure/ version 6 dated May 2022/ 083-090)
	11.	Investigators Brochure: RO7197597 (Giredestrant, GDC-9545)	Investigator's Brochure Version 6, May 2022 trackchange copy
	12.	DCGI Submission Approval of updated IB V6.0, May2022	Application No. GCT/PostAppr/2022/19238 (CT/21/000087), Cover letter dated 11Jul2022
	13.	Investigators Brochure: RO7197597 (Giredestrant, GDC-9545)	Investigator's Brochure for RO7197597(Giredestrant, GDC-9545), version 6, Addendum 1 dated November 2022
	14.	DCGI Submission Acknowledgement for IB version 6.0 Addendum 1, Main ICF v4.0 and Pregnant Partner ICF v3.0	Application No. GCT/PostAppr/2023/23900 (CT/21/000087), Cover letter dated 13Feb2023
	15.	iDMC Recommendation	Dated 06May2022
	16.	Clarification for typo in study title in the iDMC Recommendation form	Dated October 4, 2022
	17.	Charter for the independent data monitoring committee	Version 3 dated 28Sep2022
	18.	English Patient Card	Patient Card INDIA English v2.0.0 21 Jan 2022
	19.	Hindi Patient Card	Patient Card INDIA Hindi v2.0.0 21 Jan 2022
	20.	Hindi to English Patient Card	Patient Card INDIA Hindi v2.0.0 21 Jan 2022 Translation Certificate Attached
	21.	English Main Informed Consent Form	GO42784_Main_ICF_v3.0_India_English_Dr. Anand Kumar Mishra_Dated 20Sep2022
	22.	Hindi Main Informed Consent Form	GO42784_Main_ICF_v3.0_India_Hindi_Dr. Anand Kumar Mishra_Dated 20Sep2022 Translation Certificate Attached
	23.	Hindi to English Main Informed Consent Form	GO42784_Main_ICF_v3.0_India_Hindi to English_ Dr. Anand Kumar Mishra_Dated 20Sep2022 Translation Certificate Attached
	24.	English Main Informed Consent Form	GO42784_Main_ICF_v4.0_India_English_Dr. Anand Kumar Mishra_Dated 18Jan2023
	25.	Hindi Main Informed Consent Form	GO42784_Main_ICF_v4.0_India_Hindi_
		Hindi to English Main Informed	GO42784_Main_ICF_v4.0_India_Hindi

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

26.	Consent Form	
27.	English COVID-19 ICF Addendum	GO42784_COVID-19 ICF Addendum 3_India_English_Dr. Anand Kumar Mishra_Dated20Sep2022
28.	Hindi COVID-19 ICF Addendum	GO42784_COVID-19 ICF Addendum 3_India_Hindi_Dr. Anand Kumar Mishra_Dated20Sep2022
29.	Hindi to English COVID-19 ICF Addendum	GO42784_COVID-19 ICF Addendum 3_India_Hindi
30.	English Pregnant Partner ICFV3.0	GO42784_Pregnant Partner Authorization Form_Version 3.0_India_English_Dr. Anand Kumar Mishra_18Jan2023
31.	Hindi Pregnant Partner ICF V3.0	GO42784_Pregnant Partner Authorization Form_Version 3.0_India_Hindi_ Dr. Anand Kumar Mishra_18Jan2023
32.	Hindi to English Pregnant Partner ICF V3.0	GO42784_Pregnant Partner Authorization Form_Version 3.0_India_Hindi to English_ Dr. Anand Kumar Mishra_18Jan2023
33.	Clarification regarding themissing COVID-19 ICF addendum version 2	Dated 27Oct2022
34.	SWM Materials_Welcome Letter	English_v1.0_July 2022
35.	SWM Materials_Your Trial Journey Flyer	English_v1.0_July 2022, BASED ON GO42784ICF V03
36.	SWM Materials_ICF Companion Guide	English_2.0
37.	SWM Materials_Patient Service Summary	English_v1.0_July 2022
38.	SWM Materials_Thank YouCards	English_v1.0_July 2022
39.	SWM Materials_Recruitment Posters	English_v1.0_July 2022
40.	SWM Materials _IidERA Study Partner Booklet	English_ v01 September 2022
41.	SWM Materials_Content page	English_v1.0_July 2022

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	42.	SWM Materials_Welcome Letter	Hindi_v1.0_July 2022
	43.	SWM Materials_Your Trial Journey Flyer	Hindi_v1.0_July 2022, BASED ON GO42784 ICFV03Certificate of Translation
	44.	SWM Materials_ICF Companion Guide	Hindi_2.0 | JANUARY 2023, BASED ON GO42784ICF V04Certificate of Translation
	45.	SWM Materials_Patient Service Summary	Hindi_v1.0_July 2022 Certificate of Translation
	46.	SWM Materials_Thank YouCards	Hindi_v1.0_July 2022
	47.	SWM Materials_RecruitmentPosters	Hindi_v1.0_July 2022
	48.	SWM Materials _lidERA Study Partner Booklet	Hindi_ v01 September 2022
	49.	SWM Materials_Content page	Hindi_v1.0_July 2022
	50.	Shore C Video Transcript	English
	51.	LidERA_Chatbot Laminate_English	v1.0_February 2023 and Certificate of Translation
	52.	LidERA_Chatbot Laminate_Hindi	v1.0_February 2023 and Certificate of Translation

Recommendation of Primary reviewer:
Approved
EC Decision: As above

Ref. code: 115th ECMIIC/P2

2. Modification of research protocol no. 18F-MC-GPIJ entitled "***A phase 3, randomized, double-blind, placebo-controlled study to investigator the effects of tirzepatide on the reduction of morbidity and mortality in adults with obesity***" sponsored by M/s Eli Lilly Company Legal Registered submitted by Prof. Gaurav Chaudhary, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 182/Cardio/Res/23 dated 24th June, 2023.

The following documents were reviewed in the Meeting:

Sr. No	Title
1-	**Investigator's Brochure dated 28 Oct 2022**
2-	**Patient Informed Consent Form:** 2.1 India Specific ICF Version 2.0, English dated 16 Dec 2022 2.2 India Specific ICF Version 2.0, Hindi Translation dated 22 Dec 2022 with Certificate of Translation

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	3-	Recruitment and Retention Materials: English: 3.1 Lilly_SURMOUNT-MMO_emergency Card V1_IN EN 3.2 Lilly_SURMOUNT-MMO_Family Engagement Brochure V1_IN EN 3.3 Lilly_SURMOUNT-MMO_GI Side Effect Card V1_IN EN 3.4 Lilly_SURMOUNT-MMO_Recruitment Brochure V1_IN EN 3.5 Lilly_SURMOUNT-MMO_Recruitment Poster V1_IN EN 3.6 Lilly_SURMOUNT-MMO_Thank You Card V1_IN EN 3.7 Lilly_SURMOUNT-MMO_Patient Invite-to-Trial Letter_Copy Only_110922_IN EN 3.8 Lilly SURMOUNT-MMO (GPI)_COT_IN EN Hindi: 3.9 Lilly_SURMOUNT-MMO_Emergency Card V1_IN HI 3.10 Lilly_SURMOUNT-MMO_Family Engagement Brochure V1_IN HI 3.11 Lilly_SURMOUNT-MMO_GI Side Effect Card V1_IN HI 3.12 Lilly_SURMOUNT-MMO_Recruitment Brochure V1_IN HI 3.13 Lilly_SURMOUNT-MMO_Recruitment Poster V1_IN HI 3.14 Lilly_SURMOUNT-MMO_Thank You Card V1_IN HI 3.15 Lilly_SURMOUNT-MMO_Patient Invite-to-Trial Letter_Copy Only_110922_IN HI 3.16 Lilly SURMOUNT-MMO (GPI)_COT_IN HI 3.10 Lilly_SURMOUNT-MMO_Family Engagement Brochure V1_IN HI 3.11 Lilly_SURMOUNT-MMO_GI Side Effect Card V1_IN HI 3.12 Lilly_SURMOUNT-MMO_Recruitment Brochure V1_IN HI 3.13 Lilly_SURMOUNT-MMO_Recruitment Poster V1_IN HI 3.14 Lilly_SURMOUNT-MMO_Thank You Card V1_IN HI 3.15 Lilly_SURMOUNT-MMO_Patient Invite-to-Trial Letter_Copy Only_110922_IN HI 3.16 Lilly SURMOUNT-MMO (GPI)_COT_IN HI
	3.	Remote risk-based monitoring letter

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: Approved **EC Decision:** As above ***Ref. code: 122nd ECMIIC/P1***
3-	Modification of research protocol ver 3.1.2 entitled "***Evaluate the effectiveness, safety and tolerability of various doses of linezolid in combination with bedaquiline and pretomanid in adults with extensively drug-resistant (XDR),MDR with additional resistance to fluroquinolones or second line injectables, intolerant/non-responsive multidrug-resistant (MDR) pulmonary tuberculosis in India***" sponsored by ICMR, New Delhi submitted by Prof. Surya Kant, Department of Respiratory Medicine vide letter no. 700/23/Res.Med dated nil. ***Recommendation of Primary reviewer:*** • The Investigator has submitted an updated protocol version for approval but has not indicated if earlier version was ethically approved. • Although the new version is approved by the institutional ethics committee of the National Institute of Research in Tuberculosis, no evidence of KGMU approval is enclosed. • They need to submit annexure 1 and ICF as per SOP of EC IRB KGMU • Since adverse effects include lethal life threatening consequences including death, a proper patient information sheet needs to be enclosed as per SOP of EC IRB KGMU. • The PI may think of incorporating co-investigators from other specialties if there is a high chance of such side effects such as cardiac events etc.. This may further facilitate continuous monitoring. • Who will bear the cost of treatment and hospitalization of patients with adverse events: patient himself? or KGMU? or ICMR? • Where and how will the Whole Genome Sequencing be done? • Clear documents for Trial-Registration and insurance needs to be submitted. **EC Comment:** As above **EC Decision:** Approval subject to modification. Give changes done in tabular format. ***Ref. code: 109th ECM IB/P7***
IV	**Other Matter with the permission of Chair**
1	Reg. request for permission to change the guide Dr. Kamil Khan, Prof. & Head, Department of Anatomy, Integral Institute of Medical Sciences and Research, Lucknow in **place of** Dr. Mahboobul Haque because he has been shifted to AIIMS Patna under the research proposal entitled ***"Morphogenic and Morphometric study of coronary sinus in Cadaveric Heart"*** submitted by Mr. Rakesh Mishra, Ph.D. Scholar through his guide Prof. Rakesh Kumar Diwan, Department of Anatomy, K.G's Medical University, U.P., Lucknow vide letter no. 158/ANAT/2023 dated 28th June, 2023. ***The above proposal has already been approved by the IEC Meeting held on 19th April,***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	2023. **EC Decision:** Noted and permission granted ***Ref. code: 121st ECMIIB-Ph.D./P2***
2-	Reg. request for permission to archival of documents for 25 years in place of 15 years and has revised the budget for the same under the research protocol no. GS-US-417-0304: entitled ***"A multicenter, double-blind, long term extension study to assess the safety and efficacy of Filgotinib in Subjects with Rheumatoid Arthritis"*** submitted by Prof. Puneet Kumar, Head, Department of Clinical Immunology & Rheumatology, K.G's Medical University, U.P., Lucknow vide letter no.Rh/CT/71/23 dated 23rd June, 2023. **EC Decision:** Noted & permission granted ***Ref. code: 86th ECM-IIE/P1***
V	**Brought to Ethics Committee after XIX-PGTSC held on 25th July, 2023.**
	Minutes of XIX-PGTSC of "Institutional Ethics Committee" Meeting held on 25th July, 2023 from 3.00 p.m. ***virtual.*** ***The following Members were present in the Meeting:-*** 1. Dr. G.G. Agarwal -Member 2. Dr. Rajendra Nath -Member 3. Dr. Nisha Mani Pandey -Member 4. Dr. D.N. Upadhyaya -Member 5. Dr. A.A. Mahdi - Member 6. Dr. Shally Awasthi -Convener ***The following Members could not attend the Meeting:-*** 1. Dr. Anita Rani -She has sent her written comment 2. Dr. Anupam Mishra -He has sent his written comment
IA	**Action taken**
1-	Clarification of research proposal entitled ***"Comparative analysis of TNF-α and THF-β in serum and saliva of oral lichen planus patients"*** submitted by Dr. Rajlaxmi Mitra, JRI, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 251/OMSR/23 dated 23rd May, 2023.

Previous PGTSC comments	Response by Principal Investigator
Co-PI	Dr. Akhilananda Chaurasia Associate Professor, Department of Oral Medicine and Radiology Faculty of Dental Sciences, King George's Medical University, U.P. Lucknow
	Prof. (Dr). Ranjit Kumar Patil Professor and Head, Department of Oral Medicine and Radiology, Faculty of Dental Sciences,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		King George's Medical University U.P., Lucknow.
		Dr. Wahid Ali Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow.
	Sample size	Considering the suggestion from the Institutional Ethical Committee the sample size of 39 will be maintained in each group (study & control)
	Aim	To estimate and compare the levels of TNF-alpha and TGF-beta in saliva and serum in Oral Lichen Planus patients and control group.
	Control group	Comprising of age and sex matched healthy individuals who are willing to volunteer for the study
	Budget	Self-funded

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.
Recommendation of Primary reviewer:-
Approved
PGTSC Decision: Approval ratified

Ref. code: XII-PGTSC-IIA/P10

2- Clarification of research proposal entitled ***"Evaluating the efficacy of intralesional autologous platelet rich plasma (PRP) therapy in patients with oral lichen planus"*** submitted by Dr. Praveen. S, JRI, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 250/OMSD/23 dated 23rd May, 2023.

Previous PGTSC comments	Response by Principal Investigator
There are six Co-PIs in the study of which 5 are from the same department. Please justify those rules.	Dr. Vikram Khanna B.D.S., M.D.S. Additional Professor, Department of Oral Medicine and Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Dr. Ranjit Kumar Patil B.D.S., M.D.S. Professor and Head, Department of Oral Medicine and Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow
		Dr. Vandana Singh B.D.S., M.D.S. Additional Professor, Department of Oral Medicine and Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow
		Dr. Sumit Kumar Scientist – 'C' B.D.S, M.P.H, PhD., Department of health research and multidisciplinary research unit (DHR-MRU), King George's Medical University, U.P., Lucknow
	The calculated sample size is 39 for statistical significance. However, the PI is splitting this into two groups which decreases the sample size in each group. I will suggest that the sample size of 39 be maintained in each group for the study to be valid.	Considering the suggestion from the Institutional Ethical Committee the sample size of 39 will be maintained in each group (study & control)
	Who will bear the cost of PRP preparation and blood biochemistry examination for TGF?	Self funded

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XII-PGTSC-IIA/P11

3- Clarification of research proposal entitled ***"Pilot study on levels of brain derived neurotrophic factor in the cerebrospinal fluid of children with acute encephalitis syndrome"*** submitted by Dr. Shiv Kant Prakratyansh, JR1, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 426/Ped/23 dated 22nd May, 2023.

Previous PGTSC comments	Response by Principal Investigator
The study variables and study parameters should be identified.	Attached separetaly

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Research hypothesis should be defined in terms of study parameters.	Attached separetaly
	Study design is not mentioned. It simply says "pilot study".	Study design has been added as suggested by the reviewer.
	Statistical analysis section is very general. It should be specific to the research hypothesis.	Yes, Attached separately

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XIV-PGTSC-IIA/P27

4- Clarification of research proposal entitled ***"Prospective observational case control study on prevalence of non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) in overweight and obese as compared to normal weight children in pediatric population"*** submitted by Dr. Sonal Luniyal, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1372/Ped/23 dated 24th May, 2023.

Previous PGTSC comments:-

Sample size is not clear, whether total 60 cases or 60 cases and 60 control –please specify ICF-E/H not same and Child Assent Form is missing- should be corrected.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XIV-PGTSC-IIA/P46

5- Clarification of research proposal entitled ***"Socio-demographic profile, diagnosis and treatment delay and associated comorbidities in autism-A prospective observational study"*** submitted by Dr. Richa Jha, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1373/Ped/23 dated 24th May, 2023.

Previous PGTSC comments:-

- Tools- Modified Chart for Autism in Toddler (MCHAT), Indian Scale for Assessment of Autism, Developmental Behavioral Checklist- Autism Screening Algorithm- **not attached**
- Patient information sheet not related to study – should be revised
- ICF-H/E –attached, but not similar (English version is incomplete).
- Child Assent form should also be submitted
- Tools –required are not attached- please attach

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer. *Recommendation of Primary reviewer:-* Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P49***
6-	Clarification of research proposal entitled ***"Prevalence of early hyponatraemia and its association with AKI in critically ill Children in PICU"*** submitted by Dr. Chandra Prakash, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 428/Ped/23 dated 22nd May, 2023. **Previous PGTSC comments:** • Government is mentioned as Sponsor of the study, but no budget is given. • In the section on biological/Hazardous material blood collection for hematological investigations is not mentioned. • In the Methodology section blood collection and hyuponatremia estimation/grading is not mentioned. • No mention is made of the treatment protocol to be followed in children who are detected with early hyponatremia. • Assent form is not attached to the proforma. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P58***
7-	Clarification of research proposal entitled ***"Correlation of sentinel lymph node using ICG with frozen, Histo-Pathology and immune-Histochemistry in Oral Cancer"*** submitted by Dr. Anmol Bansal, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 228/SY/23 dated 19th May, 2023. **Previous PGTSC comments:** • The project has 10 C0-PIs with 8 Co-PIs from the same department besides the PI himself.Please justify • Please rationalize the number of investigators in the study. • Section on Vulnerable subjects/ Special group subjects not filled. • Section on biological/hazardous material not filled. • Proper disposal of material is ticked 'No' • Section on consent is incompletely filled. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer:- Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P66***
8-	Clarification of research proposal entitled ***"Assessment of serum fibrinogen levels as a predictive marker for postpartum haemorrhage"*** submitted by Dr. Vinita Kumari, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. 222/OBGY/23 dated 20th May, 2023. **Previous PGTSC comments:** • Section on vunerable subjects, special group subjects, use of biological/hazardous materials, patient consent and risk and benefits are not completely filled. • Sample size given in the IEC form and in the synopsis sample size calculation are different (110 and 80) ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** *Recommendation of Primary reviewer:-* Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P75***
9-	Clarification of research proposal entitled ***"Comparison of kettlebell and cycling exercise on heart rate variability"*** submitted by Dr. Aman Paisal, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 724/PHY/23 dated 8th June, 2023. **Previous PGTSC comments:** • Aims and objectives are not clear. • Identify one primary objective and classify the rest into secondary objectives. • Convert the primary objective into research hypothesis in terms of study parameters. • Study design says: Cross sectional (Pilot Study). • It should be properly identified. • Sample size calculation is missing. • Statistical analysis section is missing. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** *Recommendation of Primary reviewer:-* Approved **PGTSC Decision:** Approval ratified ***Ref. code: XV-PGTSC-IIA/P7***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

10-	Clarification of research proposal entitled ***"Effect of total body fat and anthropometric parameters on blood pressure in adolescents"*** submitted by Dr. Aaqib Husain Ansari, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2744/PHY/22 dated 21st October, 2022. **Previous PGTSC comments:** • ICF: Kindly explain the procedure to the study participants instead of writing cross sectional study) ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XV-PGTSC-IIA/P15***
11-	Clarification of research proposal entitled ***"Study of blood pressure variability during different phases of menstrual cycle in apparently healthy females"*** submitted by Dr. Shweta Singh, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 2747/PHY/22 dated 22nd October, 2022. **Previous PGTSC comments:** • Topic mentions the study is for healthy females but in IEC from 'type of subjects' is mentioned as patients instead of volunteers. • Sample size calculation has not been done and not mentioned o IEC form. • Aim of the study is mentioned as calculation on Intra-ocular pressure in subjects with Type II Diabetes Mellitus. • Measurement of salivary cortisol seems to have been added later as it is not mentioned in Aims or Objectives. • 'No' is ticked in use of body fluids in the section on Biological and Hazardous material. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XV-PGTSC-IIA/P26***
12.	Clarification of research proposal entitled ***"Comparison of intrathecal morphine vs erector spine plane block for perioperative analgesia in patients undergoing lumbar spine surgery: A prospective, single blind, randomized controlled trial"*** submitted by Dr. Arpita, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/645/23 dated 30th Mayr, 2023.

Previous PGTSC comments:	Response by the Principal-Investigator

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Scientific review committee needs modification (The name and signature of Guide-Prof. G. P. Singh and Co-guide– Dr. Manish Kr. Singh is also there) – please justify or revise.	ScientificReview committee form attached separately.
	As this is RCT –therefore PI should mention randomization method and include the Flow chart of the study.	Randomization-Computer generated random number table method flow chart attached separately.
	Case record form and Demographic profile proforma is missing.- please attach	Attached separately
	Is Clinical trial registry has been done? If not then after registering trial the document may be send to Ethics Committee.	CTRI applied paper Attached separately..

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P43

13- Clarification of research proposal entitled ***"Artificial intelligence to predict pulmonary tuberculosis using chest X-Ray of symptomatic population"*** submitted by Dr. Saroj Yadav, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 475/RD/23 dated 15th July, 2023.

Recommendation of Primary reviewer:

- Co-PI expert in AI system has not been included in the study –Please justify or Include.
- In Inclusion criteria–Age /Sex specificity not mentioned and as it is case control study, therefore inclusion criteria for control subjects should also be mentioned.
- IEC-SOP Form not filled properly as many sections not ticked –Please resubmit SOP form.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:- Approved

PGTSC Decision: Approval ratified

Ref. code: XV-PGTSC-IIA/P47

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

14- Clarification of research proposal entitled ***"Evaluation of side effect profile, quality of life and efficacy of sequential intravesical gemcitabine + docetaxel versus BCG for non muscle invasive urinary bladder cancer"*** submitted by Dr. Amber Gupta, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 474/URO/23 dated 20th June, 2023.

Previous PGTSC comments:

- Research hypothesis should be exclusive written for the primary objective.
- Sample size formula is not clear. It is using mean, standard deviations, whereas the outcome measures are in proportions.
- Statistical analysis mentioned is arbitrary. It should be given as a separate section and properly explained.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P1

15- Clarification of research proposal entitled ***"A Follow up study of adolescents with depressive disorders"*** submitted by Dr. Nagendra Khatore, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 640/Psy/23 dated 2nd June, 2023.

Previous PGTSC comments:	Response by the Principal-Investigator
The study is for adolescents. The source of sample incudes adult psychiatry OPD as well as child and adolescent psychiatry OPD.	All patients of enrolled in the OPD of Department of Psychiatry, KGMU, Lucknow.
There are quite a few instruments being used for the assessment of outcome event. But the sample size uses just one scale (BDI-21 score).	This study sample size was initially calculated based on previous studies that focused on depression and used the BDI-21 score as the primary outcome measure. We recognized the need to expand our assessment tools to better capture the complex and multifaceted nature of mental health in adolescents. Addition to measuring depression, we have added several other assessment tools to our study to evaluate a broader range of outcomes. These tools include measures of suicidality, sleep quality and overall

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		functioning, which are critical components of mental health that can greatly impact the lives of adolescents. By including these measures, we hope to gain a more compreshensive understanding of the mental health of the adolescents in our study and identify potential areas for internvention and support.
	How the aggregate scores will be obtained from the different scales?	When using multiple scales to assess different variables, it is important to note that each scale measures a specific construct or domain, and therefore, it is not appropriate to calculate an aggregate score across all the scales. In the context, the scales used are meant to assess different variables, such as outcome, sleep, suicidality, temperament, and life events as stressors. Each of these variables is measured by a specific scale that is designed to capture the nuances and complexities of that particular construct.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P8

16- Clarification of research proposal entitled ***"A comparative evaluation of saturated KI and 10% KI in the reduction of silver diammine fluoride staining under RMGIC restoration in primary teeth: A randomized clinical trial"*** submitted by Dr. Prachi Vaish, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/189/23 dated 9th June, 2023.

Previous PGTSC comments:	Response by the Principal-Investigator
Identify the study variables and study parameters.	Study variable and study parameters are mentioned on page no. 8-9
Convert the aim/objective of the study into research hypothesis in terms of the study parameters.	Aims/objective of the study is converted into research hypothesis in terms of study parameters and is included in page no. 6

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The sample size calculation can be done ater the formulation of research hypothesis.	Sample size calculation is done after formulation of research hypothesis on page no. 7
	What is the meaning by triple blinding?	Triple blinding is explained on page no. 8
	Is clinical trial registry done?	Clinical trial registry number is mentioned on page no. 9
	Data analysis should be more specific in accordance with the research hypothesis.	Data analysis is specified in accordance with research hypothesis on page no. 11-12

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P11

17- Clarification of research proposal entitled ***"Evaluation of role of urodynamic study in the diagnosis and management of lower urinary tract symptoms in young adult males"*** submitted by Dr. Abhishek Yadav, SRI, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 475/URO/23 dated 20th June, 2023.

Previous PGTSC comments:

- Review of the literature is in the beginning as well as at the end of the proposal.
- Identify the study variables and study parameters.
- Convert the primary aim of the objective into research hypothesis in terms of the study parameters.
- The study design can not ne prospective as well as retrospective.
- Sample size calculations are required.
- Statistical analysis section is missing.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P13

18. Clarification of research proposal entitled ***"Outcomes of PCNL in patient with CKD"*** submitted by Dr. Mohd Rehan Akhtar, SRI, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 141/URO/23 dated 4th February, 2023.

Previous PGTSC comments:

- The proposal is incomplete.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Aims & objectives, study design, methodology, sample size calculation etc. are missing. • Why is there is a discution section? ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P14***
19-	Clarification of research proposal entitled ***"Combination of systemic chemotherapy with short course Radiotherapy for the neoadjuvant therapy of locally advanced rectal carcinoma"*** submitted by Dr. Nirmal Kumar R, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 340/RT/23 dated 24th June, 2023. **Previous PGTSC comments:** • Kindly Attach Patient Information Sheet. • ICF: Kindly explain the procedure to the patient [What exactly will be done with him/her] in simple language. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P26***
20-	Clarification of research proposal entitled ***"Comparison of outcome of conventional palliative Radiotherapy fractionation schedule with quad shot regimen in locally advance head and neck cancer patient"*** submitted by Dr. Srishti Puraiya, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 651/RD/23 dated 31st May, 2023. **Previous PGTSC comments:** • Kindly Attach Patient Information Sheet • ICF: Kindly explain the procedure to the patient [what exactly will be done with him/her] in simple language. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P27***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

21-	Clarification of research proposal entitled ***"Estimation of serial levels of carboxypeptidase a and its role as prognostic marker in acute pancreatitis"*** submitted by Dr. Vijay Kumar Yadav, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 531SY/23 dated 24th June, 2023. **Previous PGTSC comments:** • Kindly Attach Patient Information Sheet • ICF: Kindly explain the procedure to the patient [what exactly will be done with him/her] in simple language. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P28***
22-	Clarification of research proposal entitled ***"A randomized control trial comparing outcomes in patients receiving four layered bandage with hyperbaric oxygen therapy versus only four layered bandage in patients of chronic venous ulcer"*** submitted by Dr. Ayushi Raz, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 533/SY/23 dated 24th June, 2023. **Previous PGTSC comments:** • Kindly Attach Patient Information Sheet • ICF: Kindly explain the procedure to the patient [what exactly will be done with him/her] in simple language. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P30***
23-	Clarification of research proposal entitled ***"Clinicohematological profile of refractory thrombocytopenia and immune thrombocytopenia"*** submitted by Dr. Silpa Sasi, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 696/23 dated 8th June. 2023.

Previous PGTSC comments:	Response by the Principal-Investigator
Objectives of the study not clear.	Attached Separately
How they arrived on a sample size of 100 is not clear (Sample size calculation?	Sample size is 120 (Attached separately)
Material and method section incomplete.	Sample size is 120 (Attached separately)
Although the name of a Co-PI is from the	The study will be undertaken in

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Department of Clinical Hematology but it is mentioned in the text that the study will be carried out in collaboration with the Department of Oral & Maxillofacial Surgery. | Department of Pathology, in collaboration with Department of Clinical Haematology, King George's Medical University, Lucknow. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P35***
24-	Clarification of research proposal entitled ***"Study of CDKN2A mutation in gliomas with cytohistological Correlation"*** submitted by Dr. Aisha Mahmood, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 646/23 dated 25th May, 2022. **Previous PGTSC comments:** • Materials and methods incomplete (Cite a reference for performing FISH). ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P40***
25-	Clarification of research proposal entitled ***"Study of circulating cell free tumor human papillomavirus DNA in cervical cancer"*** submitted by Dr. Apoorva Gangwar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 677/23 dated 1st June, 2023. **Previous PGTSC comments:** • Materials and methods incomplete (Cite references for performing DNA extraction RT-PCR). ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P41***
26-	Clarification of research proposal entitled ***"Evaluation of bacteriological profile and antibiotic and antibiotic susceptibility in Orthopaedics patient developing SSI following implant surgery"*** submitted by Dr. Utkarsh Upadhyay, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 520/OS/23

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

dated 10th May, 2023.

Previous PGTSC comments:	Response by the Principal-Investigator
All Co-guides' name and signature are there in Scientific Review Committee – please justify or revise.	New Scientific review committee paper Attached separately.
Name of Title should be self explanatory and no abbreviation should be there- please expand SSI abbreviation in title	As per your advice entitled "EVALUATION OF BACTERIOLOGICAL PROFILE AND ANTIBIOTIC AND ANTIBIOTIC SUSCEPTIBILITY IN ORTHOPAEDICS PATIENT DEVELOPING SURGICAL SITE INFECTION (SSI) FOLLOWING IMPLANT SURGERY"
Sample size calculation not done	Sample size attached separately.
In Inclusion /Exclusion -pregnant and lactating women criteria not mentioned	Pregnant and lactating women are excluded in the study.
Detailed questionnaire not attached	Questionnaire attached separately.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P51

27- Clarification of research proposal entitled ***"Reference values of patellotrochlear index in North Indian population: A cross sectional study"*** submitted by Dr. Rahul Kumar Tripathi, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 512/OS/23 dated 10th May, 2023.

Previous PGTSC comments:

- Name and signature of Chief supervisor in SRC is there- please justify or revise
- In inclusion criteria -Sex and age specification not mentioned
- Sample size calculation not mentioned

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P54

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

28- Clarification of research proposal entitled ***"A prospective study to compare clinical outcomes of mastoid cavity obliteration using integrated fascio-periosteal flap in canal wall down mastoidectomy versus conventional canal wall down mastoidectomy"*** submitted by Dr. Shazila, JRI, Department of Otorhinolaryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 415/ENT/23 dated 25th May, 2023.

Previous PGTSC comments:

- Flow chart in methodology section should be included
- Sample size clarification–total sample size is 84, including two gps (42 in each gp) but in calculation total sample size given is 42 -please clarify
- Child Assent form in addition to regular ICF should be included as Children in age gp of 15-17 yrs. will also be taken in study

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P65

29- Clarification of research proposal entitled ***"Prospective analysis of intra-operative neuromonitoring (IONM) in patients with intramedullary spinal cord tumors and its comparison with intramedullary surgeries without IONM: a single center study"*** submitted by Dr. Saurabh Raina, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/864/23 dated 31st May, 2023.

Previous PGTSC comments	Response by the Principal-Investigator
Project has 13 Investigators with 8 from one department. This is untenable for a post graduate thesis.	This thesis isthesis as per your advice remove Co-Investigators total 6 Co0Investigaotrs included in the study.
Sample size mentioned 120 in the IEC form and 25 in the synopsis.	Total sample size is 25 patients included in the study, By mistake 120 in IEC form.
Several sections of the IEC form are left incomplete.	Filled IEC attached separately

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P67

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

30-	Clarification of research proposal entitled ***"Phase II study of concurrent temozolomide, thalidomide plus celecoxib with radiotherapy in patients with newly diagnosed glioblastoma multiforme and its correlation with biomarkers"*** submitted by Dr. Kushal Rawal, JRI, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 310/RD/23 dated 24th May, 2023. **Previous PGTSC comments:-** • Is this study a trial? The topic mentions that this is a phase II study. • No CTRI registration is attached. • IEC form is incompletely filled. • Details on treatment of study related injuries/compensation/insurance for the trial are missing. • Sample size calculation has not been done. • Consent form and Patient information sheet for the trial is not attached. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P70***
31-	Clarification of research proposal entitled ***"Analysis of achievement of radiological parameters in uncemented total HIP replacement-A prospective cohort study"*** submitted by Dr. Raza Ahmad Khan, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1510/23 dated 30th June, 2023. **Previous PGTSC comment:-** • IEC form is incompletely filled. Please complete the form and re-submit. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P73***
32-	Clarification of research proposal entitled ***"Assessment of womac index for knee osteoarthritis and its association with serum VITAMIN D and serum cytokine profile (IL 6 TNE ALPHA)"*** submitted by Dr. Mithilesh Kannaujiya, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1511/23 dated 30th June, 2023. **Previous PGTSC comment:-** • IEC form is incompletely filled. Please complete it and re-submit.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer. *Recommendation of Primary reviewer:-* Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P74***
33-	Clarification of research proposal entitled ***"To determine the role of S-100 beta metabolite in neurological recovery in acute spinal cord injury (ASCI): A prospective case control study"*** submitted by Dr. Nagendra Kumar, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 511/23 dated 10th May, 2023. **Previous PGTSC comment:-** • Title is misleading. Case Control studies are retrospective. Suggest deleting the word 'Case Control' from the title. • IEC form is incompletely/incorrectly filled. Please complete the form and re-submit. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** *Recommendation of Primary reviewer:-* Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P75***
34-	Clarification of research proposal entitled ***"Surgical outcome assessment of addition of rivaroxaban in peripherial infrapopliteal arterial occlusion diseases-A prospective cross-sectional study"*** submitted by Dr. Gaurav Joshi, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 530/SY/23 dated 24th June, 2023. . **Previous PGTSC comments:-** • Sample size calculation formula is given but how many subjects will be recruited is not mentioned. • Hindi consent form needs to be corrected especially the words "damni roda rogon" for arterial occlusion diseases should be changed in easy language. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** *Recommendation of Primary reviewer:-* Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVII-PGTSC-IIA/P9***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

35-	Clarification of research proposal entitled ***"Adapted ERAS protocol versus conventional care in perforation peritonitis patients undergoing emergency laparotomy- A prospective comparative study"*** submitted by Dr. Johny Lalhruaitluanga, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1675/23 dated 30th June, 2023. ***Previous PGTSC Comment:-*** • Sample size calculation and data analysis sections are missing. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVIII-PGTSC-IIA/P2***
36-	Clarification of research proposal entitled ***"Tibial tuberosity-trochlear groove distance in north Indian population"*** submitted by Dr. Amit Kumar, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3435/Ortho/23 dated 29th March, 2023. **Previous PGTSC comments:-** • What is the purpose of measuring "trochlear groove distance"? Not clear. • The title says "North Indian population". But the subjects will be recruited from KGMU only. • Sample size calculation is arbitrary. What are the different parameters used in the formula? How are the values arrived at? • What is the study variables (Measurements) used in the study? A list should be prepared. • Data analysis section is very general. It should be specific to the hypothesis of the study. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVIII-PGTSC-IIA/P1***
37-	Clarification of research proposal entitled ***"Predictors of successful weaning and extubation of critically-ill patients on invasive mechanical ventilator"*** submitted by Dr. Mrityunjaya Singh, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 530/PCCM/23 dated 24th June, 2023. **Previous PGTSC comments:-**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Identify one primary objective, and the rest should be grouped into secondary objectives. • Convert the primary hypothesis into a proper research hypothesis in terms of the study population parameters. • This study seems to be developing a "predictor" model. • There are certain guidelines for developing such model. You should cite those here. • The sample size calculation is missing. There is a proper formula for this. Presently it is very arbitrary. • Statistical analysis should be given in detail for developing prediction model. • In Study period (Patient enrolment: 1.5 minimum tentative) is not clear. Kindly explain. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVII-PGTSC-IIA/P4***
38-	Clarification of research proposal entitled ***"Prospective randomized control trial to compare the efficacy of decompressive craniectomy with suture duroplasty to non suture duroplasty using oxidized regenerated cellulose in traumatic brain injury"*** submitted by Dr. Samir Kumar Madhukar, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. N/S/550/23 dated 19th June, 2023. **Previous PGTSC comments:-** • Suggest modification of 'randomized control trial' to randomized controlled study' since 'trial' would require CTRI registration. • Vulnerable subject has been ticked as 'Any other'. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVII-PGTSC-IIA/P13***
39-	Clarification of research proposal entitled ***"Limbus-insertion distance (LID) of horizontal recti On anterior segment optical coherence tomography (ASOCT) and it's correlation with comitant horizontal strabismus-A pilot study"*** submitted by Dr. Ankita, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	vide letter no. 3017/OPH/23 dated 16th May, 2023. **Previous PGTSC comments:-** • Assent form required for Children ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVII-PGTSC-IIA/P14***
40-	Clarification of research proposal entitled ***"Evaluation of serum estrogen and serum testosterone levels in patients of primary open angle glaucoma and its correlation with nerve fibre layer thickness"*** submitted by Dr. Divyanshi, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 4038/23 dated 26th May, 2023. **Previous PGTSC comments:-** • Sample size calculation has not done. • Proforma appears incomplete. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVII-PGTSC-IIA/P15***
41-	Clarification of research proposal entitled ***"A study of clinic-biochemical and cardiac profile in snake bite at a tertiary care centre in northern India"*** submitted by Dr. Tarun Pal, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1080/Med/23 dated 20th May, 2023. **Previous PGTSC comments:-** • ICF-H/E–Attached-but as the patients of age group more than 13 yrs. are to be recruited, therefore PI has to submit Child Assent Form in addition to regular ICF. • CRF not attached–Please attach ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVII-PGTSC-IIA/P21***
42-	Clarification of research proposal entitled ***"Association of academic stress with memory and attention among medical undergraduates in India: A survey based correlation***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

study" sponsored by ICMR, New Delhi submitted by Mr. Abhinav Shukla, MBBS 2020 Batch through his Mentor Prof. Bandana Gupta, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 813/Psy/23 dated 27th May, 2023.

Previous PGTSC comments	Response by the Principal-Investigator
In SOP-Checklist- serial no. 8 – Written informed consent columns not ticked- Please revise it.	Written informed consent will be taken from students in the study as subjects, Revised checklist is attached as annexure.
According to the letter (no-45/Ethics/2023 dated 05-04-2023) received through Institutional Ethics Committee, some modifications regarding sample size from 382 to 1000 is requested from PI, but he did not revised the calculation. Therefore, revised sample size calculation for increased in sample size is needed.	Revised sample size calculation is attached as annexure.
Letter of ICMR–STS-grant indicating the name of concerned researcher-not given, please attach or send the approval letter to IEC as soon as PI receive it.	The results of ICMR STS 2023 applicants are yet to be announced on their official website. The study is survey l%csed using online Google forms to collect data which is free of cost. Therefore. we would like to continue our it does not receive a grant from ICMR STS 2023.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XVII-PGTSC-IIB-STS/P1

43- Clarification of research proposal entitled ***"A study on adverse drug reactions in type 2 diabetes mellitus patients oral antidiabetic drugs in a tertiary care Hospital in Northern India"*** submitted by Dr. Neeraj Pathak, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 546/Pharm/23 dated 18th July, 2023.

Previous PGTSC Comment:-

- Sample size calculation is not clear. What are the different parameters used in the formula? How are the values in the formula arrived at?
- Statistical analysis section is very general. It should be specific to the research hypothesis of the study.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVIII-PGTSC-IIA/P4***
44-	Clarification of research proposal entitled ***"Clinical, biochemical and neuroimaging parameters of TBM patient after end of one year of antituberculosis"*** submitted by Dr. Praveen Kumar Prince, SRI, Department of Orthodontics Neurology, King George's Medical University, U.P., Lucknow vide letter no. 296/Neuro/23 dated 30th June, 2023. ***Previous PGTSC Comment:-*** • Covering letter mentions the project as 'Open label Randomized controlled trial' whereas the synopsis mentions it as being a prospective observational study. • Are any controls being used? • This is not clear from the methodology. • Will the design be altered then? • Section on 'Vulnerable subjects is mentioned as 'Yes' but no details are given. No mention of Special Group subjects in the proforma. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVIII-PGTSC-IIA/P6***
IB	**Expedited review**
1.	Expedited of research proposal entitled ***"Screening for micronutrients deficiencies among School going overweight and obese adolescents of Lucknow"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Ajit Kumar Singh, JRI through his Mentor Prof. Reema Kumari, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 230/CM/23 dated 2nd June, 2023. ***The above research proposal was forwarded to Primary reviewers, for review:-*** ***Recommendation of Primary reviewers:-*** • Kindly change the name and phone number of Member Seceratary, IEC in the patient information sheet. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIX-PGTSC-IB-IMR-R /P1***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

2-	Expedited of research proposal entitled ***"Alteration in BDNF level in traumatic brain injury patients and its correlation with cognitive & functional outcome"*** submitted by Dr. Mitrajit Sharma, SR, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 123/NX dated 18th April, 2023. ***The above research proposal was forwarded to primary reviewers.*** ***Recommendation of Primary reviewers:-:***Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IB thesis/P1***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"Comparative study on diagnostic yield in ultrasound-guided closed pleural biopsy versus thoracoscopic pleural biopsy in undiagnosed exudative pleural effusion"*** submitted by Dr. Anil Kumar Maurya, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 648/PCCM/23 dated 17th May, 2023. ***Recommendation of Primary reviewer:*** • This is a prospective study and a period of study is quoted as December 22 to October 23. Ethics clearance of prospective study should start before commencement of the work. Kindly correct the language of text in methodology that is either in past tense or future tense period. • Kindly present steps of sample size calculation. • Kindly summarise the outcome measures. • Kindly brief the anticipated statistics analytical methods. • Kindly include patient information sheet as per SOP of EC KGMU, both in English and Hindi. • Organise the description of proposal in PICO format **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Elicited intraoperative trigeminocardiac reflex during forceful mouth opening in patients undergoing surgical management of oral submucous fibrosis: an observational study"*** submitted by Dr. Deepika Kumari Jain, SRII, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. OMSD/571/23 dated 19th May, 2023. ***Recommendation of Primary reviewer:*** • Material and methods reveals that this study has already finished in May 23. • The scientific review committee has approved the project after completion of study that is on 19 May 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Patient information sheet not attached. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Efficacy of tissue engineered scaffold in recession coverage: A randomized clinical trial"*** submitted by Dr. M. Priyadarshini, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2941/P/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:*** • In annexure 1 under clinical trials investigation intends to involve use of drugs – but no further clarification is made in annexure. • In annexure 1 the risk and benefit section may be reconsidered. • The CV of collaborator from CDRI needs to be submitted. • Since this is a randomized controlled trial using drug, the relevant formalities need to be done. • The description of proposal does not indicate any text regarding method of randomisation or allocation. Kindly organise the complete proposal in PICO format and specially clarify the intervention on the patients. • Kindly clarify all the outcomes (Clinical and molecular) that are needed for analysis. • Outline briefly the anticipated statistical analysis. • Patient information sheet both in English and Hindi need to be submitted as per SOP of EC KGMU. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P3***
4.	Research proposal entitled ***"A comparative study of ozone therapy and photodynamic therapy as an adjunct to scaling and root planning in chronic periodontitis"*** submitted by Dr. Shilpi Mangal, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2942/P/23 dated 25th May, 2023. ***Recommendation of Primary reviewer:*** • As indicated in annexure 1: is the risk reasonable? Please indicate. • The design of study is Randomized controlled trial. No method of randomization or allocation is indicated. • Sample size calculation needs to be detailed- the formula used and step wise calculation. • The clinical outcomes need further detailing in context with analysis. Kindly list

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	all the anticipated outcomes (Clinical and microbiological). • Arrange the description of proposal in PICO format with emphasis on comparison and outcome, the anticipated STATISTICAL ANALYSIS needs to be summarised. • Being randomised controlled trial involving PDT, the other formalities need to be completed as per RCT. • Patient information sheet in both English and Hindi needs to be submitted as per the SOP of EC KGMU. • Who will fund the project? Kindly indicate? **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P4***
5.	Research proposal entitled ***"Evaluation of periodontal health status in patients with Hospital-acquired pneumonia: A case-control study"*** submitted by Dr. Akshita Sharma, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. nil dated 11th May, 2023. ***Recommendation of Primary reviewer:*** • After enrolment in study, how will subject / cases be allocated in three groups. • List all the outcome parameters meant for analysis. The flowchart shows only a single biochemical parameter. How will PI GI, PPD, CAL be ranked kindly brief. How will Kuppuswamy scale fit in outcome analysis. Kindly indicate. • What are the inclusion exclusion criteria for healthy subjects that is group 1 kindly indicate. • Patient information sheet both in English and Hindi needs to be submitted as per SOP of EC KGMU. • Kindly brief the anticipated surgical analysis. • While it is mentioned in annexure 1 against point 7 as 'NA', on the other hand, the investigator wishes to obtain saliva and blood samples. Kindly explain. • Group 1 are healthy subjects while flowchart states healthy patients and type of subjects in annexure 1 point 5 includes only Patients not volunteers. Kindly resolve the matter. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Medicolegal trend of firearm injuries in eastern Uttar Pradesh"*** submitted by Dr. Anup Kumar Raipuria, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	156/FMT dated 22nd May, 2023. **PGTSC Decision:** Approved ***Ref. code: XIX-PGTSC-IIA/P6***
7.	Research proposal entitled ***"Evaluation of tumor budding as a promising prognostic marker in cervical squamous cell carcinoma using immunohistochemical staining"*** submitted by Dr. Santosh Kumar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 202/Patho/23 dated 29th May, 2023. ***Recommendation of Primary reviewer:*** • The scientific review committee has stated 'NA' regarding competency of investigation team. Kindly exclude the incompetent member and resolve the issue. • Kindly fill point 7 in annexure 1 properly as well as other vacant places. • Is the risk not reasonable? • What will be the adverse events (1)Pt 11 of annexure 1). • Patient information sheet both in English and Hindi need to be submitted as per the SOP of EC KGMU • The statistical analysis needs revision as per the aim ie survival analysis The investigator mentions breast cancer analysis- how to explain this . Again what is nestin expression kindly explain. The statistical analysis should be tailored for this study not made generic. • Kindly include a data collecting protocol sheet to include all the clinical and radiological histological immunohistochemical data A two year. survival study needs to be mentioned in aims. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P7***
8.	Research proposal entitled ***"The prevalence of sarcopenia in patients with rheumatoid arthritis and its association with disease activity and use of glucocorticoid"*** submitted by Dr. Panday Pradeep, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/460/23 dated 7th June, 2023. ***Recommendation of Primary reviewer:*** Approved ***Ref. code: XIX-PGTSC-IIA/P8***
9.	Research proposal entitled ***"Outcome of marginal impaction injury of posterior wall of acetabulum fracture treated with kocher-langenback approach: A Ambi study"*** submitted by Dr. Pranav Raghuwanshi, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 220/Ortho/23 dated 8th May, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • Patient information sheet is totally missing. • At one place investigator says it is a prospective study while at 2 other places it seems tobe a mixed of prospective and retrospective study. • In ICF in study procedures it seems a retrospective study from records-then why to take consent in prospective sense. • Add Hindi version of ICF. • Summarise methodology in PICO format. • Are 7 Co-Investigotors from same department justified-one of them has superannuated- What will be his role from a different Institution-how data collection or Investigations are possible? • Annexure-fill in left blanks. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Assessment of residual cancer burden in breast cancer after neoadjuvant chemotherapy according to the subtypes and survival outcomes"*** submitted by Dr. Ananyaa, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 222/SY/23 dated 20th May, 2023. ***Recommendation of Primary reviewer:*** • Blank spaces have to be filled in annexure 1. • Is the risk not reasonable compare to benefit? • Kindly elaborate sample size calculation • Patient information sheet is not attached. Kindly attach in English and Hindi as per SOP of EC KGMU. • If ICF is planned for retrospective work then study procedure in ICF should include a meaningful statement in the language that patient can understand. The idea is to obtain consent for this work/ publication and data about his survival Include a case sheet to obtain the data as per the protocol. • Innumerate all the outcomes needed for statistical analysis. • Briefly summaries the anticipated statistical analysis. • Re-organise description of proposal in PICO format and present a flowchart of approach. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Diagnostic yield of bronchoscopy in sputum-negative pulmonary tuberculosis patients and its correlation with clinicoradiological features"*** submitted by Dr. Ojha Saurabh Ghanshyam, SR, Department of Pulmonary & Critical

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 202/PCCM/23 dated 6th May, 2023. ***Recommendation of Primary reviewer:*** • This is a revised submission of prospective study that has already started in December 22 and will be ending in next three months. • The text of methodology is in past tense. • Annexure 1 indicates sample of 80 while sample size calculation is 54?? • Annexure 1 point 7 indicates that no body fluids will be obtained but methodology clearly states that bronchial washings and biopsy will be collected for study. • While ICF is attached, patient information sheet is missing and is also stated in annexure 1. Kindly attach the patient information shee, both in English and Hindi as per SOP of EC KGMU. • Is the risk reasonable to anticipated benefits (annexure 1 point 10)? • What are the anticipated adverse events (annexure 1 point11)- it needs to be added to ICF. • Kindly innumerate all the outcomes and briefly summarise anticipated statistical analysis. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P11***
12.	Research proposal entitled ***"Comparison of bronchoalveolar lavage, mini-bronchoalveolar lavage and endotracheal aspirate in the diagnosis and management of pneumonia in intensive care unit"*** submitted by Dr. Shubham Tiwari, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 204/PCCM/23 dated 6th May, 2023. ***Recommendation of Primary reviewer:*** • This is a revised submission of prospective study that has already started in December 22 and will be ending in next three months. The text of methodology is in past tense. • Annexure 1 indicates sample of 80 while sample size calculation is 59?? Annexure 1 point 7 indicates that no body fluids will be obtained but methodology clearly states that bronchial washings will be collected for study. • While ICF is attached, patient information sheet is missing and is also stated in annexure 1. Kindly attach the patient information sheet, both in English and Hindi as per SOP of EC KGMU. • What are the anticipated adverse events (annexure 1 point 11)- it needs to be added to ICF.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Kindly innumerate all the outcomes and briefly summarise anticipated statistical analysis. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P12***
13.	Research proposal entitled ***"A study of ambulatory blood pressure monitoring in Medical Students in a tertiary care Hospital in North India"*** submitted by Dr. Arzoo Sharma, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2040/Med/23 dated 3rd May, 2023. ***Recommendation of Primary reviewer:*** • Title reflects study amongst medical students, but annexure 1 point 4 states patients • Is the risk reasonable compare to anticipated benefit (annexure 1 point 10) • What are the anticipated adverse events (annexure 1 point 11)- should be included in ICF • Patient information sheet both in English and Hindi needs to be attached as per SOP of EC KGMU. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P13***
14.	Research proposal entitled ***"Study of serum homocysteine levels in various chronic complications of type2 diabetes mellitus"*** submitted by Dr. Radha Raman Pattanayak, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 148/Med/23 dated 10th May, 2023. ***Recommendation of Primary reviewer:*** • There are two co-supervisors mentioned on page 3 while four co-supervisors on page their names are also not the same. Kindly finalise the list in annexure 1 it is stated 'NO' against "where subjects from both sexes be recruited". Now which gender is to be taken?. Kindly indicate and include in inclusion criteria. • Annexure 1 point 7 states 'NO' against use of body fluids but methodology involves blood sampling. • What are the anticipated adverse effects (annexure 1 point11)- they need to be added in ICF • Patient information sheet both in English and Hindi needs to be submitted as per SOP of EC KGMU in annexure 1, 120 sample is required. While sample size calculation is 174. Why so? • What are the various complications of type two diabetes mellitus as per the aims kindly

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	indicate. It is not even indicated in inclusion criteria • What are the outcome measures needed for analysis • Kindly summarise anticipated statistical analysis **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P14***
15.	Research proposal entitled ***"Non-alcoholic fatty liver disease in patients of hypothroidism"*** submitted by Dr. Tushar Rajoura, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 105/Med/23 dated 4th May, 2023. ***Recommendation of Primary reviewer:*** • The methodology needs to be revised and clearly subcategorised in intervention, comparison, and outcome in order to make it more clear. • The statistical tools are stated in past tense and it would be better to brief the various outcome parameters used in analysis. • Patient information sheet needs to be submitted both English and Hindi as per the • SOP of EC KGMU. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P15***
16.	Research proposal entitled ***"Role of adipsin as a biomarker in obesity and it's associated complications (Diabetes, Hypertension and Coronary Artery Disease)"*** submitted by Dr. Vishwa Deepak Tiwari, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.122/Med/23 dated 6th May, 2023. ***Recommendation of Primary reviewer:*** • Confirm the number of participants 150/190 • Patient Information sheet is not attached • Is adipsin level a routine marker in hypertensive/diabetic/coronary artery disease patients? • If not, who will bear the cost of the investigation? • Is it an additional investigation solely for the purpose of research? • Kindly, tell in which Lab this marker will be assessed and what is the cost incurred for each assay. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XIX-PGTSC-IIA/P16
17.	Research proposal entitled ***"Relationship of serum Vitamin D levels with viral replication and Hepatic Fibrosis in patients of chronic Hepatitis B and Chronic Hepatitis C"*** submitted by Dr. Pahul Ahuja, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 145/Med/23 dated 10th May, 2023. ***Recommendation of Primary reviewer:*** • Please rectify the ICF, as per standard guidelines. • Please provide a properly filled Patient Information Sheet. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P17***
18.	Research proposal entitled ***"Role of triglyceride glucose index as a novel biomarker in patients of type2 diabetes mellitus developing acute coronary syndrome"*** submitted by Dr. Princy Chaudhary, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 146/Med/23 dated 10th May, 2023. ***Recommendation of Primary reviewer:*** • Please provide affiliations of Dr. Vivek and Dr. Sharad • Please rectify the ICF, as per standard guidelines. • Please provide a properly filled Patient Information Sheet. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P18***
19.	Research proposal entitled ***"Spectrum of bacteria in infected pancreatic fluid collection in severe acute pancreatitis and their association with clinical outcome"*** submitted by Dr. Nyuwisie R Nyuwi, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 152/Med/23 dated 11th May, 2023. ***Recommendation of Primary reviewer:*** • Please rectify the ICF, as per standard guidelines. • Please provide a properly filled Patient Information Sheet. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P19***
20.	Research proposal entitled ***"Gross and microscopic study of pituitary gland in cases of alleged suicidal deaths"*** submitted by Dr. Fathima Harsha P M, JRI, Department of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 167/FMT/23 dated 30th May, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P20***
21.	Research proposal entitled ***"Correlation between phases of menstrual cycle and suicidal deaths- An autopsy based study"*** submitted by Dr. Ranjini Johnson, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 165/FMT/23 dated 30th May, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P21***
22.	Research proposal entitled***"To evaluate the expression of ectonucleotide pyrophosphate/phosphodiesterase1 (Enpp1) in breast cancer and correlate with chemotherapy response"*** submitted by Dr. Vidya Rashmi, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 668/23 dated 30th May, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P22***
23.	Research proposal entitled ***"Immunohistochemical expression of HIF 1 α and evaluation of microvascular density in gliomas and its radiological correlation"*** submitted by Dr. Diparati Mondal, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 676/23 dated 1st June, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P23***
24.	Research proposal entitled ***"Demographical study of burn cases-an observational study in King George Medical University"*** submitted by Dr. Abhipsa Senapati, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 169/FMT/23 dated 30th May, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P24***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

25.	Research proposal entitled ***"Fall risk assessment among lower limb prosthesis user-A cross-sectional study"*** submitted by Dr. Mohd Farid Ahamad, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 5251/23 dated 5th June, 2023. ***Recommendation of Primary reviewer:*** • Please attach properly filled Patient Information Sheet **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P25***
26.	Research proposal entitled ***"Study of outcome & efficacy of genicular nerve block versus saphenous nerve block in osteoarthritis of knee: A prospective randomized controlled trial"*** submitted by Dr. Arun Kumar Ojha, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 5250/23 dated 5th June, 2023. ***Recommendation of Primary reviewer:*** • Please attach properly filled Patient Information Sheet **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P26***
27.	Research proposal entitled ***"Effect of USG guided intra-articular prolotherapy versus steroid injection for sacroiliac joint dysfunction- A prospective randomized control trial"*** submitted by Dr. Ruth Kikon, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. nil dated 3rd June, 2023. ***Recommendation of Primary reviewer:*** • Please attach properly filled Patient Information Sheet **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P27***
28.	Research proposal entitled ***"The impact of low pressure negative pleural suction versus underwater seal drainage in patient of thoracic trauma: A randomized controlled trial"*** submitted by Dr. Shahnawaz Ahmad, JRI, Department of Trauma Surgery, King George's Medical University, U.P.. Lucknow vide letter no. 207/TS/23 dated 31st May, 2023. ***Recommendation of Primary reviewer:*** • Please provide sample size and its calculation • Please rectify the ICF, as per standard guidelines. • Please provide a properly filled Patient Information Sheet.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P28***
29.	Research proposal entitled ***"Outcome correlation of initial arterial blood gas (ABG) analysis in isolated thoracic injury"*** submitted by Dr. Aman Singh, JRI, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. 206/TS/23 dated 31st May, 2023. ***Recommendation of Primary reviewer:*** • Please provide sample size and its calculation • Please rectify the ICF, as per standard guidelines. • Please provide a properly filled Patient Information Sheet. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P29***
30.	Research proposal entitled ***"To study and assess role of angioembolization in solid organ injury in blunt trauma abdomen: An ambispective observational study"*** submitted by Dr. Akanksha Kumari, JRI, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. 208/TS/23 dated 31st May, 2023. ***Recommendation of Primary reviewer:-*** • Dr. Anita Singh has been shown as Chief Supervisor as well as Co-Supervisor. • Sample size calculation not provided. Why only 70 subjects will be included in the study? **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P30***
31.	Research proposal entitled ***"Outcome analysis of diagnostic laparoscopy in FAST+VE patients with blunt trauma abdomen with no solid organ injury on CECT: an observational prospective study"*** submitted by Dr. Vikash Kumar Yadav, JRI, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. 204/TS/23 dated 31st May, 2023. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P31***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

32.	Research proposal entitled ***"Study of mechanism of injury, pattern of injury and mode of transport influencing outcome of trauma patients at level I trauma center: A retrospective and prospective observational study"*** submitted by Dr. Vishal Bisan Bedi Gammey, JRI, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. 201/TS/23 dated 30th May, 2023. ***Recommendation of Primary reviewer:-*** • Sample size calculation not provided. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P32***
33.	Research proposal entitled ***"Study of clinicoserological profile of childhood onset systemic lupus erythematosus in a tertiary centre in Northern India"*** submitted by Dr. Vishal Anand, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/459/23 dated 7th June, 2023. ***Recommendation of Primary reviewer:-*** • Methodology for estimating immunological parameters not provided. • There is no co-guide for supervision of biochemical investigations. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P33***
34.	Research proposal entitled ***"Study of cardiac autonomic dysfunction in patients of systemic sclerosis in a tertiary care centre"*** submitted by Dr. Rajat Kumar Sahu, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/457/23 dated 8th June, 2023. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P34***
35.	Research proposal entitled ***"Postmortem analysis of electrolytes (Na+, K+, Ca+2) in synovial fluid and cerebrospinal fluid for determination of time since death: A comparative study"*** submitted by Dr. Tauheed Anwar, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 136/FMT/23 dated 27th May, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer:- • Consent form both in English and Hindi needs to be corrected as it is in first person, although the consent is to be taken for blood collection from the corpse. **PGTSC Comment:**As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P35***
36.	Research proposal entitled ***"Correlation of CSF and blood serotonin level with suicide"*** submitted by Dr. Harshita, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 176/FMT/23 dated 6th June, 2023. *Recommendation of Primary reviewer:-* • For supervision of biochemical investigation no Co-Guide is there. • The method for estimation of serotonin level not provided. • There is no bibliography or references. • Consent form both in English and Hindi needs to be corrected as it is in first person, although the consent is to be taken for blood collection from the corpse. **PGTSC Comment:**As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P36***
37.	Research proposal entitled ***"To study knowledge, attitude and practice with respect to infection control among healthcare workers of intensive care units in a tertiary care Government teaching Hospital, Lucknow"*** submitted by Dr. Garima Jaiswal, JRI, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/276/23 dated 14th June, 2023. *Recommendation of Primary reviewer:-* • It can be a pilot study. Title may be changed accordingly. **PGTSC Comment:**As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P37***
38.	Research proposal entitled ***"Study of prevalence and factors associated with cognitive dysfunction in systemic lupus erythematosus, attending a tertiary care centre"*** submitted by Dr. Rupal Prasad, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. 458/23 dated 8th June, 2023. *Recommendation of Primary reviewer:-*

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• There is no co-guide from Pathology or Biochemistry Department for supervising biochemical investigations. **PGTSC Comment:**As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P38***
39.	Research proposal entitled ***"Ultra low dose rituximab in rheumatoid arthritis patients refractory or intolerant to esDMARDs and JAK inhibitors- A prospective pilot study from a tertiary care center in Northern India"*** submitted by Dr. Anjum Siddiqui, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. 476/23 dated 13th June, 2023. ***Recommendation of Primary reviewer:-*** • Reference of method for carrying out flow cytometry not provided. **PGTSC Comment:**As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P39***
40.	Research proposal entitled ***"A cross-sectional study to classify dementia sub-types using transfer learning"*** submitted by Dr. Ashwin J.V, SRI, Department of Geriatric & Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 219/DGMH/23 dated 14th June, 2023. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P40***
41.	Research proposal entitled ***"A cross-sectional study to assess the role of cerebellum in cognitive functions among patients with multiple system atrophy using magnetic resonance imaging"*** submitted by Dr. Mohit Kumar Shahi, SRI, Department of Geriatric & Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 218/DGMH/23 dated 14th June, 2023. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P41***
42.	Research proposal entitled ***"Association of posterior tibial slope and functional outcome after total knee arthroplasty: An observational study in Indian population"*** submitted by Dr. Prakhar Verma, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 9777/OS/23 dated 17th June, 2023. ***Recommendation of Primary reviewer:-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• It is mentioned that the study will be conducted between September 2022 to August 2023. So it seems that the study has already been completed without Ethical clearance? **PGTSC Comment:** • Kindly clarify about timeline **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P42***
43.	Research proposal entitled ***"Study of nestin expression across spectrum of various native renal diseases and its association with progression/remission of disease"*** submitted by Dr. Shashi Nandini, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 739/23 dated 19th June, 2023. ***Recommendation of Primary reviewer:-*** • Methodology for immunohistochemistry and electron microscopy including reference of method not provided. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P43***
44.	Research proposal entitled ***"Utility of infrared thermography in gangrene patients: An observational study"*** submitted by Dr. Nidhish Chandra M, SR, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/503/23 dated 12th June, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P44***
45.	Research proposal entitled ***"Evaluation of functional outcomes of unstable intertrochanteric fractures managed by proximal femur nailing using modified harris HIP score"*** submitted by Dr. Ritesh Chaloo, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 9778/OS/23 dated 20th June, 2023. ***Recommendation of Primary reviewer:*** • The study is very similar to another study from the same department by Dr. Krishna Mani Shukla under the Dr. Devarshi Rastogi. Please reconsider either of the two studies. • There are nine Investigators in the study with overlapping roles. • Several sections of the IEC proforma have been left incomplete.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: • Kindly limit to cases who are not elderly. Specify the age range, so that there is no overlap with theses of Dr. Krishna Mani. **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P45***
46.	Research proposal entitled ***"Comparative analysis of glenohumeral and subacromial steroid injection in primary frozen shoulder: A prospective, randomized short term comparision study"*** submitted by Dr. Namkumpeung Lungalang, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 9779/OS/23 dated 20th June, 2023. ***Recommendation of Primary reviewer:*** • Several sections of the IEC proforma are left incomplete. • There are eight Investigators with overlapping roles. • Sample size calculated is 50 but that mentioned in the IEC proforma is 70 **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P46***
47.	Research proposal entitled ***"Olfaction and response to antidepressant treatment in subjects with late life depression"*** submitted by Dr. Samiksha Supranjali, SRI, Department of Geriatric & Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 228/DGMH/23 dated 24th June, 2023. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P47***
48.	Research proposal entitled ***"Analysis of expression of therapeutic biomarkers in gall bladder carcinoma"*** submitted by Dr. Arina Alam, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 811/23 dated 21st June, 2023. ***Recommendation of Primary reviewer:*** • Use of biological materials has been ticked 'No' • Vulnerable subjects not mentioned. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P48***
49.	Research proposal entitled ***"To study the role of B-regulatory cells in development of inhibitors in hemophilia a patients"*** submitted by Dr. Sana Parveen, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 819/23

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	dated 24th June, 2023. ***Recommendation of Primary reviewer:*** • Section on Consent is incompletely filled. • Use of organs/body fluids is ticked 'No' but blood sample is being drawn. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-IIA/P49***
50.	Research proposal entitled ***"Morphometric analysis of accessory palatine canals in Human Dry Skulls"*** submitted by Dr. P. Yeshwanthi, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 125/ANAT/23 dated 12th June, 2023. ***Recommendation of Primary reviewer:*** • Ethical clearance waiver has been applied for. The same may kindly be granted. **PGTSC Decision:** Waiver of Informed Consent Granted. ***Ref. code: XIX-PGTSC-IIA/P50***
51.	Research proposal entitled ***"Comparative evaluation of hyaluronic acid and injectable platelet rich fibrin (I-PRF) as a non-surgical approach for management of black triangle"*** submitted by Dr. Mansi Pal, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2962/P/23 dated 21st June, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P51***
52.	Research proposal entitled ***"Co-relation of post COVID metabolic syndrome and obstructive sleep apnea in Hospital visiting patients"*** submitted by Dr. Apurva Verma, JRII, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 225/23 dated 22nd June, 2023. ***Recommendation of Primary reviewer:*** • Does the topic of Metabolic syndrome, post-Covid complications or Obstructive sleep apnea come under the purview of Department of Prosthodontics and Crown & Bridge? Will suggest changing subject to a topic more suited for an MDS Prosthodontic candidate. • A senior Resident from the same department is listed as a Co-PI. This cannot be allowed • IEC proforma is incompletely filled • Material and Methods has list of instrumentation which is not required. • It appears to be an observational study, but Methodology mentions Randomization

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	of participants. No control group has been mentioned. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P52***
53.	Research proposal entitled ***"Study of single nucleotide polymorphisms in pik3ca gene and it's role in cervical cancer"*** submitted by Dr. Harshi Srivastava, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 753/23 dated 20th June, 2023. ***Recommendation of Primary reviewer:*** • Section on Use of Biological Materials is ticked as 'No' **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P53***
54.	Research proposal entitled ***"Ultrasound guided erector spinae plane block in Paediatric patient undergoing meningomyelocoelesurgery: A prospective, randomized controlled study"*** submitted by Dr. Akanksha Gupta, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/599/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:*** • Sample size is mentioned 80 at one place and 70 at another where sample calculation has been done. • Children is not ticked in the section on Vulnerable population. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P54***
55.	Research proposal entitled ***"Intramedullary nailing vs hemireplacement arthroplasty in unstable intertrochanteric femur fracture in elderly"*** submitted by Dr. Krishna Mani Shukla, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. nil dated 16th May, 2023. ***Recommendation of Primary reviewer:*** • The study is very similar to another studyk from the same department by Dr. Ritesh Chakoo under Dr. Mayank Mahendra. This will result in a salami study. Please reconsider either of the two studies.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• IEC proforma is incompletely filled. • Sample size is mentioned 100k at one placer and 80 at another. • No clinical end point is given when the scoring will be done. **PGTSC Comment:** • Specify the age range of elderely. **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P55***
56.	Research proposal entitled ***"Prospective analysis of flap perfusion by measuring capillary glucose levels at different body sites"*** submitted by Dr. Yash Rohatgi, SRI, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 835/23 dated 28th June, 2023. ***Recommendation of Primary reviewer:*** • Single centre/multi-centre has not been mentioned. • Devices have been mentioned in the section on 'Clinical trials'. Which device is being tested in the trial? • Use of body fluids has been mentioned as 'No' but blood glucose is being tested. • IEC form is incompletely filled. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P56***
57.	Research proposal entitled ***"Roles of preoperative and early postoperative electrodiagnosis in brachial plexus injury patients undergoing nerve transfer operations"*** submitted by Dr. Gourav Jain, SR, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 839/23 dated 30th June, 2023. ***Recommendation of Primary reviewer:*** The scientific committee's decision statement needs to be ticked. • The role of investigators is not defined. • The aim and objectives of this study seem to be interchanged. ***role of preoperative and early postoperative electrodiagnosis in brachial plexus injury patients undergoing nerve transfer operations and its association with electrodiagnostic parameters.*** • The duration of the study is written as January 2023 to October 2025 • Will the researcher get 34 months for the study? • Is the study started? • Variable no of sample size is written 20 (Checklist & protocol -see materials

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	and methods)/ 31 (in protocol on same pg)? • Hindi ICF may be written in a more comprehensive language. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P57***
58.	Research proposal entitled ***"Histopathological mapping of nodal status in patients of carcinoma gallbladder undergoing curative intent surgery: A combined retrospective and prospective study"*** submitted by Dr. Era Parasar, SR, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/738/23 dated 26th June, 2023. ***Recommendation of Primary reviewer:*** • Seven Investigators are from one department. No Investigator from Pathology department even though HPE will be needed for patients in the prospective arm. • Sample size calculation has not been done. • Section on Privacy and Confidentiality mentions use of indirect identifier. In such as case retrospective consent will be required from the patients. For consent waiver the data has to be completely anonymous. • End point of the study has not been defined. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P58***
59.	Research proposal entitled ***"Survival outcomes for non-metastatic rectal cancer in patients undergoing treatment at a tertiary care centre: A retrospective and prospective study"*** submitted by Dr. Mandeep Singh, SR, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/734/23 dated 26th June, 2023. ***Recommendation of Primary reviewer:*** • The study design is retrospective as well as prospective. • It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. • It has to be split into two different parts. • Each type shall use different subjects. • The sample size calculation is not given. The number 60 is arbitrary. • Statistical analysis section is not given

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P59***
60.	Research proposal entitled ***"Estimation of micro-RNA 429 in breast cancer"*** submitted by Dr. Shivangini Sharma, JR, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 747/23 dated 19th June, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P60***
61.	Research proposal entitled ***"Estimation of micro-RNA 155 in breast cancer"*** submitted by Dr. Taniya Suryavanshi, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 746/23 dated 19th June, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P61***
62.	Research proposal entitled ***"Caregiver burden in chronic obstructive pulmonary disease patients"*** submitted by Dr. Theepan Kumar S, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 353/CM/23 dated 1st July. 2023. ***Recommendation of Primary reviewer:*** • Nothing is said about the reliability and validity of the instrument to be used. • Can the scale be completed in a reasonable amount of time? • How much training is needed to learn how to administer it? • Sample size calculation is for prevalence study. It will use measurement scale methods. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P62***
63.	Research proposal entitled ***"Clinical outcome of idiopathic congenital talipes equinovarus treated with ponseti method"*** submitted by Dr. Nitin Jeenjwadia, SRI, Department of Pediatric Orthopedics, King George's Medical University, U.P., Lucknow vide letter no. 2466/PaedOrtho/23 dated 4th July, 2023. ***Recommendation of Primary reviewer:*** • Some details should be given about Pirani scoring method.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• How the numbers/scores would be extracted from this scale. • It seems to be a pre-post study done on a single sample. • The sample size calculation is incorrect as it is for two independent samples. • Statistical analysis section is missing. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P63***
64.	Research proposal entitled ***"Epidemiology of pediatric trauma victims admitted to the trauma centre of KGMU: A prospective observational study"*** submitted by Dr. Durga Krishna, SRI, Department of Pediatric Orthopedics, King George's Medical University, U.P., Lucknow vide letter no. 2465/PaedOrtho/23 dated 4th July, 2023. ***Recommendation of Primary reviewer:*** • The objective is not clear. It just says: To describe victim related factors like age, sex,…….. • What is the use of these variables? • Proper research hypothesis should be formulated after identifying the study parameters. • Sample size calculation, statistical analysis should be in coherence with research hypothesis. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P64***
65.	Research proposal entitled ***"CT guided evaluation of rotational deformity in femoral shaft fractures in Children treated by flexible elastic intra medullary nailing: A prospective cohort study"*** submitted by Dr. Praseeth K.R, SRI, Department of Pediatric Orthopedics, King George's Medical University, U.P., Lucknow vide letter no. 2467/PaedOrtho/23 dated 4th July, 2023. ***Recommendation of Primary reviewer:*** • Some details of evaluating Scales are required including their reliability and validity. • How are these scored? • Sample size calculation is for prevalence study, not for measurement scale. • The statistical analysis section is very general. It should be specific to the research hypothesis.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P65***
66.	Research proposal entitled ***"Recurrence and survival analysis of gynaecological cancers in view of current institutional diagnostic practices"*** submitted by Dr. Anjali Gautam, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 858/23 dated 3rd July, 2023. ***Recommendation of Primary reviewer:*** • The primary objective should be very specific and clear. • The aim says: To study various risk factors associated with…….and behaviour of four common gynaecological cancers, particulary cervical cancer. • How be these factors measured? Data collection sheet/ questionnaire is required. • Sample size calculation is incorrect. It is for prevalence study. • Statistical analysis section is missing. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P66***
67.	Research proposal entitled ***"Study of microsatellite instability expression in gallbladder cancer and its clinicopathological correlation"*** submitted by Dr. Ankit Kumar, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1088/23 dated 4th July, 2023. ***Recommendation of Primary reviewer:*** • The study design is retrospective as well as prospective. • It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. • It has to be split into two different parts. • Each type shall use different subjects. • Sample size calculations are not given. • Statistical analysis section is very general. It should be specific to the study objectives. **PGTSC Comment:** • As above **PGTSC Decision:** Revise & re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P67***
68.	Research proposal entitled ***"A study of clinicopathological profile and survival outcome of adult extremity soft tissue sarcoma after curative surgery"*** submitted by Dr. Monika

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Shekhawat, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1093/23 dated 4th July, 2023. ***Recommendation of Primary reviewer:*** • The study design is retrospective as well as prospective. • It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. • It has to be split into two different parts. • Each type shall use different subjects. • From the proforma (data collection form), it is not clear; How to derive outcomes of surgical patients in terms of disease-free survival and overall survival. • Sample size calculation and statistical analysis section is required. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P68***
69.	Research proposal entitled ***"Study of factors predicting regional lymph nodes metastasis in marjolin's ulcer"*** submitted by Dr. Prabhat Shukla, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1089/23 dated 4th July, 2023. ***Recommendation of Primary reviewer:*** • In the aim it is supposed to be a prevalence study. • The primary objective is to find a predictive model. • The two are completely different objectives. • The objective should be well defined and study should be planned accordingly. • The study design is supposed to be retrospective as well as prospective. • This is also a contradiction. • Statistical analysis section is vague. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P69***
70.	Research proposal entitled ***"Study of clinicopathological profile and survival outcomes of patients following curative surgical treatment for a second primary oral cancer"*** submitted by Dr. Priyanka Khilari, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1091/23 dated 4th July, 2023. ***Recommendation of Primary reviewer:*** • The aim and objectives are not properly defined.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The study design is retrospective as well as prospective. • It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. • It has to be split into two different parts. • Each type shall use different subjects. • Sample size calculation is missing. • Statistical analysis section is missing. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P70***
71.	Research proposal entitled ***"Survival outcomes of locally advanced (T4D) oral squamous cell cancers involving masticator space in patients undergoing surgical treatment"*** submitted by Dr. Pritesh P. Gaonkar, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1092/23 dated 4th July, 2023. ***Recommendation of Primary reviewer:*** • The study design is retrospective as well as prospective. • It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. • It has to be split into two different parts. • Each type shall use different subjects. • Sample size calculation is missing. • From the Case series form, it is not clear: How the disease free survival shall be measured. • Statistical analysis section is very general. It should be specific to the objectives of the study. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P71***
72.	Research proposal entitled ***"Surgical outcomes in cancer of the esophagus and gastroesophageal junction (Siewert's type 1&2)"*** submitted by Dr. Akshat Mishra, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1090/23 dated 4th July, 2023. ***Recommendation of Primary reviewer:*** • The study design is retrospective as well as prospective.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. • It has to be split into two different parts. • Each type shall use different subjects. • Sample size calculation is missing. • From the Case series form, it is not clear: How the disease free survival shall be measured. • Statistical analysis section is very general. It should be specific to the objectives of the study. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P72***
73.	Research proposal entitled ***"To assess the efficacy of platelet rich plasma (PRP) in patients with partial thickness facial burns as compared to conventional facial burn care"*** submitted by Dr. Shrivats Mishra, SRI, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 838/23 dated 30th June, 2023. ***Recommendation of Primary reviewer:*** • The study design is retrospective as well as prospective. • It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. • It has to be split into two different parts. • Each type shall use different subjects. • Sample size calculation is missing. • From the Case series form, it is not clear: How the disease free survival shall be measured. • Statistical analysis section is very general. It should be specific to the objectives of the study. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P73***
74.	Research proposal entitled ***"Presepsin as an early biomarker of sepsis in critically ill obstetric patients and its association with fetomaternal outcomes"*** submitted by Dr. Umang Sharma, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/711/23 dated 16th June, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • SOP Check list should be revised as Point no-5 , 7, 8 , 10 not marked appropriately • In Inclusion/Exclusion criteria Age specificity and Pregnant & lactating women criteria not mentioned-Please mention • Structured Questionnaire , Sepsis- 3 criteria and CRF not attached **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P74***
75.	Research proposal entitled ***"Correlation of L-Type fatty acid binding protein levelswith acute kidney injury in critically ill obstetrics patients and its association with fetomaternal outcome"*** submitted by Dr. Arunima Shukla, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/710/23 dated 16th June, 2023. ***Recommendation of Primary reviewer:*** • SOP Check list should be revised as Point no-5 , 7, 8 , 10 not marked appropriately • Structured questionnaire ,APACHE Score II and CRF not attached • Text component in MS Word file not appropriate ,words are intermingled - Protocol should be revised **PGTSC Comment:** • As above **PGTSC Decision:** Revise & Re-submit. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P75***
76.	Research proposal entitled ***"Implementing heat stable carbetocin in treatment of atonic post partum hemorrhage-A pilot study"*** submitted by Dr. Aradhya Garg, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/703/23 dated 15th June, 2023. ***Recommendation of Primary reviewer:*** • SOP Check list should be revised as Point no- 8 & 10 not marked appropriately • In Scientific Review Committee name of one of the Co-guide (Prof. S P Jaiswar) is also included-Please justify or revise SRC. • CRF-not attached **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XIX-PGTSC-IIA/P76
77.	Research proposal entitled ***"A prospective analysis of the instillation of streptokinase in addition to twist drill or burr hole drainage in the treatment of chronic subdural hematomas"*** submitted by Dr. Vishnu Vardhan. M, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 813/NS/23 dated 3rd July, 2023. ***Recommendation of Primary reviewer:*** • The first page having names of investigators has wrongly been attached-Please remove. • The role of Co-guides separately has not been given by PI. • SOP Check list should be revised as Point no- 8 & 10 not marked appropriately. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form.
	Ref. code: XIX-PGTSC-IIA/P77
78.	Research proposal entitled ***"Comparison of ultrasound guided suprainguinal and infrainguinal approaches of fascia iliaca compartment block for postoperative analgesia after total knee replacement: A prospective randomized trial"*** submitted by Dr. Adarsh Kumar Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/602/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:*** • Scientific Review Committee –should be revised as name of one of the Co-PI (Prof. Vinita Singh) is there in SRC document • SOP Check list should be revised as Point no- 6 & 8 not marked appropriately • The Study design in Protocol is Prospective randomized comparative study ,the Title may be corrected accordingly (in which Prospective randomized trial is written) • In methodology Flow chart is not given – please add flow chart • VAS Score and CRF –Not attached **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form.
	Ref. code: XIX-PGTSC-IIA/P78
79.	Research proposal entitled ***"Study of transdermal buprenorphine patch versus oral etoricoxib for postoperative pain management after total knee arthroplasty: A randomized comparative, an open label study"*** submitted by Dr. Sneha, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Anaes/576/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:*** • Sample size and its calculation is missing in Protocol. • Inclusion/Exclusion criteria–Pregnant and lactating women criteria not mentioned. • Methodology –Flow chart should be added. • Informed Consent Form (ICF) –Not attached. • CRF –Not attached. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P79***
80.	Research proposal entitled ***"A study to assess safety and feasibility of medical treatment discontinuation in asymptomatic patients of improved heart failure with normal left ventricular global longitudinal strain at rest and post-exercise"*** submitted by Dr. Aniket Jaiswal, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 209/Cardio/23 dated 4th July, 2023. ***Recommendation of Primary reviewer:*** • Study design in Protocol is Quasi experimental study (but in Material and method part of Protocol it is written as Randomized double blind trial) –PI to clarify the study design • SOP Check list should be revised as Point no- 5 , 8 & 10 not marked appropriately • In Inclusion criteria ,Age and sex criteria not given but in Exclusion criteria Age is mentioned as less than 16 and more than 80 –PI to include Age /sex criteria in Inclusion criteria as well • In methodology Flow chart should be attached • CRF –Not attached • If Pts of less than 18 yrs. are to be included then PI has to submit Child Assent form (E/H) also in addition to regular ICF **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P80***
81.	Research proposal entitled ***"Role of dexmedetomidine in reduction of arrhythmias post long cardiopulmonary bypass exposure"*** submitted by Dr. Kamna Nagar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/578/23 dated 24th May, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • SOP Check list should be revised as Point no- 5 & 8 not marked appropriately – Please revise SOP Check list • In Inclusion criteria, Sex /Pregnancy &lactating women criteria not mentioned • Case record form (CRF) -not attached **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P81***
82.	Research proposal entitled ***"A comparison between fentanyl and nalbuphine for intubating conditions during awake fiberoptic broncoscopy in oral carcinoma surgeries: A randomized comparative prospective study"*** submitted by Dr. Kumar Saurabh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/569/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:*** • In methodology, Flow chart is not given -as it is a randomized controlled study, please include Flow chart. • CRF-not attached **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P82***
83.	Research proposal entitled ***"Comparison of clinical performance of LMA proseal and LMA blockbuster in adult patient undergoing elective laproscopic surgery: prospective randomized controlled study"*** submitted by Dr. Ranjeet Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/600/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:*** • In methodology ,Flow chart is not given- please include Flow chart of the study • Please attach Mallampti I and II criteria. • CRF -not attached. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P83***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

84.	Research proposal entitled ***"Prospective, randomized comparison of LMA protector versus LMA blockbuster for laparoscopic surgery"*** submitted by Dr. Sharon Shiu, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/603/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:*** • SOP Check list should be revised as Point no- 10 (Risk and benefit) not marked appropriately • In methodology .Flow chart is not given – please include as it is a randomized controlled study • CRF -not attached **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P84***
85.	Research proposal entitled ***"Comparison of opioid free and opioid based anaesthesia in patient undergoing thyroid surgery on post operative outcome: a prospective randomized study"*** submitted by Dr. Garima, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/604/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:*** • SOP Check list should be revised as Point no- 6 and 11 (ADR) not marked appropriately –(PI mentioned in Protocol that ADRs to be monitored-Please revise SOP Check list • In methodology Flow chart is not given-please include as it is randomized controlled study • ICF -attached (but Hindi version is incomplete)-PI to attach Complete Hindi version of ICF • CRF and VAS Score -not attached **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P85***
86.	Research proposal entitled ***"Evaluation of different bedside clinical tests in predicting difficult laryngoscopy and intubation in oral cancer surgery patients- An observational study"*** submitted by Dr. Smita Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/585/23 dated 24th May, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • SOP Check list should be revised as Point no-5 (vulnerability) and 10 (Risk and benefit) not marked appropriately • Study design- Prospective observational study (but written in Protocol as Prospective longitudinal study) -PI to clarify • In inclusion criteria -Pregnant & lactating women criteria -not mentioned • CRF -not attached **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P86***
87.	Research proposal entitled ***"To determine role of methylene blue in septic shock as a vasopressor sparing agent: A prospective randomized controlled study"*** submitted by Dr. Adityaparmar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/595/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:*** • In Inclusion criteria-Sex specificity and Lactating women criteria not mentioned • In methodology-Flow chart to be attached as it is a randomized controlled study • APACHE, n SOFA score and CRF -not attached. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-IIA/P87***
II-B	**IMR- Resident**
1-	Research proposal entitled ***"A comparative analysis of histopathological findings in optic nerve in poisoning and snake bite cases"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Anup Kumar Raipuria, JRI, Through his Mentor Dr. Shiuli, Associate Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 155/FMT/23 dated 22nd May, 2023. ***Recommendation of Primary reviewer:*** • In scientific review committee CO-PI is also a member. • Objective: The objective of the study is to find and compare the histopathological changes in the optic nerve between different type of poisoning cases and different types of snake bite cases; types need to be clarified. • Sample size: The researcher assumes prevalence of poisoning 0.03%, a basis for the assumption may give more clarity.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-II B IMR-R/P1***
2.	Research proposal entitled ***"Estimation of time since death of human cadaver in view of cellular changes in cerebrospinal fluid"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Tauheed Anwar, JRI, Through his Mentor Dr. Anshu Priya, Assistant Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 164/FMT/23 dated 27th May, 2023. ***Recommendation of Primary reviewer:*** • In scientific review committee CO-PI is also a member. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. ***Ref. code: XIX-PGTSC-II B IMR-R/P2***
3.	Research proposal entitled ***"Appraisal of salivary biomarkers as skeletal maturity indicators in cleft LIP and palate subjetcs"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Balaji. R, JRII, Through his Mentor Dr. Dipti Shastri, Additional Professor, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 383/Ortho/23 dated 17th May, 2023. ***Recommendation of Primary reviewer:*** • In the study setting the researcher mentions participants' age range between 18-35 however, inclusion criteria reveal age between 7-22 years. • The flowchart needs to be modified. The instruction given in the box on the right side of the sample collection needs to be corrected. • The study procedure needs to be modified as it indicates work is already done. • It would be better to state the description of the procedure for acquiring lateral cephalograms in future tense using the referencing. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-II B IMR-R/P3***
4.	Research proposal entitled ***"Diagnosis of early myocardial infarction by histochemical staining on autopsy"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Fathima Harsha P M, JRI, Through her

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Mentor Dr. Raja Rupani, Additional Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 166/FMT/23 dated 30th May, 2023. ***Recommendation of Primary reviewer:*** • The third objective seems like a directive for creating policy; it might be regarded as a secondary objective. • Is the study started? As the first sentence is written in present tense. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-II B IMR-R/P4***
5.	Research proposal entitled ***"Study of sexual dimorphism on cranial Index in King George Medical University"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Abhipsa Senapati, JRI, Through his Mentor Dr. Raja Rupani, Additional Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 170/FMT/23 dated 30th May, 2023. ***Recommendation of Primary reviewer:*** • The purpose of this study is to evaluate the cranial index. However, it is worth mentioning that the researcher intends to examine the correlation between body statures and hand and foot dimensions in the statistical analysis. This particular aspect is not explicitly mentioned in the proposal or objectives. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-II B IMR-R/P5***
6.	Research proposal entitled ***"Assessment of correlation between biofilm adhesion on different archwires with their surface roughness"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Maheshwar Singh, JRII, Through his Mentor Prof. Gulshan Kumar Singh, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1453/Ortho/23 dated 15th June, 2023. ***Recommendation of Primary reviewer:*** • Is the work done? As description written in quantiitative biofilm measurement are in past tense. . • Hindi ICF needs to be modified with simple and understandable words so that the participant could comprehend it.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-II B IMR-R/P6***
7.	Research proposal entitled ***"Efficacy of pre-operative lugol's Iodine in reducing peri-operative complications in patients with graves' disease following thyroidectomy- A randomized control trial"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Mithum Raam, SR, Through his Mentor Prof. Anand Kumar Mishra, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. 209/23 dated 12th June, 2023. ***Recommendation of Primary reviewer:*** • The study mentions that IEC & RC approval: Nov 2022; Time line is incorrect. Study period is written as Dec 2022, is the study started? **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-II B IMR-R/P7***
8.	Research proposal entitled ***"Prevalence of microsatellite instability and BRCA-1 in epithelial ovarian cancers at molecular and protein level in Northern India"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Richa Singh, JR, Through her Mentor Dr. Preeti Agarwal, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 689/23 dated 7th June, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-II B IMR-R/P8***
9.	Research proposal entitled ***"Correlation between intraoperative quantitative assessment of parathyroid gland perfusion during total thyroidectomy after gland excision using indocyanine green with post-operative hypocalcemia-a prospective interventional study"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Ashwinee Rahalkar, SR through her Mentor Prof. Anand Kumar Mishra,, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/208/23 dated 10th June, 2023. ***Recommendation of Primary reviewer:*** • Only of 2 experts are there in the scientific review committee of the project. • The items of checklist are not ticked.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Timeline is written as 1 Dec 2022 to 30 June 2024 is the study started? • In the consent form the aim of the study needs to be written in simple language. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-II B IMR-R/P9***
10.	Research proposal entitled ***"An in-vivo study on release of metal lons and DNA damage in buccal mucosa during fixed orthodontic treatment"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Chandana Himanshu, JRII, Through her Mentor Prof. Amit Nagar, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1458/Ortho/23 dated 19th June, 2023. ***Recommendation of Primary reviewer:*** • In checklist section the type of study is not ticked. • In inclusion criteria, Indian population is to be targeted; this may be written as patient population consulting KGMU, OPD. • Sentences of investigative procedures indicate that proceudure are already one. • Language of Hindi ICF need to be rechecked. **PGTSC Comment:** • As above **PGTSC Decision:** Approval subject to modification. Give changes done in a tabular form. ***Ref. code: XIX-PGTSC-II B IMR-R/P10***
II-B	**MHA**
1.	Research proposal entitled ***"A study on compliance with disabled friendly Hospital guidelines in rehabilitation & Artificial limb centre (RALC) in a tertiary care Government Hospital, Lucknow, India"*** submitted by Dr. Shifa Kausar, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/219/23 dated 13th May, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-II B-MHA/P1***
2.	Research proposal entitled ***"A study on compliance with disabled friendly Hospital guidelines in main building of a tertiary care Government Hospital, Lucknow,"*** submitted by Dr. Saumya Rawat, under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	U.P., Lucknow vide letter no. HA/220/23 dated 13th May, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-II B-MHA/P2***
3.	Research proposal entitled ***"To study national quality assurance standards (NQAS) compliance in In-patient Department (IPD) of endocrine surgery Department in a tertiary care Government Teaching Hospital, Lucknow,"*** submitted by Dr. Saumya Rawat, under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/221/23 dated 13th May, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-II B-MHA/P3***
4.	Research proposal entitled ***"To study national quality assurance standards (NQAS) compliance in operation theatre (OT) endocrine surgery Department in a tertiary care Government Teaching Hospital, Lucknow,"*** submitted by Dr. Mahwish Suhaib, under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/230/23 dated 17th May, 2023. **PGTSC Decision:** Approved ***Ref. code: XIX-PGTSC-II B-MHA/P4***
5.	Research proposal entitled ***"A study on level of compliance with disabled friendly Hospital guidelines in microbiology, Pathology, forensic Medicine and toxicology CV hostel Department in a tertiary care Government Teaching Hospital, Lucknow, India,"*** submitted by Dr. Meenu Pal, under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/295/23 dated 20th June, 2023. **PGTSC Decision:** Approved ***Ref. code: XIX-PGTSC-II B-MHA/P5***
6.	Research proposal entitled ***"A study on level of compliance with disabled friendly Hospital guidelines in gandhi ward, Neurology Department and TG Hostel in a tertiary care Government Teaching Hospital, Lucknow, India,"*** submitted by Dr. Paayas Raj Verma under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/296/23 dated 20th June, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-II B-MHA/P6***
7.	Research proposal entitled ***"A study on level of compliance with disabled friendly Hospital Guidelines in University environment Department, Plastic Surgery and Paediatric Surgery Department in a tertiary care Government Teaching Hospital, Lucknow, India,"*** submitted by Dr. Junaid Ali, under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/294/23 dated 20th June, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-II B-MHA/P7***
II-B	**Research proposal for STS grant**
1.	Research proposal entitled ***"Monitoring of anxiety, pain, and cardiovascular changes during root canal treatment: an observational clinical study"*** sponsored by ICMR STS submitted by Mr. Rishabh Pandey, BDS, through his Mentor Dr. Pragya Pandey, Associate Professor, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 76/Coms&Endo/23 dated 13th May, 2023. ***Recommendation of Primary reviewer:*** • In Hindi ICF language to be modified. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIX -PGTSC-IIB-STS/P1***
II-B	**IMR Student**
1.	Research proposal entitled ***"A morphometric study of retromolar fossa and incidence of finding of retromolar foramen in dry bones"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Mr. Dwiz Dwivedi, BDS 2021, Through his Mentor Dr. Noor Us Saba, Assistant Professor, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 87/ANAT/23 dated 15th May, 2023. ***Recommendation of Primary reviewer:*** • As the study is to be done on madibles of unknown sex on completely anonmyzed sample thus, waiver may be given. **PGTSC Decision:** Waiver of ethical consent granted ***Ref. code: XIX-PGTSC-IIB-IMR-S/P1***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

2.	Research proposal entitled ***"A morphometric study of mandibular foramen, lingual and incidence of accessory mandibular foramina in dry mandible"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Ms. Yashaswi Singh, BDS 2020, Through her Mentor Dr. Pratibha Shakya, Assistant Professor, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 89/ANAT/23 dated 15th May, 2023. **PGTSC Decision:** Waiver of ethical consent granted ***Ref. code: XIX-PGTSC-IIB-IMR-S/P2***
II-B	**IMR Student**
3.	Research proposal entitled ***"IL-23 expression in subjects with ankylosing spondylitis: a case control study"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Mr. Timil Suresh, MBBS 2020, Through his Mentor Dr. Arpit Singh, Associate Professor, Department of Orthopedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 9555/OS/23 dated 12th May, 2023. ***Recommendation of Primary reviewer:-*** • Patient information sheet both in English and Hindi need to be submitted as per SOP of EC KGMU. • Details about where, how and under whom will the IL-23 expression be conducted needs to be submitted. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIX-PGTSC-IIB-IMR-S/P3***
4.	Research proposal entitled ***"Molecular detection of carbapenem sensitivity in klebsiella pneumonia causing ventilator associated pneumonia: A cross sectional observational study"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Mr. Mayank Dhiman, MBBS 2020, Through his Mentor Prof. Avinash Agrawal, Head, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1496/23 dated 20th May, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIB-IMR-S/P4***
5.	Research proposal entitled ***"Effect of post operative antimicrobial therapy on the healing sockets of tooth extractions done for orthodontic purposes-A randomized controlled trial"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Mr. Prakhar Mittal, BDS 2020, Through his Mentor Dr. Amiya Agrawal, Professoe Jr. Grade, Department of Oral & Maxillofacial Surgery, Faculty of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 559/OMSD/23 dated 16th May, 2023. ***Recommendation of Primary reviewer:*** • Please provide a properly filled Patient Information Sheet. **PGTSC Commnet:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIX-PGTSC-IIB-IMR-S/P5***
6.	Research proposal entitled ***"Assessment of sleep quality using Pittsburgh sleep quality index and it' correlation with anxiety level in undergraduate medical student"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Ms. Prachi, MBBS 2021 & Mr. Pragyesh Mishra, MBBS 2021, Through her Mentor Prof. Sandeep Bhattacharya, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3134/PHY/23 dated 26th May, 2023. ***Recommendation of Primary reviewer:*** • Sample size calculation not done –Please include • Patient information sheet –not related to study. **PGTSC Commnet:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIX-PGTSC-IIB-IMR-S/P6***
7.	Research proposal entitled ***"The hormonal profile of fibrocystic breast disease and its correlation with PCOD, BMI, waist-hip ratio, dietary pattern and lifetime physical activity"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Ms. Rachna Singh, MBBS 2020 Through her Mentor Prof. Gitika Nanda Singh, Professor Jr. Grade, Department of Surgery General, King George's Medical University, U.P., Lucknow vide letter no. 1246/23 dated 15th May, 2023. ***Recommendation of Primary reviewer:*** • Sample size calculation not done (only formula is written) • Intramural Short term research Fellowship Grant letter and budget –not attached-please provide. **PGTSC Commnet:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XIX-PGTSC-IIB-IMR-S/P7***
8-	Research proposal entitled ***"Social media impact on self-perceived oral health practices among patients"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Ms. Aruna Singh, BDS 2019 Batch Through her Mentor Dr. Gaurav Mishra, Professor Jr. Grade, Department of Public Health Dentistry, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. 373/PHD/23 dated 15th May, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:**As above ***Ref. code: XIX-PGTSC-IIB-IMR-S/P8***
9.	Research proposal entitled ***"Perceived clinical competence of undergraduate dental students in rendering essential dental services"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Ms. Shivangi Singh, BDS Through her Mentor Prof. Saumyendra Vikarm Singh, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 167/23 dated 7th June, 2023. ***Recommendation of Primary reviewer:*** Approved **PGTSC Decision:**As above ***Ref. code: XIX-PGTSC-IIB-IMR-S/P9***

- Secrency check for incomplete submission will be developed incomplete proposal will be reverted to the proper within 7 days.
- **The next Meeting will be held on 1st September, 2023 from 3.00 P.M. offline.**

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 126th ECM held on 1st September, 2023

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the 126th Institutional Ethics Committee Meeting ***Physically as well as virtually*** held on **1st September, 2023 from 3:00 PM on wards** in the 2nd Floor, Seminar Room, Central Library, King George's Medical University, U.P., Lucknow.

The following Members were present in the Meeting:-

1. Dr. Alok Dhawan -Chairman
2. Dr. Akash Agarwal -Member
3. Dr. Anita Rani - Member
4. Dr. K.K. Yadav -Member
5. Dr. D.N. Upadhyaya - Member
6. Dr. Anupam Mishra -Member
7. Dr. Rajendra Nath -Member
8. Dr. G.G. Agarwal -Member
9. Dr. Shally Awasthi -Member-Secretary, IEC

The following members were not Present in the Meeting:-

1. Dr. Shubha R Phadke - She has given her written comment
2. Mrs. Vasundhara Kumari
3. Mr. Ujjawal Krishna
4. Mrs. Akansha Dubey
5. Dr. A.A. Mahdi
6. Dr. Nisha Mani Pandey

I	Action taken
1-	Clarification of research proposal entitled ***"FOXTROT 2 India: pilot randomised trial evaluating neoadjuvant chemotherapy in older and/or frail patients with locally advanced but operable colon cancer"*** submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1330/23 dated 27th July, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous EC Comment	PI response
Point 6 on page 17, Hindi consent mentions about CMC Ludhiana and not KGMU [Copy paste effect]. Same issue in English consent.	ICF has been updated as per the comment and the same has been attached.
They should check carefully to confirm if the consent is tailored for KGMU.	ICF has been updated as per the comment and the same has been attached.
Who will pay for the chemotherapy, surgery and complications, if they are there?	As this is a Pilot study and we are not proposing any change in treatment but timing, cost of chemotherapy and surgery have to be covered by the participating institution. Sponsor will cover the cost of 1 CT SCAN per patient recruited from KGMU Lucknow. However, If this pilot trial is found to be safe and efficacious then it will lead to the main trial in India and other global south countries which will be funded. The main trial will recruit a larger sample size with more centers involved having the potential to answer questions conclusively regarding our hypothesis and will be a funded trial. Any complications arising from the treatment as per the protocol will be covered through the Insurance for Foxtrot 2 India. Financial considerations are mentioned in the attached letter provided by the sponsor.
What about the issue of compensation?	Any complications arising from the treatment as per the protocol will be covered through the Insurance for Foxtrot 2 India. Financial considerations are letter provided by the sponsor.
These two issues and use of previously used drugs in different protocol - Expert in drug trial need to be consulted.	The drugs used in these trials are exactly the same which are used in routine practice. There is no change in the protocol of the drug administration. The Department of Surgical Oncology,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		KGMU is providing chemotherapy for cancer patients including colon cancer for last 25 years. We have all the expertise to administer the chemotherapy drugs to the patients for this study. In addition we have included Prof. Kirti Srivastava, Department of Radiotherapy, who is also treating the colon cancer patients with these drugs on routine basis. We believe her vast experience as a drug expert will help in the study.
	The IEC of CMC, Ludhiana [list of documents is mentioned in the approval letter but it is not attached] and AIIMS, Rishikesh have approved the trial.	The same has been attached.
	The font of consent should be 14 and the line spacing should be more [1.5 at least]	Changes as per the comment have been updated in the ICF and same has been attached.

EC Comments:

- Kindly provide the insurance

EC Decision: Approved

Insurance received on 2nd September, 2023 by email & valid till 17th August, 20204.

Ref. code: 119th ECM IIA/P10

2- Clarification of research proposal entitled ***"Evaluation of the safety and efficacy of Ganges water phage therapy in H. pylori related dyspepsia: A randomized controlled pilot-trial"*** submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1668/MED/23 dated 10th August, 2023.

Previous EC Comment	PI response
The documents/certificates from government approved labs proving the water is untreated from Ganga river at Prayag should be submitted about quality of water, bacterial content etc. To prove that it is potable.	The water sampling will be done from Rudraprayag not Prayag. The water source has been tested by the state pollution control board government of Uttarakhand. The water from Rudraprayag is safe for drinking without Conventional water treatment and has been classified as "Class A". Please refer to the attached report, page No. 13, serial no. 4 ofthe provided table.
As far as I know, informally that the water in the river is not of quality to be	Please refer to the attached report Page No. 13 serial no. 4 of the provided table.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	used as drinkable	
	The project has ethical issues. Though people may be drinking this water, as medical doctors cannot give it to patients because the city municipality treats river water before supplying to the city homes	No conventional water treatment is required. The report is attached for reference.

Recommendation of Primary reviewer:

- H. pylori dyspepsia of medical condition for which treatment is available. Ganga water is not a medication; hence it cannot be prescribed by a doctor.

EC Comment: As above

EC Decision: Not approved

Ref. code: 121st ECM IIA/P4

3- Clarification of research proposal entitled ***"Effect of prospective bilateral superficial cervical plexus nerve block on post-thyroidectomy headache and cervical pain: A randomised controlled trial"*** submitted by Dr. Pooja Ramakant, Prof. Junior Grade, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/2023/213 dated 15th June, 2023.

Previous EC Comment	PI response
Compensation for injury: What if someone has allergic reaction to drug?	Although those patients who are allergic to the drugs will be excluded, still if they develop allergic reactions, they will be managed as per the guidelines and protocol of LAST (Local Anaesthetic Systemic Toxicity). The above has now been included in the methodology section and the Informed Consent forms.
Objectives very vague Objectives not well defined	Objectives have been modified and rewritten in a better manner: **Primary Objective:** To compare the efficacy of Preoperative Bilateral Superficial Cervical Nerve Block versus no block, on Post-Thyroidectomy Headache and Cervical Pain, as self-perceived by the patient using a Visual Analogue Scale. **Secondary Objective:** To compare intensity of pain in postoperative phase through visual analog scale. To compare total requirement of analgesic consumption

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	during the post-operative stay. To compare the duration of first request for analgesic. To compare the incidence of headache
Elements of RCT need to be mentioned	RCT Protocol has been attached
Data Analysis: What tests?	Student t-test and chi-square test will be used. The significant level will be considered as less than 0.05 (p<0.05). The above has been written now in the Methodology as well.
Implications: accurate dosage….Dosage is not being studied.	Accurate dosage— this phrase has now been removed.
Why subject participation for 4 months?	We believe, as per our department statistics, that 4 months will be enough to achieve the required sample size. Hence, subject participation will be for 4 months, followed by 2 months of data analysis and final report preparation.
Senior Resident can't be Co-Principal Investigator.	Senior Residents name has been removed from the list of Co-Principal Investigators.

Recommendation of Primary reviewer:

- Given the objectives, title can be notified as a Comparative study rather than a RCT.

EC Comment: As above

EC Decision: Approved with condition to change of Title

Ref. code: 123rd ECM IIA/P3

4- Clarification of research proposal entitled ***"Morphological and morphometric analysis of cadaveric lung in North Indian population"*** submitted by Dr. Arvind Kumar Pankaj, Additional Professor, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 263/ANAT/23 dated 14th August, 2023.

Previous EC Comment	PI response
Title	Morphological and Morphometric analysis of adult lung in north Indian population: a cadaveric study
OBJECTIVE	AIM- The aim of the study is to observe the morphology and morphometry of right and left human cadaveric lung. OBJECTIVE- 1. To study the normal length, breadth and

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	thickness of both right and left lungs. 2. To study the variations in the length, breadth and thickness, of both right left lungs. 3. To study the normal fissures, lobes and their variations, of both right and left lung. 4 To study the number of bronchi, pulmonary artery, pulmonary vein.
SAMPLE SIZE	100 Cadaveric Lung (50 Right and 50 Left Lung)
METHODOLOGY	One hundred isolated, adult formalin fixed cadaveric lungs preserved in the dissection hall of anatomy department of King George`s medical University, Lucknow were observed for the study. The lungs belonged to the adult age group between 45-75 years. No gender difference of the lungs was made in this study. Each lung was washed with water and carefully measured using a thread, measuring tape and measuring scale. Length, breadth, thickness of both right and left lungs were measured and recorded. So also the length of fissures (both horizontal and oblique fissures in case of right lung and oblique fissure in case of left lung), their depth were measured and recorded. Any unusual or rare variations were photographed using a DSLR camera.
STATISTICAL SECTION	Sample Size: The sample size formulae used are as follows: (Bernard, 5th edition) n= Sample size σ = Standard Deviation Δ = Difference of means κ= Ratio Z 1-α/2 = Two-sided Z value Z 1-β = Power • Statistical analysis of the data will be performed by using Statistical Package for Social Studies (SPSS) 23 rd version

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	package. • The mean, standard deviations and standard errors of all measurements will be estimated and 95% confidence interval, both upper and lower, will be calculated for all.
INFORMED CONSENT	I had attached waiver with ethical form.

Recommendation of PR:
Provisionally Approved
EC Decision: Approved

Ref. code: 124th ECM IIA/P6

5- Clarification of research proposal entitled ***"Randomized control trial of direct pulp capping using laser"*** submitted by Prof. Rakesh Kumar Yadav, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 238/Coms&Endo/23 dated 11th August, 2023.

Previous EC Comment	PI response
For example, (i) proper formulation of research hypotheses (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc), (v) How double blinding is done, (vi) how the success of masking assessed.	i. Proper formulation of research hypothesis Null Hypothesis: There is no significant difference in the success rates of direct pulp capping in permanent molars when using:- a. Biodentine and GIC, b. Er: YAG Laser and GIC and c. Er: YAG Laser, biodentine and GIC. Alternative Hypothesis: There is a significant difference in the success rates of direct pulp capping in permanent molars when using a. Biodentine and GIC, b. Er: YAG Laser and GIC and c. Er: YAG Laser, biodentine and GIC. ii. Study variables Success was assessed via evaluation of clinical symptoms a. Spontaneous pain b. Sensitivity on percussion and palpation c. Change of colour

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		d. Presence of edema or fistula in the soft tissue e. Pathologic mobility f. Lymphadenopathy of the related region And radiological outcomes a. Radiolucency at periapical or furcation area b. Pathological internal or external resorption c. Widening of the periodontal space d. Calcification of the pulp anal iii. Primary and secondary outcome measures. The primary outcome was the survival of the teeth. Survival was defined as a monosymptomatic tooth that responded to sensibility testing and did not exhibit any periapical changes radiographically. Follow up included pulp testing and periapical radiograph at 1 month and 6 months. The secondary outcome measure was Postoperative pain 1 week after treatment. The patients were asked whether they had any pain during the first 3 days after treatment. iv. Method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.) Random allocation sequence will be generated using random allocation software. v. How double blinding is done, The participants and the examiner will be blinded. The operator will not be blinded. vi. How the success of masking assessed

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Masking cannot be done as Biodentine and laser used during the pulp capping procedure. will be revealed to the principal investigator at the time of surgery.
There seems to be three groups for comparison	This is a multi-arm trial that uses a parallel- group design for the 3 groups included in the study.
The sample size calculation is arbitrary. It is for two group's comparison. It is due to absence of proper research hypothesis	The sample size calculation is based on the research article " Direct pulp capping with calcium hydroxide, mineral trioxide aggregate and biodentine in permanent young teeth with caries- Randomized Controlled trial" by Brizuela et.al.. Sample size n= Z 2 (1-P) x P e 2 here P=13.64% (failure of capping in calcium hydroxide) Z= 1.96 e=5% (margin of error) n= 1.96 2 x (1-0.1364) x 0.1364 0.05x 0.05 ~177 n=177 (for large population >10000) For small population, Sample size for small population N N'=N x n/N+n N'=42 for small population We divide the sample size 42 into three groups in one to one ratio (1:1). The sample size for each group is 14.
The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses.	Data collected will be compiled on to a MS Office excel worksheet & will be subjected to statistical analysis using an appropriate package like SPSS software. Fischer exact test will be used to determine if there are nonrandom associations between two categorical variables.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Keeping alpha error at 5% and Beta error at 20%, power at 80%, p<0.05 will be considered statistically significant. At the time of sample size calculation, beta error was kept to be at 10% and power at 90%.
	How the results will be presented (i)participants flow, (ii)baseline data, (iii)outcomes and estimation, (iv)adverse events, etc.	(i)Participants flow Details of participant flow will be given in the form of a diagram describing the total number of participants enrolled in the study, and those excluded (based on the inclusion and exclusion criteria) or lost to follow up. Any protocol deviations if occur, will be specified. The time period of recruitment along with the period of follow up will be mentioned. (ii)Baseline data A tabular presentation providing details about baseline demographics and clinical Characteristics of the participants will be given. (iii)Outcomes and estimation For every outcome, a summary of study results including the mean and standard deviation will be specified for each group. (iv)Adverse events No adverse events have been reported so far with either of the planned interventions, but in case they occur will be specified.
	Recommendation of PR: Provisionally Approved **EC Decision:** Approved	
		Ref. code: 124th ECM IIA/P7
6-	Clarification of research proposal entitled ***"To evaluate polymorphism in CYP2C19 gene and its impact on clinical outcome in patients of coronary artery disease (CAD) treated with combined clopiogrel and aspirin therapy"*** sponsored by Council of Science & Technolohu, UP (UPCST) submitted by Dr. Akshyaya Pradhan, Prodessor Jr Grade, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 242/Cardio/Res/23 dated 26th July, 2023. ***Recommendation of PR:***	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Provisionally Approved
EC Decision: Approved

Ref. code: 124th ECM IIA/P12

7- Clarification of research proposal ***"Practice pattern of intraoperative fluid therapy in elective major gastrointestinal cancer surgeries in India (I-INFUSE)- A multicentre observational study"*** submitted by Dr. Hemlata, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1006/23 dated 24th August, 2023.

Previous EC Comment	PI response
Ethics form is not attached	Ethics form was attached earlier also and a copy of the same is being attached for your kind perusal.
What constitutes intraoperative fluid is not defined	All the crystalloids, colloids and blood products used during the intraoperative period when the patient is inside the operation theatre constitutes intraoperative fluid.
What is the definition of massive blood loss ?	Massive blood is defined as loss of one blood volume within a 24 hr period OR 50% blood volume loss in 3 hours OR blood loss; 150mL/min
Radical/revision cholecystectomy for cancer needs liver resection : can't be included in inclusion criteria.	Agreed. Radical/revision cholecystectomy has been removed from inclusion criteria.

EC Decision: Approved

Ref. code: 124th ECM IIA/P18

8- Clarification of research proposal ***"Development of risk scoring algorithm using clinical, biochemical, ultrasound and molecular markers to predict preeclampsia-A pilot study"*** sponsored by UP-CST submitted by Prof. Amita Pandey, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/241/23 dated 17th August, 2023.

Previous EC Comment	PI response
If females with 11-16 weeks pregnancy are to be included in the study, inclusion criteria should denote the same.	In this study 100 pregnant women with singleton pregnancy have to be registered in 2 groups depending on their past obstetric history – whether they have a history of PE/Eclampsia in previous pregnancy or not. Pregnant women come for antenatal booking and check-up anytime between missing a

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		period to late in pregnancy. After their first registration visit, they usually come after 2-3 months. In order to avoid missing any patient who comes before 11 weeks of pregnancy, all women coming for ANC booking upto 16 weeks of pregnancy will be registered. Patients who are registered before 11 weeks gestation will be appropriately instructed to come between 11- 16 weeks for the investigations. Pregnant women with singleton pregnancy attending antenatal OPD upto 16 weeks gestation. **Inclusion criteria –** **Group A**- 50 pregnant women with a history of PE/ eclampsia in previous pregnancy **Group B**- 50 pregnant women without any history of PE/ eclampsia in previous pregnancy
	In Hindi consent form space missing between words	Necessary correction made in the Hindi consent form.

Recommendation of PR:
Provisionally Approved
EC Decision: Approved

Ref. code: 124th ECM IIA/P21

9- Clarification of research proposal entitled ***"Effectiveness of meta cognitive therapy in patients with obsessive compulsive disorder"*** submitted by Ms. Ayushi Gaur, Ph.D. Scholar, Amity Institute of Behavioral & Allied Sciences, Amity University Uttar Pradesh, Lucknow under the guidance Dr. Shivali Sharma, Assistant Professor, Amity University Uttar Pradesh, Lucknow. Through Dr. Shweta Singh, Professor Jr. Grade, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1194/Psy/23 dated 1st August, 2023.

Previous EC Comment	PI response
No Guide/Co-Guide from KGMU mentioned on first page of Annexure 1	Dr. Shweta Singh Professor Jr. Grade, KGMU, Lucknow (Co-Guide) Dr. Shivali Sharma Assistant Professor, Amity University, Lucknow (Chief Guide)
Scientific Committee Report not attached	The Doctoral Review Committee has already been attached in the submitted proposal. The topic has been approved by the Committee.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	In Hypothesis, 4 points are repeated	The hypotheses have been modified and approved by guides and co-guides
	Sample Size Calculation elaboration	As per the formulae N=2X (Zα/2+Zβ) ^2 SD^2/D^2 a sample size of 30 is calculated
	Statistical Analysis to be mentioned	The t-test shall be applied to find out the mean difference in both the groups.
	Patient information sheet to be submitted as per SOP	The patient information sheet was already submitted in the prescribed standard operating procedure in the proposal.

Recommendation of PR:
Provisionally Approved
EC Decision: Approved

Ref. code: 124th ECMIIB-Ph.D/P2

10- Clarification of research proposal entitled ***"Association of aldose reductase activity and aldose reductase (ALR 2) gene polymorphism with Diabetic Neuropathy in patients of type 2 diabetes mellitus: A case control study"*** submitted by Dr. Shivam Verma a post MD-PhD. Scholar under the guidance of Prof. Narsingh Verma, Department of Physiology, K.G's Medical University, U.P., Lucknow vide letter no. 3306/PHY/2023 dated 25th August, 2023.
EC Decision: Approved

Ref. code: 125th ECMIB/P3

11- Clarification of research ***"Management of whole body burns-experience at our center and review of literature"*** submitted by Prof. Vijay Kumar, Head, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1064/23 dated 24th August, 2023.

Previous EC Comment	PI response
Scientific Review Sheet ICF to be written as NA	ICF written as NA
None of the decision comments is ticked	The decision comment which states that the proposal is scientifically sound can be forwarded for ethical review is ticked.
Title of the study needs modification	Title changed to " Management of whole body burns- Experience at a tertiary care center and review of literature" as advised.

Recommendation of PR:
Provisionally Approved
EC Decision: Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: 125th ECMIIA/P19

12- Clarification of research proposal entitled ***"Epidemiology of pediatric burn in tertiary care centre of north India-A pilot study"*** submitted by Prof. Vijay Kumar, Head, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1063/23 dated 24th August, 2023.

Previous EC Comment	PI response
Scientific Review Sheet ICF to be written as NA	ICF written as NA
None of the decision comments is ticked	The decision comment which states that the proposal is scientifically sound can be forwarded for ethical review is ticked.
Exclude name of patient from proforma	Name excluded from proforma and given unique ID.
Waiver for Study	Waiver included

Recommendation of PR:
Provisionally Approved
EC Decision: Approved

Ref. code: 125th ECMIIA/P20

13- Clarification of research proposal entitled ***"Association of serum osteocalcin level and bone gamma-cardoxyglutamate protein gene (BGLAP) polymorphism with type2 diabetes mellitus patients in India"*** sponsored by ICMR submitted by Dr. Ritu Tiwari, Ph.D Scholar, under the guidance Prof. Shraddha Singh, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3307/PHY/23 dated 25th August, 2023.

Recommendation of PR:
Provisionally Approved
EC Decision: Approved

Ref. code: 125th ECMIIB-Ph.D/P1

14- Clarification of research protocol no. PMZ-1620/CT-2.4/2022: CT NOC No. CT/ND/37/2022 entitled ***"A multicentre, randomized, double-blind, placebo-controlled, phase-II trial to assess safety, and efficacy of sovateltide in the treatment of hypoxic-ischemic encephalopathy in neonates"*** sponsored by M/s Pharmazz India Pvt. Ltd submitted by Prof. S. N. Singh, Department of Pediatrics, King George's Medical University, U.P., Lucknow, vide letter no. Ped/CT/06/2023 dated 18th August, 2023.

Previous EC Comment	PI response
DCGI CT NOC does not mention KGMU P1/Site	Requirements of CT NOC from DCGI for addition of new clinical trial site or Investigator regarding circular are attached for the reference.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of PR: Provisionally Approved **EC Decision:** Approved ***Ref. code: 125th ECMIIC/P4***
I-B	**Expedited review**
1-	Expedited review of research proposal entitled "***Establishment of genetic diagnostic unit (NIDAN Kendra) at King George's Medical University under the DBT-UMMID initiative***" **Component 1: Prenatal testing for genetic disorders: Beta thalassemia, sickle cell disease and other hemoglobinopathies Component 2: New-born screening for relatively common treatable genetic metabolic disorders-[BT/PR4087/MED/12/900/2021]** submitted by Dr. Mili Jain, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 954 dated 18th July, 2023. ***The above research proposal was forwarded to two reviewers, for review*** ***Recommendation of First reviewer:*** • In the section on 'Use of biological/hazardous material' use of body fluids is ticked as 'No', and proper disposal of material is ticked as 'No' • From the synopsis it is not clear what sample will be obtained from antenatal women and from new born babies? What volume of the sample will be obtained for genetic testing? • Will all antenatal mothers who consent for the study will also be asked to subject their new born children to the same testing? • ICF for the two components of the study have to be different since the source population of subjects is different. ***The above comment forwarded to PI: Reply has not given by PI.*** ***Recommendation of Secondary reviewer:*** • Type of study-It is not basics but clinical and epidemiologic. • Item 7-Use of body fluids-Written No • Use of gene therapy-written Yes as well as No • There should be 2 separate consent forms. One for thalassemia screening and other for Newborn screening. Each should have appropriate information [Patient Information Sheet] about beta thalassemia and newborn screening. Which diseases will be included in NBS? • Last page mentions-Patient Information Sheet, but it is actually CRF. Two separate CRFs will be needed for thalassemia and NBS. **EC Comment:** AS above **EC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: 126th ECM IB/P1***
2-	Expedited review of research proposal entitled "***Unstructured leisure time activity by***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	exposure of ALAN (by electronic devices) during night time in young adults and their association with Biochemical, Epigenetic & clock gene expression" submitted by Dr. Qulsoom Naz, Young Scientist (ICMR-DHR) through her Mentor Prof. Kausar Usman Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1529/MED/2023 dated 18th July, 2023. ***The above research proposal was forwarded to two reviewers, for review.*** ***Recommendation of First reviewer:*** • The study title states there would be Young adults, whereas in the enclosed brief description, the inclusion criteria state healthy young adult students Age 21-45 years…needs clarification. • In the IEC form, subjects are indicated as volunteers but in the description, the place of the study is not mentioned. • Furthermore, the description states subgroup 4B patients without intervention; if the study sample is to be taken as healthy young adults the term patient shouldn't be used. • The data analysis method is not mentioned. • Hindi and English, both ICFs, need to be modified (both ICFs need to be written in an understandable language not copied and pasted from study objectives and methodology) ***The above comment forwarded to PI was reviewed by Primary reviewer:*** ***Recommendation of First Primary reviewer:*** Provisionally approved ***Recommendation of Secondary reviewer:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 126th ECM IB/P2***
3-	Expedited review of research proposal entitled ***"Assessment of acute postoperative pain management practices and pain scores in patients undergoing abdominal surgeries in Indian Hospitals-A multicentre study"*** submitted by Dr. Manish Kumar Agarwal, Associate Professor, Department of Surgery (General), King George's Medical University, U.P., Lucknow vide letter no. 1937 dated 25th July, 2023. ***The above research proposal was forwarded to two reviewers , for review*** ***Recommendation of First Primary reviewer:*** • In Inclusion criteria sex specificity /Pregnant and lactating mother criteria not mentioned. • As it is a multicentric study – PI has not mentioned the number / details of various centers in India • Letter of inclusion of KGMU as one of the center/site for this study by Collaborating. Institute is not attached -Please give letter of inclusion /collaboration. ***The above comment forwarded to was reviewed by Primary reviewer.*** ***Second opinion of First Primary reviewer:*** Provisionally approved ***Recommendation of Secondary reviewer:*** Provisionally approved **EC Decision:** Approved ***Ref. code: 126th ECM IB/P3***
4-	Expedited review of research proposal entitled ***"Exploring small RNA expression in***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	oral potentially malignant disorder (OPMD) and oral squamous cell carcinoma (OSCC)" submitted by Mrs. Jaya Singhal, Laboratory Technician, Department of Health Research Multidisciplinary Research Unit through her Mentor Prof. Raghuwar D. Singh, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. DHR/MRU/3654 dated 17th July, 2023. ***The above research proposal was forwarded to Primary reviewer, for review*** ***Recommendation of Primary reviewer:*** • Sponsor information-The PI has mentioned ICMR as the sponsor and has attached a proposed budget but approval from ICMR is not present. • Sample size calculation has not been done. • The PI is using direct identifiers. • In the section on Data monitoring the answer to the question 'Is there plan of reporting adverse events' is mentioned as 'No' • Patient information sheet has not been attached. ***The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer.*** • Patient information sheet is not attached **EC Comment:** As above **EC Decision:** Approval subject to modification ***Ref. code: 126th ECM IB/P4***
II-A	**New Proposal**
1.	Research proposal entitled ***"Cleft lip and palate, and its's rare presentations"*** submitted by Prof. Vijay Kumar, Head, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 943/23 dated 22nd July, 2023. **EC Decision:** Approved ***Ref. code: 126th ECM IIA/P1***
2.	Research proposal entitled ***"Role of preoperative chlorhexidine mouth wash in the prevention of postoperative respiratory complications in patients with poor oral hygiene undergoing elective surgery-randomized controlled trial"*** sponsored by UPCST submitted by Dr. Shefali Gautam, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/855/23 dated 24th July, 2023. ***Recommendation of Primary reviewer:*** • The study objectives are not clear. • At one place, it says that primary objective of the study is to see the incidence of postoperative complication. • At another place, it says that "the proposed study is a prospective randomized controlled double blind study to identify role of chlorhexidine

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	mouthwash.....". • In the absence of proper formulation of study objectives, it is difficult to plan a study. • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary in the absence of proper research hypothesis. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **EC Comment:** As above **EC Decision:** Revise & Re-submit with response to queries in tabular format. ***Ref. code: 126th ECM IIA/P2***
3.	Research proposal entitled "***Analysis of pitfalls encountered in squash cytology in adult and pediatric patients with central nervous system lesions: A tertiary Hospital experience***" submitted by Dr. Shalini Bhalla, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 984/23 dated 25th July, 2023. ***Recommendation of Primary reviewer:*** • This is a retrospective observational study. • How the pitfalls are evaluated? The outcome variable should be properly defined. • What will be the use of pitfall evaluation? • After identifying the study variables and parameters, the research hypothesis should be properly formulated. • In the absence of research hypothesis, sample size calculation seems to be arbitrary and out of context. • Statistical analysis section is missing. **EC Comment:** As above **EC Decision:** Revise & Re-submit with response to queries in tabular format. ***Ref. code: 126th ECM IIA/P3***
4.	Research proposal entitled "***Prospective analysis in histopathology services in a Government Teaching Hospital: A road map to internal quality assessment***" submitted by Dr. Shalini Bhalla, Additional Professor, Department of Pathology, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. 985/23 dated 25th July, 2023. ***Recommendation of Primary reviewer:*** • In the KGMU proforma where form has to be filled by PI, under the heading of type of study, the PI has marked on both single centre and multicentric study. • In patient information sheet: PI has copy pasted the guidelines. • Aims and Objectives are not clear. Objective should be precise. • It would have been better if data collection instruments were added in the proposal. • Waiver form is wrongly filled. Since this study will be a research without involvement of identification of individual subjects, therefore the appropriate has to be filled. • Being a retrospective study, it would be better if it is mentioned in the study title as well as in the methodology section. **EC Comment:** As above **EC Decision:** Revise & Re-submit with response to queries in tabular format. ***Ref. code: 126th ECM IIA/P4***
5.	Research proposal entitled "***Comparative study of the analgesic and sedation effect between infusion ketamine versus infusion dexmedetomidine in thermal burn injury patient: A prospective randomized study***" submitted by Dr. Anshu Singh, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 971/23 dated 28th July, 2023. ***Recommendation of Primary reviewer:*** • Since researchers will compare the scores in between two groups, in statistical methods tests appropriate for comparing scores should be mentioned. • ICF Hindi is Google translation only. Kindly correct it. ICF should be simple and understandable for a lay man. **EC Comment:** As above **EC Decision:** Revise & Re-submit with response to queries in tabular format. ***Ref. code: 126th ECM IIA/P5***
6.	Research proposal entitled "***Assessment of facial soft tissue changes using 3D stereophotogrammetry in maxillectomy patients before and after prosthodontics rehabilitation: A pilot study***" sponsored by DHR-MRU submitted by Prof. Sunit Kumar Jurel, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 219/23 dated 28th July, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 126th ECM IIA/P6***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

7.	Research proposal entitled "***TLR-6,8 polymorphisms and gene expression in leprosy patients from North Indian population***" sponsored by Council of Science & Technology U.P Vigyam Bhawan submitted by Dr. Swastika Suvirya, Additional Professor, Head, Department of Dermatology Venereology & Leprosy, King George's Medical University, U.P., Lucknow vide letter no. 192/Skin/23 dated 27th July, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 126th ECM IIA/P7***
8.	Research proposal entitled "***Correlation of serum and salivary trace elements in the delineation of prognosis and survival of oral potentially malignant disorders and oral squamous cell carcinoma: A quantitative biochemical analysis***" submitted by Dr. Fahad Mansoor Samadi, Additional Professor, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1785/OP/23 dated 3rd August, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above ***Ref. code: 126th ECM IIA/P8***
9.	Research proposal entitled "***Comparison between the efficacy and safety of nebulized heparin versus nebulized ketamine in patients with inhalational burn injury. A prospective double blinded randomized controlled study***" submitted by Dr. Bhavya Naithani, Assistant Professor, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 897/23 dated 14th July, 2023. ***Recommendation of Primary reviewer:*** • The proforma has been written in Past Tense, giving the impression that the proposed work has already been done. 1- Sample size has not been calculated. 2- The latest reference cited is from 2010. Kindly look for recent references in the field. 3- ICF; Kindly explain the study procedure in detail. The benefits of the study are not clear from the patient's perspective. Justify the statement that there is no risk from the new intervention. 4- A duly filled-out information sheet has not been attached. **EC Comment:** As above **EC Decision:** Revise & Re-submit with response to queries in tabular format. ***Ref. code: 126th ECM IIA/P9***
	Research proposal entitled "***Preventive strategy practices for pressure injury in Indian ICUs (Prevent-PI-ICU)***" submitted by Dr. Sai Saran, Assistant Professor, Department

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1721/23 dated 7th August, 2023. ***Recommendation of Primary reviewer:*** • While on PI states that this is a single center study in annexure 1, on the other hand in point 4 annexure 1 there are indications of it being a multicenter study across ICUs at hospitals in India with involvement of many medical colleges and at least 10-15 institutes/ hospitals. • Point 4 annexure 1 indicates that no patient related data will be collected – then why ICF? • In undertaking by principal investigator – only one name is entered for other institutes whereas others are missing – kindly include. • Since it is stated that current study is online survey with no actual patient related data – then what is the role of patient information sheet. • Kindly include the steps of sample size calculation. Is it the number of beds or number of ICUs or number of hospitals? • How will data and safety monitoring board be involved? What sort of adverse effects are anticipated if there is no actual patient involvement? **EC Comment:** As above **EC Decision:** Revise & Re-submit with response to queries in tabular format. ***Ref. code: 126th ECM IIA/P10***
11.	Research proposal entitled "***A retrospective study of the epidemiological and clinical features of patients presenting with obstructive sleep apnea in a North Indian tertiary care centre***" submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 569/23 dated 2nd June, 2023. ***Recommendation of Primary reviewer:*** • Annexure 1 belongs to another project- kindly submit the relevant one. • To attach patient information sheet in Hindi. • As per point 4 of annexure 1, kindly specify the outcome measures and summarize the anticipated statistical analysis. • To attach the data collection sheet as will be used in the project. **EC Comment:** As above **EC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: 126th ECM IIA/P11***
12.	Research proposal entitled "***Efficacy of low-dose naltrexone for the treatment of burning mouth syndrome. A randomized clinical trial***" submitted by Dr. Akhilanand Chaurasia, Associate Professor, Department of Oral Medicine & Radiology, Faculty of

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 363/OMS&R/23 dated 31st July, 2023. ***Recommendation of Primary reviewer:*** • 5.i No of Subjects is written as 110? Should be 120 (3 grps 40 each for cases, control and placebo) • The language of Hindi ICF needs to be simplified. **EC Comment:** As above **EC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: 126th ECM IIA/P12***
13.	Research proposal entitled "***Indian Childhood acute promyelocytic leukemia study***" submitted by Dr. Nishant Verma, Additional Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2039/Ped/23 dated 8th August, 2023. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** As above ***Ref. code: 126th ECM IIA/P13***
14.	Research proposal entitled "***Integrated clinic-pathological and treatment outcome analysis of extra-cranial malignant germ cell tumors in children and adolescents in India: A retrospective observational study***" submitted by Dr. Nishant Verma, Additional Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2091/Ped/23 dated 10th August, 2023. **EC Decision:** Waiver of IEC approved ***Ref. code: 126th ECM IIA/P14***
II-B	**New Ph. D. Proposal**
1.	Research proposal entitled "***Study on clinical outcomes and drug resistance profile (both phenotypic and genotypic) in MDR tuberculosis patients treated with bedaquiline containing regimen***" submitted by Mrs. Rashmi Ratnam, Ph.D. 2021 Scholar through her guide Prof. R.A.S. Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 597/23 dated 8th June, 2023. ***Recommendation of Primary reviewer:*** • Budget has to be mentioned in Rupees, not by naming the funding agency. • Number of Subjects to be recruited not mentioned. • Why vulnerable subjects have been ticked? • Biobanking is being done: what will be stored, for what purpose? • Hindi patient information sheet should be written properly. Google translate should not be used. • Is the Ph.D. student not going to work in the laboratory?

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• What are the primary and secondary objective measures? • How long will patients be followed? • Why 2 groups have been included? • When and why will drug resistance profiling be done? • Statistical tests and methodology need to be elaborated. **EC Comment:** As above **EC Decision:** Revise & Re-submit with response to queries in tabular format. ***Ref. code: 126th ECMIIB-Ph.D/P1***

2.	Research proposal entitled "***To explore the relationship between periodontitis and preterm delivery with fcγ receptor polymorphisms as genetic susceptibility factor***" submitted by Dr. Iman Baig, Ph.D 2019 Scholar through her guide Prof. Pavitra Kumar Rastogi, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1325/P/23 dated 1st August, 2023.
	Recommendation of Primary reviewer:
	• In the IEC proforma
	  • Sponsor information row related to **1. Indian** the PI has added self.
	  • Status of the review indicates as revised; however, the review is not added in a tabular form.
	  • Statement 7. ii and iv are ticked but, details are nowhere mentioned in the protocol.
	• This is a Ph.D. proposal, which needs to be written thoroughly with a proper, rationale, literature review, and knowledge gap. Further, the proposal should include a robust methodology with the outcome of the study.
	• The questionnaire uses words like bad habit/ adverse habit in personal history, better to use one type of word at both places.
	• Hindi ICF needs to be written in simple sentences, at many places श्र is written as ष, needs to be modified.
	EC Comment:
	As above
	EC Decision: Revise & Re-submit with response to queries in tabular format.
	Ref. code: 126th ECMIIB-Ph.D/P2

3.	Research proposal entitled "***Development and implication of adhesive scaffold for regenerative and mechanical advances in immediate dental implants***" submitted by Dr. Samiksha Dubey, Ph.D. 2022 Scholar through her guide Prof. Rameshwari Singhal, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 133/P/23 dated 7th August, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 126th ECMIIB-Ph.D/P3
4.	Research proposal entitled ***"Seasonality in older adults"*** submitted by Ms. Anamika Srivastava, Ph.D Scholar, Through her Guide Prof. Shrikant Srivastava, Department of Geriatric & Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 275/DGMH/23 dated 4th August, 2023. ***Recommendation of Primary reviewer:*** Approved **EC Decision:** As above *Ref. code: 126th ECMIIB-Ph.D/P4*
II-C	**Review of New Drug Trial**
1.	Research protocol no. EX6018-4915 entitled ***"Effects of ziltivekimab versus placebo on morbidity and mortality in patients with heart failure with mildly reduced or preserved ejection fraction and systemic inflammation"*** sponsored by M/s Nova Nordisk India Pvt. Ltd submitted by Dr. Monika Bhandari, Department of Cardiology, King George's Medical University, U.P.,Lucknow, vide letter no. 234/Cardio/Res/2023 dated 20th July, 2023. ***Recommendation of Primary reviewer:*** • Permission to send sample abroad –Not attached • No other Ethical Issue **EC Decision:** Defer to the next Meeting because quorum was incomplete *Ref. code: 126th ECMIIC/P1*
2.	Research protocol no. VTX958-202 entitled ***"A phase 2, multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of VTX958 in participants with moderately to severely active crohn's disease"*** sponsored by M/s Ventyx Biosciences, Inc. submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/17/2023 dated 20th July, 2023. ***Recommendation of Primary reviewer:*** • CTRI document should be submitted to EC office as soon as trial registration occurs. • Permission to send sample abroad –Not attached • No other Ethical Issue **EC Decision:** Defer to the next Meeting because quorum was incomplete *Ref. code: 126th ECMIIC/P2*
3.	Research protocol no. 1366-0031 entitled ***"A phase II, randomized, placebo-controlled, double-blind, parallel-group, and efficacy and safety study of at least 48 weeks of oral BI 685509 treatment in adults with early progressive diffuse cutaneous systemic sclerosis"*** sponsored by M/s Boehringer Ingelheim Pharma GmbH & Co KG, Birkendorfer submitted by Dr. Puneet Kumar, Associate Professor, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P.,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Lucknow vide letter no. Rh/CT/23/2023 dated 7th August, 2023. ***Recommendation of Primary reviewer:-*** • IEC proforma Clinical Trials sections mentions the study as a Phase III study but the title and detailed synopsis mention it as Phase II study. • DCGI approval doesn't mention KGMU site. • CTRI registration doesn't mention KGMU site. • CTA form is without details and signatures. • IEC form mentions blood sample being sent abroad but protocol mentions list of routine tests which can be done inside the county. • Please specify which tests will be conducted outside India and why? **EC Decision:** Defer to the next Meeting because quorum was incomplete ***Ref. code: 126th ECMIIC/P3***
III-A	**Modification**
1.	Modification of research protocol no. LTE15174 entitled "***ATLAS-OLE: An open label long term safety and efficacy study of fitusiran in patients with Hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX***" submitted by Dr. S.P. Verma, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. CH/CT/09/23 dated 15th July, 2023. ***Recommendation of Primary reviewer:*** • Approved **EC Decision:** Defer to the next Meeting because quorum was incomplete ***Ref. code: 90th ECMIIC/P2***
2.	Modification of research proposal entitled "***Multi-centric prospective cohort study of TB recurrence free cure among microbiologically confirmed new pulmonary tuberculosis patients treated under NTEP with the 4-Month moxifloxacin containing daily regimen"*** submitted by Prof. Rajiv Garg, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. MOXI/56/23 dated 1st August, 2023. ***Recommendation of Primary reviewer:-*** • Approved **EC Decision:** As above ***Ref. code: 110th ECMIB/4***
3.	Modification of research protocol no. CTQJ230A12301 entitled "***A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease"(Horizon Study)*** sponsored by M/s Novartis Health Care Pvt. Ltd submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 264/Cardio/Res/23 dated 1st August, 2023. ***Recommendation of Primary reviewer:-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Approved **EC Decision:** Defer to the next Meeting because quorum was incomplete ***Ref. code: 101stECMIIC/P18***
IVA	**Brought to Ethics Committee after XIX-PGTSC held on 25th July, 2023**
	Minutes of XX-PGTSC of "Institutional Ethics Committee" Meeting held on 24th August, 2023 from 3.00 PM *virtual.* ***The following Members were present in the Meeting:-*** 1. Dr. G.G. Agarwal -Member 2. Dr. Rajendra Nath -Member 3. Dr. Nisha Mani Pandey -Member 4. Dr. D.N. Upadhyaya -Member 5. Dr. A.A. Mahdi - Member 6. Dr. Anita Rani - Member 7. Dr. Shally Awasthi -Convener ***The following Member could not attend the Meeting:-*** 1. Dr. Anupam Mishra -He has sent his written comment
1-	Clarification of research proposal entitled ***"Utility of lung ultrasound, lymphocyte: monocyte and neutrophil: lymphocyte in differentiating bacterial and viral pneumonia in children"*** submitted by Dr. Prachi Joshi, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 615/Ped/23 dated 9th August, 2023. **Previous PGTSC comment:** • Detailed sample size calculation not done. • Guardian and Child Assent form are not complete and English/Hindi versions are not similar. Please resubmit Guardian consent and Child Assent form separately. • Case record form should be given separately from Questionnaire. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P34***
2-	Clarification of research proposal entitled ***"Percutanneous image guided management of vascular malformations and comparison of sclerosing agents and their outcome"*** submitted by Dr. Shaivya Sirohi, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 425/RD/23 dated 10th July, 2023.

Previous PGTSC comments	Response by Principal Investigator
Kindly provide details of all sclerosing agents, which will be used during	Agents to be used are: • Bleomycin

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	intervention along with their indications and efficacy.	• Sodium tertadecyl sulphate • Polodocanol Indications and efficacy attached separately.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XIV-PGTSC-IIA/P109

3- Clarification of research proposal entitled ***"TMJ reconstruction using stock prosthesis: A study"*** submitted by Dr. S. Hemanth Kumar, JRI, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. OMSD/726/23 dated 27th July, 2023.

Previous PGTSC comments	Response by Principal Investigator
The study design is not mentioned	Study design has been mentioned. (Enclosed in Proforma) STUDY DESIGN This is a prospective study and the pre-op study variables will be compared with that of post op variables.
Aims and objectives should be converted into proper research hypothesis in terms of the study variables and parameters.	Aims and objectives has been converted into proper research hypothesis in terms of the study variables and parameters. (Enclosed in Proforma) RESEARCH HYPOTHESIS Stock TMJ prosthesis in patients needing Total Joint Replacement will lead to relief of symptoms and improved study variables involving electromyography study, bite force, maximum inter-incisal opening, pain, functional and aesthetic rehabilitation along with patient satisfaction pre- and post-Operatively.
Sample size calculation is arbitrary. It can be done only after identifying the study design and the research hypothesis.	Sample size calculation has been revised after identifying the study design and the Research hypothesis. (Enclosed in Proforma) SAMPLE SIZE CALCULATION

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Sample Size at 80% Power of Study Sample size is calculated on the basis of proportion of mean pain reduction in the study cases using the formula: Where p1 = 0.67 [=(8.5-2.8)/2.8] expected proportion of mean pain reduction in the study cases p2 = 1.0 expected proportion of mean pain reduction in the study cases under null hypothesis when procedure not applied (Ref. Eric J. Granquist; Peter D. Quinn (2011). Total Reconstruction of the Temporomandibular Joint with a Stck Prosthesis., 19(2), 221–232.) e = 0.5, the attributable risk considered to be clinically significant Type I error, α=5% Type II error β=20% for setting power of study 80%. The sample size is calculated to be n = 6.
	Statistical analysis section is incomplete. It can also be done only after identifying the proper research hypothesis.	Statistical analysis section is completedafter identifying the proper research hypothesis. (Enclosed in Proforma) STATISTICAL ANALYSIS: SPSS latest available version (presently ver 29) and MS Excel will be used for statistical analysis of the data. Continuous variables conforming to a normal distribution will be expressed as mean ± standard deviation. Counting data will be expressed as number and percentages. The unpaired test/ANOVA will be used for inter-group analysis. The χ2 test will be used to compare the proportion data between the groups. Other appropriate statistical tests will be used. In all of the statistical analyses, P < 0.05 will be consid red to be statistically significant.
	The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer:- Approved **PGTSC Decision:** Approval ratified ***Ref. code: XV-PGTSC-IIA/P1***
4-	Clarification of research proposal entitled ***"Trend in utilization of Health Benefit package under AYUSHMAN BHARAT PRADHAN mantra JAN AROGYA in tertiary care institution, Lucknow district"*** submitted by Dr. Ritika Chaturvedi, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 521/CM/23 dated 9th August, 2023. ***Previous PGTSC comments:-*** • For obtaining the objectives of the study, the proper questionnaire is required. • All the other components of the study can be described on the basis of the questionnaire. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P10***
5-	Clarification of research proposal entitled ***"Role of muscle transfer in anal incontinence"*** submitted by Dr. Vikramaditya, SRI, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 922/23 dated 18th July, 2023.

Previous PGTSC comments	Response by Principal Investigator
In SOP-Check list serial no-6-Confidentiality statement ticked as No (please correct or justify)	It is marked no by mistake, response yes
In Inclusion criteria- PI did not mentioned the Age / sex specificity	Both male and female are involved.Age criteria is 10 years to 70 years.
Second opinion of Primary reviewer:- In inclusion criteria age/sex specificity is now given but as the patient will be included are of age from 10 years to 70 years, therefore Child Assent Form should also be attached in addition to the regular ICF. Kindly submit Child Assent form (English and Hindi version)	Attached (English and Hindi)

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Third opinion of Primary reviewer:- PI has attached the Guardian consent form instead of giving child Assent Form PI is requested again to please attaché child assent form.	Copy attached

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Approved

PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P62

6- Clarification of research proposal entitled ***"Assessment of bone mineral density and stone composition in patients with urolithiasis: A prospective study"*** submitted by Dr. Abhijeet Kumar, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 691/Uro/23 dated 14th August, 2023.

Previous PGTSC Comments:

- A reference for the stone analysis method shall be provided along with the lab in which it will be carried out.
- In the Hindi consent form the name of the institution needs to be corrected, instead of King George's Medical University, "George Medical University" is given.
- It is mentioned at many places that the work will start in December 2022, how without ethical clearance study was undertaken. A clarification is needed.

The above comments was forwarded to PR:

- Approved

PGTSC Decision: Approval ratified

Ref. code: XVII-PGTSC-IIA/P8

7- Clarification of research proposal entitled ***"Radiographic evaluation of root canal filling material and its relationship with periapical status in Indian subpopulation"*** sponsored by ICMR, New Delhi submitted by Ms. Nandini Garg, BDS 3rd year student through her Mentor Dr. Vijay Kumar Shakya, Additional Professor, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. nil dated 12th July, 2023.

Previous PGTSC Comments	Response by Principal Investigator
Study design clarification from PI is needed that whether this is Retrospective or Prospective Cross sectional study (as PI mentioned the duration of study in	This study is will observational study in which OPG X-ray taken during January, 2022 to December, 2022 (from any region will be collected and evaluated as

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Protocol is from January 2022 to December 2022)	per protocol.
	PI to submit the approval letter of STS grant from ICMR, New Delhi or send to IEC as soon as he receives the ICMR-grant letter.	Result from STS grant form ICMR is still awaited.

Recommendation of Primary reviewer:-
Approved
PGTSC Decision: As above

Ref. code: XVII-PGTSC-IIB-STS/P2

8- Research proposal entitled ***"Development of cost effective methods for molecular detection of human immunodeficiency virus, hepatitis B C virus"*** sponsored by ICMR, New Delhi submitted by Mr. Rishabh Agarwal, MBBS student through his Mentor Dr. Shivanjali Raghuvanshi, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1105/23 dated 18th Auagust, 2023.

Previous PGTSC comments:-

- Sample size clarification is needed as PI mentioned in Inclusion criteria that 120 Blood units reactive to Viruses (HIV, HBV and HCV) + 120 non reactive blood units will be taken, but in sample size given in Protocol, total 220 blood units are mentioned and In SOP-Checklist -120 subjects are mentioned.
- Moreover, sample size calculation not done. Please give calculated sample size.
- PI is requested to give flow chart of the study.
- Patient information sheet attached but not related to study
- ICMR- STS-Grant letter to be attached or send to IEC as soon PI receive the approval.

The above comment was forwarded to PI was reviewed by PR:-.

- Revised patient information sheet related to study-not attached.
- Flow chart not given
- ICMR-STS-Grant letter –not attached

PGTSC Decision: Reminder should be forwarded to the Principal Investigator.

Ref. code: XVII-PGTSC-IIB-STS/P3

9- Clarification of research proposal entitled ***"To study time-driven activity-based costing of computed tomography scans in a tertiary care Government teaching Hospital, Lucknow"*** submitted by Dr. Moina Wasi Khan, JRI, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/406/23 dated 9th August, 2023.

Previous PGTSC comments	Response by Principal Investigator
The title of the research project should not have location or Institution specifics.	As per your Recommendation I have taken out the word Lucknow from my

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Will suggest removal of the word 'Lucknow'	title. Now my Title is "To study time-driven activity-based costing of computed tomography scan in a tertiary care government teaching hospital"
	In the Methodology, no mention is made of what kind of data will be collected to calculate the per unit time cost of CT Scans.	Process mapping, time-motion study, and activity-based costing are three major tools that will be used to calculate the per unit time cost of CT scan.
	What volume of data will be collected is also not mentioned? How many studies are required to reach a valid conclusion? No data sheet/data collection format is attached to the proforma.	Total of three CT scan machines functional in main KGMU will be taken for the study. All cases of the functional CT scan machine will be taken for the study for a period of one month each.The observational data will be collected for one month each, of all three functional CT scan units to reach a conclusion. As per your recommendation, I have attached the datasheet.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.
Recommendation of Primary reviewer:-Approved
PGTSC Decision: Approval ratified

Ref. code: XVIII-PGTSC-IIA/P7

10- Clarification of research proposal entitled ***"Neurological involvement in sarcoidosis-An ambispective study"*** submitted by Dr. Nagmani, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 227/Neuro/23 dated 21st July, 2023.

Previous PGTSC comments	Response by Principal Investigator
Exact calculated sample size for Ambispective study not given	All consecutive patients enrolled during the study period (18 months) shall be analysed. We expect to enroll approximately 40 patients during the study period.
ICF-E/H –Attached [whether it is for both type –(Retro/Prospective) of study or if only for Prospective study then PI to clarify that how he will take consent for Retrospective study which will be done on previous 5 yrs. registered pts or PI will attach HSRWF for these pts]-PI to	For addressing this issue the study design has been changed from Ambispective study to observational study.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	clarify. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVIII-PGTSC-IIA/P11***
11-	Clarification of research proposal entitled ***"Salivary insulin like growth factor-1 and osteocalcin as skeletal maturity indicators in cleft lip and palate subjects"*** submitted by Dr. Balaji. R, JRII, Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1535/Ortho/23 dated 28th July, 2023. **Previous PGTSC comments:-** • In SOP-Checklist-Vulnerability section (5-vi)-ticked –No, but children are to be included-should be corrected and section 7–vii, viii, ix subsections not ticked properly. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVIII-PGTSC-IIA/P15***
12-	Clarification of research proposal entitled ***"To study the cost associated in managing Bio-Medical waste (BMW) in a tertiary care Government Hospital Lucknow, India"*** submitted by Dr. Mahwish Suhaib under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/255/23 dated 19th July, 2023.

Previous PGTSC comments	Response by Principal Investigator
In all the proposals of the Chief supervisor, co-guide roles are not defined; in the role column only their sign is present.	Role of the Chief supervisor and co-guide has been defined in the role column.
In all proposals, the type of data analysis is not mentioned clearly. This study requires a waiver as it is to assess the cost of BMW in the University, which can be provided.	In methodology, under the head Data Analysis, type of date analysis has been mentioned and highlighted in the protocol.
This study requires a waiver as it is to assess the cost of BMW in the University, which can be provided.	Waiver form is already attached with the protocol. Kindly refer last page of the protocol.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Waiver of Informed Consent approved

PGTSC Decision: As above

Ref. code: XVIII-PGTSC-II B-MHA/P1

13- Clarification of research proposal entitled ***"To study COVID-19 vaccination at district level with focus on wastage multiplication factor (WMF)"*** submitted by Dr. Mahwish Suhaib, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/254/23 dated 19th July, 2023.

Previous PGTSC comments	Response by Principal Investigator
In all the proposals of the Chief supervisor, co-guide roles are not defined; in the role column, only their sign is present.	Role of the Chief supervisior and co-guide has been defined in the role column.
In all proposals, the type of data analysis is not mentioned clearly.	In methodology under the head Data Analysis and Interpretation, type of data analysis is mentioned.
A waiver request is made which can be provided.	Waiver form is already attached with the protocol. Kindly refer last page of the protocol.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Waiver of Informed Consent approved

PGTSC Decision: As above

Ref. code: XVIII-PGTSC-II B-MHA/P2

14- Clarification of research proposal entitled ***"To study nutritional supplements prescribed in a tertiary care Government Hospital Lucknow, India"*** submitted by Dr. Shifa Kausar, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/256/23 dated 19th July, 2023.

Previous PGTSC comments	Response by Principal Investigator
In all the proposals of the Chief supervisor, co-guide roles are not defined; in the role column, only their sign is present.	Role of the Chief supervisior and co-guide has been defined in the role column.
In all proposals, the type of data analysis is not mentioned clearly.	In methodology under the head Data Analysis, type of data analysis has been

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	memtioned and highlighted in the protocol.
This is a pilot study, which is to be carried out in the surgical oncology department only need to be mentioned in the title for clarity.	The title has been modified and surgical oncology department has been incorporated in the title.
An information guide for obtaining the data should be prepared and provided to understand the process of the study.	Observational checklist has been attached as Annexure I & II which willk help to understand the process of the study.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-

Waiver of Informed Consent approved

PGTSC Decision: As above

Ref. code: XVIII-PGTSC-II B-MHA/P3

15- Clarification of proposal entitled ***"To assess the lead time of central medical store in a tertiary care Government Hospital Lucknow, India"*** submitted by Dr. Saumya Rawat, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/257/23 dated 19th July, 2023.

Previous PGTSC comments	Response by Principal Investigator
In all the proposals of the Chief supervisor, co-guide roles are not defined; in the role column, only their sign is present.	Role of the Chief supervisor and co-guide has been defined in the role column.
In all proposals, the type of data analysis is not mentioned clearly.	In methodology under the head Data Analysis, type of data analysis has been mentioned and highlighted in the protocol.
Study duration is written as 8 months but the split in the timeline is of 8 weeks.	In methodology study duration has been changed to 8 weeks and highlighted in the protocol.
In data collection, the PI informs that the data has been collected and records maintained. If data is collected waiver is requested for the analysis?	Data will be collected by an observational checklist and records review, changes made has been highlighted in the protocol. Waiver form is already attached, kindly refer last page of the protocol.
What analysis will be done is not clarified.	In methodology under the head data analysis type of data analysis has been

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	mentioned and highlighted in the protocol.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-
Waiver of Informed Consent approved
PGTSC Decision: As above

Ref. code: XVIII-PGTSC-II B-MHA/P4

16- Clarification of proposal entitled ***"To study cost incurred of compost production, in a tertiary care Government Hospital, Lucknow, India"*** submitted by Dr. Saumya Rawat, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/258/23 dated 19th July, 2023.

Previous PGTSC comments	Response by Principal Investigator
In all the proposals of the Chief supervisor, co-guide roles are not defined; in the role column, only their sign is present.	Chief supervisor and co-guide have been defined in the role column.
In all proposals, the type of data analysis is not mentioned clearly.	In methodology under the head data analysis, type of data analysis has been mentioned and highlighted in the protocol.

The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of Primary reviewer:-
Waiver of Informed Consent approved
PGTSC Decision: As above

Ref. code: XVIII-PGTSC-II B-MHA/P5

17- Clarification of proposal proposal entitled ***"A comparative study on Ayushman Bharat Pradhan mantri Jan Arogya Yojana (AB-PMJAY) packages with respect to the cost incurred in Orthopedic Department of a tertiary care Government Hospital, Lucknow"*** submitted by Dr. Nabila Asif, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/359/23 dated 20th July, 2023.

Previous PGTSC comments	Response by Principal Investigator
In all the proposals of the Chief supervisor, co-guide roles are not defined; in the role column, only their sign is present.	Role of the Chief supervisor and co-guide has been defined in the role column.
In all proposals, the type of data analysis	In methodology under the head Data

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	is not mentioned clearly	Analysis, type of data analysis has been memtioned and highlighted in the protocol.
	In Checklist some of the statements are not filled.	Checklist has been attached as Annesure 1 and 2 with filled statements.
	Inclusion/ exclusion criteria show that the investigator wishes to identify and recruit the patients from dept of orthopedics; however, the study title/ parameters indicate it is to be done by observing the records by talking to the record keepers/coordinators.	In inclusion/exclusion criteria, it has been mentioned that records of the patients will be seen.
	Kindly ensure that patient's case sheets will be revised and all identifiers anonymized.	In ethical consideration it has been mentioned that patients's case sheet will be revised and identity of patient willk remain anonymous.
	The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer. ***Recommendation of Primary reviewer:-*** Approved with condition to apply for waiver of Informed Consent. **PGTSC Decision:** As above ***Ref. code: XVIII-PGTSC-II B-MHA/P6***	
18-	Clarification of proposal proposal entitled "***Exploration of three proteins panel to predict prognosis in oral squamous cell carcinoma***" sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Priya Devi, JRI, Through her Mentor Prof. Shalini Gupta, Head, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, KGMU via letter no. 1760/OP/23 dated 20th July, 2023. **Previous PGTSC comments** • Material and Methods section: What are health patients? Please provide details as also the inclusion and exclusion criteria for the same. ***The above comment was forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XVIII-PGTSC-II B IMR-R/P2***	
19-	Clarification of proposal proposal entitled "***Efficacy of digital reconstruction at varying trauma: an innovative approach in forensic odontology***" sponsored by Office	

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	of Dean, Research & Development, KGMU Lucknow KGMU, UP, Lucknow submitted by Dr. Ayushi Jain, JRI through her Mentor Prof. Shalini Gupta, Head, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, KGMU vide letter no. 1774/OP/23 dated 1st August, 2023. **Previous PGTSC Comment:** • Although consent forms are given but the subjects to be taken for the study are no where defined. What will be the inclusion and exclusion criteria? ***The above comments were forwarded to PR:*** • Approved **PGTSC Decision:** As above ***Ref. code: XVIII-PGTSC-II B IMR-R/P3***
20-	Clarification of proposal proposal entitled ***"Role of adipsin as a biomarker in obesity and it's associated complications (Diabetes, Hypertension and Coronary Artery Disease)"*** submitted by Dr. Vishwa Deepak Tiwari, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no.1431/Med/23 dated 12th August, 2023.

Previous PGTS Comment:	**PI response**
Confirm the number of participants 150/190	Total 190 participants including in the study
Patient Information sheet is not attached	Attached separately
Is adipsin level a routine marker in hypertensive/diabetic/coronary artery disease patients?	Yes, All patients of coronary artery disease
If not, who will bear the cost of the investigation?	Co-Investigators bear the cost, CSIR-CDRI, Lucknow
Is it an additional investigation solely for the purpose of research?	Yes, This study association of serum adipsin levels to other clinical/biochemical markers relation to obesity.
Kindly, tell in which Lab this marker will be assessed and what the cost is incurred for each assay.	Laboratory markers will be assessed by CSIR-CDRI, Lucknow provide a kit and testing a sample.

	The above comments were forwarded to PR: Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P16***
21-	Clarification of proposal proposal entitled ***"Role of triglyceride glucose index as a novel biomarker in patients of type2 diabetes mellitus developing acute coronary syndrome"*** submitted by Dr. Princy Chaudhary, JRI, Department of Medicine, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

George's Medical University, U.P., Lucknow vide letter no. 1432/Med/23 dated 12th August, 2023.

Previous PGTS Comment:	PI response
Please provide affiliations of Dr. Vivek and Dr. Sharad.	**Affiliations-**Dr. Vivek and Dr. Sharad Sharma, Scientst, Clinical & Experimental medicine, CSIR & CDRI, Lucknow.
Please rectify the ICF, as per standard guidelines.	Attached separately
Please provide a properly filled Patient Information Sheet.	Attached separately

Recommendation of Primary reviewer:
The above comments were forwarded to PR:
Approved
PGTSC Decision: As above

Ref. code: XIX-PGTSC-IIA/P18

22- Clarification of proposal proposal entitled ***"Outcome correlation of initial arterial blood gas (ABG) analysis in isolated thoracic injury"*** submitted by Dr. Aman Singh, JRI,Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. 822/TS/23 dated 18th August, 2023.

Recommendation of Primary reviewer:

- Please provide sample size and its calculation
- Please rectify the ICF, as per standard guidelines.
- Please provide a properly filled Patient Information Sheet.

The above comments were forwarded to PR:
Approved
PGTSC Decision: As above

Ref. code: XIX-PGTSC-IIA/P29

23- Clarification of proposal proposal entitled ***"To study and assess role of angioembolization in solid organ injury in blunt trauma abdomen: An ambispective observational study"*** submitted by Dr. Akanksha Kumari, JRI, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. 301/TS/23 dated 10th August, 2023.

Previous PGTSC Comment:-

- Dr. Anita Singh has been shown as Chief Supervisor as well as Co-Supervisor.
- Sample size calculation not provided. Why only 70 subjects will be included in the study?

The above comments were forwarded to PR:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P30***
24-	Clarification of proposal proposal entitled ***"Study of clinicoserological profile of childhood onset systemic lupus erythematosus in a tertiary centre in Northern India"*** submitted by Dr. Vishal Anand, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. 654/23 dated 12th August, 2023. ***Previous PGTSC Comment:-*** • Methodology for estimating immunological parameters not provided. • There is no co-guide for supervision of biochemical investigations. ***The above comments were forwarded to PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P33***
25-	Clarification of proposal proposal entitled ***"Study of prevalence and factors associated with cognitive dysfunction in systemic lupus erythematosus, attending a tertiary care centre"*** submitted by Dr. Rupal Prasad, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. 652/23 dated 12th August, 2023.

Previous PGTS Comment:	**PI response**
There is no co-guide from Pathology or Biochemistry Department for supervising biochemical investigations.	Study is based on only clinical questionnaire. Blood investigation will be performed routinely; no additional investigation will be done for the study. Hence Co-guide from pathology and biochemistry is not necessary for the study.

The above comment was forwarded to PR:
Approved
PGTSC Decision: As above
Ref. code: XIX-PGTSC-IIA/P38

26-	Clarification of proposal proposal entitled ***"Ultra low dose rituximab in rheumatoid arthritis patients refractory or intolerant to esDMARDs and JAK inhibitors- A prospective pilot study from a tertiary care center in Northern India"*** submitted by Dr. Anjum Siddiqui, SRI, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. 653/23 dated 12th August, 2023. ***Previous PGTSC Comment:***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Reference of method for carrying out flow cytometry not provided.

The above comments were forwarded to PR:
Approved
PGTSC Decision: As above

Ref. code: XIX-PGTSC-IIA/P39

27- Clarification of proposal proposal entitled ***"Recurrence and survival analysis of gynaecological cancers in view of current institutional diagnostic practices"*** submitted by Dr. Anjali Gautam, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1104/23 dated 17th August, 2023.

Previous PGTS Comment:	**PI response**
The primary objective should be very specific and clear.	Primary objective: To record and study survival of gynaecological cancer patients in and around Lucknow
The aim says: To study various risk factors associated with…….and behaviour of four common gynaecological cancers, particulary cervical cancer.	Aim: To statistically co-relate findings of various diagnostic tests currently being used in our institute, for gynaecological cancer management. Secondary objective: To study associated risk factors and recurrence in different histological cancer types.
How are these factors measured? Data collection sheet/ questionnaire is required	These factors will be measured from archival data available in department of Pathology, at the time of biopsy submission. Phone numbers of patients who received histopathology reports will be retrieved and patients will be contacted either on phone or during their follow up visits in department of Obstetrics & Gynecology. Questionnaire and data collection excel sheets are being finalised.
Sample size calculation is incorrect. It is for prevalence study.	Sample size is calculated based on previous studies conducted as follows: nevent ≥ $2(Z1-\alpha/2 + Z1-\beta)$ 2 (log4 HR) 2

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Where, n- sample size HR- Hazard ratio (1.25) α- type 1 error (0.05) β-type 2 error (0.2) Z- Z statistic for a level of confidence,for the level of confidence of 95%,which is conventional, Z value is 1.96 Sample size= 316 Reference: Matsuo K, Purushotham S, Jiang B, Mandelbaum RS, Takiuchi T, Liu Y, Roman LD. Survival outcome prediction in cervical cancer: Cox models vs deep-learning model. Am J ObstetGynecol. 2019 Apr;220(4):381.e1-381.e14. doi: 10.1016/j.ajog.2018.12.030. Epub 2018 Dec 21. PMID: 30582927; PMCID: PMC7526040.
	Statistical analysis section is missing.	Statistical analysis is done as follows- A range of bivariate/multivariate statistical analysis will be used to fulfil the objective of the proposed study. The mean and its standard error will be calculated for continuous variable. The categorical variable will be described using frequency distribution and percentages. The t-test, the chi-square test, log rank test and Kaplan meier plots will be used to check the significance of independent variables. Besides cox-proportional hazard model will also be employed to analyse the risk factor of survival of cancers.

The above comments were forwarded to PR:

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Approved
PGTSC Decision: As above

Ref. code: XIX-PGTSC-IIA/P66

28- Clarification of proposal proposal entitled ***"Presepsin as an early biomarker of sepsis in critically ill obstetric patients and its association with fetomaternal outcomes"*** submitted by Dr. Umang Sharma, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1143/23 dated 17th August, 2023.

Previous PGTS Comment:	**PI response**
SOP Check list should be revised as Point no-5,7, 8, 10 not marked appropriately.	SOP check list attached separately.
In Inclusion/Exclusion criteria Age specificity and Pregnant & lactating women criteria not mentioned-Please mention.	Attached separately
Structured Questionnaire, Sepsis-3 criteria and CRF not attached.	Attached separately

The above comments were forwarded to PR:

- Approved

PGTSC Decision: As above

Ref. code: XIX-PGTSC-IIA/P74

29- Clarification of proposal proposal entitled ***"A prospective analysis of the instillation of streptokinase in addition to twist drill or burr hole drainage in the treatment of chronic subdural hematomas"*** submitted by Dr. Vishnu Vardhan. M, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 935/NS/23 dated 17th August, 2023.

Previous PGTS Comment:	**PI response**
The first page having names of investigators has wrongly been attached-Please remove.	Ok, Attached separately
The role of Co-guide separately has not been given by PI	Attached separately
SOP Check list should be revised as Point no.8 and 10 not marked appropriately.	Attached separately

The above comments were forwarded to PR:

- Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: As above ***Ref. code: XIX-PGTSC-IIA/P77***
30-	Clarification of proposal proposal entitled ***"Study of transdermal buprenorphine patch versus oral etoricoxib for postoperative pain management after total knee arthroplasty: A randomized comparative, an open label study"*** submitted by Dr. Sneha, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/920/23 dated 17th August, 2023. ***Previous PGTSC Comments:-*** • Sample size and its calculation is missing in Protocol. • Inclusion/Exclusion criteria–Pregnant and lactating women criteria not mentioned. • Methodology –Flow chart should be added. • Informed Consent Form (ICF) –Not attached. • CRF –Not attached. ***The above comments were forwarded to PR:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIA/P79***
31-	Clarification of proposal proposal entitled ***"A study to assess safety and feasibility of medical treatment discontinuation in asymptomatic patients of improved heart failure with normal left ventricular global longitudinal strain at rest and post-exercise"*** submitted by Dr. Aniket Jaiswal, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1670/Cardio/23 dated 17th August, 2023.

Previous PGTS Comment:	**PI response**
Study design in Protocol is Quasi experimental study (but in Material and method part of Protocol it is written as Randomized double blind trial)–PI to clarify the study design.	Changes done as per your advice. Attached separately.
SOP Check list should be revised as Point no-5,8 & 10 not marked appropriately.	Changes done as per your advice, Attached separately.
In Inclusion criteria, Age and sex criteria not given but in Exclusion criteria Age is mentioned as less than 16 and more than 80–PI to include Age /sex criteria in Inclusion criteria as well.	Exclision and inclusion criteria have been well defined attached separately.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	In methodology Flow chart should be attached.	A flowchart has been added. Attached separately.
	CRF–Not attached.	Attached separately.
	If Pts of less than 18 years are to be included then PI has to submit Child Assent form (E/H) also in addition to regular ICF.	Children are not involved in this study.

The above comments were forwarded to PR:

- Approved

PGTSC Decision: As above

Ref. code: XIX-PGTSC-IIA/P80

32- Clarification of proposal proposal entitled ***"A comparison between fentanyl and nalbuphine for intubating conditions during awake fiberoptic broncoscopy in oral carcinoma surgeries: A randomized comparative prospective study"*** submitted by Dr. Kumar Saurabh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/944/23 dated 17th August, 2023.

Previous PGTSC Comment:

- In methodology, Flow chart is not given -as it is a randomized controlled study, please include Flow chart.
- CRF-not attached

The above comments were forwarded to PR:

- Approved

PGTSC Decision: As above

Ref. code: XIX-PGTSC-IIA/P82

33- Clarification of proposal proposal entitled ***"Comparison of clinical performance of LMA proseal and LMA blockbuster in adult patient undergoing elective laproscopic surgery: prospective randomized controlled study"*** submitted by Dr. Ranjeet Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/945/23 dated 17th August, 2023.

Previous PGTSC Comment:

- In methodology,Flow chart is not given- please include Flow chart of the study
- Please attach Mallampti I and II criteria.
- CRF -not attached.

The above comments were forwarded to PR:

- Approved

PGTSC Decision: As above

Ref. code: XIX-PGTSC-IIA/P83

34- Clarification of proposal proposal entitled ***"Effect of post operative antimicrobial therapy on the healing sockets of tooth extractions done for orthodontic purposes-A randomized controlled trial"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Mr. Prakhar Mittal, BDS 2020 through his Mentor Dr.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Amiya Agrawal, Professoe Jr. Grade, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 786/OMSD/23 dated 19th August, 2023. ***Previous PGTSC Comment:-*** • Please provide a properly filled Patient Information Sheet. ***The above comments were forwarded to PR:*** • Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIB-IMR-S/P5***
35-	Clarification of proposal proposal entitled ***"The hormonal profile of fibrocystic breast disease and its correlation with PCOD, BMI, waist-hip ratio, dietary pattern and lifetime physical activity"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Ms. Rachna Singh, MBBS 2020 through her Mentor Prof. Gitika Nanda Singh, Professor Jr. Grade, Department of Surgery General, King George's Medical University, U.P., Lucknow vide letter no. 2156/23 dated 17th August, 2023. ***Previous PGTSC Comment:-*** • Sample size calculation not done (only formula is written) • Intramural Short term research Fellowship Grant letter and budget not attached-please provide. ***The above comments were forwarded to PR:*** Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IIB-IMR-S/P7***
36-	Clarification of proposal proposal entitled ***"Appraisal of salivary biomarkers as skeletal maturity indicators in cleft LIP and palate subjetcs"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Balaji. R, JRII through his Mentor Dr. Dipti Shastri, Additional Professor, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1572/Ortho/23 dated 16th August, 2023. ***Previous PGTSC Comment:*** • In the study setting the researcher mentions participants' age range between 18-35 however, inclusion criteria reveal age between 7-22 years. • The flowchart needs to be modified. The instruction given in the box on the right side of the sample collection needs to be corrected. • The study procedure needs to be modified as it indicates work is already done. • It would be better to state the description of the procedure for acquiring lateral cephalograms in future tense using the referencing. ***The above comments were forwarded to PR:*** • Approved

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: As above ***Ref. code: XIX-PGTSC-II B IMR-R/P3***
IB	**Clarification of Expedited review**
1-	Expedited of research proposal entitled ***"Screening for micronutrients deficiencies among School going overweight and obese adolescents of Lucknow"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Ajit Kumar Singh, JRI through his Mentor Prof. Reema Kumari, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 445/CM/23 dated 25th July, 2023. ***The above research proposal was forwarded to Primary reviewers, for review:-*** ***Recommendation of Primary reviewers:-*** • Kindly change the name and phone number of Member Seceratary, IEC in the patient information sheet. ***The above comment was forwarded to PI was reviewed by PR:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XIX-PGTSC-IB-IMR-R /P1***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"Study on association of circulatory homocysteine, LP(a) and triglyceride-glucose index in young adult (age<45 years) of acute coronary syndrome subjects: A case control study"*** submitted by Dr. Deeksha Chaurasiya, SR, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 869/23 dated 5th July, 2023. ***Recommendation of Primary reviewer:*** • In the consent form it is given that 3-5 ml of the blood sample will be collected while in the project it is mentioned that 10 ml of fasting blood samples will be collected. Please seek clarification. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Retraction clefts as a prognostic marker in breast cancer-A study from tertiary care center of Northern India"*** submitted by Dr. Fatima Khan, SR, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 878/23 dated 7th July, 2023. ***Recommendation of Primary reviewer:-*** • It is mentioned that 200 cases will be recruited but on what basis this number of cases are going to be taken is not mentioned. Sample size calculation needs to

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	be provided. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Study of expression of CD24 IHC marker in breast cancer cells and its clinic-pathological correlation"*** submitted by Dr. Mantasha Mukhtar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 870/23 dated 5th July, 2023. ***Recommendation of Primary reviewer:-*** • IHC methodology not mentioned **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P3***
4.	Research proposal entitled ***"A study of sarcopenia and its impact on short term post-operative outcomes on malignancies of GI tract"*** submitted by Dr. Dhruv Sharma, SR, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SG/483/23 dated 7th July, 2023. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-IIA/P4***
5.	Research proposal entitled ***"Clinicopathological study of bone tumors with expression of DEPDC1 in osteosarcoma"*** submitted by Dr. Harshpreet Kaur Sall, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 888/23 dated 7th July, 2023. ***Recommendation of Primary reviewer:-*** • It is a retrospective as well as prospective study. It is mentioned that 106 cases will be taken but how many of them will be for retrospective and how many are for prospective study is not mentioned. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Study to assess the morphological characteristics of left main coronary artery in patients undergoing percutaneous coronary intervention using intravascular ultrasound"*** submitted by Dr. Somya Mahalawat, SR, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1382/Cardio/23 dated 30th June, 2023. ***Recommendation of Primary reviewer:-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Although the aim of study is mentioned, objectives have not been properly defined. Needs clarification. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P6***
7.	Research proposal entitled ***"Prevalence of sleep related breathing disorder in heart failure patients and its correlation with ejection fraction, natriuretric peptide levels and diastolic dysfunction"*** submitted by Dr. Manoj Kumar Rai, SR, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1382/Cardio/23 dated 30th June, 2023. ***Recommendation of Primary reviewer:-*** • The duration of study is mentioned as 1st August 2022 to 30th October 2023. Has the study been already undertaken without IEC approval? **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to clarification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Coronary plaque characteristics by computed tomographic coronary angiography in subclinical high-risk subjects"*** submitted by Dr. Nilay Tripathi, SR, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1382/Cardio/23 dated 30th June, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-IIA/P8***
9.	Research proposal entitled ***"To study the role of T-REGULATORY cells in development of inhibitors in hemophilia a patients"*** submitted by Dr. Shada Bari, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 899/23 dated 11th July, 2023. ***Recommendation of Primary reviewer:-*** • Method for modified Bethesda Assay has not been provided in the material and methods section. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Early efficacy of oral lipid lowering therapy in achieving LDL-C targets following acute coronary syndrome"*** submitted by Dr. Ambresh Kumar Gautam, SR, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1382/Cardio/23 dated 30th June, 2023.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer:- • It is mentioned that 500 cases will be recruited but on what basis this number of cases are going to be taken is not mentioned. Sample size calculation needs to be provided. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Role of parasternal intercostals plane block using ropivacaine in attenuating hemodynamic fluctuations at the time of sternotomy in patients undergoing elective cardiac surgery"*** submitted by Dr. Mohd Akhtar Ansari, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/575/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:-*** • In SOP-Checklist-point-6-confidentiality statement and point-12-Compensation -not ticked-please revise • As this is RCT, according to CONSORT guidelines, Flow chart and description of blinding should be given in Protocol -which is not mentioned. • In Inclusion/Exclusion criteria-Sex specificity and pregnant & lactating women criteria not mentioned • Patient information sheet -not related to study-please revise **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P11***
12.	Research proposal entitled ***"A prospective observational study on impact of injection of plasma rich fibrin around the anastomotic sites and the leak rates after major surgical procedures"*** submitted by Dr. Arun M, SR, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SG/497/23 dated 14th July, 2023. ***Recommendation of Primary reviewer:-*** • SOP-Checklist -not marked properly-please revise • Protocol is not complete and not in the given format -Please revise and resubmit. **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P12***
13.	Research proposal entitled ***"Screening for CCR5 ΔA 32 variant mutation in exposed uninfected spouse of HIV-1 patients: a potential target of hematopoietic stem cell***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	transplantation in HIV" submitted by Dr. Sahivangi Nayak, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 947/23 dated 18th July, 2023. ***Recommendation of Primary reviewer:-*** • In Scientific Review Committee, the name of one of the Co-guides (Prof. U S Singh) is there-please clarify or revise SRC. • In Inclusion criteria - Age specificity & Pregnant and lactating women criteria not mentioned • Case record form is incomplete –Please attach proper CRF **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P13***
14.	Research proposal entitled ***"Immunohistochemical expression of col11A1 & KI67 breast carcinoma and its correlation with tumor infiltrating lymphocytes and clinicopathological parameters"*** submitted by Dr. Somya Agarwal, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 953/23 dated 19th July, 2023. ***Recommendation of Primary reviewer:-*** • In Inclusion criteria-Age specificity & Pregnant and lactating women criteria not mentioned. • How PI will assess/take consent for Retrospective part of the study which will be done on previous 1 year registered patients or PI will attach HSRWF for these patients –PI to clarify. • CRF has not been attached-please attach. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format.decision. ***Ref. code: XX-PGTSC-IIA/P14***
15.	Research proposal entitled ***"Profiling of T cells in newly diagnosed ITP patients and their correlation with response to steroid therapy"*** submitted by Dr. Radhika Singh, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 946/23 dated 18th July, 2023. ***Recommendation of Primary reviewer:-*** • In Inclusion criteria-Age range and sex specificity of patients -not mentioned. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject tot modification ***Ref. code: XX-PGTSC-IIA/P15***
16.	Research proposal entitled ***"Elevated selenoprotein p levels in thalassemia major***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	patients" submitted by Dr. Aashi Singhal, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 877/23 dated 6th July, 2023. ***Recommendation of Primary reviewer:-*** • In Inclusion criteria – Cases and control pts and Pregnant and lactating women criteria not mentioned. • Study design is given as Prospective study but it seems to be Prospective case control study-PI to clarify and modify in protocol. • In Methodology- grouping of patients not described and Flow chart of the study not given-PI to give detailed methodology with Flow chart. • CRF-not attached **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P16***
17.	Research proposal entitled ***"Safety and efficacy of azathioprine in the treatment of paradoxical reaction in patients with tuberculous meningitis: A randomized clinical trial"*** submitted by Dr. Saritesh Kumar Thakur, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 291/Neuro/23 dated 17th July, 2023. ***Recommendation of Primary reviewer:-*** • In SOP-Checklist -Point-6 -confidentiality statement- ticked as No, Point-7 -use of body organ /fluids not ticked for taking CSF -Please revise • Detailed sample size calculation -not done (written that calculation will be done by sample size calculator along with reference)-please give calculated sample size • CTRI document after registration should be send to office of Ethics Committee as soon as it will get registered (as it is RCT study) • Please attach diagnostic criteria for TBM according to Marais et al **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P17***
18.	Research proposal entitled ***"A study on episodic memory impairments and functional connectivity networks using resting state functional MRI in patients of intractable mesial temporal lobe epilepsy- A prospective observational study"*** submitted by Dr. Om Prakash, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 290/Neuro/23 dated 17th July, 2023. ***Recommendation of Primary reviewer:-*** • In Inclusion criteria- Pregnant & lactating women criteria not given • In SOP Checklist-Point 6- Confidentiality -not ticked • Sample size calculation not done

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Study design should be Prospective observational case control study -PI to clarify • All mentioned tools for study and questionnaire -not attached • CV of Dr. Uttam Kumar (Addl. Prof.) ,CBMR-SGPGI ,Lucknow should be attached • PI to clarify that whether all pts /control subjects after recruitment will go to SGPGI for fMRI (whether it is practical) **PGTSC Comment:** As above **PGTSC Decision:** Revise & Re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P18***
19.	Research proposal entitled ***"A study of emotional dysregulation in adolescents with conversion disorder"*** submitted by Dr. Yogesh Gupta, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1092/Psy/23 dated 18th July, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-IIA/P19***
20.	Research proposal entitled ***"Study of psychiatric morbidity, coping and quality of life in patients with burn injury"*** submitted by Dr. Rakshit Tripathi, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1091/Psy/23 dated 18th July, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-IIA/P20*** ***(Primary Reviewer: Dr. Rajendra Nath)***
21.	Research proposal entitled ***"Early exposure to screen in children presenting with autistic symptoms: An observational study"*** submitted by Dr. Shivank Tomer, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1090/Psy/23 dated 18th July, 2023. ***Recommendation of Primary reviewer:-*** • Guardian consent form instead of regular ICH in both English /Hindi version should be attached. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P21***
22.	Research proposal entitled ***"A study of screen use profile, internet addiction, and cyberchondria in patients with unipolar depression"*** submitted by Dr. Isha Prakash,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1097/Psy/23 dated 19th July, 2023. ***Recommendation of Primary reviewer:-*** • Kindly provide a properly filled Patient Information Sheet. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P22***
23.	Research proposal entitled ***"Therapeutic effect of ketamine nebulization in acute respiratory distress syndrome: A randomized controlled trial"*** submitted by Dr. Amna Khatoon, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/588/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:-*** • Kindly provide a properly filled Patient Information Sheet. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P23***
24.	Research proposal entitled ***"Prospective cohort study to determine the safety of direct discharge to home from Indian ICU"*** submitted by Dr. Shikha Yadav, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/586/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:-*** • Kindly provide a properly filled Patient Information Sheet. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P24***
25.	Research proposal entitled ***"To compare the impact of mccoy, mcintosh and video laryngoscope on intracranial pressure in supratentorial tumor surgery using ultrasonography measurement of optic nerve sheath diameter: A randomized control study"*** submitted by Dr. Sunanda Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/583/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:-*** • Kindly provide a properly filled Patient Information Sheet. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P25***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

26.	Research proposal entitled ***"A study of sexual functioning in male subjects with alcohol dependence"*** submitted by Dr. Saikat Sahu, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1123/Psy/23 dated 20th July, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-IIA/P26***
27.	Research proposal entitled ***"A study of expressed emotions and family accommodation in adolescents with obsessive compulsive disorder"*** submitted by Dr. Rahul Saini, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1124/Psy/23 dated 20th July, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-IIA/P27***
28.	Research proposal entitled ***"Expression of pdl1 in renal cell carcinoma and its clinicopathological correlation"*** submitted by Dr. Amit Kumar Verma, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 960/23 dated 20th July, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-IIA/P28***
29.	Research proposal entitled ***"Socioeconomic problems of ICU survivors identified by structured follow up critical care clinic: a prospective observation study"*** submitted by Dr. Namrata Shukla, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/598/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:-*** • Kindly provide properly filled patient Information Sheet. Please provide detailed information about the procedure to patient in the Informed Consent form. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P29***
30.	Research proposal entitled ***"Role of metal alloy impregnated foley's catheter in catheter associated urinary tract infection in ICU patients: A prospective randomized comparative study"*** submitted by Dr. Naman Gupta, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Anaes/574/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:-*** • Kindly provide properly filled Patient Informed Sheet. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P30***
31.	Research proposal entitled ***"A study of prevalence and correlates of DHAT syndrome in young males diagnosed with depression"*** submitted by Dr. Abhay Narayan Dwivedi, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1114/Psy/23 dated 19th July, 2023. ***Recommendation of Primary reviewer:-*** • Approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-IIA/P31***
32.	Research proposal entitled ***"Prevalence and correlates of obsessive compulsive symptoms and obsessive compulsive disorder in patients of schizophrenia"*** submitted by Dr. Rahul, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1113/Psy/23 dated 19th July, 2023. ***Recommendation of Primary reviewer:*** • Null hypothesis is not properly defined. The correlation is measured between two continuous variables, not between "prevalences". • The sample size calculation is not clear. The right formula is required. • The statistical section is very general. It should be specific to the hypothesis and objectives. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P32***
33.	Research proposal entitled ***"Additive effect of nitroglycerine spray with lignocaine spray lignocaine spray alone on haemodynamic responses to laryngoscopy and endotracheal intubation a comparative study"*** submitted by Dr. Vasioullah Khan, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/577/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:*** • Title should be: ""Additive effect of nitroglycerine spray with lignocaine spray and lignocaine spray alone on haemodynamic responses to laryngoscopy and endotracheal intubation: a comparative study". • The study design is "prospective cohort study". • The patients will be divided randomly among two cohorts. • Give the details of randomization.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Sample size calculation is not clear. Explain the different parameters (standard deviation, mean etc.) used in the formula. What are the variables whose mean and standard deviations are used? Actually the research hypothesis should be stated in terms of parameters of the study design. • The statistical section is very general. It should be specific to the hypothesis and objectives. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P33***
34.	Research proposal entitled ***"Role of soluble triggering receptor expressed on myeloid cells-1 (sTREM-1) in neonates with early and late-onset neonatal sepsis"*** submitted by Dr. Shradha Gupta, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 501/23 dated 22nd July, 2023. ***Recommendation of Primary reviewer:*** • It is not clear whether it is a comparative study (Comparison between sTerM-1 levels of two kinds of neonates) or correlation study (Correlation or association between SterM-1 level and severity of infection). • The severity of infection has to be defined. • The sample size formula is for prevalence study. Anyway, it can be formulated after clarification of "primary objective" as in point 1. • Statistical analysis section is missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P34***
35.	Research proposal entitled ***"Impact of left bundle branch area pacing vs right ventricular apical pacing on cardiac function on intermediate (3 Month) term"*** submitted by Dr. Usha Kiran Kurrey, SR, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1382/Cardio/23 dated 30th June, 2023. ***Recommendation of Primary reviewer:*** • It is a prospective cohort study. • Two groups (cohorts) are being compared. • The study variables (including outcome variable "LV systolic function") and study parameters should be exclusively defined. • The primary objective should be converted into research hypothesis using the study parameters. • The sample size calculation is arbitrary. It should be specific to the research hypothesis. • The statistical analysis section is general. It should be specific to the research

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P35***
36.	Research proposal entitled ***"Efficacy of microvascular couplers for venous microanastomosis in the reconstruction of oral defects"*** submitted by Dr. Ranjeet Singh, JR, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 730/OMFS/23 dated 27th July, 2023. ***Recommendation of Primary reviewer:*** • This seems to be a comparative study. • The control group should be properly defined. • The null hypothesis is not properly defined. It should be defined in terms of study parameters and variables, which should be identified for the study. • The sample size is for prevalence study. It should be specific to the research hypothesis. • The statistical analysis section is general. It should be specific to the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P36***
37.	Research proposal entitled ***"A study of weekly brief telephonic intervention in patients with alcohol Dependence"*** submitted by Dr. Shobhit Nain, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1127/Psy/23 dated 20th July, 2023. ***Recommendation of Primary reviewer:*** • The outcome "Cumulative abstinence duration" should be exclusively defined. Its method of measurement should be outlined. • The null hypothesis is defined in terms of the parameter (e.g. mean, proportion etc.) not the variables. • How the controls are selected. The detail is required. • Sample size calculation is arbitrary. It can be defined after properly defining the research hypothesis. • Statistical analysis section is missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P37***
38.	Research proposal entitled ***"Clinical audit on peripartum and postpartum***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	hysterectomy at a tertiary care center and its outcome" submitted by Dr. Ananya Verma, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/935/23 dated 1st August, 2023. ***Recommendation of Primary reviewer:*** • The primary objective is not clear. It says to find "incidence" and "risk factors". • The two objectives are completely different paradigms. Both require different kinds of study designs and methods. • The primary objective should be specific and converted into a proper research hypothesis involving study variables and study parameters. • In the absence of proper hypothesis, sample size calculation, methodology etc. has no meaning. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P38***
39.	Research proposal entitled ***"To evaluate the additional diagnositic role of thoracoscopic pleural lavage and brush in undiagnosed exudative pleural effusion"*** submitted by Dr. Ravi Kant Pandey, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 935/PDCC/23 dated 31st July, 2023. ***Recommendation of Primary reviewer:*** • In the title word "additional" is not clear. IN addition to "what"? • Aim and objective is not clear. How "diagnostic role of thoracoscopic pleural lavage and pleural brush" is measured? • The study variables and parameters should be exclusively identified. • Research hypothesis should be formulated in terms of the study parameters. • Sample size calculation is arbitrary. It should be done in accordance to the proper research hypothesis. • Methodology and statistical analysis section should be properly explained. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P39***
40.	Research proposal entitled ***"A comparative study of maternal serum lactate level during pregnancy and after delivery and it's correlation with fetomaternal outcome"*** submitted by Dr. Pratibha Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/934/23 dated 1st August, 2023. ***Recommendation of Primary reviewer:*** • Aims & Objectives gives a list of measuring different maternal lactate levels. • No proper research hypothesis is formulated.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• In the absence of research question, everything does not seem into proper place. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P40***
41.	Research proposal entitled ***"To compare opioid free and opioid based anaesthesia techniques for intraoperative hemodynamic stability and overall outcome in patients undergoing supratentorial craniotomy"*** submitted by Dr. Prachi, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/570/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:*** • It is a prospective cohort comparative study. • Two groups are being compared. These groups should be exclusively defined. Randomization will be performed in allotting the subjects to the two groups. Method of randomization should be explained. • Research hypothesis should be defined in terms of the parameters after identifying these from the study. • Sample size calculation is arbitrary. It can be formulated only after formulating the proper research hypothesis. • The statistical analysis section is very general. It should be specific to the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P41***
42.	Research proposal entitled ***"Comparative study between analgesic effect of conventional radio freouency vs pulsed radio frequency lesioning of glossopharyngeal nerve in patients of oropharyngeal cancer suffering from orofacial pain"*** submitted by Dr. Yashika Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/594/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:*** • It is a prospective cohort comparative study. • Two groups are being compared. These groups should be exclusively defined. Randomization will be performed in allotting the subjects to the two groups. Method of randomization should be explained. • Research hypothesis should be defined in terms of the parameters after identifying these from the study. • Sample size calculation is arbitrary. It can be formulated only after formulating the proper research hypothesis.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The statistical analysis section is very general. It should be specific to the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P42***
43.	Research proposal entitled ***"To compare the efficacy of intravenous ketamine, fentanyl and dexmedetomidine infusions on hemodynamic controland overall outcome in paediatric infraumbilical surgeries: prospective randomized controlled study"*** submitted by Dr. Abdul Haseed, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/591/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:-*** • Section on subject selection/biological material/patient information sheet/risks and benefits incompletely filled. • Assent form for children not attached. • Study does not have any co-supervisor from General Surgery/Paediatric Surgery. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P43***
44.	Research proposal entitled ***"The prognostic value of lactate albumin ratio and prob natriuretic peptide for predicting 28 days mortality in burn patients presenting to the burn intensive care unit: A prospective study"*** submitted by Dr. Surabhi, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/605/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:-*** • Section on Vulnerable subjects incorrectly filled. • Section on biological material ticked as 'No' but blood samples being collected. • Section on patient information sheet/risks and benefits incomplete. • Who will bear the cost of the Investigators? **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P44***
45.	Research proposal entitled ***"Comparison of IL-6, procalcitonin and CRP in the post-operative courses after lung decorication"*** submitted by Dr. R. Sankara Narayanan, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/580/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:-***

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Scientific review committee signatures incomplete. • Use of body fluids is ticked as 'No' but serum markers are being used. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P45***
46.	Research proposal entitled ***"Quantifying the risk association between size of lesions of endodontic origin and systemic inflammatory burden: A clinicobiochemical study"*** submitted by Dr. Priya Pal, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 218/Coms&Endo/23 dated 31st July, 2023. ***Recommendation of Primary reviewer:-*** Approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-IIA/P46***
47.	Research proposal entitled ***"Effect of musical therapy on hemodynamic parameters and inflammatory markers in patients undergoing surgery for varicose veins under spinalanaesthesia"*** submitted by Dr. Mohd Pervez Alam, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/582/23 dated 24th May, 2023. ***Recommendation of Primary reviewer:-*** • IEC form incompletely filled **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P47***
48.	Research proposal entitled ***"Clinico-pathological study of cases of oropharyngeal squamous cell carcinoma at a tertiary care centre with evaluation of human papilloma virus status"*** submitted by Dr. Suteerth Vajpeyi, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1039/23 dated 5th July, 2023. ***Recommendation of Primary reviewer:-*** • In a clinicopathological study, 'Use of Biological material' is ticked as 'No. Use of organs/body fluids is ticked as 'No' **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIA/P48***
II-B	**MHA**
1.	Research proposal entitled ***"To study out-patient Department (OPD) in Respiratory Medicine Department of a tertiary care Government Hospital, Lucknow"*** submitted

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	by Dr. Nabila Asif through her guide Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/331/23 dated 6th July, 2023. ***Recommendation of Primary reviewer:-*** • Approved waiver may be given. **PGTSC Decision:** Waiver of Informed Consent approved ***Ref. code: XX-PGTSC-II B-MHA/P1***
2.	Research proposal entitled ***"To study national quality assurance standards compliance in O.T. of Urology Department in a tertiary care Government teaching Hospital, Lucknow"*** submitted by Dr. Nabila Asif through her guide Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/329/23 dated 6th July, 2023. ***Recommendation of Primary reviewer:-*** • Sample size for patient interview/staff interview not mentioned. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-II B-MHA/P2***
3.	Research proposal entitled ***"A study on compliance with disabled friendly Hospital Guidelines in Girls hostel of a tertiary care Government Hospital Lucknow, India"*** submitted by Dr. Stuti Mishra through her guide Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/342/23 dated 13th July, 2023. ***Recommendation of Primary reviewer:-*** Waiver of Informed Consent approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-II B-MHA/P3***
4.	Research proposal entitled ***"To study on compliance with disabled friendly Hospital Guidelines in Pediatric and Ophthalmology Department in a tertiary care Government Hospital, Lucknow, India"*** submitted by Dr. Nabila Asif through her guide Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/330/23 dated 6th July, 2023. ***Recommendation of Primary reviewer:-*** • Waiver of Informed Consent approved. **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-II B-MHA/P4***
5.	Research proposal entitled ***"To study on compliance with disabled friendly Hospital Guidelines in dental department of a tertiary care Government Hospital, Lucknow, India"*** submitted by Dr. Monika through her guide Dr. Nitin Dutt Bharadwaj, Associate

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/339/23 dated 13th July, 2023. ***Recommendation of Primary reviewer:-*** • Waiver of Informed Consent approved. **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-II B-MHA/P5***
6.	Research proposal entitled ***"To study calculate the average cost of haemodialysis that a patient has to bear in a tertiary care Government Hospital in Lucknow."*** submitted by Dr. Monika through her Guide Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/340/23 dated 13th July, 2023. ***Recommendation of Primary reviewer:-*** Waiver of Informed Consent approved. **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-II B-MHA/P6***
7.	Research proposal entitled ***"To study calculate the average lead time in procurement of surgical items in a tertiary care Government Hospital in Lucknow."*** submitted by Dr. Monika through her Guide Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/338/23 dated 13th July, 2023. ***Recommendation of Primary reviewer:-*** Waiver of Informed Consent approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-II B-MHA/P7***
8.	Research proposal entitled ***"To study on compliance with disabled friendly building guidelines in central library, new Teaching block and atal scientific convention centre in a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Seema Khan through her Guide Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/368/23 dated 24th July, 2023. ***Recommendation of Primary reviewer:-*** Waiver of Informed Consent approved. **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-II B-MHA/P8***
9.	Research proposal entitled ***"To study on level of compliance with disabled friendly Hospital Guidelines in PHI building, registrar office, VC office in a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Deepu Sharma through her guide Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	HA/369/23 dated 24th July, 2023. ***Recommendation of Primary reviewer:-*** Waiver of Informed Consent approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-II B-MHA/P9***
10.	Research proposal entitled ***"To study on compliance with disabled friendly Hospital Guidelines in shatabdi phase 1 and 2 buildings of a tertiary care Government Teaching Hospital, Lucknow, India."*** submitted by Dr. Diksha Dwivedi through her guide Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/370/23 dated 24th July, 2023. ***Recommendation of Primary reviewer:-*** Waiver of Informed Consent approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-II B-MHA/P10***
11.	Research proposal entitled ***"A comparative study on Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) packages with respect to the actual cost incurred in Neurosurgery Department of a tertiary care Government Teaching Hospital, Lucknow"*** submitted by Dr. Stuti Mishra through her Guide Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George`s Medical University, U.P., Lucknow vide letter no. HA/371/23 dated 24th July, 2023. ***Recommendation of Primary reviewer:-*** Waiver of Informed Consent approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-II B-MHA/P11***
12.	Research proposal entitled ***"A study on the level of compliance with disabled friendly Hospital guidelines in Obstetrics & Gynaecology Department and Buddha hostel in a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Sakshi Pathak through her guide Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/373/23 dated 26th July, 2023. ***Recommendation of Primary reviewer:-*** Waiver of Informed Consent approved **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-II B-MHA/P12***
13.	Research proposal entitled ***"A study on compliance with disabled friendly Hospital guidelines in the department of anatomy, biochemistry, physiology and preventive medicine/community medicine (PMS) of a tertiary care Government Hospital, Lucknow, India"*** submitted by Dr. Vishika Singh through her guide Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. HA/374/23 dated 26th July, 2023. ***Recommendation of Primary reviewer:-*** • Waiver of Informed Consent Form may be granted. **PGTSC Decision:** As above ***Ref. code: XX-PGTSC-II B-MHA/P13***
IIC	**Nursing KGMU Institute**
1.	Research proposal entitled ***"A descriptive study to assess the perception regarding nursing profession among intermediate students of Lucknow, U.P."*** submitted by Ms. Shashi Gautam, Ms. Shikha Mall, Ms. Shikha Pal, Mr. Shiv Kumar Kushwaha, Ms. Shivani Verma, Ms. Shivanshi Srivastava, Mr. Shubham Pal, Ms. Sneha Verma, Mr. Subodh Kumar, Ms. Sushmita Tadav through their Guide Ms. Aditi Mecarty & Mrs. Jyoti Grace Masih, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1069/23 dated 28th July, 2023. ***Recommendation of Primary reviewer:*** • Kindly provide Patient Information Sheet as per EC SOP. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIC/P1***
2.	Research proposal entitled ***"A study to assess the social stigma and familial attitudes related to infertility among women with infertility attending infertility clinic at Queen Mary Hospital, KGMU, Lucknow"*** submitted by Ms. Swati Mishra, Ms. Sweta Yadav, Ms. Tanu Yadav, Mr. Tanveer Rashid, Mr. Vaibhav Singh, Ms. Vibha Yadav, Mr. Sandeep Kumar through their guide Ms. Sarita Singh & Mrs. Mathivathani M, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1072/23 dated 28th July, 2023. ***Recommendation of Primary reviewer:*** • Kindly provide Patient Information Sheet as per EC SOP and brief plan of statistical analysis regarding establishing association & correlation between variables as stated in objectives of study. **PGTSC Comment:** As above **PGTSC Decision:** Revise & resubmit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIC/P2***
3.	Research proposal entitled ***"A study to assess the level of stress and coping strategies adopted by primigravida Mother admitted in antenatal ward, department of Obstetrics and Gynecology KGMU, Lucknow."*** submitted by Ms. Pratibha, Ms. Preeti Yadav, Ms. Priya Mishra, Ms. Priyanka Ghauhan, Ms. Priyanka Ghosh, Ms. Priyanshi Patel, Mr. Ravi Kumar, Ms. Reema, Ms. Rekha Singh, Ms. Renu Verma through their guide Mrs. Suman Lata, Clinical Instructor, Department of KGMU College of Nursing, King

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no.1074/23 dated 28th July, 2023. ***Recommendation of Primary reviewer:*** • Kindly provide Patient Information Sheet as per EC SOP and brief summary of statistical analysis regarding establishing association & Plan analysis. • A Co-guide from Obst. & Gynaecology may facilitate the project. **PGTSC Comment:** As above **PGTSC Decision:** Revise & resubmit with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIC/P3***
4.	Research proposal entitled ***"A descriptive study to assess the knowledge and attitude towards organ donation among care givers in OPD KGMU Lucknow."*** submitted by Ms. Manorama, Ms. Mahima, Ms. Nainsi, Ms. Nisha, Ms. Oppja Sikdar, Ms. Pratibha, Ms. Puja Maurya, Ms. Renu Kumari, Ms. Sarita, Ms. Shabnam through their guide Mrs. Shikha Malik, Clinical Instructor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1066/23 dated 28th July, 2023. ***Recommendation of Primary reviewer:*** • Kindly provide patient Information Sheet as per EC SOP and analysis plan of association study as stated in objective. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIC/P4***
5.	Research proposal entitled ***"A descriptive study to assess the knowledge and attitude towards palliative care among staff nurses of King George's Medical University, Lucknow, Uttar Pradesh."*** submitted by Ms. Mansi Mishra, Ms. Neelu, Ms. Neetu Verma, Ms. Neha Singh, Ms. Neha Singh, Ms. Nikki Sharma, Ms. Nilanshi Pathak, Mr. Nitish Chaurasiya, Mr. Owais Jamal Lone, Ms. Parul Mishra through their Guide Mrs. Sarita Dubey, Clinical Instructor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1068/23 dated 28th July, 2023. **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIC/P5***
6.	Research proposal entitled ***"A study to assess the electronic gadgets usage and its impact on health, social relationships and academics performance among nursing students of College of nursing, KGMU, Lucknow U.P."*** submitted by Ms. Afsana Khatoon, Ms. Anjali Singh, Ms. Anjali Verma, Ms. Anjali Verma, Ms. Ankita Singh, Ms. Ankita Singh, Ms. Anshu Bharti, Ms. Anupam Dwivedi, Ms. Anushree Dixit, Ms. Aparna Kumari through their Guide Mrs. Anugrah Charan, Clinical Instructor, & Miss. Loveena Arpita Samuel, Clinical Instructor, Department of KGMU College of Nursing,

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	King George's Medical University, U.P., Lucknow vide letter no.1073/23 dated 28th July, 2023. **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIC/P6***
7.	Research proposal entitled ***"A study to assess the knowledge and attitude on self care among Mothers diagnosed with PIH attending department of Obstetrics & Gynaecology, KGMU, Lucknow U.P."*** submitted by Ms. Shashikala, Ms. Shiva, Ms. Sunita, Ms. Swati Ranjan, Ms. Uttara, Ms. Pooja Singh, Ms. Anjali Pandey, Ms. Lalita Chaudhari, Mr. Manish Yadav, Ms. Manju Devi through their guide Mrs. Tanima Verma, Clinical Instructor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1067/23 dated 28th July, 2023. ***Recommendation of Primary reviewer:*** • Kindly provide Patient Information Sheet as per EC SOP and summary of association analysis. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIC/P7***
8.	Research proposal entitled ***"A descriptive study to assess the depression anxiety and burden of care among caregivers of oral cancer patients undergoing chemotherapy in the department of Surgical Oncology, KGMU, Lucknow"*** submitted by Mr. Aryan Kumar, Mr. Ashutosh Kumar, Ms. Ayasha Bano, Ms. Ayushi Verma, Ms. Bavita Verma, Ms. Deepali Dubey, Mr. Dhananjay Singh, Mr. Dharmendra Yadav, Ms. Divya Maurya, Ms. Eshita Singh through their guide Mr. G. Srinivasan, Clinical Instructor, & Miss. Amanjeet Kaur, Nursing Tutor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1071/23 dated 28th July, 2023. ***Recommendation of Primary reviewer:*** • Kindly provide Patient Information Sheet as per EC SOP and plan of analysis. • A Co-Investigator from Department of Surgical Oncology & Psychiatry may better facilitate the project. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIC/P8***
9.	Research proposal entitled ***"A study to assess the effectiveness of planned teaching programme on knowledge regarding prevention of coronary artery disease among obese patients at Medicine OPD of K.G.M.U., Lucknow, U.P."*** submitted by Ms. Ganga, Ms. Jyoti Agrahari, Ms. Jyoti Yadav, Mr. Kalishanker, Ms. Karuna Kushwaha, Ms. Anuradha Kushwaha, Ms. Apoorva Singh, Ms. Asha, Ms. Garima, Ms. Kanchan through their Guide Mr. Migron Rubin, Clinical Instructor, & Mrs. Priyanka Singh.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of Primary reviewer: • Kindly provide the Patient Information Sheet as per EC SOP and anticipated plan of analysis descriptive and inferential statistics as mentioned in objectives. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIC/P9***
10.	Research proposal entitled ***"A study to assess the knowledge regarding risk factors and warning signs of stroke among hypertensive patients attending OPD in KGMU Lucknow"*** submitted by Miss. Ruchi Kumari, Mr. Rudra Pratap Singh, Miss. Sandhya Kumari, Mr. Sangam Verma, Miss. Sangeeta Yadav, Miss. Sarita Verma, Miss. Sarjahan, Mr. Satya Prakash Nishad, Miss. Saumya Upadhyay, Miss. Shalinee Medhankar through their guide Mrs. Urvashi Sharma, Clinical Instructor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1070/23 dated 28th July, 2023. *Recommendation of Primary reviewer:* • Kindly provide Patient Information Sheet as per EC SOP. • The ICF English version describes oral cancer instead of hypertensive Patient Information Sheet. Kindly rectify. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XX-PGTSC-IIC/P10***
IID	**Corrigendum**
1-	There is a typo error in the thesis title Inadvertently by PI had written in the cover letter of following research proposal entitled:- **Incomplete topic:** ***"A study to estimate circulating level of serum osteoprotegerin (OPG) and analysis of it's gene expression"*** **Complete topic:** ***"A study to estimate circulating level of serum osteoprotegerin (OPG) and analysis of it's gene expression in Prediabates"*** however, title in Scientific Review Committee, Thesis Proforma and consent form is correct and complete **and approved by the XIV-PGTSC Committee held on 21st December, 2022** submitted by Dr. Kriti Kathuria, JR-I, Department of Biochemistry, King George's Medical College, Lucknow vide letter no. Bio/2023/517 dated 19th August, 2023 **& the IMR grant sanctioned on the same topic without Ethical Clearance i.e. waived off.** **PGTSC Decision:** • Correction of topic for Thesis noted

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• IMR project noted to be put-up to IEC for waiver approval *Ref. code: XIV-PGTSC-IIA/P51*

The Next Meeting will be held on ~~22nd~~ 25th October, 2023 from 11.00 A.M.

(Shally Awasthi)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 127th ECM held on 25th October, 2023

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the 127th Institutional Ethics Committee Meeting in ***hybrid mode*** held on **25th October, 2023 from 11:30 A.M. till 02.45 P.M.** in the Committee Room, Administrative Block King George's Medical University, U.P., Lucknow.

The following Members were present in the Meeting:-

1. Dr. Alok Dhawan -Chairman
2. Dr. G.G. Agarwal -Member
3. Dr. A.A. Mahdi -Member
4. Dr. Akash Agarwal -Member
5. Mrs. Akansha Dubey -Member
6. Mrs. Vasundhara Kumari -Member
7. Mr. Ujjawal Krishna -Member
8. Dr. Rajendra Nath -Member
9. Dr. Nisha Mani Pandey -Member
10. Dr. Anupam Mishra -Member
11. Dr. D.N. Upadhyaya -Additional Member-Secretary, IEC
12. Dr. Hardeep Singh Malhotra -Member-Secretary, IEC, ex-officio

The following Member was not present in the Meeting:-

1. Dr. K..K.Yadav -He has given his comments
2. Dr. Anita Rani -She has given her comments
3. Dr. Shubha R Phadke

I	**Minutes of previous Meeting held on 01-09-2023.** **The following documents have been brought from the last meeting because the quorum was incomplete.**
	Attendance
	The following Members were present in the Meeting:- 1. Dr. Alok Dhawan -Chairman 2. Dr. Akash Agarwal -Member 3. Dr. Anita Rani - Member 4. Dr. K.K. Yadav -Member 5. Dr. D.N. Upadhyaya - Member 6. Dr. Anupam Mishra -Member 7. Dr. Rajendra Nath -Member 8. Dr. G.G. Agarwal -Member 9. Dr. Shally Awasthi -Member-Secretary, IEC ***Dr. Shally Awasthi superannuated on 6th September, 2023.***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The following members were not present in the Meeting:- 1. Dr. Shubha R Phadke- She has given her comments 2. Mrs. Vasundhara Kumari 3. Mr. Ujjawal Krishna 4. Mrs. Akansha Dubey
IA	**Previous- Action taken**
14-	Clarification of research protocol no. PMZ-1620/CT-2.4/2022; CT NOC No. CT/ND/37/2022 entitled ***"A multicentre, randomized, double-blind, placebo-controlled, phase-II trial to assess safety, and efficacy of sovateltide in the treatment of hypoxic-ischemic encephalopathy in neonates"*** sponsored by M/s Pharmazz India Pvt. Ltd. submitted by Prof. S. N. Singh, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. Ped/CT/06/2023 dated 18th August, 2023.

Previous EC Comment	PI response
DCGI CT NOC does not mention KGMU P1/Site.	Requirements of CT NOC from DCGI for addition of new clinical trial site or Investigator regarding circular are attached for the reference.

Recommendation of rewiver:
Provisionally Approved

Previous Decision: Defer to the next Meeting because quorum was incompleteDecision: Approval subject to fulfillment & Administrative formalities.

Ref. code: 125th ECMIIC/P4

II-C	**Previous- Review of New Drug Trial**
1.	Research protocol no. EX6018-4915 entitled ***"Effects of ziltivekimab versus placebo on morbidity and mortality in patients with heart failure with mildly reduced or preserved ejection fraction and systemic inflammation"*** sponsored by M/s Nova Nordisk India Pvt. Ltd submitted by Dr. Monika Bhandari, Department of Cardiology, King George's Medical University, U.P.,Lucknow, vide letter no. 234/Cardio/Res/2023 dated 20th July, 2023. ***Recommendation of reviewer:*** • Permission to send sample abroad –Not attached • No other Ethical Issue **Previous IEC Decision:** Defer to the next Meeting because quorum was

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	incomplete. **Comment:** As above **Decision:** Approval subject to modification ***Ref. code: 126th ECMIIC/P1***
2.	Research protocol no. VTX958-202 entitled ***"A phase 2, multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of VTX958 in participants with moderately to severely active crohn's disease"*** sponsored by M/s Ventyx Biosciences, Inc. submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/17/2023 dated 20th July, 2023. ***Recommendation of reviewer:*** • CTRI document should be submitted to IEC office as soon as trial registration occurs. • Permission to send sample abroad–Not attached • No other Ethical Issue **Previous IEC Decision:** Defer to the next Meeting because quorum was incomplete. ***The above documents had received by the PI which was reviewed in the IEC Meeting vide letter no. MED/CT/20/2023 dated 14th September, 2023. The following documents were reviewed in the Meeting:-***

S. No.	Documents for EC Submission	Version No.	Version dated
1-	Protocol	V 2.0	29 Nov 2022
2-	Protocol Signature Page_ Ajay Kumar Patwa	V 2.0	30-Jan-2023
3-	Investigator Brochure	V 3.0	03-Oct-2022
4-	IB AoR_ Ajay Kumar Patwa	V 3.0	30-Jan-2023
5-	PI CV_Ajay Kumar Patwa	NA	26-Sep-2022
6-	PI Medical Registration Certificate	NA	17-Jun-2007
7-	PI GCP Certificate	NA	12-Jan-2021
8-	DCGI Approval Letter	NA	12-Jun-2023
9-	CRF Ver	V1.0	12-Dec-2022
10-	Draft CTA	NA	16-Nov-2022
11-	Investigator Undertaking	NA	30-Jan-2023
12-	Confidentiality Undertaking	NA	14-Sep-2022
13-	Insurance and Indemnification Certificate [Initial]	NA	01-Mar-2023
14-	Final Main Master PIS and ICF for	V1.0-01	09-Jun-2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	India, Site#356103 V1.0-01 09Jun2023 English		
15-	Final Master Pregnant Partner PIS & ICF for India, Site #356103, V1.0- 01 dd. 09Jun2023 English	V1.0-01	09-Jun-2023
16-	Final Master Genetic Testing PIS ICF, Site #356103, V1.0- 01, dd. 09Jun2023 English	V1.0-01	09-Jun-2023
17-	Final Main Master PIS and ICF for India, Site#356103 V1.0-01 22Jun2023 Hindi	V1.0-01	20-Jun-2023
18-	Final Main Master PIS and ICF for India, Site#356103 V1.0-01 22Jun2023 Hindi CoT	NA	20-Jun-2023
19-	Final Main Master PIS and ICF for India, Site#356103 V1.0-01 22Jun2023 Hindi BT	V1.0-01	20-Jun-2023
20-	Final Main Master PIS and ICF for India, Site#356103 V1.0-01 22Jun2023 Hindi BT CoT	NA	20-Jun-2023
21-	Final Master Pregnant Partner PIS & ICF for India, Site #356103, V1.0- 01 dd. 20Jun2023 Hindi	V1.0-01	20-Jun-2023
22-	Final Master Pregnant Partner PIS & ICF for India, Site #356103, V1.0- 01 dd. 20Jun2023 Hindi CoT	NA	20-Jun-2023
23-	Final Master Pregnant Partner PIS & ICF for India, Site #356103, V1.0- 01 dd. 20Jun2023 Hindi BT	V1.0-01	20-Jun-2023
24	Final Master Pregnant Partner PIS & ICF for India, Site #356103, V1.0- 01 dd. 20Jun2023 Hindi BT CoT	NA	20-Jun-2023
25	Final Master Genetic Testing PIS ICF, Site #356103, V1.0- 01, dd. 20Jun2023 Hindi	V1.0-01	20-Jun-2023
26	Final Master Genetic Testing PIS ICF, Site #356103, V1.0- 01, dd. 20Jun2023 Hindi CoT	NA	20-Jun-2023
27	Final Master Genetic Testing PIS ICF, Site #356103, V1.0- 01, dd. 20Jun2023 Hindi BT	V1.0-01	20-Jun-2023
28	Final Master Genetic Testing PIS ICF, Site #356103, V1.0- 01, dd. 09Jun2023 English	V1.0-01	09-Jun-2023
29	Final Main Master PIS and ICF for	V1.0-01	20-Jun-2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	India, Site#356103 V1.0-01_22Jun2023_Hindi		
30	Final Main Master PIS and ICF for India, Site#356103 V1.0-01_22Jun2023_Hindi CoT	NA	20-Jun-2023
31	VTX958-202_eCOA Device label_Smartphone (version _n/a) English [No date]	NA	NA
32	VTX958-202_eCOA Screenshots_IBDQ, English [22-SEP-2022]	NA	22-Sep-2022
33	VTX958-202_eCOA Screenshots_Medication Diary, English [21-NOV-2022]	NA	21-Nov-2022
34	VTX958-202_eCOA Screenshots_Patient Cloud Data Privacy Notice, English [30-SEP-2016]	NA	30-Sep-2016
35	VTX958-202_eCOA Screenshots_Patient Cloud Terms of Use, English [11-OCT-2013]	NA	11-Oct-2013
36	VTX958-202_eCOA Screenshots_Pregnancy Diary, English [21-NOV-2022]	NA	21-Nov-2022
37	VTX958-202_eCOA Screenshots_Standard Screens - Patient Mode, English [05-MAY-2022]	V2.4	05-May-2022
38	VTX958-202_eCOA Screenshots_Standard Screens - Site Mode, English [08-JAN-2021]	V2.2	08-Dec-2021
39	VTX958-202_eCOA Screenshots_Symptoms Diary, English [21-NOV-2022]	NA	21-Nov-2022
40	VTX958-202_Master Patient Instructions_eCOA Participant User Guide (version 1.0) [18-OCT-2022]	V1.0	18-Oct-2022
41	VTX958-202_Master Patient Instructions_Patient Dosing Instructions (version 2.0) [22-NOV-2022]	V2.0	22-Nov-2022
42	VTX958-202_Recruitment Material-Patient Flyer_V1.0 27-Oct-2022	V1.0	27-Oct-2022
43	VTX958-202_Recruitment Material-Referral Letter_v.2.0 dd.22-Nov-2022_Final	V2.0	22-Nov-2022
44	VTX958-202_Recruitment Materials (Referral Fact Card, version 2.0) [25-	V2.0	25-Nov-2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	NOV-2022]		
45	VTX958-202_Stool Sample Instructions for Samples Collected at Home_ver.2.0_22Nov2022	V2.0	22-Nov-2022
46	VTX958-202_eCOA Device label_Smartphone (version _N_A) Hindi [No date]	NA	NA
47	VTX958-202_eCOA Screenshots_IBDQ, Hindi [No date]	NA	NA
48	VTX958-202_eCOA Screenshots_IBDQ, Hindi Translation Certificate [11-APR-2023]	NA	11-Apr-2023
49	VTX958-202_eCOA Screenshots_Medication Diary, Hindi [No date]	NA	NA
50	VTX958-202_eCOA Screenshots_Medication Diary, Hindi Translation Certificate [09-MAR-2023]	NA	09-Mar-2023
51	VTX958-202_eCOA Screenshots_Patient Cloud Data Privacy Notice, Hindi [30-SEP-2016]	NA	30-SEP-2016
52	VTX958-202_eCOA Screenshots_Patient Cloud Terms of Use, Hindi [11-OCT-2013]	NA	11-Oct-2013
53	VTX958-202_eCOA Screenshots_Pregnancy Diary, Hindi [No date]	NA	NA
54	VTX958-202_eCOA Screenshots_Pregnancy Diary, Hindi Translation Certificate [09-MAR-2023]	NA	09-MAR-2023
55	VTX958-202_eCOA Screenshots_Standard Screens - Patient Mode, Hindi [10-NOV-2022]	NA	10-Nov-2022
56	VTX958-202_eCOA Screenshots_Standard Screens - Site Mode, Hindi [10-NOV-2022]	NA	10-Nov-2022
57	VTX958-202_eCOA Screenshots_Symptoms Diary, Hindi [No date]	NA	NA
58	VTX958-202_eCOA Screenshots_Symptoms Diary, Hindi Translation Certificate [09-MAR-2023]	NA	09-MAR-2023
59	VTX958-202_Master Patient Card (version 2.0) translation (Hindi) [22-DEC-2022]	V1.0	22-DEC-2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

60	VTX958-202_Master Patient Card (version 2.0) translation (Hindi) translation (English) [22-DEC-2022]	V1.0	22-DEC-2022
61	VTX958-202_Master Patient Card (version 2.0) translation (Hindi) translation (English) Translation Certificate [22-DEC-2022]	NA	22-Dec-2022
62	VTX958-202_Master Patient Card (version 2.0) translation (Hindi) Translation Certificate [22-DEC-2022]	NA	22-Dec-2022
63	VTX958-202_Patient Dosing Instructions (version 2.0) translation (Hindi) [22-DEC-2022]	V2.0	22-Dec-2022
64	VTX958-202_Patient Dosing Instructions (version 2.0) translation (Hindi) translation (English) [22-DEC-2022]	V2.0	22-Dec-2022
65	VTX958-202_Patient Dosing Instructions (version 2.0) translation (Hindi) translation (English) Translation Certificate [22-DEC-2022]	NA	22-Dec-2022
66	VTX958-202_Patient Dosing Instructions (version 2.0) translation (Hindi) Translation Certificate [22-DEC-2022]	NA	22-Dec-2022
67	VTX958-202_Patient Instructions_eCOA Participant User Guide (Hindi) (version 1) [18-OCT-2022]	V1.0	18-Oct-2022
68	VTX958-202_Patient Instructions_eCOA Participant User Guide (Hindi) (version 1) Translation Certificate [09-FEB-2023]	NA	09-Feb-2023
69	VTX958-202_Recruitment Materials (Patient Flyer, version _1.0) translation (Hindi) [01-DEC-2022]	V1.0	01-Dec-2022
70	VTX958-202_Recruitment Materials (Patient Flyer, version _1.0) translation (Hindi) translation (English) [01-DEC-2022]	V1.0	01-Dec-2022
71	VTX958-202_Recruitment Materials (Patient Flyer, version _1.0) translation (Hindi) translation (English) Translation Certificate [01-DEC-2022]	NA	01-Dec-2022
72	VTX958-202_Recruitment Materials	NA	01-Dec-2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		(Patient Flyer, version _1.0) translation (Hindi) Translation Certificate [01-DEC-2022]		
	73	VTX958-202_Stool Sample Instructions for Samples Collected at Home (version 2.0) translation (Hindi) [22-DEC-2022]	V2.0	22-DEC-2022
	74	VTX958-202_Stool Sample Instructions for Samples Collected at Home (version 2.0) translation (Hindi) translation (English) [22-DEC-2022]	V2.0	22-DEC-2022
	75	VTX958-202_Stool Sample Instructions for Samples Collected at Home (version 2.0) translation (Hindi) translation (English) Translation Certificate [22-Dec-2022]	NA	22-DEC-2022
	76	VTX958-202_Stool Sample Instructions for Samples Collected at Home (version 2.0) translation (Hindi) Translation Certificate [22-Dec-2022]	NA	22-DEC-2022

Decision: Approval subject to fullfillment & Administrative formalities

Ref. code: 126thECMIIC/P2

3. Research protocol no. 1366-0031 entitled ***"A phase II, randomized, placebo-controlled, double-blind, parallel-group, and efficacy and safety study of at least 48 weeks of oral BI 685509 treatment in adults with early progressive diffuse cutaneous systemic sclerosis"*** sponsored by M/s Boehringer Ingelheim Pharma GmbH & Co. KG, Birkendorfer submitted by Dr. Puneet Kumar, Associate Professor, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/91/2023 dated 7th August, 2023.

Recommendation of reviewer:-

- IEC proforma Clinical Trials' section mentions the study as a Phase III study but the title and detailed synopsis mention it as Phase II study.
- DCGI approval doesn't mention KGMU site.
- CTRI registration doesn't mention KGMU site.
- CTA form is without details and signatures.
- IEC form mentions blood sample being sent abroad but protocol mentions list of routine tests which can be done inside the county.
- Please specify which tests will be conducted outside India and why?

Previous IEC Decision: Defer to the next Meeting because quorum was incomplete.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above documents had received by the PI which was reviewed in the IEC Meeting vide letter no. MED/CT/20/2023 dated 14th September, 2023. The following documents were reviewed in the Meeting:- 1.1 BI_1366-0031_Investigator Brochure_Version12.0_24May2022 2.1_BI_1366-0031_Protocol_Version_2.0_19 Oct 2022 2.2 BI_1366-0031_Protocol_Version_2.0_19 Oct 2022_PSP_Dr. Puneet Kumar_16Mar2023 2.3 BI_1366-0031_Protocol_Version_3.0_11 May 2023 2.4 BI_1366-0031_Protocol_Version_2.0_19 Oct 2022_PSP_Dr. Puneet Kumar_13Jul2023 3.1 Main Consent Form_ M_02_IND01_En_6-01_31Jan2023 3.2 Main Consent Form_ M_02_IND01_hi_01_6-01_13Jul2023 3.3 Main Consent Form_Translation Certificate of M_02_IND01_hi_01_6-01_13Jul2023 3.4 Main Consent Form_Back translation of Generic_M_02_IND01_hi_6-01_08Mar2023 3.5 Main Consent Form_Back translation of Site_M_02_IND01_hi_01_6-01_13Jul2023 3.6 Main Consent Form_ Back translation Certificate of M_02_IND01_hi_01_6-01_13Jul2023 4.1 Trial Subject Information and Consent Form_Biological Samples Collection Storage and Use_B_02_IND01 Eng_01_ 6-01 31Jan2023 4.2 Trial Subject Information and Consent Form_Biological Samples Collection Storage and Use_ B_02_IND01 hi_01_6-01 14Jul2023 4.3 Trial Subject Information and Consent Form_Biological Samples Collection Storage and Use_TranslationCert of B_02_IND01 hi_01_6-01 14Jul2023 4.4 Trial Subject Information and Consent Form _Biological Samples Collection Storage and Use_Generic_Back translation of B_02_IND01 hi_01_08Mar2023 4.5 Trial Subject Information and Consent Form _ Biological Samples Collection Storage and Use_site_Back translation of B_02_IND01 Hi_01_6-01 14Jul2023 4.6 Trial Subject Information and Consent Form_Biological Samples Collection Storage and Use-Back Translation Cert of B_02_IND01 hi_01_6-01 14Jul2023 5.1 Optional Subject Information and Consent Form MRA Sub-Study_S1_IND01_Eng_01_6-01 31Jan2023 5.2 Optional Subject Information and Consent Form MRA Sub-Study_S1_IND01_hi_01_6-01 13Jul2023 5.3 Optional Subject Information and Consent Form MRA Sub-Study_Translation Certificate_S1_IND01_hi_01_6-01 13Jul2023 5.4 Optional Subject Information and Consent Form MRA Sub-Study_ Back Translation_Generic_S1_IND01_hi_01_08Mar2023 5.5 Optional Subject Information and Consent Form MRA Sub-Study_ Back Translation_Site_S1_IND01_hi_01_6-01 13Jul2023 5.6 Optional Subject Information and Consent Form MRA Sub-Study_Translation and Back Translation Certificate_S1_IND01_hi_6-01 13Jul2023 6.1 Subject Information and Consent Form optional Skin-Biopsy Sub-

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Study_S2_IND01_Eng_01_6-01_31Jan2023 6.2 Subject Information and Consent Form optional Skin-Biopsy Sub-Study_S2_IND01_ Hi_01_6-01_13Jul2023 6.3 Subject Information and Consent Form optional Skin-Biopsy Sub-Study_Translation Certificate_S2_IND01_ Hi_01_6-01_13Jul2023 6.4 Subject Information and Consent Form optional Skin-Biopsy Sub-Study_Back Translation_Generic_S2_IND01_hi_01_1_01_08Mar2023 6.5 Subject Information and Consent Form optional Skin-Biopsy Sub-Study_Back Translation_Site_S2_IND01_ Hi_01_6-01_13Jul2023 6.6 Subject Information and Consent Form optional Skin-Biopsy Sub-Study_ Back Translation Certificate_S2_IND01_ Hi_01_4-01_13Jul2023 7.1 Information and Consent for Pregnant Partner_O1_IND01_Eng_01_6-01_31Jan2023 7.2 Information and Consent for Pregnant Partner_O1_IND01_Hi_01_6-01_13Jul2023 7.3 Information and Consent for Pregnant Partner_Translation and Back Translation Certificate of Site_O1_IND01_Hi_01_6-01_13Jul2023 7.4 Information and Consent for Pregnant Partner_Back Translation of Generic_O1_IND01_hi_1_01_01_08Mar2023 7.5 Information and Consent for Pregnant Partner_Back Translation of Site_O1_IND01_Hi_01_6-01_13Jul2023 7.6 Information and Consent for Pregnant Partner_Translation and Back Translation Certificate of Site_O1_IND01_Hi_01_6-01_13Jul2023 8.1 1366-0031_Final eCRF 08Nov2022 9.1 1366-0031 EQ-5D-5L IndiaEnglish Version 1.0 dated 11 Aug 2022 9.2 1366-0031 EQ-5D-5L IndiaHindi Version 1.0 dated 11 Aug 2022 10.1 1366-0031 FACIT-Fatigue Scale English (Universal) Version 1.0, dated 28 Jun 2022 10.2 1366-0031 FACIT-Fatigue Scale IndiaHindi Version 1.0, dated 28 Jun 2022 11.1 1366-0031 Pain NRS IndiaEnglish Version 1.0 dated 11 Aug 2022 11.2 1366-0031 Pain NRS IndiaHindi Version 1.0 dated 11 Aug 2022 12.1 1366-0031 PGI-C IndiaEnglish Version 1.0 dated 11 Aug 2022 12.2 1366-0031 PGI-C IndiaHindi Version 1.0 dated 11 Aug 2022 13.1 1366-0031 PGA IndiaEnglish Version 1.0 dated 11 Aug 2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	13.2 1366-0031 PGA IndiaHindi Version 1.0 dated 11 Aug 2022 14.1 1366-0031 SHAQ IndiaEnglish Version 1.0 dated 08 Aug 2022 14.2 1366-0031 SHAQ IndiaHindi Version 1.0 dated 08 Aug 2022 14.3 1366-0031 SHAQ IndiaHindi Version 1.0 dated 08 Aug 2022_Translation Certificate date 17Jun15 15.1 1366-0031 SSPRO IndiaEnglish Version 1.0 dated 28 Sep 2022 15.2 1366-0031 SSPRO IndiaHindi Version 1.0 dated 28 Sep 2022 15.3 1366-0031 SSPRO IndiaHindi Version 1.0 dated 28 Sep 2022_Translation Certificate date 21Sep2022 16.1 Trial Identification Card _INDIA_EE_SC-English_Version 1.0_22 Oct 2019 16.2 Trial Identification Card _INDIA_EE_SC-Hindi_Version 1.0_22 Oct 2019 16.3 Trial Identification Card _INDIA_EE_SC-Hindi_Version 1.0_22 Oct 2019_Translation Certificate dated 05Oct2023 17.1 1366-0031-PRR-IND-diary-drug-time-v1.0-2022-06-10_English 17.2 1366-0031-PRR-IND-diary-drug-time-v1.0-2023-01-19_Hindi SD1 L2 17.3 1366-0031-PRR-trial-diary-drug-time-v1.0-2023-01-19_Hindi_Translation Certificate dat 03Feb2023 18.1 1366-0031-PRR-IND-Medication Chart-v1.0-2022-06-10_English 18.2 1366-0031-PRR-IND-Medication Chart-v1.0-2023-01-19_Hindi SD1 L2 18.3 1366-0031-PRR-IND-Medication Chart-v1.0-2023-01-19_Hindi_Translation Certificate dated 03Feb2023 19.1 1366-0031-PRR-IND-Raynaud-diary-d-1-v1.0-2022-06-10_English 19.2 1366-0031-PRR-IND-Raynaud-diary-d-1-v1.0-2023-01-19_Hindi D1 L1 19.3 1366-0031-PRR-IND-Raynaud-diary-d-1-v1.0-2023-01-19_Hindi_Translation Certifcate dated 03Feb2023 20.1 1366-0031-PRR-IND-Raynaud-diary-d-7--2-v1.0-2022-06-10_English 20.2 1366-0031-PRR-IND-Raynaud-diary-d-7--2-v1.0-2023-01-19_Hindi SD1 L1 20.3 1366-0031-PRR-IND-Raynaud-diary-d-7--2-v1.0-2023-01-19_Hindi_Translation Certific dated 03Feb2023 21.1 1366_0031_Insurance Certificate and Policy_15Dec2022_Valid till 27May2025

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	22.1 1366_0031_RA Submission cover letter dated 20Feb2023 22.2 1366_0031_RA Submission_dated20Feb2023 22.3 1366_0031_RA approval letter dated 30Jun2023 22.4 1366_0031_IL permission dated 30Jun2023 23.1 Boehringer Ingelheim_1366-0031_Dr. Puneet Kumar_CV_31Jan2023 23.2 Boehringer Ingelheim_1366-0031_Dr. PuneetKumar_MRC 23.3 Boehringer Ingelheim_1366-0031_Dr. Puneet Kumar_GCP_25Jan2023 23.4 Boehringer Ingelheim_1366-0031_Dr. Puneet Kumar_IU_10Mar2023 24.1 Boehringer Ingelheim_1366-0031_IQVIA CTA template_Draft_14Mar2023 25.1 Boehringer Ingelheim_1305-0031_CTRI dataset registered_05 Jul 2023 26.1 Patient will be recruited from Rheumatology OPD **Decision:** Approval subject to fulfillment & Administrative formalities. ***Ref. code: 126th ECMIIC/P3***
III-A	**Previous- Modification**
1.	Modification of research protocol no. LTE15174 entitled "***ATLAS-OLE: An open label long term safety and efficacy study of fitusiran in patients with Hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX***" submitted by Dr. S.P. Verma, Prof. Jr. Grade, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. CH/CT/09/23 dated 15th July, 2023. ***Recommendation of reviewer:*** • Approved **Previous IEC Decision:** Defer to the next Meeting because quorum was incomplete. ***The following documents were reviewed in the Meeting:-***

Sr. No.	Document/Language	Document Details/Versions
1-	Investigator's Brochure (Clean copy)	Investigator's Brochure Edition 13 07 June 2023 (Controlled Copy No: PPD/ LTE15174/ Investigator's Brochure/Edition 13/Dated 07 June 2023/004-005)

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

				1.1 Investigator's Brochure Edition 12 dated 24 May 2023 (Controlled Copy No: PPD/ LTE15174/ Investigator's Brochure/Edition 12/Dated 24 May 2023 /004 – 005)
		2-	Investigator's Brochure (Track change copy)	Investigator's Brochure Edition 13 dated 07 June 2023 2.1 Investigator's Brochure Edition 12 dated 24 May 2023
		3-	Investigator's Brochure (Summary of changes)	Investigator's Brochure Edition 13 dated 07 June 2023 3.1 Investigator's Brochure Edition 12 dated 24 May 2023
		4.	DCGI Acknowledgment for Submission Email and Screenshot_Investigator's Brochure Edition 12 Sep 2023	Email acknowledgement dated 12 Sep 2023
		5.	Memo Justification for IB Ed 13	Justification for replacement of Investigator's Brochure version 12 with version 13_07Aug2023_signed
	Decision: Approved ***Ref. code: 90thECMIIC/P2***			
3.	Modification of research protocol no. CTQJ230A12301 entitled "*A **randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease"(Horizon Study)*** sponsored by M/s Novartis Health Care Pvt. Ltd submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 264/Cardio/Res/23 dated 1st August, 2023. ***Recommendation of reviewer:-***			

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Approved

Previous IEC Decision: Defer to the next Meeting because quorum was incomplete.

The following documents were reviewed in the Meeting:

Sl.No.	Documents
1	Clinical Trial Protocol (Version Number: 04; Release Date: 10-May-2023)
2	Summary of changes: Clinical Trial Protocol (Version Number: 04; Release Date: 10-May-2023
3	Informed Consent Form: Core IF (Version Number 5.0; Version Date: 19 May 2023)_English
4	Informed Consent Form: Core IF (Version Number 5.0; Version Date: 19 May 2023)_ Translated from English to Hindi on 2-Jun-23
5	Informed Consent Form: Core IF (Version Number 5.0; Version Date: 19 May 2023)_ Back Translated from Hindi to English on 16-Jun-23
6	Translation and back translation certificate for Informed Consent Form: Core ICF (Version Number 5.0; Version Date: 19 May 2023): • Hindi
7	DOGI Acknowledgement letter of Protocol amendment 04 and Core IF Version 5.0 submission

Decision: Approved

Ref. code: 101st ECMIIC/P18

Minutes of 127th IEC-25-10-2023

IA — **Action Taken**

1- Clarification of research proposal entitled ***"Intraoperative precursor events correctable and non-correctable associated with postoperative major and minor adverse events in vascular surgeries"*** submitted by Dr. Amit Chaudhary, Assistant Professor, Department of Vascular Surgery, King George's Medical University, U.P., Lucknow vide letter no. VS/513/2023 dated 13th September, 2023.

Previous EC Comment	PI response
Aim and objectives are not explicitly defined, to be converted into proper research hypotheses. The research hypothesis should be in term of the parameters involved in the study	Attached Separately
In the absence of proper research hypothesis, other components of a well-planned study are	Attached Separately

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	meaningless; including study subjects, sample size calculation etc.	
	The sample size calculations are not clear. In sample size calculation, the number is shown to be 160, whereas in material and methods, it is mentioned "approximately 200 subjects"	Attached Separately
	The study design is not mentioned.	This study is prospective study
	The methodology section is incomplete.	Attached Separately
	The statistical analysis section is missing.	Attached Separately

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-
Recommendation of reviewer:
Provisionally Approved
Decision: Approved

Ref. code: : 112th ECM IIA/P8

2- Clarification of research protocol no. DEN302 entitled "***A randomized, double-blind, placebo-controlled, phase 3 trial to investigate the safety and immunogenicity of a dengue tetravalent vaccine (Live Attenuated) (TDV) administered subcutaneously to healthy subjects aged 4 to 60 years in India***" sponsored by M/s Takeda Vaccines, Inc. submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/21/2023 dated 26th September, 2023.

Previous EC Comment	PI response
Permission for sending samples abroad and the DCGI Approval letter have still not been given.	As per your valuable comment this is to inform you that in the clinical study the Blood samples are collected and send to the abroad inadvertently tick mark **YES.** This mentioned Lab is also work in India and collected samples are proceeding in India office. DCGI Approval copy is attached

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	with PI and Site name for the reference.
	The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:- ***Second opinion of reviewer:-*** • Permission to send sample abroad is not needed (Principal-Investigator has given the clarification). • DCGI permission letter to conduct Clinical trial is now attached. • Provisionally Approved **Decision:** Approved with condition to kindly provide the above mentioned documents. ***Ref. code: : 121st ECMIIC/P2***
3-	Clarification of research proposal entitled "***Biomarkers for chemoresistance in oral squamous cell carcinoma (OSCC)***" submitted by Prof. Seema Gupta, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 904/RT/23 dated 22nd September, 2023. ***Previous IEC Comments:*** • In the Materials and methods section the name of the candidate gene Primer is not mentioned. • Sample size calculation not given. ***The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-*** ***Recommendation of reviewer:-*** • Provisionally Approved **Decision:** Approved ***Ref. code: : 123rd ECM IIA/P1***
4-	Clarification of research ***"Effects of prospective bilateral superficial cervical plexus nerve block on post-thyroidectomy headache and cervical pain:A ariables controlled trial"*** submitted by Dr. Pooja Ramakant, Prof. Junior Grade, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/2023/377 dated 3rd October, 2023. ***Previous IEC Comments:*** 1. Given the objectives, title can be notified as a Comparative study rather than a RCT ***The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-*** ***Recommendation of reviewer:*** • The authors need to submit a proposal with the new title or whatever

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	the policy is. ***The above comments forwarded to the Principal-Investigator:-*** Reply has not been received from the Principal-Investigator. **Decision:** Reminder will be send to the Principal-Investigator ***Ref. code: : 123rd ECM IIA/P3***
5-	Clarification of research proposal entitled "***Evaluation of high risk proteins involved in breast cancer and their correlation with tumor aggressiveness and chemotherapy response: A retrospective study***" sponsored by CSIR-CDRI submitted by Dr. Sumaira Qayoom, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1405/23 dated 30th September, 2023. **Previous EC Comment:** 1. Annexure one needs to be filled up such as for 'risk and benefit', 'data monitoring', 'compensation for injury', etc. 2. It is indicated by asterix that written consent will be taken. Kindly clarify since consent waiver form is also attached. 3. Kindly indicate other centers involved in this multicenter study. 4. The first objective indicates that metanalysis will be undertaken to shortlist six high risk genes while budget indicates that immunohistochemistry will be undertaken from the very beginning of the study. Have those six genes been identified? If yes, then kindly mention them and if not then the budget quoted may change depending upon the antibody cost of specific gene that needs to be assessed. Kindly clarify. 5. Regarding the third objective to correlate protein expression with chemotherapeutic response, kindly mention the clinical parameters that need to be recorded and the RCB scoring. In addition, also attach the data-sheet-proforma that will be used to record the various observations. 6. The second objective states a comparison between TNBC versus non-TNBC patients. What would be the sample size of each group- 100 or 200? Kindly state. 7. Also mention clearly in methodology section as how will you approach each objective clearly. 8. What are the chronic immunological disorders that need to be excluded? Kindly state. 9. It is stated in hypothesis section that "in a related study m-RNA expression will be analyzed in fresh biopsy tissue sample" Is this ethically approved or will it be submitted? Since this seems to be a prospective study, the current submission being retrospective (based on blocks) seems different. Kindly clarify. 10. Kindly attach pre-designed proforma as indicated in data management section. 11. Briefly mention the summary of anticipated statistical analysis ***The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-*** ***Recommendation of reviewer:*** • Kindly provide summary of changes in a tabular format. ***The above comments forwarded to the Principal-Investigator was reviewed by reviewer:-*** **Second opinion of Primary** | **PI response**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	reviewers	
	The clarification needs to be given regarding if immunological disorders are not excluded (or included in the exclusion criteria), would they not affect the results.	According to the recent literature:- 1. Thyroid disorders 1 2. Diffuse scleroderma 2 3. Psoriasis 2 Have been found to be associated with Breast cancer. Therefore mentioned diseases should be excluded. These conditions have been added as exclusion criteria. The point is highlighted in revised. Protocol submitted.
	Also, regarding consent waiver, care need to be undertaken not to disclose identity of archived samples.	The identity of the patients will not be disclosed. The cases will be completely anonymised and will be studied by PI and CO-PI.

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

Decision: Approved

Ref. code: : 123rd ECM IIA/P4

6- Clarification of research proposal entitled ***"Effect of nutraceutical potential of pumpkin seeds on glycaemic and lipid profile in type 2 diabetes mellitus patients"*** submitted to CST U.P under supervision of Miss. Poonam Sahu, Ph.D. Scholar under the guidance Prof. Dileep Kumar Verma, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3399/PHY/23 dated 4th October, 2023.

Previous EC Comment	PI response
This is a clinical study of herbal remedies. Therefore, an Ayurvedic co-investigator can be included. Moreover, kindly clarify if the processes of inclusion as a clinical trial need to be done?	The modification has been done and an Ayurvedic co-investigator has been included in the study. Details are as follows: Dr. Naresh Patel BAMS Emergency Medical Officer, Nishat Hospital, Lalbagh, Lucknow Mobile No.- 9450110180 Yes, the study will be registered on the CTRI (Clinical Trial Registry of India) website soon after the Ethical approval of the

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		study from the Institution.
	Informed consent form for volunteers (as indicated in annexure 1 that volunteers and patient will be recruited). Study design as indicated in case Control- does Control refer to healthy subjects?	Modification has been done – Only the T 2 DM patients coming to the OPD will be a part of the study. No, the term Control does not indicate healthy subjects. T 2 DM patients who are receiving standard conventional treatment for the disease, and to whom pumpkin seed administration will not be done in the study, will act as 'Control.'
	While study design flow chart suggests it to be ariables controlled trial- Kindly clarify.	The study design is Randomised Control Study and the modified study design has been attached.
	Patient information sheet to be included in detail both in Hindi and English.	Attached
	Sample size to be made molecular in respect to primary objective. Elaborate the numbers mentioned in difference in expected means.	The sample size has been calculated with respect to primary objective on the basis of previous study done. Study reference: Monica, S. J., John, S., Madhanagopal, R., Sivaraj, C., Khusro, A., Arumugam, P., ... & Emran, T. B. (2022). Chemical composition of pumpkin (Cucurbita maxima) seeds and its supplemental effect on Indian women with metabolic syndrome. Arabian Journal of Chemistry, 15(8), 103985. The sample size required in each group was calculatedby solving the following formula: Where, Z α/2 = the critical value of the Normal distribution at α/2

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Z β = the critical value of the Normal distribution at β σ 2 = the population variance d = the difference in means Formula Reference: Kirwood, B. R., & Sterne 2nd, J. A. C. (2003). Essential Medical Statistics, Blackwell Publishing. Edition II. Chapter 35. Page 420 From the above mentioned study, 94.71 was the mean at baseline and 89.86 was the mean after intervention. Thus the difference in the mean would be 4.85. So, the value of d = 4.85 & d 2 =23.52.
	Who will fund for pumpkin seed?	ICMR will fund for pumpkin seed.
	Who will bear the cost of biochemical analysis and how much cost is expected for these tests per case basis?	The cost of biochemical analysis will be funded by ICMR by the purchase of test kits from the project fund. The estimated cost of a biochemical test per patient is Rs. 680/-.
	Summarize the anticipated statistical analysis briefly.	Data analysis will be carried out using SPPS software. We will compare each group pre- and post- intervention by paired T-tests. With the help of unpaired T-tests, we compare the intervention and control groups. Biochemical variables will be compared by ANOVA. For all statistical tests, the significance level will set at P & lt; 0.05.
	Summarize randomization process. Will this be age and gender matched – kindly brief.	Simple random sampling method will be used in which each member of the population has an equal chance of being selected. Random number table method will

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	be used. The study does not use age or gender matching during the randomization process. Patients will be assigned randomly to different groups with the help of random no. table method without considering age or gender to maintain unbiased allocation to both the groups and equal opportunity for all the patients in each group.

The above comments forwarded to the Principal-Investigator was reviewed by Primary reviewer:-

Second opinion of Primary reviewer:-	**PI response**
The Co-Investigator is just and Ayurvedic graduate working as emergency medical officer in a private (Nishot) hospital. It would have been better to recruit the Co-Investigator from some academic background (Ayurvedic College or Ayurvedic research center). Moreover the CV of Investigator from outside of KGMU also needs to be included.	The modification has been done. Details are as follows:- Dr. Prakash Raj Singh, Assistant Professor, Department of Kriya Sharir, Govt. P.G. Ayurvedic College & Hospital, SSVV, Varanasi. Mobile No.-9415228314 Email- prakashrajsingh65@gmail.com CV attached
To make sure that CTRI registration is approved before start of project.	Yes, the study will be registered on the CTRI (Clinical Trial Registry of India) website soon after the Ethical approval of the study from the Institution.
Also attach ICMR letter if available that indicats funding for pumpkin seeds & biochemical testing. A split overall budget in this regard would be appreciated.	Attached

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The above comments forwarded to the Principal-Investigator was reviewed by Primary reviewer:-

Third opinion of reviewer:-

- The Investigator has indicated the funding resource from another project)of ICMR) that has specific budget for specific simultaneous study and also the Ph.D. guide along with Principal-Investigator of ICMR project to comment if both projects can be carried out simultaneously rationally with funding (& manpower) from the budget allocated from single project only.

The above comments forwarded to the Principal-Investigator response have given by the Principal-Investigator.

Comment:

- Kindly provide the UPCST proposal.

Decision: Revise & Re-submit with response to queries in tabular format.

Ref. code: 124thECMIIB-Ph.D/P1

7- Clarification of research proposal entitled ***"Elucidate the regulatory role of miRNAs in epithelial to mesenchymal transition in cervical cancer patients"*** submitted by Mr. Praveen Kumar, Ph.D Scholar under the guidance Dr. Nitu Nigam, Associate Professor, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 187/CFAR/23 dated 16th September, 2023.

Previous Comment	PI response
The account of budget not indicated and sponsor is indicated as NA. Kindly specify the total budget (split up) and kindly specify the source of funding.	Corrected included the budget and the source of funding included. Page No. 1
Attach the CSIR-JRF papers pertaining to the candidate.	The JRF-NET Certificate has been enclosure
Kindly fill up the left blanks in annexure-1	Corrected. Page No. 1-4
'National significance with rational' indicates the detail about prostate cancer (in male) while the project is for cervical cancer in females.	Corrected Page No. 6
Patient information sheet in Hindi is to be included.	Patients information sheet in Hindi has been attached Page No.12-13

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Name and contact of Guide to be included in informed consent form.	Name and contact of guide included in informed consent form. Page No. 14 and 16.	
	All study procedures undertaken on patient's sample need to be briefed in informed consent form to the patient and not labeled as NA.	I have mentioned briefly about the study procedure. Page No. 14 and 16	
	The second and third aims pertain to the progression of cervical cancer and prognostic aspects of cervical cancer respectively, but there is neither indication of any clinical data been collected nor any follow-up data. Kindly attach a case sheet to record the clinical findings and specify which specific clinical prognostic marker is intended be correlated with molecular outcomes.	Socio-demographic and clinical data were added and patients case sheet were attached in methodology. Page No.27.	
	It is indicated that 60 normal cervical samples will be collected. Does it mean from normal subject? What will be the indication to take samples from normal person??Kindly specify.	Corrected, methodology Page No. 27	
	It is further indicated that patients will be included on the basis of well-defined inclusion and exclusion criteria. Those criteria included both cervical cancer and other serious uncontrollable medial conditions, decreasing life expectancy please clarify. Inclusion and exclusion criteria may be modified accordingly.	Changes done, inclusion and exclusion criteria has been modified. Page No.26 and 27	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The study design is case control and experimental if any control is included then kindly mention the inclusion criteria and include informed consent form as well as in information sheet for control.	This study is only case and control, inclusion and exclusion criteriais mention according controls. Page No.27
How will clinical validation be done as shown in last flowchart? Also specify some tentative micro RNA and EMT markers.	Changes done in flowchart. Some tentative miRNA and EMT markers already show in Review of literature and mention in the methodology also Page No. 31 and 32

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

Second opinion	PI response
Split budget need to be added.	Total budgets has been added Colom No.04 and CSIR-JRF/SRF award letter attached on page no.45
Regarding patients 9 & 11- Kindly enclosed ICF & information sheet for health controls both in English & Hindi.	We have to take 2ml blood sample from patients which do not have to be reported, Colom 11 ICE got tick by mistake and information sheet for health controls both English and Hindi are attaché. Page no.05 and 37 to 42.

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

Third opinion of reviewer:-

1. Split budget needs to be indicated in term of manpower and contingency, including consumables & needed instrument etc if needed.
2. Total budget as indicated is 2,42,646/- While the letter quoted in Annexure indicates 4,40,000/-? Why this discrepancy? There is no indication for contingency.
3. The above quoted letter suggest stipend for only one year (Nov 22 to Oct 23) While duration of prospective project is quoted as 3 yrs. What will be the source of funding after October, 2023. Kindly clarify through proper documents.
4. Mention the source of funding for laboratory work through proper documentation form funding agency.
5. Hence a three yr prospective funding should be submitted for this 3 yr

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

prospective study.

6. Kindly rectify your mistake in annexure 1.

The above comments forwarded to the Principal-Investigator vide this office letter no.1744/Ethics/2023 dated 27th September, 2023.

IEC Decision: Comments to be forwarded to PI to seek her in the forthcoming IEC Meeting

Ref. code: 124thECMIIB-Ph.D/P3

8- Clarification of research proposal entitled ***"Assessment of Th2 inflammatory mediators and their correlation with clinical parameters in phenotypes of bronchial Asthma"*** submitted by Ms. Shreya Tripathi, Ph.D. Scholar, under the guidance Dr. Ajay Kumar Verma, Professor Junior Grade, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 992/23 dated 16th September, 2023.

Previous EC Comment	PI response
The left blanks in annexure 1 should be filled.	Left blanks in Annexure 1 is filled as mentioned in EC comments. [Pg-1-3]
Methodology indicates that blood sample will be collected but is indicated otherwise in annexure.	We apologize for the same. Now, blood sample collection is mentioned in the ethical SOP. Please refer to page no.2
Kindly mention inclusion criteria of controls. The criteria of selecting attendants of patients need to be made carefully as attendants of asthmatics may have some genetic predisposition to influence the markers under study.	Thanks for the suggestion. I have added the inclusion criteria of controls. Healthy controls will be enrolled who are medically fit and has no underlying disease. It will be taken care that if attendants of asthmatics will participate as control, they are medically fit and not having any respiratory symptoms. Inclusion criteria of controls is added in the revised summary. Please refer to page no 24, 25.
It is indicated that age and gender matched controls will be collected. The criteria of selecting control child of 6 y age should also be mentioned.	The inclusion criteria of control child & gt;= 6 years of age is mentioned in the summary. Please refer to page no.25.
Where will the lab work be done or	Laboratory work will be carried out

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	undertaken?	in the Food Toxicology Laboratory, CSIR-IITR, Lucknow under the guidance of Dr. Prabhanshu Tripathi, Senior Scientist. Dr. Tripathi is co-guide in this PhD Thesis (Letter attached). [Pg- 6, 22]
	What will be the total budget of lab Investigations? Kindly submit a rough split estimate.	Thanks for your comment. I have added the budget estimate. Detailed list of lab expenses is mentioned in annexure 'X'. (Attached) [Pg. 4]
	No evidence is enclosed by the sponsor (University Grants Commission) that is indicated to fund the project.	I, Shreya Tripathi am working as UGC-JRF. Expenditure related to my laboratory work will be managed by my own fellowship; additionally in collaboration with CSIR-IITR. Certificate of UGC-JRF is attached in the given document. [Pg-5]
	Informed consent document from healthy subjects (controls) need to indicate that they will not directly be benefitted from this 5 ml blood collection.	As suggested, informed consent has been revised. It has been indicated that there will not be any direct benefit to the healthy volunteers after 5 ml blood sample collection.[Pg- 7,9].

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

Second opinion of reviewer:-

- The PI has clarified all the raised accept that separate ICF for cases & controls be used.

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

Second opinion of reviewer:-
Provisionally Approved

Decision: Approved

Ref. code: 124thECMIIB-Ph.D/P4

9-	Clarification of research proposal entitled ***"Elucidate the role of miRNA mediating epithelial to mesenchymal transition in chronic myeloid***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

leukemia" sponsored by DST Inspire Fellowship submitted by Ms. Surbhi Gupta, under the guidance Dr. Nitu Nigam, Associate Professor, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 190/CFAR/23 dated 20th September, 2023.

Previous EC Comment	PI response
The objectives are unclear, vague.	To analyze differential micro RNA in peripheral blood mononuclear cells (PBMC) of chronic myeloid leukemia patients for epithelial to mesenchymal transition. 2. Validation of differential differentially expressed (DE) genes in CML patients through qPCR. 3. To explore the role of screened miRNA in CML pathobiology and disease course.
What is the primary objective?	The primary objective of the study is to identify the different differential microRNA and to investigate their expression in chronic myeloid leukemia mediating through epithelial to mesenchymal transition.
Sample size calculation is based on which objective?	It is based on the first objective in which different micro RNA will be determined through sequencing. After that expression of selected miRNA having vital role in chronic myeloid leukemia mediating through epithelial to mesenchymal transition (EMT). Then the identified miRNA will be validated in all the CML patient samples through RT-PCR Finally, the pathobiology and disease course will be analyzed in CML modulating through epithelial to mesenchymal transition. Therefore the miRNA that has impact in CML regulating through

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		epithelial to mesenchymal will work as biomarkers for disease diagnosis.
	Sample size of 30, appears to be too little for this type of research.	The study is not related to population of India but the population of chronic myeloid leukemia epithelial cases in India whose prevalence is very small and we are studying the status of miRNA expressions in these cases. The CML in correlation with epithelial to mesenchymal transition (EMT) is yet more to explore. The new sample size for the proposed study is 55.

The above comments were forwarded to the Principal-Investigator which was put-up in the IEC Meeting:-

Decision: A Sub-Committee will be constituted & call to PI with her guide for discussion.

Ref. code: 124th ECM II B-FS/P1

10- Clarification of research proposal entitled "***Pulmonary rehabilitation program for patient with chronic Respiratory disease***" submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. KGMU/PRC/27/23 dated 28th August, 2023.

Previous IEC Comment:-

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	• Kindly provide properly filled Patient Information Sheet and kindly explain patient about standard procedure instead of writing as per SOP. ***The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-*** ***Recommendation of reviewer:-*** Provisionally Approved **Decision:** Approved ***Ref. code: 125th ECM IIA/P3***
11-	Clarification of research proposal entitled ***"Sentinel surveillance for national one health programme for prevention and control of zoonotic diseases"*** sponsored by National Center for Diseases Control, MOHFW, Shamnath Marg, Delhi submitted by Dr. Suruchi Shukla, Assistant Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 665/23 dated 29th August, 2023. ***Previous IEC Comment:-*** • Project is very sketchy. • No references cited/listed. • Although they will be collecting biological samples (blood/ urine/ CSF) yet they have applied for a consent waiver. ***The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-*** ***Recommendation of reviewer:-*** Provisionally Approved **Decision:** Approved ***Ref. code: 125th ECMIA/P6***
12-	Clarification of research proposal entitled ***"Integrated transciptomic and metabolmic analysis of metabolic disturbances in hormone receptor positive breast cancer cells"*** sponsored by Council of Science & Technology U.P. Lucknow submitted by Prof. Anand Kumar Mishra, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. EndoSurg/359/23 dated 22nd September, 2023.

Previous EC Comment	PI response
Comment 1: The project is very sketchy.	Initially, We were submitting the short

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		summary of the proposal. Now We submit the detailed proposal which contain all necessary information regarding the project.
	Comment 2: Sample size, inclusion, or exclusion of subjects not included.	**Sample Size:** The sample size was calculated based on a previous study that reported the average fold-changes of metabolites (Amino acid, bile acid, carbohydrates, vitamins and cofactors) in breast cancer is 3.3% (Park et al.,2019), 95% level of confidence and Error rate, usually set at 0.05 level is 4. Total 50 patients will be included in this study. We have used following statistical formula to calculate patient's sample size. Same has been mentioned in method section of research proposal on page on. 6. n=Z 2 P(1-P)/d 2 Where, • n = sample size, • Z = Z statistic for a level of confidence, for the level of confidence of 95%, which is conventional, Z value is 1.96. • P = expected prevalence or proportion (in proportion of one; if 3.3%, P = 0.033), • d = precision (in proportion of one; if 5%, d = 0.05). n=1.96x1.96x0.033x0.967/0.05 2 n=49.04
	Comment 3: Matched controls not properly defined.	Tissue adjacent to a tumor will be considered as matched control in this study. It represent a patient's normal cells, has characteristics

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	that distinguish it from both healthy and tumor tissue.
Comment 4: In objective 2 it is mentioned that expression analysis of corresponding genes will be carried out, but neither any gene has not been mentioned nor methodology for the same provided.	Please find the list of metabolites of interest. Patient survival will be correlated by using bioinformatics software Kaplan Meier Plotter. Mentioned in page number 6. Metabolites Boric acid Carbonate Citrate lactic acid L-Valine Glycine Phosphoric acid Lactate Isocitrate Succinate Butanedioic acid Uracil Serine L-Threonine Tromethamine α-Ketoglutarate L-Aspartic acid L-Glutamic acid D-Fructofuranose D-Glucose Palmitic acid Myo-inositol
Comment 6: how come the molecular biology unit (it is mentioned as the department) of the university can be the sponsoring Institution?	Pardon, It happened by mistake. This study is funded by Council of Science and technology, Uttar Pradesh.

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

Recommendation of reviewer:

Provisionally Approved

Decision: Approved

Ref. code: 125thECMIA/P7

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

13- Clarification of research proposal entitled ***"Longterm single versus dual antiplatelet therapy in patients with ischemic stroke due to intracranial atherosclerotic disease: A randomized trial"*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 410/Neuro/23 dated 14th September, 2023.

Previous EC Comment	PI response
Study variable and study parameters	Mentioned in Case Record Form
Research hypothesis	Already mentioned in Methodology of study. It includes study parameter such as Intracranial Atherosclerotic Disease; Bleeding risk
Sample size	Calculated from CHANCE trial (already mentioned in Methodology)
Statistical methods	Already mentioned in Methodology of study. Various tests like Two-tailed Chi-square test, Kaplan Meir survival analysis, Cox proportional hazard regression will be used.
Results presentation	Baseline data – is presented in case record form. Primary outcome – Recurrent ischemic stroke or transient ischemic attack, any Intracranial hemorrhage at the end of 12 months Adverse outcome – Intracranial hemorrhage using GUSTO classification

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

Recommendation of reviewer:

Provisionally Approved

Decision: Approved

Ref. code: 125th ECMIIA/P11

14- Clarification of research proposal entitled ***"Effect of incentive spirometer exercise on pulmonary function in children with spastic cerebral palsy-A prospective randomized case-control study"*** submitted by Dr. Sandeep

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Kumar Gupt, Assistant Professor, Department of PMR, King George's Medical University, U.P., Lucknow vide letter no. 5658/23 dated 14th September, 2023.

Previous EC Comment	PI response
Study design and planning	Cohort of Spastic cerebral palsy children are divided into two group after randomization a) First group (study group) also called Cases will do incentive spirometer plus conventional respiratory exercises and PFT parameters and MPT will be measured at base line and after 4 weeks of exercise program. b) Second group called control will do only conventional respiratory exercise and PFT parameter/variables will be measured at base line and after 4 weeks of exercise program.
Study variable and parameters	Study independent variable are age, gender, height, GMFCS score etc. Pulmonary function testing parameters or outcome variables like Vital capacity (VC), Forced expiratory volume in 1st second (FEV 1), FEV 1 /FVC, Tidal Volume (TV), Peak expiratory flow (PEF), Expiratory Reserve Volume (ERV) and Maximum Phonation Time (MPT). Specified and mentioned in revised proposal.
Research Hypothesis should be stated in terms of parameters.	Study Parameters are stated in hypothesis in revised proposal.
Sample size Calculation	Revised sample size is 27 in each group (Total-54)
Statistical Analysis	Rewritten in accordance with research hypothesis.

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer: Provisionally Approved **Decision:** Approved ***Ref. code: 125th ECMIIA/P12***
15-	Clarification of research proposal entitled "***Transfer learning assisted classification of dementia sub-types using voice recordings: a cross-sectional study***" submitted by Dr. Shailendra Mohan Tripathi, Associate Professor, Department of Geriatric & Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 314/DGMH/23 dated 6th September, 2023.

Previous EC Comment	PI response
The title should be more specific. The objective of the study is not clear from the title.	Revised title of my research proposal is: "Transfer Learning assisted classification of Dementia Subtype Using Speech sample from patients and healthy individuals : A Cross-Sectional Study.
It is prospective comparative cohort study.The two groups are being compared.	The above study is neither a cohort or a case control study. It is cross sectional study. We are going to do a Multiple class Classification. The classes used in the study are Cognitive normal individuals, Alzheimer's dementia, Vascular dementia, Fronto-temporal lobe dementia and Dementia of Lewy body".
Sample size calculation is not given.	We are going to use "Transfer learning (MFCC based neural network algorithm)- an artificial intelligent technique", which can work with a small sample size. However, it needs a minimum of 15-20 samples to

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		provide meaningful output. So, we have decided on 20 samples which is the minimum requirement of the algorithm to produce good results.
	The statistical analysis section is very general. It should be specific to the research hypothesis.	The voice recordings will be analyzed and classified using Convoluted neural network. The performance of the model will be assessed using F1 score, Accuracy, Area under the curve, Recall and Precision. Basic stats are not applicable for this study, as we are trying to build a artificial intelligence model.

The above comments were forwarded to the Principal-Investigatór and the response was reviewed by reviewer:-
Recommendation of reviewer:
Provisionally Approved
Decision: Approved

Ref. code: 125th ECMIIA/P13

16- Clarification of research proposal entitled "***Effect of combination treatment with escitalopram and risperidone in punding behavior among patients with dementia-a retrospective study***" submitted by Dr. Shailendra Mohan Tripathi, Associate Professor, Department of Geriatric & Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 313/DGMH/23 dated 6th September, 2023.

Previous EC Comment	PI response
This is retrospective case-control study.	This retrospective study will be conducted within a hospital setting to investigate the impact of combining Escitalopram and Risperidone on pounding behavior in individuals with dementia. In this study only patients with dementia (diagnosed) will be recruited. 2. This is not a case- control study

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		rather a hospital records-based study.
	The cases and controls should be exclusively defined for studying the effectiveness.	Subjects who have received a formal diagnosis of dementia, in accordance with the ICD-10 or DSM-5 criteria, will be enrolled as "cases." 2. The assessment of effectiveness will be centered around the changes observed in the scores of two standardized measures, namely the Neuropsychiatric Inventory (NPI) and QUIP-RS scale. 3. As it is a hospital record-based study, so we have no controls.
	Sample size calculation is not given	It is a hospital record-based study, this study will utilize data from the previous 12 months.
	In the absence of proper research hypothesis, the statistical analysis section looks arbitrary and in complete.	This study will adopt a hospital record-based approach, drawing on data from the preceding 12 months. 2. Additionally, hypothesis of the study had been added to new protocol. HYPOTHESIS- Null Hypothesis (H0): There is no significant change in the severity of punding ariable among patients with dementia when treated with a combination of Escitalopram and Risperidone. Alternative Hypothesis(H1): Treatment with a combination of Escitalopram and Risperidone leads to a significant reduction in the severity of pending behavior among patients with dementia. Statistical analysis:

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		In our analysis, we'll differentiate between parametric and non-parametric tests based on data distribution. For parametric data assuming normality, we'll use Repeated Measures ANOVA, within-group contrasts, and post hoc tests (Tukey's HSD or Bonferroni correction) for significant interval identification. Subgroup analysis will employ independent t-tests. Non-parametric data will undergo the Wilcoxon Signed-Rank Test for change assessment, the Friedman Test for multi-time point evaluation, and the Mann-Whitney U Test for subgroup comparison. We'll calculate effect sizes, conduct regression analysis, explore correlations, and visualize data using line plots orscatterplots.

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-
Recommendation of reviewer:
Provisionally Approved
Decision: Approved

Ref. code: 125thECMIIA/P14

17- Clarification of research proposal entitled "***Artificial intelligence guided BI-RADS classification for suspected breast mass using mammographic imaging data***" submitted by Dr. Priyanka Yadav, Assistant Professor, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 1057/RD/23 dated 19th September, 2023.

Previous EC Comment	PI response
This is a diagnostic test study	Explained
Nothing is said about the evaluation of proposed method of classification.	Explained
The sensitivity and specificity of	Explained

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	the proposed method are not discussed.	
	The sample size calculation is not given.	Explained
	What kind of AI models shall be used?	Explained
	The statistical analysis section is missing.	Explained

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-
Recommendation of reviewer:
Provisionally Approved
Decision: Approved

Ref. code: 125thECMIIA/P15

18- Clarification of research proposal ***"Association of advanced glycation end products with microvascular and neurodegenerative changes in diabetic retinopathy"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Dr. Nibha Mishra, Assistant Professor, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 1444/OPH/23 dated 1st September, 2023.

Previous IEC Comment:

- IEC form incomplete

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-
Second opinion of reviewer:

- Please resend full proposal. Only IEC form is attached in this and preceding mail.

The above comment were forwarded to the Principal-Investigator vide this office letter no.1842/Ethics/2023 dated 7th October, 2023: Reply awaited for
Decision: Reminder will be send to the Principal-Investigator

Ref. code: 125thECM II B-IMR-F/P1

19- Clarification of research protocol no. BCD-178-2/PREFER entitled ***"A double-blind, randomized clinical study of the efficacy and safety of BCD-178 and perjeta® as neoadjuvant therapy of HER2-positive breast cancer"*** sponsored by M/s JSC Biocad, Russia submitted by Prof. Abhinav Arun Sonkar, Head, Department of General Surgery, King George's Medical University, U.P., Lucknow, vide letter no. nil dated 2nd September, 2023.

Previous EC Comment	PI response
Budget sheet to be mentioned	Budget Sheet is attached
DCGI acknowledgment and permission letter awaited(if	Response awaited from sponsor side

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	required) |
	CTRI document to be send after registry | Response awaited from sponsor side

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

- The site budget is now attached.
- The DCGI Permission letter is awaited and this document is necessary to start the trial.

Decision: Conditional approved, kindly provide the above mentioned documents.

Ref. code: 125th ECMIIC/P1

20- Clarification of research protocol no. ABX464-105 entitled "***A randomized, double-blind, placebo-controlled, multicenter phase III study to evaluate the efficacy and safety of ABX464 once daily for induction treatment in subjects with moderately to severely active ulcerative colitis***" sponsored by M/s ABIVAX submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SGE/CT/12/2023 dated 22nd August, 2023.

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

- CTRI document should be submitted to EC Office as soon as trial registration occurs.

The above comment forwarded to the Principal-Investigator:-CTRI received.

The above documents were reviewed in the Meeting:-

1.1 ABX464-105_Clinical Study Protocol_Version 3.0 dated 06October2022

1.2 ABX464-105_Clinical Study Protocol_Version 3.0 dated 06October2022_Protocol Signature Page_08Dec2022

1.3 ABX464-105_Clarification_letter_All_CSP_28Nov2022_Final

1.4 ABX464-105_Rationale of Placebo use in the induction studies_25Aug2022

1.5 ABX464-105_Justification for including Pediatric and elderly population_25Aug2022

1.6 ABX464-105_Justification for collecting ethnicity data_25Aug2022

1.7 ABX464-105_Remote Data Verification Process_28Apr2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

2.1	ABX464_Investigator Brochure_Ed 8.2_17October2022
3.1	Abivax_ABX464_105_Version 2.0_17Sep2022_Masterdashboard_ATD
3.2	Abivax_ABX464_105_Version2.0_17Sep2022_Unique Forms
4.1	Main_V3.0IND(en)1.0(20Dec2022)
4.2	Main_V3.0IND(hi)1.0(20Dec2022)
4.3	Main_V3.0IND(hi)1.0(20Dec2022)_Translation Certificate dated 04Jan2023
4.4	Back Translation of Main_V3.0IND(hi)1.0(20Dec2022)
4.5	Back Translation of Main_V3.0IND(hi)1.0(20 Dec 2022)_Back Translation Certificate dated 04Jan2023
5.1	Other_V8.0IND(en)1.0(20 Dec 2022)
5.2	Other_V8.0IND(hi)1.0(20 Dec 2022)
5.3	Other_V8.0IND(hi)1.0(20 Dec 2022)_Translation Certificate dated 04 Jan 2023
5.4	Back Translation of Other_V8.0IND(hi)1.0(20 Dec 2022)
5.5	Back Translation of Other_V8.0IND(hi)1.0(20 Dec 2022)_Back Translation Certificate dated 04 Jan 2023
6.1	Assent(16-17 years)_V3.0IND(en)1.0(20 Dec 2022)
6.2	Assent(16-17 years)_V3.0IND(hi)1.0(20 Dec 2022)
6.3	Assent(16-17 years)_V3.0IND(hi)1.0(20 Dec 2022)_Translation Certificate dated 04 Jan 2023
6.4	Back Translation of Assent(16-17 years)_V3.0IND(hi)1.0(20 Dec 2022)
6.5	Back Translation of Assent(16-17 years)_V3.0IND(hi)1.0(20 Dec 2022)_Back Translation Certificate dated 04Jan2023
7.1	PMain_V3.0IND(en)1.0(20Dec2022)
7.2	PMain_V3.0IND(hi)1.0(20Dec2022)
7.3	PMain_V3.0IND(hi)1.0(20Dec2022)_Translation Certificate dated 04Jan2023
7.4	Back Translation of PMain_V3.0IND(hi)1.0(20Dec2022)
7.5	Back Translation of PMain_V3.0IND(hi)1.0(20Dec2022)_Back Translation Certificate dated 04Jan2023
8.1	Preg_V2.0IND(en)1.0(20Dec2022)
8.2	Preg_V2.0IND(hi)1.0(20Dec2022)
8.3	Preg_V2.0IND(hi)1.0(20Dec2022)_Translation Certificate dated 04Jan2023
8.4	Back Translation of Preg_V2.0IND(hi)1.0(20Dec2022)
8.5	Back Translation of Preg_V2.0IND(hi)1.0(20Dec2022)_Back Translation Certificate dated 04Jan2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	9.1 Option Cardiac Safety Sub Study_V3.0IND(en)1.0(20Dec2022) 9.2 Option Cardiac Safety Sub Study_V3.0IND(hi)1.0(20Dec2022) 9.3 Option Cardiac Safety Sub Study_V3.0IND(hi)1.0(20Dec2022)_Translation Certificate dated 04Jan2023 9.4 Back Translation of Option Cardiac Safety Sub Study_V3.0IND(hi)1.0(20Dec2022) 9.5 Back Translation of Option Cardiac Safety Sub Study_V3.0IND(hi)1.0(20Dec2022)_Back Translation Certificate dated 04Jan2023 10.1 ABX464-105_Audio Visual (A-V) Recording Declaration_V5.0IND(en)1.0(20Dec2022) 11.1 Abivax_ABX464-105_eCOA Daily eDiary_enIN_22Aug2022 11.2 Abivax_ABX464-105_eCOA Daily eDiary_enIN_22Aug2022_Translation Certificate_22Aug2022 11.3 Abivax_ABX464-105_eCOA Daily eDiary_hiIN_22Aug2022 11.4 Abivax_ABX464-105_eCOA Daily eDiary_hiIN_22Aug2022_Translation Certificate_22-Aug-2022 12.1 Abivax_ABX464-105_eCOA Inflammatory Bowel Disease Questionnaire_enIN_30Aug2022 12.2 Abivax_ABX464-105_eCOA Inflammatory Bowel Disease Questionnaire_enIN_30Aug2022_Translation Certificate_30Aug2022 12.3 Abivax_ABX464-105_eCOA Inflammatory Bowel Disease Questionnaire_hiIN_05Dec2019 12.4Abivax_ABX464-105_eCOA Inflammatory Bowel Disease Questionnaire_hiIN_5Dec2019_Translation Certificate_05Dec2019 13.1 Abivax_ABX464-105_eCOA EQ-5D-5L_enIN_23Sep2022 13.2 Abivax_ABX464-105_eCOA EQ-5D-5L_enIN_23Sep2022_Translation Certificate_23Sep2022 13.3 Abivax_ABX464-105_eCOA EQ-5D-5L_hiIN_23Sep2022 13.4 Abivax_ABX464-105_eCOA EQ-5D-5L_hiIN_23Sep2022_Translation Certificate_23Sep2022 14.1 Abivax_ABX464-105_eCOA WPAI UC V2_enIN_22Aug2022 14.2 Abivax_ABX464-105_eCOA WPAI UC V2_enIN_22Aug2022_Translation Certificate_22Aug2022 14.3 Abivax_ABX464-105_eCOA WPAI UC V2_hiIN_22Aug2022 14.4 Abivax_ABX464-105_eCOA WPAI UC V2_hiIN_22Aug2022_Translation Certificate_22Aug2022 15.1 Abivax_ABX464-105_eCOA FACIT-Fatigue_enIN_13Jan2023 15.2 Abivax_ABX464-105_eCOA FACIT-Fatigue_enIN_13Jan2023_Translation Certificate_13Jan2023

(Hardeep Singh) Malhotra
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	15.3 Abivax_ABX464-105_eCOA FACIT-Fatigue_hiIN_13Jan2023 15.4 Abivax_ABX464-105_eCOA FACIT-Fatigue_hiIN_13Jan2023_Translation Certificate_13Jan2023 16.1 Abivax_ABX464-105_eCOA Login Screens_English v3.0_11May2022 16.2 Abivax_ABX464-105_eCOA Login Screens_English v3.0_11May2022_Translation Certificate_31Aug2022 16.3 Abivax_ABX464-105_eCOA Login Screens_hindi v3.0_12Dec2020 16.4 Abivax_ABX464-105_eCOA Login Screens_Hindi - V3.0_12Dec2020_Translation Certificate_21Dec2020 17.1 Abivax_ABX464-105_FZA86006_DeviceLabel_DL1196.01enUS01_iPad_10 May 2022 17.2 Abivax_ABX464-105_FZA86006_DeviceLabel_DL1196.02enIN01_iPhone_22 Aug 2022 17.3Abivax_ABX464105_FZA86006_DeviceLabel_DL1196.02enIN01_iPhone_22 Aug2022_Translation Certificate_22Aug2022 18.1 Abivax_ABX464-105_Menu Screenshots_enIN_V1.0_22Aug2022 18.2 Abivax_ABX464-105_Menu Screenshots_enIN_22Aug2022_Translation Certificate_22Aug2022 18.3 Abivax_ABX464-105_eCOA Menu Screenshots_hiIN_22Aug2022 18.4 Abivax_ABX464-105_eCOA Menu Screenshots_hiIN_22Aug2022_Translation Certificate_22Aug2022 19.1 Abivax_ABX464-105_eCOA Study Drug Intake_enIN_22Aug2022 19.2 Abivax_ABX464-105_eCOA Study Drug Intake_enIN_22Aug2022_Translation Certificate_22Aug2022 19.3 Abivax_ABX464-105_eCOA Study Drug Intake_hiIN_22Aug2022 19.4 Abivax_ABX464-105_eCOA Study Drug Intake_hiIN_22Aug2022_Translation Certificate_22Aug2022 20.1 Abivax_ABX464-105_eCOA Training_enIN_22Aug2022 20.2 Abivax_ABX464-105_eCOA Training_enIN_22Aug2022_Translation Certificate_22Aug2022 20.3 Abivax_ABX464-105_eCOA Training_hiIN_22Aug2022 20.4 Abivax_ABX464-105_eCOA Training_hiIN_22Aug2022_Translation Certificate_22Aug2022 21.1 Abivax_ABX464-105_Patient ID Card_V01 IND(en)_16May2022 21.2 Abivax_ABX464-105_Patient ID Card_V01 IND(en)_16May2022_Translation Certificate_26Aug2022 21.3 Abivax_ABX464-105_Patient ID Card_V01 IND(hi)_16May2022 21.4 Abivax_ABX464-105_Patient ID Card_V01 IND(hi)_16May2022_Translation Certificate_13Sep2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	22.1 Abivax_ABX464-105_Urgency Card_V01 IND(en)_10May2022 22.2 Abivax_ABX464-105_Urgency Card_V01 IND(en)_10May2022_Translation Certificate_26Aug2022 22.3 Abivax_ABX464-105_Urgency Card_V01 IND(hi)_10May2022 22.4 Abivax_ABX464-105_Urgency Card_V01 IND(hi)_10May2022_Translation Certificate_13Sep2022 23.1 Patient Poster, 16 May 2022 [V01 IND(en)] 23.2 Patient Poster, 16 May 2022 [V01 IND(en)]_Translation Certificate_26Aug2022 23.3 Patient Poster, 16 May 2022 [V01 IND(hi)] 23.4 Patient Poster, 16 May 2022 [V01 IND(hi)]_Translation Certificate_13Sep2022 24.1 Abivax_ABX464-105_Headache Questionnaire_English_Version 3.0_25Feb2022 24.2 Abivax_ABX464-105_Headache Questionnaire_Version 3.0_25Feb2022_Translated from English to Hindi on 06October2022 24.3 Abivax_ABX464-105_Headache Questionnaire_Version 3.0_25Feb2022_Translated from English to Hindi on 06October2022_Translation Certificate_06Oct2022 25.1 Doctor-to-Patient Letter, 23 Aug 2022 [V01 IND(en)01] 25.2 Doctor-to-Patient Letter, 23 Aug 2022 [V01 IND(en)01]_Translation Certificate_26Aug2022 25.3 Doctor-to-Patient Letter, 24 Aug 2022 [V01 IND(hi)01] 25.4 Doctor-to-Patient Letter, 24 Aug 2022 [V01 IND(hi)01]_Translation Certificate_13Sep2022 26.1 ePRO Patient Training_Animation Video Storyboard_11 Oct 2022 [V02 IND(en)] 26.2 ABTECT Studies_ePRO Patient Training_India_EN_V1-720p-221114 26.3 ePRO Patient Training_Animation Video Storyboard_11 Oct 2022 [V02 IND(en)]_Translation Certificate_31Oct2022 26.4 ePRO Patient Training_Animation Video Storyboard_11 Oct 2022 [V02 IND(hi)] 26.5 ABTECT Studies_ePRO Patient Training_Hindi_India_v-720p-221124 26.6 ePRO Patient Training_Animation Video Storyboard_11 Oct 2022 [V02 IND(hi)]_Translation Certificate_07Nov2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	27.1 Bowel Prep Patient Training_Animation Video Storyboard_01 Jul 2022 [V01 IND(en)] 27.2 Bowel Prep Patient Training_Animation Video Storyboard_01 Jul 2022 [V01 IND(en)]_Translation Certificate_26Aug2022 27.3 Bowel Prep Patient Training_Animation Video Storyboard_01 Jul 2022 [V01 IND(hi)] 27.4 Bowel Prep Patient Training_Animation Video Storyboard_01 Jul 2022 [V01 IND(hi)]_Translation Certificate_13Sep2022 28.1 Patient Bowel Preparation Card, 27 May 2022 [V01 IND(en)] 28.2 Patient Bowel Preparation Card, 27 May 2022 [V01 IND(en)]_Translation Certificate_26Aug2022 28.3 Patient Bowel Preparation Card, 27 May 2022 [V01 IND(hi)] 28.4 Patient Bowel Preparation Card, 27 May 2022 [V01 IND(hi)]_Translation Certificate_13Sep2022 29.1 Photo card for skin lesions, 01 Jul 2022 [V01 IND(en)] 29.2 Photo card for skin lesions, 01 Jul 2022 [V01 IND(en)]_Translation Certificate_26Aug2022 29.3 Photo card for skin lesions, 01 Jul 2022 [V01 IND(hi)] 29.4 Photo card for skin lesions, 01 Jul 2022 [V01 IND(hi)]_Translation Certificate_13Sep2022 30.1 ABX464 Skin lesion Form_Template V1.0_01June2022_English 30.2 ABX464 Skin lesion Form_Template_V1.0_01June2022_Translated from English to Hindi_06Oct22 30.3 ABX464 Skin lesion Form_Template_V1.0_01June2022_Translated from English to Hindi_06Oct22_Translation Certificate_06Oct2022 31.1 ABX464 Instruction in case of Skin lesion_Template V1.0_03June2022 31.2 ABX464 Instruction in case of Skin lesion – Template V1.0_03June 2022_Translated from English to Hindi on 19Jan2023 31.3 ABX464 Instruction in case of Skin lesion – Template V1.0_03June 2022_Translated from English to Hindi on 19Jan2023_Translation Certificate_19Jan2023 32.1 ABX464_Skin Lesion File Note_13Jun2022 33.1 ABX464-105_Stool collection instruction for patients_Global v 1.0_24 June 2022_English 33.2 ABX464-105_Stool collection instruction for patients_Global version 1.0_24Jun22_Hindi_Translated from English to Hindi on 06Oct2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	33.3 ABX464-105_Stool collection instruction for patients_Global version 1.0_24Jun22_Hindi_Translated from English to Hindi on 06Oct2022_Translation Certificate_06Oct2022 34.1 Informed Consent Guide, 22 Nov 2022 [V02 IND(en)] 34.2 Informed Consent Guide, 22 Nov 2022 [V02 IND(en)]_Translation Certificate_20Dec2022 34.3 Informed Consent Guide, 22 Nov 2022 [V02 IND(hi)] 34.4 Informed Consent Guide, 22 Nov 2022 [V02 IND(hi)]_Translation Certificate_28Dec2022 35.1 Patient Brochure, 22 Nov 2022 [V02 IND(en)] 35.2 Patient Brochure, 22 Nov 2022 [V02 IND(en)]_Translation Certificate_20Dec2022 35.3 Patient Brochure, 22 Nov 2022 [V02 IND(hi)] 35.4 Patient Brochure, 22 Nov 2022 [V02 IND(hi)]_Translation Certificate_28Dec2022 36.1 Patient Brochure (Adult Participants Only), 22 Nov 2022 [V02 IND(en)] 36.2 Patient Brochure (Adult Participants Only), 22 Nov 2022 [V02 IND(en)]_Translation Certificate_20Dec2022 36.3 Patient Brochure (Adult Participants Only), 22 Nov 2022 [V02 IND(hi)] 36.4 Patient Brochure (Adult Participants Only), 22 Nov 2022 [V02 IND(hi)]_Translation Certificate_28Dec2022 37.1 Patient Study Guide, 22 Nov 2022 [V02 IND(en)] 37.2 Patient Study Guide, 22 Nov 2022 [V02 IND(en)]_Translation Certificate_20Dec2022 37.3 Patient Study Guide, 22 Nov 2022 [V02 IND(hi)] 37.4 Patient Study Guide, 22 Nov 2022 [V02 IND(hi)]_Translation Certificate_28Dec2022 38.1 Pediatric Assent Guide, 22 Nov 2022 [V02 IND(en)] 38.2 Pediatric Assent Guide, 22 Nov 2022 [V02 IND(en)]_Translation Certificate_20Dec2022 38.3 Pediatric Assent Guide, 22 Nov 2022 [V02 IND(hi)] 38.4 Pediatric Assent Guide, 22 Nov 2022 [V02 IND(hi)]_Translation Certificate_28Dec2022 39.Abivax_ABX464105_106_107_eCOA_Technologies_Translation_Document_Versions_and_Dates_NTF_v1.0_22Nov2022 40. Investigator Welcome Letter, 28 Jul 2022 [V01 Global(en)] 41. Site Poster, 06 Jul 2022 [V01 Global(en)] 42.1 Physician Referral Letter, 08 Nov 2022 [V02 Global(en)]

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	43. Study information slides, 08Nov2022[V02Global(en)] 44.1 Chart Review Checklist, 08 Nov 2022 [V02 Global(en)] 45.1 Eligibility Criteria Booklet, 08 Nov 2022 [V02 Global(en)] 46. ABX464-105_Mini Protocol Cover_V3.0_06Oct2022 47.1 ABX464-105_Certificate of Insurance dated 21Dec2022_Policy number P0023200001-9999-100091_Expiry date31Aug2025 47.2 ABX464-105_Policy schedule_Policy number P0023200001-9999-100091_Expiry date 31Aug2025_Issued on 14Dec2022 48.1 Abivax_ABX464-105_India CTA Template 49.1 ABX464-105_Independent Data Monitoring Committee charter_V1.0_10Oct2022 50.1 ABX464-105_Independent Cardiovascular Safety Committee Charter_Version1.0_25August2022 51.1 Abivax_ABX464-105_FZA86006_RA submission letter_27Dec2022 51.2 Abivax_ABX464-105_FZA86006_RA submission Acknowledgement_28Dec2022 52.1 Abivax_ABX464-105_FZA86006_59104_Dr. Abhijit Chandra_CV_22Sep2022 52.2 Abivax_ABX464-105_FZA86006_59104_Dr. Abhijit Chandra_MRC 52.3 Abivax_ABX464-105_FZA86006_59104_Dr. Abhijit Chandra_GCP_04Mar2022 52.4 Abivax_ABX464-105_FZA86006_59104_Dr. Abhijit Chandra_IU_08Dec2022 53. Drug Import License for examination, test and analysis bearing no.Tl/CT/23/000088 dated 11-May-2023 54. Drug import License for examination, test and analysis bearing no. TL/CT/23/000089Dated 11-May-2023 55.DCGI Approval dated 12- May-2023 **Decision:** Approval subject to fulfillment & Administrative formalities. ***Ref. code: 125th ECMIIC/P2***
21-	Clarification of research protocol no. ABX464-107 entitled "***A randomized, double-blind, multicenter phase III study to evaluate the long-term efficacy and safety of ABX464 25mg or 50mg once daily as a maintenance therapy in subjects with moderately to severely active ulcerative colitis (Short title: ABTECT-Maintenance)***" sponsored by M/s ABIVAX submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology, King

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. SGE/CT/13/2023 dated 22nd August, 2023. August, 2023. ***The above comments were forwarded to the Principal-Investigator and the response was reviewed by Primary reviewer:-*** • CTRI document should be submitted to EC Office as soon as trial registration occurs. ***The above comment forwarded to the Principal-Investigator:-***CTRI received. ***The following documents were reviewed in the Meeting:-*** 1.8 ABX464-105_Clinical Study Protocol_Version 3.0 dated 06October2022 1.9 ABX464-105_Clinical Study Protocol_Version 3.0 dated 06October2022_Protocol Signature Page_08Dec2022 1.10 ABX464-105_Clarification_letter_All_CSP_28Nov2022_Final 1.11 ABX464-105_Rationale of Placebo use in the induction studies_25Aug2022 1.12 ABX464-105_Justification for including Pediatric and elderly population_25Aug2022 1.13 ABX464-105_Justification for collecting ethnicity data_25Aug2022 1.14 ABX464-105_Remote Data Verification Process_28Apr2022 2.1 ABX464_Investigator Brochure_Ed 8.2_17October2022 3.1 Abivax_ABX464_105_Version 2.0_17Sep2022_Masterdashboard_ATD 3.2 Abivax_ABX464_105_Version2.0_17Sep2022_Unique Forms 4.1 Main_V3.0IND(en)1.0(20Dec2022) 4.2 Main_V3.0IND(hi)1.0(20Dec2022) 4.3 Main_V3.0IND(hi)1.0(20Dec2022)_Translation Certificate dated 04Jan2023 4.4 Back Translation of Main_V3.0IND(hi)1.0(20Dec2022 4.5 Back Translation of Main_V3.0IND(hi)1.0(20 Dec 2022)_Back Translation Certificate dated 04Jan2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	5.1 Other_V8.0IND(en)1.0(20 Dec 2022) 5.2 Other_V8.0IND(hi)1.0(20 Dec 2022) 5.3 Other_V8.0IND(hi)1.0(20 Dec 2022)_Translation Certificate dated 04 Jan 2023 5.4 Back Translation of Other_V8.0IND(hi)1.0(20 Dec 2022) 5.5 Back Translation of Other_V8.0IND(hi)1.0(20 Dec 2022)_Back Translation Certificate dated 04 Jan 2023 6.1 Assent(16-17 years)_V3.0IND(en)1.0(20 Dec 2022) 6.2 Assent(16-17 years)_V3.0IND(hi)1.0(20 Dec 2022) 6.3 Assent(16-17 years)_V3.0IND(hi)1.0(20 Dec 2022)_Translation Certificate dated 04 Jan 2023 6.4 Back Translation of Assent(16-17 years)_V3.0IND(hi)1.0(20 Dec 2022) 6.5 Back Translation of Assent(16-17 years)_V3.0IND(hi)1.0(20 Dec 2022)_Back Translation Certificate dated 04Jan2023 7.1 PMain_V3.0IND(en)1.0(20Dec2022) 7.2 PMain_V3.0IND(hi)1.0(20Dec2022) 7.3 PMain_V3.0IND(hi)1.0(20Dec2022)_Translation Certificate dated 04Jan2023 7.4 Back Translation of PMain_V3.0IND(hi)1.0(20Dec2022) 7.5 Back Translation of PMain_V3.0IND(hi)1.0(20Dec2022)_Back Translation Certificate dated 04Jan2023 8.1 Preg_V2.0IND(en)1.0(20Dec2022) 8.2 Preg_V2.0IND(hi)1.0(20Dec2022) 8.3 Preg_V2.0IND(hi)1.0(20Dec2022)_Translation Certificate dated 04Jan2023 8.4 Back Translation of Preg_V2.0IND(hi)1.0(20Dec2022) 8.5 Back Translation of Preg_V2.0IND(hi)1.0(20Dec2022)_Back Translation Certificate dated 04Jan2023 9.1 Option Cardiac Safety Sub Study_V3.0IND(en)1.0(20Dec2022) 9.2 Option Cardiac Safety Sub Study_V3.0IND(hi)1.0(20Dec2022) 9.3 Option Cardiac Safety Sub Study_V3.0IND(hi)1.0(20Dec2022)_Translation Certificate dated 04Jan2023 9.4 Back Translation of Option Cardiac Safety Sub Study_V3.0IND(hi)1.0(20Dec2022) 9.5 Back Translation of Option Cardiac Safety Sub Study_V3.0IND(hi)1.0(20Dec2022)_Back Translation Certificate dated 04Jan2023 10.1ABX464-105_AudioVisual(A-V)Recording Declaration_V5.0IND(en)1.0(20Dec2022) 11.1 Abivax_ABX464-105_eCOA Daily eDiary_enIN_22Aug2022 11.2 Abivax_ABX464-105_eCOA Daily eDiary_enIN_22Aug2022_Translation Certificate_22Aug2022 11.3 Abivax_ABX464-105_eCOA Daily eDiary_hiIN_22Aug2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	11.4 Abivax_ABX464-105_eCOA Daily eDiary_hiIN_22Aug2022_Translation Certificate_22-Aug-2022 12.1 Abivax_ABX464-105_eCOA Inflammatory Bowel Disease Questionnaire_enIN_30Aug2022 12.2 Abivax_ABX464-105_eCOA Inflammatory Bowel Disease Questionnaire_enIN_30Aug2022_Translation Certificate_30Aug2022 12.3 Abivax_ABX464-105_eCOA Inflammatory Bowel Disease Questionnaire_hiIN_05Dec2019 12.4Abivax_ABX464-105_eCOA Inflammatory Bowel Disease Questionnaire_hiIN_5Dec2019_Translation Certificate_05Dec2019 13.1 Abivax_ABX464-105_eCOA EQ-5D-5L_enIN_23Sep2022 13.2 Abivax_ABX464-105_eCOA EQ-5D-5L_enIN_23Sep2022_Translation Certificate_23Sep2022 13.3 Abivax_ABX464-105_eCOA EQ-5D-5L_hiIN_23Sep2022 13.4 Abivax_ABX464-105_eCOA EQ-5D-5L_hiIN_23Sep2022_Translation Certificate_23Sep2022 14.1 Abivax_ABX464-105_eCOA WPAI UC V2_enIN_22Aug2022 14.2 Abivax_ABX464-105_eCOA WPAI UC V2_enIN_22Aug2022_Translation Certificate_22Aug2022 14.3 Abivax_ABX464-105_eCOA WPAI UC V2_hiIN_22Aug2022 14.4 Abivax_ABX464-105_eCOA WPAI UC V2_hiIN_22Aug2022_Translation Certificate_22Aug2022 15.1 Abivax_ABX464-105_eCOA FACIT-Fatigue_enIN_13Jan2023 15.2 Abivax_ABX464-105_eCOA FACIT-Fatigue_enIN_13Jan2023_Translation Certificate_13Jan2023 15.3 Abivax_ABX464-105_eCOA FACIT-Fatigue_hiIN_13Jan2023 15.4 Abivax_ABX464-105_eCOA FACIT-Fatigue_hiIN_13Jan2023_Translation Certificate_13Jan2023 16.1 Abivax_ABX464-105_eCOA Login Screens_English v3.0_11May2022 16.2 Abivax_ABX464-105_eCOA Login Screens_English v3.0_11May2022_Translation Certificate_31Aug2022 16.3 Abivax_ABX464-105_eCOA Login Screens_hindi v3.0_12Dec2020 16.4 Abivax_ABX464-105_eCOA Login Screens_Hindi - V3.0_12Dec2020_Translation Certificate_21Dec2020 17.1 Abivax_ABX464-105_FZA86006_DeviceLabel_DL1196.01enUS01_iPad_10 May 2022 17.2Abivax_ABX464-105_FZA86006_DeviceLabel_DL1196.02enIN01_iPhone_22 Aug 2022 17.3Abivax_ABX464105_FZA86006_DeviceLabel_DL1196.02enIN01_iPhone_22 Aug2022_Translation Certificate_22Aug2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	18.1 Abivax_ABX464-105_Menu Screenshots_enIN_V1.0_22Aug2022 18.2 Abivax_ABX464-105_Menu Screenshots_enIN_22Aug2022_Translation Certificate_22Aug2022 18.3 Abivax_ABX464-105_eCOA Menu Screenshots_hiIN_22Aug2022 18.4 Abivax_ABX464-105_eCOA Menu Screenshots_hiIN_22Aug2022_Translation Certificate_22Aug2022 19.1 Abivax_ABX464-105_eCOA Study Drug Intake_enIN_22Aug2022 19.2Abivax_ABX464-105_eCOA Study Drug Intake_enIN_22Aug2022_Translation Certificate_22Aug2022 19.3 Abivax_ABX464-105_eCOA Study Drug Intake_hiIN_22Aug2022 19.4 Abivax_ABX464-105_eCOA Study Drug Intake_hiIN_22Aug2022_Translation Certificate_22Aug2022 20.1 Abivax_ABX464-105_eCOA Training_enIN_22Aug2022 20.2 Abivax_ABX464-105_eCOA Training_enIN_22Aug2022_Translation Certificate_22Aug2022 20.3 Abivax_ABX464-105_eCOA Training_hiIN_22Aug2022 20.4 Abivax_ABX464-105_eCOA Training_hiIN_22Aug2022_Translation Certificate_22Aug2022 21.1 Abivax_ABX464-105_Patient ID Card_V01 IND(en)_16May2022 21.2 Abivax_ABX464-105_Patient ID Card_V01 IND(en)_16May2022_Translation Certificate_26Aug2022 21.3 Abivax_ABX464-105_Patient ID Card_V01 IND(hi)_16May2022 21.4 Abivax_ABX464-105_Patient ID Card_V01 IND(hi)_16May2022_Translation Certificate_13Sep2022 22.1 Abivax_ABX464-105_Urgency Card_V01 IND(en)_10May2022 22.2 Abivax_ABX464-105_Urgency Card_V01 IND(en)_10May2022_Translation Certificate_26Aug2022 22.3 Abivax_ABX464-105_Urgency Card_V01 IND(hi)_10May2022 22.4 Abivax_ABX464-105_Urgency Card_V01 IND(hi)_10May2022_Translation Certificate_13Sep2022 23.1 Patient Poster, 16 May 2022 [V01 IND(en)] 23.2 Patient Poster, 16 May 2022 [V01 IND(en)]_Translation Certificate_26Aug2022 23.3 Patient Poster, 16 May 2022 [V01 IND(hi)] 23.4 Patient Poster, 16 May 2022 [V01 IND(hi)]_Translation Certificate_13Sep2022 24.1 Abivax_ABX464-105_Headache Questionnaire_English_Version 3.0_25Feb2022 24.2Abivax_ABX464-105_HeadacheQuestionnaire_Version 3.0_25Feb2022_Translated from English to Hindi on 06October2022 24.3Abivax_ABX464-105_HeadacheQuestionnaire_Version

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	3.0_25Feb2022_Translated from English to Hindi on 06October2022_Translation Certificate_06Oct2022 25.1 Doctor-to-Patient Letter, 23 Aug 2022 [V01 IND(en)01] 25.2 Doctor-to-Patient Letter, 23 Aug 2022 [V01 IND(en)01]_Translation Certificate_26Aug2022 25.3 Doctor-to-Patient Letter, 24 Aug 2022 [V01 IND(hi)01] 25.4 Doctor-to-Patient Letter, 24 Aug 2022 [V01 IND(hi)01]_Translation Certificate_13Sep2022 26.1 ePRO Patient Training_Animation Video Storyboard_11 Oct 2022 [V02 IND(en)] 26.2 ABTECT Studies_ePRO Patient Training_India_EN_V1-720p-221114 26.3 ePRO Patient Training_Animation Video Storyboard_11 Oct 2022 [V02 IND(en)]_Translation Certificate_31Oct2022 26.4 ePRO Patient Training_Animation Video Storyboard_11 Oct 2022 [V02 IND(hi)] 26.5 ABTECT Studies_ePRO Patient Training_Hindi_India_v-720p-221124 26.6 ePRO Patient Training_Animation Video Storyboard_11 Oct 2022 [V02 IND(hi)]_Translation Certificate_07Nov2022 27.1 Bowel Prep Patient Training_Animation Video Storyboard_01 Jul 2022 [V01 IND(en)] 27.2 Bowel Prep Patient Training_Animation Video Storyboard_01 Jul 2022 [V01 IND(en)]_Translation Certificate_26Aug2022 27.3 Bowel Prep Patient Training_Animation Video Storyboard_01 Jul 2022 [V01 IND(hi)] 27.4 Bowel Prep Patient Training_Animation Video Storyboard_01 Jul 2022 [V01 IND(hi)]_Translation Certificate_13Sep2022 28.1 Patient Bowel Preparation Card, 27 May 2022 [V01 IND(en)] 28.2 Patient Bowel Preparation Card, 27 May 2022 [V01 IND(en)]_Translation Certificate_26Aug2022 28.3 Patient Bowel Preparation Card, 27 May 2022 [V01 IND(hi)] 28.4 Patient Bowel Preparation Card, 27 May 2022 [V01 IND(hi)]_Translation Certificate_13Sep2022 29.1 Photo card for skin lesions, 01 Jul 2022 [V01 IND(en)] 29.2 Photo card for skin lesions, 01 Jul 2022 [V01 IND(en)]_Translation Certificate_26Aug2022 29.3 Photo card for skin lesions, 01 Jul 2022 [V01 IND(hi)] 29.4 Photo card for skin lesions, 01 Jul 2022 [V01 IND(hi)]_Translation Certificate_13Sep2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	30.1 ABX464 Skin lesion Form_Template V1.0_01June2022_English 30.2 ABX464 Skin lesion Form_Template_V1.0_01June2022_Translated from English to Hindi_06Oct22 30.3 ABX464 Skin lesion Form_Template_V1.0_01June2022_Translated from English to Hindi_06Oct22_Translation Certificate_06Oct2022 31.1 ABX464 Instruction in case of Skin lesion_Template V1.0_03June2022 31.2 ABX464 Instruction in case of Skin lesion – Template V1.0_03June 2022_Translated from English to Hindi on 19Jan2023 31.3 ABX464 Instruction in case of Skin lesion – Template V1.0_03June 2022_Translated from English to Hindi on 19Jan2023_Translation Certificate_19Jan2023 32.1 ABX464_Skin Lesion File Note_13Jun2022 33.1 ABX464-105_Stool collection instruction for patients_Global v 1.0_24 June 2022_English 33.2 ABX464-105_Stool collection instruction for patients_Global version 1.0_24Jun22_Hindi_Translated from English to Hindi on 06Oct2022 33.3 ABX464-105_Stool collection instruction for patients_Global version 1.0_24Jun22_Hindi_Translated from English to Hindi on 06Oct2022_Translation Certificate_06Oct2022 34.1 Informed Consent Guide, 22 Nov 2022 [V02 IND(en)] 34.2 Informed Consent Guide, 22 Nov 2022 [V02 IND(en)]_Translation Certificate_20Dec2022 34.3 Informed Consent Guide, 22 Nov 2022 [V02 IND(hi)] 34.4 Informed Consent Guide, 22 Nov 2022 [V02 IND(hi)]_Translation Certificate_28Dec2022 35.1 Patient Brochure, 22 Nov 2022 [V02 IND(en)] 35.2 Patient Brochure, 22 Nov 2022 [V02 IND(en)]_Translation Certificate_20Dec2022 35.3 Patient Brochure, 22 Nov 2022 [V02 IND(hi)] 35.4 Patient Brochure, 22 Nov 2022 [V02 IND(hi)]_Translation Certificate_28Dec2022 36.1 Patient Brochure (Adult Participants Only), 22 Nov 2022 [V02 IND(en)] 36.2 Patient Brochure (Adult Participants Only), 22 Nov 2022 [V02 IND(en)]_Translation Certificate_20Dec2022 36.3 Patient Brochure (Adult Participants Only), 22 Nov 2022 [V02 IND(hi)] 36.4 Patient Brochure (Adult Participants Only), 22 Nov 2022 [V02 IND(hi)]_Translation Certificate_28Dec2022 37.1 Patient Study Guide, 22 Nov 2022 [V02 IND(en)] 37.2 Patient Study Guide, 22 Nov 2022 [V02 IND(en)]_Translation Certificate_20Dec2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	37.3 Patient Study Guide, 22 Nov 2022 [V02 IND(hi)] 37.4 Patient Study Guide, 22 Nov 2022 [V02 IND(hi)]_Translation Certificate_28Dec2022 38.1 Pediatric Assent Guide, 22 Nov 2022 [V02 IND(en)] 38.2 Pediatric Assent Guide, 22 Nov 2022 [V02 IND(en)]_Translation Certificate_20Dec2022 38.3 Pediatric Assent Guide, 22 Nov 2022 [V02 IND(hi)] 38.4 Pediatric Assent Guide, 22 Nov 2022 [V02 IND(hi)]_Translation Certificate_28Dec2022 39.Abivax_ABX464105_106_107_eCOA_Technologies_Translation_Document_Versions_and_Dates_NTF_v1.0_22Nov2022 40. Investigator Welcome Letter, 28 Jul 2022 [V01 Global(en)] 41. Site Poster, 06 Jul 2022 [V01 Global(en)] 42.1 Physician Referral Letter, 08 Nov 2022 [V02 Global(en)] 43. Study information slides, 08Nov2022[V02Global(en)] 44.1 Chart Review Checklist, 08 Nov 2022 [V02 Global(en)] 45.1 Eligibility Criteria Booklet, 08 Nov 2022 [V02 Global(en)] 46. ABX464-105_Mini Protocol Cover_V3.0_06Oct2022 47.1 ABX464-105_Certificate of Insurance dated 21Dec2022_Policy number P0023200001-9999-100091_Expiry date31Aug2025 47.2 ABX464-105_Policy schedule_Policy number P0023200001-9999-100091_Expiry date 31Aug2025_Issued on 14Dec2022 48.1 Abivax_ABX464-105_India CTA Template 49.1 ABX464-105_Independent Data Monitoring Committee charter_V1.0_10Oct2022 50.1 ABX464-105_Independent Cardiovascular Safety Committee Charter_Version1.0_25August2022 51.1 Abivax_ABX464-105_FZA86006_RA submission letter_27Dec2022 51.2Abivax_ABX464-105_FZA86006_RAsubmission Acknowledgement_28Dec2022 52.1 Abivax_ABX464-105_FZA86006_59104_Dr. Abhijit Chandra_CV_22Sep2022 52.2 Abivax_ABX464-105_FZA86006_59104_Dr. Abhijit Chandra_MRC 52.3Abivax_ABX464-105_FZA86006_59104_Dr.Abhijit Chandra_GCP_04Mar2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	52.4 Abivax_ABX464-105_FZA86006_59104_Dr. Abhijit Chandra_IU_08Dec2022 53. Drug Import License for examination, test and analysis bearing no.TI/CT/23/000088 dated 11-May-2023 54. Drug import License for examination, test and analysis bearing no. TL/CT/23/000089Dated 11-May-2023 55.DCGI Approval dated 12- May-2023 **Decision:** Approval subject to fulfillment & Administrative formalities. ***Ref. code: 125th ECMIIC/P3***
22-	Clarification of research proposal entitled ***"Exploring small RNA expression in oral potentially malignant disorder (OPMD) and oral squamous cell carcinoma (OSCC)"*** submitted by Mrs. Jaya Singhal, Laboratory Technician, Department of Health Research Multidisciplinary Research Unit through her Mentor Prof. Raghuwar D. Singh, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. DHR/MRU/3731 dated 18th September, 2023. ***The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 126th ECMIB/P4***
23-	Clarification of research proposal entitled ***"Role of preoperative chlorhexidine mouth wash in the prevention of postoperative respiratory complications in patients with poor oral hygiene undergoing elective surgery-randomized controlled trial"*** sponsored by UP Council of Science & Technology, Lucknow submitted by Dr. Shefali Gautam, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1221/23 dated 29th September, 2023.

Previous EC Comment	PI response
The Study of objective are not clear	Study objective revised
RCT fundamentals are missing	Methodology revised as per CONSORT Guidelines.
Sample size calculation is arbitrary	Sample size recalculated as per primary objective
Statistical method for analysis not clear	Revised

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	How will the result have presented?	Data analysis revised and CONSORT Flow diagram added

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-
Recommendation of reviewer:
Provisionally Approved
Decision: Approved

Ref. code: 126th ECMIIA/P2

24- Clarification of research proposal entitled "***Analysis of pitfalls encountered in squash cytology in adult and pediatric patients with central nervous system lesions: A tertiary Hospital experience***" submitted by Dr. Shalini Bhalla, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1425/23 dated 6th October, 2023.

Previous EC Comment	PI response
This is a retrospective observational study.	Retrospective observational study mentioned in study design
How the pitfalls are evaluated? The outcome variables should be properly defined.	For identifying the pitfalls, the clinical and radiological information provided would be reviewed for incomplete information. Squash cytology smears would be reviewed for the cause of pitfalls as insufficient material, nonrepresentative material and missed diagnosis. Added in material and methods of proposal.
What will be the use of pitfall evaluation?	1) To create awareness of pitfalls encountered during intraoperative squash cytology diagnosis. 2) To highlight importance of good clinical-radiological correlation with squash cytology for definitive diagnosis Added in aims and objectives
After identifying the study variables and parameters, the research hypothesis should be properly formulated.	Knowledge of limitations and errors of squash smear cytology help pathologists identify pitfalls that can

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		occur during intraoperative diagnosis Added in Hypothesis and objectives.
	In the absence of research hypothesis, sample size calculation seems to be arbitrary and out of context.	Sample size recalculated and minimum Sample size is 182. The calculation for sample size has now been added in heading sample size
	Statistical analysis section is missing	The cases were categorized into true positives, false positives, true negatives, and false negatives. Diagnostic accuracy, sensitivity, and specificity, Positive and negative predictive value will be calculated from Galan and Gambino method. Added in data management and analysis.

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-
Recommendation of reviewer:
Provisionally Approved
Decision: Approved

Ref. code: 126th ECMIIA/P3

25- Clarification of research proposal entitled "***Prospective analysis in histopathology services in a Government Teaching Hospital: A road map to internal quality assessment***" submitted by Dr. Shalini Bhalla, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1426/23 dated 6th October, 2023.

Previous EC Comment	PI response
In the KGMU proforma where form has to be filled by PI, under the heading of type of study, The PI has marked on both single center and multicentric study.	Single center study has been mentioned in the type of study.
In the patient information sheet: PI has copy pasted the guidelines.	Since it is a retrospective study so patient information sheet is not required
Aims and objectives are not clear.	To identify reasons for the delay in

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	Objective should be precise.	release of complete histopathology reports in the preanalytical, analytical and post analytical phases. To take measures to correct the cause of delay in each of the three phases. To calculate the improvement in the turnaround time of histopathology reports post implementation of corrective measures Objectives are redefined under heading Aims and objectives.	
	It would have better if data collection instruments were added in the proposal.	Preanalytical, analytical and post analytical quality variables were analysed.Preanalytical variables: 1.Requistion form-name, age, sex, UHID, Lab number, clinician name, department name, clinical diagnosis mentioned, specimen name, clinical history relevant, investigations mentioned or not, date of specimen collection. 2.Specimen-Preoper ariable with name, age, sex and site of specimen, formalin adequacy. 3.Grossing-Adequate number of cassettes taken and ariable, grossing done as perprotocol, worksheet attached, regressing done & amp; for what was ariables.4. Tissue processing & embedding (power failure/technical fault of automatic tissue processor)5. Cutting of sections (restain/deep cut)6. Staining of slides mounting& labelling7. Special satins required.Analytical variables:1.Concurrence of histology and cytology reports if available 2.Misclassification –	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		positive/negative or benign/malignant, grade, stage, margins etc. 3. .Delay due to incorrect block/ slide identification 4. Delay due to incomplete information- contact number, Investigation, immunohistochemistry.Post analytical ariables: 1.Turnaround Time (TAT)maintained or not (the time between thereceipt of a sample in the laboratory andwhen the report is ready forcollection/dispatch)2.Erroneous/ missing non diagnostic information; dictation/typing error.3. 3.Delay in dispatch of report in somecases for already generated reports because of haphazard arrangement ofoffline reports Data collection instruments are added in study design and methods section.
	Waiver form is wrongly filled. Since this study will be research without involvement of identification of individual subjects, therefore the appropriate has to be filled.	The waiver form is filled appropriately again and attached.
	Being a retrospective study, it would be better if it is mentioned in the study title as well as in the methodology section.	Prospective has been change to retrospective study in the study title andmethodology section "Retrospectiveanalysis in histopathology services in aGovernment teaching Hospital: A road map to internal quality assessment"

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

Recommendation of reviewer:

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

- Provisionally approved

Decision: Approved

Ref. code: 126th ECMIIA/P4

26- Clarification of research proposal entitled "***Preventive strategy practices for pressure injury in Indian ICUs (Prevent-PI-ICU)***" submitted by Dr. Sai Saran, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1868/23 dated 22nd September, 2023.

Previous EC Comment	PI response
While on PI states that this is a single center study in Annexure 1 on the other hand there are indications of it being a multicentre study across ICU at hospitals in India which involvement of many medical colleges and with these 10 to 15 institutions per hospitals	Changed as multicenter
Point 4 annexure 1 indicates that no patient related data will be collected. Then why ICF?	Informed Consent form removed
In the Undertaking by Principal Investigator- only one name is entered for other institutes. Include others too.	Names of other investigators were added
Since it is stated that current study is online survey with no actual patient related data-then what is the role of patient information sheet	As per the suggestion, Patient information sheet was removed
Kindly include the steps of sample size calculation. Is it the number of beds or number of ICUs or number of hospitals?	As per a study by Lebuo et al, the prevalence of is 64.8%. [9] The following simple formula would be used for calculating the adequate sample size in prevalence study; $n=Z^2 P(1-P)d^2$ Where n is the sample size, Z is the statistic corresponding to level ofconfidence, P is expectedprevalence. [10]The sample size was calculated based on beds.
How will data and safety	Based on the suggestion, data and

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	monitoring board be involved? What sort of adverse effects are anticipated if there is no actual patient involvement?	safety monitoring board is removed.

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

Recommendation of reviewer:

- The Investigator has addressed the comments raised and as no consent will be taken (as per investigator), the same is to be mentioned in point 8 of annexure-1 (Not Otherwise), Also approval subject to above rectifications.
- Waiver of consent may be given.

Decision: Approved

Ref. code: 126th ECMIIA/P10

27- Clarification of research proposal entitled "***A retrospective study of the epidemiological and clinical features of patients presenting with obstructive sleep apnea in a North Indian tertiary care centre***" submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1014/Res/23 dated 18th September, 2023.

Previous EC Comment	PI response
Annexure 1	Kindly find the relevant annexure 1 attached.
Attach patient Information sheet in Hindi	Kindly find patient information sheet in Hindi attached.
Outcome Measures and statistical analysis	Outcome measures: 1. Polysomnography parameters (as mentioned in data collection sheet) 2. Correlation of laboratory parameters with polysomnography parameters 3. Correlation of imaging findings with polysomnography parameters 4. Correlation of presenting symptoms with polysomnography parameters Statistical analysis will be done for both quantitative as well as qualitative data.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Attach data collection sheet | Kindly find the data collection sheet attached. ***The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 126thECMIIA/P11***
28-	Clarification of research proposal entitled "***Efficacy of low-dose naltrexone for the treatment of burning mouth syndrome. A randomized clinical trial***" submitted by Dr. Akhilanand Chaurasia, Associate Professor, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 477/OMS&R/23 dated 29th September, 2023. ***The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 126thECMIIA/P12***
29-	Clarification of research proposal entitled "***Study on clinical outcomes and drug resistance profile (both phenotypic and genotypic) in MDR tuberculosis patients treated with bedaquiline containing regimen***" submitted by Mrs. Rashmi Ratnam, Ph.D. 2021 Scholar through her guide Prof. R.A.S. Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1089/23 dated 29th September, 2023.

Previous EC Comment	PI response
Budget has to be mentioned in rupees, not by naming the funding agency?	150000/- Rs. As this is only a Ph. D. thesis work, no budget is provided by any funding agency. The TB testing consumables are supplied by National Tuberculosis Elimination Program (NTEP).The bedaquiline drug and other required items will be purchased by the scholar herself.
No. of subjects to be recruited not mentioned?	90 MDR patients will be recruited in the study. The sample size and its estimation were already mentioned in the proforma attached

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	with the checklist.
Why Vulnerable Samples have been ticked?	As any of the mentioned vulnerable subjects can be a MDR patient if he/she found suitable for the study then only they will be included.
Bio-banking is beingdone: what will be stored, for what purposes?	Sputum culture positive isolates are being stored according to sample retention policy of NABL accredited lab, this is a routine T B Laboratory activity not only for the purpose for Ph.D. thesis.
Hindi patient information sheet should be written properly. Google translate should not be used?	Amendment has been done.
Is the Ph.D. student will not work in the laboratory?	The student will enroll the patients from the dept. of respiratory medicine, collect sputum samples, process samples in T.B. Laboratory, perform the MIC, perform gene sequencing, maintain and analyze data.
What are the primary secondary objective measures?	For primary objectives, outcome measures will be: □ Culture conversion □ Treatment outcome in terms of cured, died, treatment failure and lost to follow up □ Frequency of primary and secondary drug resistance For secondary objectives, outcome measures will be: □ Comparative efficacy of culture conversion and treatment outcome of all oral longer with shorter oral bedaquiline containing regimens.
How long will Patient be followed?	It will be done at intervals defined by the NTEP for both the regimens for maximum 6 months (Bedaquiline is given to the patients for a maximum period of 6 months).

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Why 2 groups have been included?	Two groups have been included because we want to know the frequency of primary and secondary Bedaquiline resistance.
	When and why will drug resistant profiling be done?	Drug resistant profiling will be done at the time of initial screening of patient samples and when any follow up sample will be culture positive. This will be done to check any change in drug resistant status of M. tuberculosis.
	Statistical tests and methodology need to be elaborated.	For primary objective outcome: Cox regression method for relationship between an event (death, recurrence) occurring over time. To study frequencies chi square test will be used. For secondary objective: Kappa statistics for agreement between two groups.

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-

Recommendation of reviewer:

- Researcher has not made the changes in the manuscript as per the reviewer comments and her reply. The modified manuscript must be submitted for review.

The above comment forwarded to the Principal-Investigator:-

Reply has not given by the Principal-Investigator.

Decision: Reminder will be send to the Principal-Investigator

Ref. code: 126th ECMIIB-Ph.D/P1

30- Clarification of research proposal entitled ***"To explore the relationship between periodontitis and preterm delivery with fcγ receptor polymorphisms as genetic susceptibility factor"*** submitted by Dr. Iman Baig, Ph.D 2019 Scholar through her guide Prof. Pavitra Kumar Rastogi, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1400/P/23 dated 3rd October, 2023.

Previous EC Comment	PI response
Sponsor information row related to 1. Indian the PI has added self	The study is self-sponsored by PI hence sponsor information says Self-

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	funded
Statement 7 ii. And iv. Are ticked but details are nowhere mentioned in the protocol	Statement 7 ii. And iv. Relating to information regarding nature of samples and state of samples. Samples will be venous blood 2 ml and will be analysed after storage in -20 degrees Celsius
This is a PhD proposal, which needs to be written thoroughly with a proper, rationale, literature review and knowledge gap. Further the proposal should include a robust methodology with outcome of the study.	Proposal has been corrected to be more thorough with addition of rationale and knowledge gap. Methodology has been updated with outcome of the study
The questionnaire uses words like bad habit/adverse habit in personal history, better to use one type of word at both places.	Questionnaire has been updated to reflect the same wording in both places.
Hindi ICF needs to be written in simple sentences, at many places she is written as she needs to be modified.	Hindi ICF has been re-written in simpler language and the error of she has been corrected.

The above comments were forwarded to the Principal-Investigator and the response was reviewed by reviewer:-
Recommendation of reviewer:

- As is clear from the 1st subsection of IEC, i.e., Sponsor Information, it is for external funding agencies, be they Indian or any other. It needs to be filled out as none or not applicable, and then PI may declare that the expenses would be borne by him.
- IEC point no. 7. iv PI chooses the option yes and states the collected sample will be stored. The point is about the use of preexisting samples..., so the option to be chosen is 'No'
- In Pt Information Sheet (both English & Hindi) point no. 7 to be revisited, why to write **you can** drive, **drink**.....मदिरा का सेवन कर सकते हैं. ICF and Patient information sheets need to be written in simple language.
- Kindly clarify the current status.

Decision: Revise & Re-submit with response to queries in tabular format.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 126thECMIIB-Ph.D/P2
31	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 25th October, 2023 from 11:00 a.m. till 12:30 p.m. ***physically as well as virtually*** in the Committee Room, Administrative Block, KGMU, U.P., Lucknow. ***The following Members were present in the Meeting:*** 1. Dr. Alok Dhawan -Chairman 2. Dr. Rajendra Nath -Member 3. Dr. Nisha Mani Pandey -Member 4. Mrs. Akansha Dubey -Member 5. Mr. Ujjawal Krishna -Member 6. Dr.D.N. Upadhyaya -AdditionalMember-Secretary, IEC 7. Dr. Hardeep Singh Malhotra-Member-Secretary, IEC, ex-officio ***The following Member was not present in the Meeting:*** 1. Mrs. Vasundhara Kumari
	DCGI
Ia-	ADR of research proposal entitled CKJX839B12302 entitled **"*A randomized, double-blind, placebo-controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT)*"** sponsored by M/s Novartis Healthcare Pvt. Ltd. submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 358/Cardio/Res/23 dated 20th September, 2023 & **preliminary email dated 9th September, 2023 at 4:04 p.m.** **Death** **Patient ID & age and gender:** K-1014042/59 yrs. Male **Patient Diagnosis:** Death **Patient enrollment date:** 20-10-2022 **Patient follow up under study**-Randomization (Day 1), M-3, M-9, M-15, M-21, M-27, M-33, M-39, M-45, M-51, M 57 to M-69.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Follow up visit completed-Randomization (Day-1) **Planning on visit-** 9th Month, 16 July (2023) **SAE reported on date:** 09th June, 2023 **Follow up visits remaining:** M-15, M-21, M-27 to M-69 **24 hours, notified to EC, Sponsor**-09-09-2023 **14 days analysis report submitted to EC**-09-09-2023 **Subject History:** A letter was received in the Office of the Ethics Committee on 21st September, 2023 from PI informing that the Subject's LAR had informed on 9th September, 2023 that the Subject passed away on 9th June, 2023 around 01:30 hrs. As per patient's LAR the patient was having complaints of loss of appetite and generalized weakness. The patient was not hospitalized and passes away at home on 9th June, 2023 at 01:30 PM. and a local practitioner visited to his place and confirmed subject's death. No autopsy was done. **Death Certificate has not been provided by the patient's LAR.** ***Recommendation of Primary reviewer:-*** • SAE (Death) on 09-05-2023 is likely due to disease the outcome (FTC of Ant. wall MI) and not due to intervention (Inclisiran) as patient was randomized on 20-10-22 and more than 7 months had elapsed after intervention when SAE occurred. Patient died at home on 9th June, 2023 at 01:30 PM. • Therefore causal relationship can not be established and no compensation is required as death occurred at home and no autopsy was done. • (Death certificate has not been provided by the patient's LAR) **ADR sub Committee Decision:** Noted as above ***Ref. code: 114th ECM IIC/P4***
32	**Non-DCGI**
	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 25th October, 2023 from 11:00 a.m. till 11:30 a.m. ***physically as well as virtually*** in the Committee Room, Administrative Block, King George's Medical University, U.P., Lucknow.***The following Members were present in the Meeting:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	1.Dr. Alok Dhawan -Chairman 2.Dr. Rajendra Nath -Member 3.Dr. Nisha Mani Pandey -Member 4.Mrs. Akansha Dubey -Member 5.Mr. Ujjawal Krishna -Member 6.Dr.D.N. Upadhyaya -Additional Member-Secretary, IEC 7.Dr. Hardeep Singh Malhotra-Member-Secretary, IEC, ex-officio ***The following Member was not present in the Meeting:*** 1.Mrs. Vasundhara Kumari
33	**Non-DCGI**
I	**The following documents have been brought from the last meeting held on 1st September, 2023 because the quorum was incomplete.**
	Attendance -01-09-2023 ***The following Members were present in the Meeting:*** 1. Dr. Alok Dhawan -Chairman 2. Dr. Rajendra Nath -Member 3. Dr.D.N. Upadhyaya -Additional Member-Secretary, IEC 4. Dr.Shally Awasthi -Member-Secretary, IEC ***The following Members were not present in the Meeting:*** 1. Dr. Nisha Mani Pandey 2. Mrs. Akansha Dubey 3. Mrs. Vasundhara Kumari 4. Mr. Ujjawal Krishna

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

34	Previous-Non-DCGI
Ia-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 237/Cardio/Res/2023 dated 22nd July, 2023 & preliminary email dated 10th July, 2023 at 10:46 AM. **Hospitalization** **Patient ID & age and gender:** 127/42 year/female **Patient Diagnosis:** RHD/Sev-MS/MVA 1.7 ccm **Patient enrollment date:** 14-06-2023 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit**- 6th Month **SAE detected on date:** 08th July, 2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours Notified to EC, Sponsor**-10-07-2023 **14 days analysis report submitted to EC**-23-07-2023 **Subject History:** A letter was received in the Office of the Ethics Committee on 22nd July, 2023 from PI informing that the Subject's LAR has informed on 9th July, 2023 that the Subject was having complaint of breathlessness since night, for which she was hospitalized in the ICU on 8th July, 2023. The patient was managed conservatively and got stabilized. She got discharged on 11th July, 2023. The patient has been advised to go for MVR Surgery. Hence, She has been advised to temporary discontinue the IP. ***Recommendation of reviewer:-*** • SAE (Hospitalization) is likely due to disease outcome (RHD/Sev.-MS/MVA 1.7) and not due to intervention (Tab Digoxin) as patient was randomized in enrolment arm-on 14-06-2023 and SAE occurred on 08-07-2023, more than 20 days have elapsed after intervention. Patient was admitted in ICU due to breathlessness on 8th July, 2023 and managed conservatively and got stabilized. Patient was discharged on 11th July, 2023. • Causal relationship can not be established and as the patient was

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	treated successfully and discharged on stable condition therefore no compensation is required. **Previous ADR sub Committee Decision:** Defer to the next Meeting because quorum was incomplete **ADR sub Committee Decision:** Noted as above ***Ref. code: 102nd ECM IIA/P24***
Ib	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 266/Cardio/Res/2023 dated 1st August, 2023 & preliminary email dated 19th July, 2023 at 10:19 AM. **Death** **Patient ID & age and gender:** 063/39 year/Female **Patient Diagnosis:** RHD/Sev-MS/MVA 0.8.cm **Patient enrollment date:** 07-12-2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit**- 6th M **SAE detected on date:** 04th May-2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Notified to EC, Sponsor**-19th July-2023 **14 days analysis report submitted to EC**-1st August, 2023 **Subject History:** A letter was received in the Office of the Ethics Committee on 1st August, 2023 from PI informing that the subject's LAR has informed to the PI repeated reminder calls for 6 months follow-up, but, the telephonic calls were not answered by the subject. The subject's LAR informed to PI on 18th July, 2023 that the patient had complaints of acute excruciating pain in abdomen on 3rd May, 2023 for which she underwent a few Investigations and was referred to some higher treatment centre. The subject could not be hospitalized anywhere and she passed away on 4th May 2023 morning around 6:30 AM at her home. As per the previous consultation and reports of ultrasound submitted by the LAR, it seems that the subject had gross ascites with absent peristalsis and intestinal perforation that might be the cause of the subject's death. The death of the subject is not related to the Investigational

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	drug. No autopsy was done. ***Recommendation of reviewer:-*** • Patient enrolment date 07-12-2022. Skipped 6 month follow up in May, 2022. SAE occurred-04-05-2023. SAE detected on 18-07-2023. Notification to EC-19-07-2023. • Patient was suffering from ascites and possible ileus and passed away due to this-The SAE doesn't appear to be related to the drug under study. **ADR sub Committee Comment:** • Letter asking for explanation that why 6th month visit was skipped and the SAE was detected on 18th July. 2023. **ADR sub Committee Decision:** Defer to the next Meeting because quorum was incomplete. **DR sub Committee Decision:** Approval subject to response reviewed from PI. ***Ref. code: 102nd ECM IIA/P24***
	Minutes of -25-10-2023
35	**Non-DCGI**
IIa-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 333/Cardio/Res/2023 dated 4th September, 2023 & preliminary email dated 22nd August, 2023 at 01:40 p.m. **Death** **Patient ID & age and gender:** G-D-93/49 year/female **Patient Diagnosis:** RHD/Sev-MS/MVA 1.0cm **Patient enrollment date:** 15-02-2023 **Patient enrollment arm-**Digoxin **Patient follow up under study-**6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed-**Enrolment & Baseline Follow-up **Planning on visit-** 6th Month **SAE detected on date:** 09th May-2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed:** Enrolment & Baseline Follow-up **Planning on Visit:** 6th month

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	24 hours, notified to EC, Sponsor-22-08-2023 **14 days analysis report submitted to EC**-04-09-2023 **Subject History:** A letter was received in the Office of the Ethics Committee on 4th September, 2023 from PI informing that the Subject's LAR has informed on 22nd August, 2023 that the Subject was having complaint of severe pain in abdomen, urinary retention and inability to pass stools since 30th July, 2023. The pain in her stomach deteriorated on 31st July, 2023 (Morning). The subject passed away on 31st July 2023 evening around 4:45 PM at her home, she could not was hospitalized anywhere and a local practitioner visited to her place and confirmed subject's death. No autopsy was done. ***Recommendation of reviewer:-*** 1. Enrolment date- 15-02-2023. 2. The SAE occurred on 31-07-2023. 3. SAE detection date is mentioned as 31st July at one place and 9th May at another place. In the letter of Causality assessment by Investigator the SAE detection date in 22-08-2023. 4. SAE reporting date is 22nd August which is not within 24 hrs. 5. Patient complained of abdominal distention and urinary retention and died at home. No Autopsy was done. 6. The SAE appears to be unrelated to the drug being used in the trial (Digoxin) 7. The dates of SAE detection need to be clarified/corrected in records. **ADR sub Committee Decision:** Approval subject to modification. ***Ref. code: 102nd ECM IIA/P24***
IB	**Expedited review**
1-	Research proposal entitled ***"Targeting epigenetic modulators of EZH2 and SGLT to mitigate renal toxicity and chronic kidney disease progression"*** submitted by Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 451/Nephro/23 dated 12th October, 2023. ***The above research proposal was forwarded to two Primary reviewers:-***

Recommendation of First Primary reviewer	PI response
Reporting of adverse events has been ticked as 'No'. Adverse events	We had changed the status of adverse event from "No" to "Yes"

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	must be reported to the regulatory bodies including the IEC.	with reporting to sponsor and IEC.
	Physical risk/discomfort has also been ticked as 'No' whereas kidney biopsy is planned to be done which will entail physical discomfort and risk. Please clarify.	We had changed the status from "No" to "Yes" We are primarily focused to take the urine sample for the proposed study. If kidney biopsy will be done form management point of view (Kidney biopsy is not always done for the management) then the biopsy sample will be shared to PI.
	Possible risks of renal biopsy must be mentioned in the patient information sheet.	The kidney biopsy now a day done by ultrasound guided with 18 G needle by using the Doppler mode the chances of injury to vessels is negligible. The patient discomfort is also very minimal. In the case of renal biopsy there is no risk or minimal risk available. However, the department of Nephrology, KGMU is equipped with state of art technology and yet we have not found any major risk or problem associated with renal biopsy. Although the possible risk has been mentioned in the patient's information sheet.
	The above comments were forwarded to the Principal-Investigator, reply received by the Principal-Investigator which were forwarded to Primary reviewer:- Provisionally approved ***Recommendation of Secondary reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: 127th ECMIB/P1***	
2-	Research proposal entitled ***"Pan-India epidemiological, virological and genomic surveillance for Human Influenza, COVID 19 and RSV through DHR-ICMR VRDL Network"*** submitted by Dr. Shruti Radera, Assistant Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 885 dated 11th October, 2023. ***The above research proposal was forwarded to three Primary reviewers:-*** ***Recommendation of Primary reviewer:***	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

1. In the following project the consent form needs to be corrected. As the consent is to be taken from parents for the children so it cannot be in first person. Both Hindi and English formats need to be corrected.
2. Title of the Project: Pan India Epidemiological, Virological and Genomic Surveillance for Human Influenza, RSV and COVID-19 through DHR-ICMR VRDL Network.

Recommendation of Secondary reviewer	PI response
The calculated sample size is 329-330, but the sample being collected has been declared as 240. Please clarify.	Calculated sample size in proposed study is 329-330, however it is a multicentric study which will be conducted at 15 centers. It was thought to screen 3600 children to achieve this sample size assuming 10% positivity as per available data. To achieve this target, 240 children will be screened at each study center (240x15=3600)
Title and methodology of the study (molecular/genomic analysis of viral samples) does not correlate with the stated objectives of the study (Clinical profile of patients/factors associated with hospitalization and death)	As per research protocol, clinical details of enrolled cases will be collected which will help to meet objectives of the proposed study on various forms/data sheets eg. at the time of admission, on admission summary form, laboratory related information will be collected on laboratory form and at the time of discharge, on discharge summary form. Required specimen will be processed for various respiratory viruses. Blood specimen will be collected and investigated for various investigations as per clinical condition of the patient which will be recorded on data sheets. All this information will help us in meeting the objectives of proposed study (Data sheets/forms attached)
ICMR approval/budget sanction letter not attached.	The submitted proposal is a part of DHR-ICMR-VRDL network.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Therefore, no separate budget has been sanctioned, however one junior nurse will be appointed as an additional manpower (Sanctioned letter attached)

The above comments forwarded to the Principal-Investigator was reviewed by secondary reviewer:-

Second opinion of secondary reviewer, received on 19th October, 2023:-

1. The response to query numbers 1 and 2 are adequate, however the response to query number 3 is inadequate since the Grant letter attached is not for the said study. In such a case who will bear the cost of the investigations/treatment being offered to the subjects enrolled in the study?

Recommendation of third reviewer	**PI response**
In Scientific review Committee report, the name of one of the Co-PI (Prof. Amita Jain) is there: therefore it is requested to revise the SRC.	SRC has been revised and is attached in enclosures.
ICF (E/H)-regular attached but as the recruited subjects are children in age group of 1 month and Hindi version.	Informed consent form (E/H) has been revised as advised (Enclosure attached)
Letter of inclusion of KGMU as one of the center/site for this study by sponsoring authority (ICMR/New Delhi) is not attached. Please give the letter of inclusion/collaboration.	The submitted proposal is a part of DHR-ICMR-VRDL network.(Letter of collaboration is attached in enclosure)

The above comments were forwarded to the Principal-Investigator, response received on 18th October, 2023.

Comment:

- Discussion was done with Prof. Amita Jain to clarify whether KGMU was included as one of the Centre for the study or not, to which she confirmed that KGMU is an inherent part of DHR/ICMR VRDL Network.
- A letter has also been attached by the PI

Decision: The above response is being forwarded to the third reviewer for his comments while the comments of the first and second reviewers shall be sent to the Principal Investigator.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 127thECMIB/P2
3-	Research proposal entitled ***"Role of newer HBV infection related markers in diagnosis and management of hepatitis B patients"*** submitted by Dr. Shruti Radera, Assistant Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 916/2023 dated 19th October, 2023. ***The above research proposal forwarded to two reviewers, for review.*** ***Recommendation of First reviewer:*** • Marken in Diagnosis and Management of Hepatitis B Patients") • Provisionally approved ***Recommendation of Secondary reviewer:-*** 1. In scientific review Committee report, the name of one of the Co-PI (Prof. Amita Jain) is there; therefore it is requested to revise the SRC. 2. In inclusion criteria, Age and Sex specification-not mentioned. 3. Tentative approval letter from ICMR through email is attached but PI to submit the final approval letter from ICMR for this project. ***The above comments forwarded to the Principal-Investigator, response received on 19th October, 2023.*** **Comment:** • Kindly provide the screenshot of ICMR website. • Kindly provide Consent/Child Ascent form • The above response to be forwarded to Secondary reviewer for review. **Decision:** The above response to be forwarded to First & Secondary reviewer for review. ***Ref. code: 127thECMIB/P3***
II-A	**New Proposal**
1.	Research proposal entitled "***A prospective research study to collect images from oral cavity of participating subjects to build an artificial intelligence based tool for supporting the early detection of oral cancers***" submitted by Prof. U.S. Pal, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 762/OMSD/23 dated 10th August, 2023. ***Recommendation of reviewer:-*** 1. On one hand sponsor is ORAICLE Company of UK but it is mentioned in annexure 1 as Rikaian technology Private Limited. Why is this discrepancy? 2. The budget per patient includes honorarium for research team and not for patients visit. Kindly indicate the total budget including institutional overhead.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	3. In annexure 1 kindly indicate anticipated duration of study period. 4. In point 7 of annexure 1 it is indicated that NO organ tissue will be sampled. Then how will biopsies be obtained? 5. In annexure 1 it is indicated that sample will not be sent abroad but the protocol (page 10) indicates that sponsor (from UK) may request for blocks at the end of the study. 6. While 'NO' is indicated in data monitoring (annexure 1), it is clearly indicated in protocol that severe adverse event data needs to be monitored and reported to ethical committee as well as to sponsor (page 22) 7. In brief description of protocol, kindly categories methodology in PICO format, (population, intervention comparison, outcome) 8. Regarding potential risk, kindly summaries the specific anticipated adverse events. 9. The sample size selection specifies that study will be shared by ORAICLE and participating sites. What are those other participating sites? Has ethical clearance, been opted? 10. If compensation for injuries is included, more specific details regarding the type of injuries with examples and the amount of compensation for them needs to be stated in informed consent form rather than a generic statement. 11. Kindly indicate the names of other medical institutes, hospitals or institutions where the study is to be conducted. 12. Will the clinical expert or panel of expert belong to other sites or ORAICLE 13. Patient information sheet should detail about possible side-effects as stated in company's protocol as well as elaborate the compensation part. 14. Indemnity and insurance document sare legal document and should be submitted separately. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format. ***Ref. code: 127th ECM IIA/P1***
2.	Research proposal entitled ***"Outbreak analysis of acute conjunctivitis in Lucknow district of Uttar Pradesh"*** submitted by Prof. Prashant Gupta, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 595/23 dated 11th August, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 127th ECM IIA/P2***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

3.	Research proposal entitled "***Exploring the role of hybrid multidimensional MRI in the detection of clinically significant prostate cancer: A virtual biopsy***" submitted by Dr. Durgesh Dwivedi, Associate Professor, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 971/RD/23 dated 25th August, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 127th ECM IIA/P3***
4.	Research proposal entitled "***An analysis of the anomalous fissure of ligamentum teres hepatis: A morphological perspective in North Indian population***" submitted by Dr. Heena Singh, Assistant Professor, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 293/ANAT/23 dated 30th August, 2023. ***Recommendation of reviewer:-*** 1. Ph.D. scholar cannot be made a Co-PI. 2. Number of subjects: not mentioned. 3. Other points of section 5 not addressed. 4. Section 6: not addressed 5. Section 8: Consent: form whom/for what? 6. Section 10: If risks are not reasonable compared to anticipated benefits: Unethical to do the study. In view of this, there is no point doing this research. The rest of the proposal has thus not been reviewed. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format. ***Ref. code: 127th ECM IIA/P4***
5.	Research proposal entitled "***Differential profiling and assessment of early phase non-coding RNAs and adipokines in healthy controls, pre-diabetic, and diabetic patients- A pilot study***" submitted by Prof. Wahid Ali, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1243/23 dated 29th August, 2023. ***Recommendation of reviewer:-*** • It is CDRI sponsored project, to be conducted by KGMU, SMS Jaipur and CDRI. It is clear that the patients will be enrolled from Medicine Department but the role of SMS Jaipur and CDRI is unclear. Will the samples be transferred to Jaipur/ CDRI for some part of the study. What will be the contributions of KGMU pathology department. Kindly explain the workflow clearly. • Who will collect informed consent from patients and when? • Kindly, define criteria to Label study subjects as healthy, pre-diabetic

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	or diabetic. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format. ***Ref. code: 127th ECM IIA/P5***
6.	Research proposal entitled "***Study of clinical outcomes of neuropsychiatric events in systemic lupus erythematosus patients attending Rheumatology clinic at a tertiary care centre***" submitted by Dr. Kriti Kishor, Assistant Professor, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/698/23 dated 29th August, 2023. ***Recommendation of reviewer:-*** 1. This seems to be one-group pretest-posttest design. 2. In the present form, the primary objective does not indicate it clearly. 3. The study variables and study parameters should be explicitly outlined. 4. The primary objective should be converted into research hypothesis in terms of the study parameters. 5. The sample size formula is arbitrary. It is for prevalence study. This is not a prevalent study. 6. The statistical analysis section is incomplete. It should be specific to the research hypothesis. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127th ECM IIA/P6***
7.	Research proposal entitled "***Effect of flipped classroom teaching as an addon to the routine Teaching in understanding of Anatomy during first professional Teaching***" submitted by Prof. Rakesh Kumar Diwan, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 297/ANAT/23 dated 4th September, 2023. ***Recommendation of reviewer:-*** 1. They are trying to compare two different teaching methods. 2. This is prospective cohort study. 3. The two groups should be explicitly defined. 4. The questionnaire is required. Its detail of construction (including items) is required. 5. The method of assessment of the questionnaire should be outlined. 6. How the reliability and validity of the questionnaire would be assessed? 7. How much training is needed to learn how to administer it? 8. Sample size calculation and statistical analysis section is required. **Comment:** As above

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Decision: Revise & Re-submit with response to comments in tabular format ***Ref. code: 127th ECM IIA/P7***
8.	Research proposal entitled "***Development and assessment of Nanopore sequencing protocol for rapid drug resistance testing of Mycobacterium tuberculosis against 13 drugs of the new anti-tubercular drug regimens targeting multiple genes***" submitted by Prof. Amita Jain, Head, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 689/23 dated 6th September, 2023. ***Recommendation of reviewer:-*** • Approved for waiver **Decision:** Approved for waiver ***Ref. code: 127th ECM IIA/P8***
9.	Research proposal entitled "***Assessment of pain and discomfort during scaling and root planning procedures with topical anesthetic agents***" submitted by Prof. Pavitra Rastogi, Department of Periodontology & Implantology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1375/P/23 dated 15th September, 2023. ***Recommendation of reviewer:-*** 1. Title of the proposed study says "Assessment of pain and discomfort" but when and how these assessments will be done is not clear. It is better to give a flow of planned study. 2. In KGMU proforma authors have marked "None" under the heading of clinical trials while in methodology it is clearly mentioned that this is a clinical trial. 3. Under the heading of study design, it has been mentioned that the proposed study will be a randomised split mouth clinical trial. How randomisation, blinding levels and methods are being done, not mentioned. 4. It would be better if the title clearly mention it as a randomised control trial. 5. Basis of sample size estimation is not mentioned. 6. How authors will reach some conclusion is not mentioned. At least there should be a plan of statistical analysis given. 7. There should be a mention of a clinical trial registry that will be done once we get ethical clearance. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127th ECM IIA/P9***
10.	Research proposal entitled "***Role of heavy metal toxicity in progression of bladder cancer and their effect on quality of life***" sponsored by CST-UP submitted by Prof. Vishwajeet Singh, Department of Urology, King George's

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Medical University, U.P., Lucknow vide letter no. 753/URO/23 dated 5th September, 2023. ***Recommendation of reviewer:-*** 1. In this case control study the sample size as indicated is 94 cases and 94 controls i.e. total 180. So kindly rectify the total sample size as 180 in your submission. (Annexure 1 and text) 2. If Controls are healthy subjects then kindly mention their source and inclusion criteria. 3. If healthy controls are to be sampled then separate informed consent and information sheets need to be re-submitted both English and Hindi. 4. Kindly indicate a split budget as submitted. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127th ECM IIA/P10***
11.	Research proposal entitled "***Identification of metabolic signature and their role among unknown aetiology of chronic kidney disease (CKDu)***" submitted by ICMR under supervision of Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 384/Nephro/23 dated 5th September, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 127th ECM IIA/P11***
12.	Research proposal entitled "***Ellipsoid zone restoration correlates with final visual outcome in diabetic macular edema and macular hole surgery: A comparative analysis***" submitted by Prof. Sandeep Saxena, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 2020/OPH/23 dated 19th September, 2023. ***Recommendation of reviewer:-*** 1. Regarding sponsor information it is written as 'NA'. Then it is regarded as being ''international government'' as well as ''national industry''. Kindly resolve 2. While laboratory work up includes blood sampling, why annexure 1 indicates NO against the use of body fluids 3. Is the risk not reasonable compare to benefits (annexure 1, point10) 4. Kindly elaborate the role of DSMB. What are the anticipated adverse events that need to be reported to EC 5. If this is a retrospective study, then how will informed consent be obtained? Will the patient be called again? kindly make it clear

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	6. It is indicated as retrospective study, while methodology indicates that "after admission all patients will be assessed ----------". Kindly rectify the language and indicate whether it is analysis of archival records 7. In informed consent form the purpose of study procedure and benefit from studies, is not patient friendly. Kindly simplify the language for patient to understand. Both English and Hindi versions needs correction 8. The patient information sheet needs revision in a language that the patient may understand better. Also kindly examined carefully to exclude 'chronic dacryocystitis'(point 5) and replace it with your actual diagnosis. Both English and Hindi versions need correction. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127th ECM IIA/P12***
13.	Research proposal entitled ***"Nurse-led genetic counseling in improving awareness and implementation of screening services for hereditary women's cancer (NuGenA)"*** submitted by Govt. of West Bengal under supervision of Prof. Nisha Singh, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1240/23 dated 30th August, 2023. ***Recommendation of reviewer:-*** 1. In IEC proforma each box has a question mark which is probably an inadvertent error; however, this needs to be deleted. 2. The letter of intent is in the form of an email, which was sent to the PI long back on 27th January 2023 for which a reply was solicited by 5th Feb. Also ethical approval letter from the study site is enclosed, which is very old i.e. 4-12-2020. There is no mention of KGMU. A fresh letter of intent along with details will be needed. 3. Is there any provision for compensation and/or insurance for healthy relatives of the Cancer patient? 4. KGMU is not mentioned as a study site not in the CTRI. It seems from the proposal that only samples will be taken from KGMU. 5. IEC subsection 5 reveals 30 subjects in a year will be recruited whereas the proposal of 100 women in the first 24 months (preparatory phase) will be identified. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127th ECM IIA/P13***
14.	Research proposal entitled ***"A quality improvement study to assess patient satisfaction in surgical out patient Department at a tertiary care Hospital in North India: A cross sectional study"*** submitted by ICMR under supervision

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	of Dr. Saumya Singh, Associate Professor, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2355/23 dated 29th August, 2023. ***Recommendation of reviewer:-*** 1. Section 5: Duration of Subjects participation: not mentioned. 2. What is the role of volunteers in this study? 3. Why take Vulnerable Subjects in this study? 4. Why take Special group: "Staff" in this study? 5. Section 6: Why use direct identifiers? 6. Section 8 ii: Volunteer consent is not checked 7. Section 10: If risks are not reasonable compared to anticipated benefits: Unethical to do the study. In view of this, there is no point doing this research. The rest of the proposal has thus not been reviewed. 8. Section 10 iii: What is the expected direct benefit to the subject? **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127th ECM IIA/P14***
15.	Research proposal entitled "***An analysis of risk factors associated with delayed presentation, neglected presentation and relapse in cases of clubfoot treated with ponseti technique at the clubfoot clinic of KGMU: A record review***" submitted by Dr. Vikas Verma, Associate Professor, Head, Department of Paediatric Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 2585/PaedOrtho/23 dated 15th September, 2023. ***Recommendation of reviewer:-*** 1. Kindly submit the list of anticipated outcome variables and summaries the statistical analysis as per the respective variables. **Comment:** As above **Decision:** Approval subject to modification as per comments ***Ref. code: 127th ECM IIA/P15***
16.	Research proposal entitled "***Prospective global platform to evaluate and enhance cognitive and functional trajectories after stroke (PROSPECT)***" submitted by Hamilton Health Sciences through its Population Health Research Institute Hamilton General Hospital under supervision of Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 426/Neuro/23 dated 21st September, 2023. ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	1. It is a multicentric global registry for stroke to be conducted under PHRI, Hamilton Health Sciences, Canada. The other two sites in India are St. Johns's Medical College, Bangalore and CMC, Ludhiana. **It can be approved.** **Comment:** As above **Decision: Approved** ***Ref. code: 127th ECM IIA/P16***
17.	Research proposal entitled "***Delirium care in a tertiary Geriatric Mental Health set-up: a chart audit***" submitted by Dr. Akanksha Sonal, Assistant Professor, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 300/DHMH/23 dated 24th August, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 127th ECM IIA/P17***
18.	Research proposal entitled "***Introduction* of *hyperbaric oxygen therapy (HBOT) as an effective modality in management of hearing loss–A Randomized Trial***" submitted by Prof. Vijay Kumar, Head, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1244/23 dated 30th September, 2023. ***Recommendation of reviewer:-*** 1. The patient information sheet is missing. 2. The title reveals it is a randomized trial but the protocol does not follow the CONSORT guideline. And, study design states as an observational study. 3. The study includes a sample age range of 10-65 years; however, an assent form is not provided. 4. Methodology section needs revision; if it is a prospective study methodology needs to be corrected and written in future tense. 5. Hindi consent form needs revision; contraindication is written as मतभेद should be विपरीत or प्रतिकूल प्रभाव sshould be written in simple language. 6. The patient information sheet is missing. 7. The title reveals it is a randomized trial but the protocol does not follow the CONSORT guideline. And, study design states as an observational study. 8. The study includes a sample age range of 10-65 years; however, an assent form is not provided.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	9. Methodology section needs revision; if it is a prospective study methodology needs to be corrected and written in future tense. 10. Hindi consent form needs revision; contraindication is written as मतभेद should be विपरीत or प्रतिकूल प्रभाव should be written in simple language. **Comment:** As above **I Decision:** Revise & Re-submit with response to queries in tabular format ***Dr. Anupam Mishra did not take part in the discussion and making decision.*** ***Ref. code: 127th ECM IIA/P18***
19.	Research proposal entitled "***Radiation induced damage in head and neck and its management by hyperbaric oxygen therapy-randomized control trial***" submitted by Prof. Vijay Kumar, Head, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1245/23 dated 30th September, 2023. ***Recommendation of reviewer:-*** 1. If it is really, RCT, all the fundamentals are missing. 2. For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. 3. The two comparative groups should be explicitly identified. 4. The sample size calculation is not given. 5. The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. 6. How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127th ECM IIA/P19***
20-	Research proposal entitled "***Oral health practice of dental professionals towards self oral care***" submitted by Dr. Sumit Kumar, Professor Jr. Grade, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 607/PHD/23 dated 27th September, 2023. ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	1. There are some primary guidelines, which should be followed in the construction of a scale. 2. Only some textual references are given for the questionnaire. It should be given explicitly, explaining where the items come from: (i) previous scale, (ii) clinical observations, (iii) expert opinion, (iv) patients' report, (v) research finding, (vi) theory. 3. Are they were assessed for (i) endorsement frequency, (ii) restriction in range, (iii) comprehensions, (iv) lack of ambiguity, (v) lack of value-laden or offensive content? 4. How is the scale checked for internal consistency? 5. Does it have good test-retest reliability? 6. What method is used to find the reliability coefficient? 7. How was the sample size calculated? 8. Does the scale have face validity? 9. Is there evidence of content validity? 10. Has it been evaluated for criterion validity? 11. With what groups has the scale been validated? 12. Can the scale be completed in a reasonable amount of time? 13. How much training is needed to learn how to administer it? 14. How the questionnaire will be evaluated to generate numerical score, so that it can be used in the assessment of the attitude and practices of the dental professionals? **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127th ECM IIA/P20***
II-B	**IMR-Faculty**
1.	Research proposal entitled ***"To investigate the potential source of DNA and its STR-DNA profiling for human identification from the most challenging body fluids in a medico-legal setting"*** submitted by Office of the Dean, Research & Development, KGMU Lucknow under supervision of Dr. Anshu Priya, Assistant Professor, Department of Forensic Finger Printing Lab (CFAR) King George's Medical University, U.P., Lucknow vide letter no. 315/FMT/23 dated 2nd September, 2023. ***Recommendation of reviewer:-*** 1. IEC form to be filled properly. 2. The study is to be done on corpses, who is going to give informed consent? If consent is to be taken from diseased relatives or LAR. She has to modify the ICF accordingly. 3. Who will be there to see the patient information sheet? If it is to be shown and given to the LAR/relative the texts of different subsections of the Information sheet need to be written as per the need of the

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	study. 4. In the role of the investigators' sheet- investigator-specific share for this particular study is not given which needs to be added. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127th ECM II B-IMR-F/P1***
II-B	**New Ph. D Proposal**
1.	Research proposal entitled "***Development of an efficient post mortem interval (PMI) estimation method using RNA degradation pattern and gene expression in human dental pulp tissue under varied temperature & time intervals***" submitted by Ms. Amita Sangwan, Ph.D. Scholar under the guidance of Prof. Shalini Gupta, Head, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1795/OP/23 dated 10th August, 2023. ***Recommendation of reviewer:-*** 1. Hypothesis not provided. 2. In the consent form (both Hindi and English) it is mentioned that it is an *in vitro* study, however, on going through the methodology it is not clear what *in vitro* studies are to be performed. 3. RNA isolation protocol not provided **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127th ECMIIB-Ph.D/P1***
2.	Research proposal entitled "***Effectiveness of a School based health promotion intervention for prevention of non-communicable diseases among adolescents of Lucknow-A quasi experimental study***" sponsored by ICMR New Delhi submitted by Dr. Sugandha Jauhari, Ph.D. Scholar under the guidance Prof. Monika Agarwal, Head, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 577/CM/23 dated 25th August, 2023. ***Recommendation of reviewer:-*** • All scientific committee members including chairman are CO PI in the Project. I request IEC members to kindly comment during discussion. • Roles allotted to all Co-PI are similar. Unique roles have to be specified. • Though ethically proposal is appropriate but certain issues like. • Discrepancy in number of participants 303 written in flow charts and 333 decided with dropouts after calculating as 288 raises concern. • Study participants are students of classes 6th to 8th, whereas in the

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	inclusion criteria students of class 9th are included. • Age parameter is also varying at places. • Proforma defines MET but such parameter is never mentioned anywhere else in the project. • Why the study will be registered with CTRI. • Study proposal need re review from scientific review committee. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127thECMIIB-Ph.D/P2***
3.	Research proposal entitled "***Interplay of microbiome and tumor microenvironment in oral squamous cell carcinoma***" submitted by Ms. Turya Singh, Ph.D. Scholar, under the guidance Dr. Sumaira Qayoom, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1244/23 dated 29th August, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 127thECMIIB-Ph.D/P3***
4.	Research proposal entitled "***Study the role of tumor suppressor genes as a biomarker for early detection of lung cancer***" submitted by M/s Climate Trends Limited Liability Partnerships under supervison of Ms. Afreen Mehdi, Ph.D. Scholar under the guidance of Prof. Surya Kant, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 991/Res/23 dated 15th September, 2023. ***Recommendation of reviewer:-*** 1. IEC needs to be filled properly. 2. The project seems to be an industry-sponsored study but the PI indicates it as a Govt. sponsored. 3. Is the budget sanctioned in the name of the PI? Related documents to the same need to be enclosed. 4. Pt information sheet needs to be filled properly. 5. Consent is to be written in simple and comprehensive language. 6. PI wishes to add healthy controls, inclusion, and exclusion criteria for the same to be included and separate ICF to be prepared. 7. If healthy controls are to be added, who will pay for their investigations? 8. The study title and aim are to determine the role of tumor suppressor genes as a biomarker but in the objectives, the first objective is to find out the epidemiological status of Lung cancer, which needs revision. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 127thECMIIB-Ph.D/P4
5.	Research proposal entitled "***Role of mitochondrial DNA and TLR 9 in endothelial cell activation and preeclampsia***" submitted by ICMR under supervision of Ms. Sonam Gautam, Ph.D. Scholar under the guidance of Prof. Narayan Prased, Head, Department of Nephrology through Co-PI Prof. Renu Singh, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1452/23 dated 27th September, 2023. ***Recommendation of reviewer:-*** 1. Age of the subjects to be taken in the study not mentioned. 2. It is mainly a biochemical study and no co-guide has been taken from that background. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127thECMIIB-Ph.D/P5***
II-C	**Review of New Drug Trial**
1.	Research protocol no. CTIN816A12201 entitled "***A randomized, multi-centric, placebo-controlled, participant, and investigator blinded study to evaluate the safety, tolerability and efficacy of TIN816 in adult patients at risk for acute kidney injury following cardiac surgery***" submitted by M/s Novartis Healthcare Private Limited under supervision of Dr. Sarvesh Kumar, Professor Junior Grade, Department of Cardiovascular & Thoracic Surgery, King George's Medical University, U.P., Lucknow, vide letter no. 02/CVTS/2023 dated 24th August, 2023. ***Recommendation of reviewer:-*** 1. Section 3 (ii) of IEC form is incorrectly answered as NA. Please answer Yes or No. 2. IEC form section 3 (iii) please comment on DCGI permission. 3. IEC form section 3 (iv) Please comment on the Phase of the study and whether copy of DCGI application is attached. 4. IEC form Section 5 (vi) Pregnant women is not ticked whereas the protocol copy has ICF for pregnant women. Please clarify. 5. IEC form Section 7 mentions no samples will be collected. Protocol has ICF for exploratory genetic study and section 7 (ix) mentions samples being sent abroad. Please address this discrepancy. 6. Reasons for sending samples abroad are not clear. No clarify on what will happen to samples after the project is over. Will participants be informed if their tissue/samples are used for further research? 7. Samples size is 10. No justification of this sample size has been given. 8. No contact details are given in ICF. 9. Letter from sponsor (Novartis) to DCGI does not mention KGMU

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	site. 10. Insurance certificate not attached. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 127thECMIIC/P1***
2.	Research protocol no. BIO-PERTUZ-301 entitled "***A multicenter, double-blind, randomized, parallel-group, phase 3 study to compare the efficacy and safety of the proposed biosimilar PERT-IJS and EU-Perjeta® along with trastuzumab and chemotherapy (Carboplatin and Docetaxel) as neo adjuvant treatment in patients with hormone receptor negative (HR-ve) human epidermal growth factor receptor2 (HER2) positive early stage or locally advanced breast cancer***" submitted by M/s Biocon Biologics UK Limited under supervision of Dr. Sameer Gupta, Additional Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow, vide letter no. SONC/1520/2023 dated 6th September, 2023. ***Recommendation of reviewer:-*** 1. Permission to conduct clinical trial-Awaited (Submission acknowledgement-attached) 2. Permission to import the biosimilar drugs from abroad-Awaited (Submission acknowledgement-attached) 3. Permission letter to send sample abroad-missing (But mentioned in SOP-Checklist-point 7-ix) **Comment:** As above **Decision:** Approval subject to modification ***Ref. code: 127thECMIIC/P2***
III A-	**Additional Document**
1.	Additional document of research Protocol no. CTQJ230A12301 entitled "***A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with pelacarsen TQJ230 on major cardiovascular events in patients with established cardiovascular disease***" **(Horizon Study)** submitted by M/s Novartis Health Care Pvt. Ltd. under supervision of Prof. S.K. Dwivedi, Head, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 265/Cardio/Res/23 dated 1st August, 2023. ***Recommendation of reviewer:-*** 1. The additional documents submitted for scrutiny, may kindly be approved. **Decision:** Approved ***Ref. code: 101stECMIIC/P18***
2.	Addendum CTA of research protocol no. QPT-ORE-006 entitled ***"A PhaseII,***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Double-blind, placebo-controlled, multicenter clinical trial comparing chemoimmunotherapy (Paclitaxel-carboplatin-oregovomab) versus chemotherapy (Paclitaxel-carboplatin-Placebo) as neoadjuvant therapy in patients with advanced epithelial ovarian, fallopian tube or peritoneal carcinoma" submitted by M/s Onco Quest Pharmaceuticals Inc under supervision of Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/1418/2023 dated 22nd August, 2023. ***Recommendation of reviewer:-*** 1. Additional document in the form of updating of Interval Debulking Surgery cost from Rs. 75,000/ to 1,10,000 in CTA document from Sponsoring firm–Raptim Research Pvt. Ltd.–Attached. 2. Insurance document (valid from 01-06-2022 to 01-12-2025- attached **Decision:** Approved ***Ref. code: 117thECMIIC/P4***
III-B	**Modification**
1.	Modification of research protocol no. QPT-ORE-006 entitled ***"A Phase 2, Double-blind, placebo-controlled, multicenter clinical trial comparing chemoimmunotherapy (Paclitaxel-carboplatin-oregovomab) versus chemotherapy (Paclitaxel-carboplatin-Placebo) as neoadjuvant therapy in patients with advanced epithelial ovarian, fallopian tube or peritoneal carcinoma"*** submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONS/1358/2023 dated 12th August, 2023. ***Recommendation of reviewer:-*** 1- The proposed changes (change in the name of sponsor) may kindly be approved. **Decision:** Approved ***Ref. code: 117thECMIIC/P4***
2.	Modification of research protocol no. RCLS-CIP-01 entitled ***"A prospective open-level, single arm, interventional, multicentric, pilot study to evaluate the safety and effectiveness of OZYN-D, a novel intraosseousdevice for delivery of medications and fluids"*** submitted by Prof. Sandeep Tiwari, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. TS/590/2023 dated 11th September, 2023. ***Recommendation of reviewer:-*** Following documents regarding modification/ awaited documents for Protocol are attached:-

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	-Patient information Sheet and ICF version 03 (English / Hindi) with translation & back translation certificates are attached and both the documents are merged as per DCGI recommendations DCGI Permission letter Insurance policy renewal document CTRI document Test license permission letter Approved **Decision:** Approved with condition to kindly submit the above-mentioned documents. ***Ref. code: 123rd ECMIIC/P1***
3.	Modification of research proposal entitled ***"A hybrid type-2 study of next generation pulse oximeters to support the integrated management of childhood illness in primary care settings"*** submitted by Prof. S. N. Singh, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 20/Hybrid/10/23 dated 11th September, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 117th ECM IIA/P5***
4.	Modification of research protocol no. BCD-178-2/PREFER entitled ***"A double-blind, randomized clinical study of the efficacy and safety of BCD-178 and perjeta® as neoadjuvant therapy of HER2-positive breast cancer"*** submitted by Prof. Abhinav Arun Sonkar, Head, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2474/2023 dated 13th September, 2023. ***Recommendation of reviewer:-*** 1- The proposed changes (Change in the language of ICF to explain insurance coverage for study related injuries) may kindly be approved. **Decision:** Approved ***Ref. code: 125th ECMIIC/P1***
5.	Modification of research protocol no. CTQJ230A12301 entitled ***"A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease" (LPA Horizon Study)*** submitted by Prof. S. K. Dwivedi, Head, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no. 384/Cardio/2023 dated 27th September, 2023. ***Recommendation of reviewer:-*** 1-The Protocol has been Amended from Amendment 4 (10¯05-2023 to Amendment 5 (19-09-2023) to implement the recommendation of the

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	independent Data Monitoring Committee to end the urgent safety measures. 2- Additional revisions are made to align the trial with the upcoming European Union Clinical Trials Regulation (EU CTR) as well as editorial changes. 3- Summary of changes/ revisions is given. **Decision:** Approved ***Ref. code: 101st ECMIIC/P18***
IV	**Other Matter with the permission of Chair**
1-	Regarding seeking permission of Ethical approval in respect of Dr. G.Prasad Rao, Ph.D. Scholar through Prof. Vivek Agarwal, Head, Department of Psychiatry, KGMU, UP, Lucknow. **Previous Comment:** 1. Whether ASHA Hospital Ethics Committee is registered with ICMR? 2. Submit the number of Registration also. ***The above comments were forwarded to Prof. Vivek Agarwal, Head, Department of Psychiatry, KGMU, UP, Lucknow vide this office letter no. 1518/Ethics/2022 dated 16th November, 2022 & the reminder was forwarded vide letter no.1788/Ethics/2023 dated 4th October, 2023 with following guidelines but reply has not received till date.*** **Comment:** • No reply received from the Ph.D. scholar • **An appraisal of *"Rules & Regulations of Ph.D. Programme, 2019" was done. As mentioned in the above rules (clause no. 6.3), "No Ph.D. work will be allowed without prior approval from Institutional Ethics Committee (KGMU). Ethical clearance should be ensured before enrolment of first subject (patient) in the work. All national norms of Bio-medical research and research work on animals need to be followed".*** **Decision:** Pending
2-	The following research proposals recently received but these Principal-Investigators wants expedited review. **For faculties:-**

Name of Principal-Investigators	**Title**
1-Dr. Shailendra Mohan Tripathi, Additional Professor, Department of G.M.H.	***Optical coherence tomography (OCT) and its brain volume correlated in Alzheimer's disease: A cross-sectional study*** received on 16th October, 2023.
127th IEC Decision	Permission granted for an expedited review.
2-Prof. Uma Shankar	***Development of artificial intelligence (AI)***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Pal, Department of Oral and Maxillofacial Surgery, FODS, KGMU, UP, Lucknow	***for screening, early diagnosis and treatment of oral potentially malignant disorders (OPMDs) through population-based registry*** received on 17th October, 2023.
	127th IEC Decision	Permission granted for an expedited review.
	3-Prof. Apul Goel, Department of Urology, KGMU, UP, Lucknow	***Primary obstructive megaureter with urolithiasis: 20 years' single centre experience*** received on 18th October, 2023.
	127th IEC Decision	Forwarded to the forthcoming IEC Meeting will be scheduled on 08th December, 2023.
	PGTSC proposals	
	4-Ms. Pragati Maurya, MBBS student for STS grant under the guidance of Prof. Dileep Kumar Verma, Department of Physiology, KGMU, UP, Lucknow	***To study effect of examination stress on autonomic functions and salivary pH among medical students'*** received on 17th October, 2023.
	127th IEC Decision	Permission granted for an expedited review.
	5-Dr. Ujjawal Yadav, JR-I under the guidance of Prof. Avinash Agarwal, Head, Critical Care Medicine, KGMU. UP, Lucknow	***Comparative evaluation of different priming solutions in prevention of hypotension in critically ill patients undergoing slow low efficiency extended dialysis (SLED) a randomized controlled trial*** received on 17th October, 2023. He has submitted incomplete ICF
	127th IEC Decision	Returned in original to the Principal-Investigator with condition to kindly provide the complete Informed Consent form, Patient Information Sheet & full proposal.
3-	1. Regarding applications for an expedited review, it was noted that some proposals that were missing the deadline had been intimated well in advance by the funding agencies and a timely submission to the IEC was delayed on part of the Principal Investigator. 2. It was also noted that applications for an expedited review were being submitting arbitrarily instead of conforming to the IEC-SOP. To ease submission, a new form is being developed stating the need of an expedited review. 3. Similarly, applications seeking waiver of consent were not conforming the	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	IEC-SOP. A new waiver form is being developed to aid smooth submission and processing of the submitted proposal. 4. Concerns were raised regarding suppositional and anticipatory grant of IEC approval for proposals being submitted to funding agencies or regulatory authorities where the approval is not mandatory such as CTRI, WHO, etc. It was, thus, decided that in instances where there is lack of clarity, that the Principal Investigator answers the query "Is it mandated by the Funding agency/ Regulatory authority to submit an IEC approval along with the proposal?". 5. Several proposals list self-funding in the section on funding. It was approved that such inadvertent errors must be avoided to the best possible extent. 6. An urgent need to have a unit (a department in the long-term) of Biostatistics for the teaching and training of UG/PG/PhD/Faculty/others, as well as for the pre-submission vetting of proposals (especially for theses) was observed. 7. There was an alarming concern regarding several projects seeking permission to send samples (blood/tissue/etc.) abroad without regulatory approval. Additionally, most Principal Investigators have failed to disclose these facts explicitly in their proposals raising doubts on the intention and sanctity of the proposal. An appraisal of ***"National Ethical Guidelines For Biomedical And Health Research Involving Human Participants, Indian Council Of Medical Research 2017"*** was done and following sections were noted: a. 3.8.3 International collaboration; - The institution/EC should not accept international proposals which cannot be conducted in the country of origin. b. 11.4.2 Transfer of biospecimens: - An MTA should be executed if the biospecimens are likely to be shipped from the host institution to collaborating institutions within the country or abroad. The EC should oversee the process of the in-country and international material transfer. Mandatory regulatory clearances with appropriate MoU are required if biospecimens are to be sent overseas. *See section 3.8.3 for further details.* Directorate General of Foreign Trade (DGFT) has issued a notification related to transfer of human biological material for commercial purposes.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

V	Guidelines of PGTSC
-4	**XXI-PG Thesis Sub-Committee (PGTSC)** met on 12th October 2023 to discuss the proposals to be presented in the **127th Institutional Ethics Committee (IEC)** scheduled on 25th October 2023. As per agenda item IV (Other Matter), discussion was held to revise the existing SOP drafted on 1st April 2021. The revision was necessitated to cope up with an increase in the number of theses submitted and to upgrade the current guidelines to suit the changing landscape of research. Following members were present and contributed to the discussion. 1. Prof. Rajendra Nath - Member 2. Prof. Anupam Mishra - Member 3. Prof. Anita Rani - Member 4. Prof. Divya Narain Upadhyaya - Member 5. Prof. Nisha Mani Pandey - Member 6. Prof. Hardeep Singh Malhotra - Convener Following members were not present: Prof. Abbas Ali Mahdi (Committed elsewhere) and Prof. G.G. Agarwal (Ill-health). The proceedings, and decisions taken thereof, were as follows: 1. All theses will be submitted ONLY after "**Departmental Scientific Committee (DSC)**" review. These shall mandatorily include: a. Declaration on statistical review, stating the name of the person (faculty/statistician internal or external to KGMU; may or may not be a part of DSC) conducting the same. **b.** CONSORT Statement, ***if a randomised controlled trial is being conducted.*** c. STROBE Statement, ***if an observational study is being conducted.*** 2. To meet an increasing demand of PG Theses evaluation, it was proposed that the number of members be increased from an existing 10 to 15 members; it was unanimously accepted. 3. The quorum for **PGTSC** will be of 50% of all members (including Member-Secretary of **IEC**). 4. The existing criteria on proposal allocations was modified where each member will get "not more than 10" thesis/dissertation proposals (down from up to 15) at least 10 days prior to the date of the meeting. Only in exceptional circumstances, and with permission of the member concerned, shall this number be increased. 5. Members are expected to submit their suggestions/comments to the office of **IEC** electronically (by e-mail) at least 3 days before the scheduled

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	meeting of the **PGTSC**. 6. It was reiterated that the **PGTSC** should meet once a month to evaluate the thesis proposals. In the event that the number of proposals is ≤5, the same may be deferred to the next meeting but before the scheduled **IEC** to prevent any inadvertent delay. 7. PGTSC meeting will preferably be done in-person. Members, who are out-of-town or cannot attend in-person due to work exigencies, etc. can join online, the link of which shall be provided by the office of IEC. 8. Minutes of the meeting will be prepared and approved by circulation by the PGTSC preferably within 3 working days (not beyond 5 working days). 9. Decisions taken in the PGTSC need to be communicated to the student concerned within 7 working days of approval. 10. Minutes of PGTSC will be put up for ratification before the ensuing IEC. 11. Theses work involving drugs/ devices/ or similar interventions will be sent directly to IEC. 12. PG Thesis/Dissertation proposals will be evaluated as follows: Dental Sciences/ Medical Sciences/ M.Phil courses/ Nursing courses. 13. To serve as a ready reckoner, it was decided to prepare and post "eContent", including the Checklist of the required documents, to everyone concerned in KGMU. It is expected that it would streamline the process of submission and reduce the number of errors.
VI	**Brought to Ethics Committee after XIX-PGTSC held on 21st November, 2023**
	Minutes of XXI-PGTSC of "Institutional Ethics Committee" Meeting held on 12th October, 2023 from 12.30 PM to 2.30 PM in the Seminar Hall, II floor, Central Library, KGMU UP, Lucknow. ***The following Members were present in the Meeting:-*** 13. Dr. Rajendra Nath -Member 14. Dr. Anupam Mishra -Member 15. Dr. D.N. Upadhyaya -Member 16. Dr. Anita Rani -Member 17. Dr. Nisha Mani Pandey - Member 18. Dr. Hardeep Singh Malhotra -Convener ***The following Members could not attend the Meeting:-*** 1. Dr. G.G. Agarwal -He has sent his written comment 2. Dr. A.A. Mahdi -He has sent his written comment
IA	**Action taken**
1-	Clarification of the research proposal entitled ***"To identify the preoperative and intraoperative factors that are responsible for the development of sepsis after PCNL"*** submitted by Dr. Mayank Kesharwani, SRI, Department of

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Urology, King George's Medical University, U.P., Lucknow vide letter no. 735/URO/23 dated 2nd September, 2023.

Previous PGTSC Comment	PI response
This seems to be a cause-effect relationship study.	Yes
So it should be planned according to that. Comparative groups should be identified	Yes, After PCNL patients will be divided into two groups on the basis of development sepsis: Group 1: Sepsis and Group II: Non sepsis.
Proper research hypothesis should be formulated.	Attached separately
Study design just says "prospective study". It should be clearly mentioned.	This study is prospective study
Sample size calculation and statistical analysis section are missing.	Attached separately

The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XVI-PGTSC-IIA/P2

2- Clarification of the research proposal entitled ***"Comparison of diagnostic Accuracy Of 300 Versus 500 cell differential count in bone marrow smears: A prospective observational study"*** submitted by Dr. Rehna Raju, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 855/23 dated 21st September, 2023.

Previous PGTSC Comment	PI response
Aims and objectives of the study not clear.	Attached Separately
The study is to be carried out in collaboration of the Department of clinical Hematology but it is not mentioned in the Material & Method section.	Attached Separately
Material and method section is incomplete.	Attached Separately

The above comment forwarded to Principal-Investigator was reviewed by y reviewer.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of y reviewer. • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P37***
3-	Clarification of the research proposal entitled ***"A cross sectional study of stress, self esteem, life satisfaction and subjective happiness in students of Medical Colleges of Lucknow"*** submitted by Dr. Divyansh Singh, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 595/CM/23 dated 29th August, 2023. **Previous PGTSC Comment:** • PI should submit authentically developed questionnaires that will be used in study before starting the study. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** ***Recommendation of reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVI-PGTSC-IIA/P59***
4-	Clarification of the research proposal entitled ***"Histological evaluation of pulpal response at varying remaining dentin thickness in teeth restored with various restorative materials: An ex vivo study"*** submitted by Dr. Ankita Agarwal, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 332/Cons & Endo/23 dated 20th September, 2023. ***Previous PGTSC Comments:*** • Identify one primary objective. • In the present form objectives are ambiguous. The outcome event for evaluation of the pulp dentin complex should be clearly identified. • The primary objective should be converted into proper research hypothesis in terms of the study population parameters. • Sample size calculation and statistical analysis section are missing. ***The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of Primary reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVII-PGTSC-IIA/P5***
5-	Clarification of the research proposal entitled ***"Development of cost effective methods for molecular detection of human immunodeficiency virus, hepatitis B C virus"*** sponsored by ICMR, New Delhi submitted by Mr.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

Rishabh Agarwal, MBBS student through his Mentor Dr. Shivanjali Raghuvanshi, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1329/23 dated 16th September, 2023.

Previous PGTSC Comment	PI response
Revised patient information sheet related to study-not attached.	Revised patient information sheet is attached.
Flow chart not given	Flow chart is attached
ICMR-STS-Grant letter –not attached	ICMR-STS-Grant letter has not been received till yet.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

Recommendation of reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XVII-PGTSC-IIB-STS/P3

6- Clarification of the research proposal entitled ***"Evaluating the relation between surface characteristics and biofilm adhesion over different archwires and brackets- An in vivo study"*** submitted by Dr. Maheshwar Singh, JRII, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1646/Ortho/23 dated 12th September 2023.

Previous PGTSC Comment:-

- Sample size mentioned is 33. However, in the sample size calculation it is mentioned that the sample size is 11 per type of wire.
- There are six subgroups (there in each metallic as well as ceramic)
- Shouldn't the sample size be 66?

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

Recommendation of reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XVIII-PGTSC-IIA/P8

7- Clarification of the research proposal entitled ***"Observation of oral microbiota and their effect on periodontium three months before and after debonding of fixed orthodontic appliance"*** submitted by Dr. Amar Dipika Singh, JRII, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1602/Ortho/23 dated 28th August, 2023.

Previous PGTSC Comment	PI response
Sections on Type of	This study includes collection of

(Hardeep Singh) Malhotra
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

subjects/Vulnerable subjects left blank in the proforma	GCF from volunteers hence the reponse of (5-v) has been made to 'Volunteers' and this study excludes children hence the response of (5-vi) has been made to 'No'

The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XVIII-PGTSC-IIA/P9

8- Clarification of the research proposal entitled ***"Comparative evaluation of maxillofacial morphology in unilateral and bilateral cleft lip and palate subjects: A CBCT study"*** submitted by Dr. Nainsi Jain, JRII, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1649/Ortho/23 dated 12th September, 2023.

Previous PGTSC Comment	PI response
Will such patients be included into the study who have been already operated for cleft repair or those in which no surgery has been done?	In this study only those patients will be used in whom no surgery is done.
Will the three groups be age and sex matched?	Yes
Sample size is mentioned 57 at one place and 60 at one place.	Corrected, to maintain evenness of 3 groups and 6 subgroups 60 is the sample size we are taking in this study.
Vulnerable subjects has been ticked as 'No' whereas children are being used as study subjects.	Corrected as children or adolescent children from age group of 15-19 are bing included in studyk so the response has been made yes in children and vunerable subjects.
Who will bear the cost of the CBCT?	CBCT is required investigation in cleft lip and palate patients so patient will bear the cost.
Is this investigation part of standard treatment protocol?	Yes in cleft lip and palate patients CBCT is done to examine the extent of clefts.
How much radiation will the children be exposed to?	Since examining arches require small FOVs there radiation exposure will be on average 103μSv. The "as low as reasonably achievable" (ALARA) principle is recommended also for the use of CBCT.
Will this help in their further treatment?	Yes, for surgical treatment planning and

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	orthodontic treatment.
Why will the controls undergo CBCT and the associated radiation to be a part of the study?	Controls are the patients have undergone CBCT for other pathological condition and dental treatment. Their CBCT records can be obtained from Oral medicine and Radiology department KGMU.

The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer.

Recommendation of reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XVIII-PGTSC-IIA/P10

9- Clarification of the research proposal entitled ***"A double blinded randomized controlled trial on the effect of electrostimulation on saliva production in oral cancer patients undergoing radiotherapy"*** submitted by Dr. Ajith Kumar. E, JRI, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 382/OMSD/23 dated 3rd August, 2023.

Previous PGTSC Comment	PI response
It is an Academic RCT but PI in SOP –Checklist in section-3-Clinical Trials –mentioned as NA-PI to justify	Correction done as advised
In Inclusion criteria -Age/Sex specificity not mentioned Control group-Physiotherapy (as Placebo)-details not given as to what type of Physiotherapy?	Added as advised
Control group	Details added as advised
Clinical Trial Registry document may be submitted to IEC as soon as registration is being done.	Clinical trial registry document will be submitted to IEC after receiving approval.

The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer.

Second opinion of reviewer:

- Tools still not given

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

Third opinion of Primary	PI response

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

reviewer	
Tools-case record form. ECOG (Estern cooperative oncology group) performance score chart-still not submitted.	Added as advised
As the study is double blinded randomized controlled trial-Please get registered this study in CTRI and send the concerned document to Office of the Ethics Committee as soon as it is registerd.	Clinical trial registry document will be submitted to IEC after ethical approval.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

Approved

PGTSC Decision: Approval ratified

Ref. code: XVIII-PGTSC-IIA/P13

10- Clarification of the research proposal entitled ***"Total blinded randomized controlled trial to evaluate the efficacy of melatonin in treatment of tempromandibular disorder"*** submitted by Dr. Bipin Tiwari, JRI, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 418/OMSR/23 dated 22nd August, 2023.

Previous PGTSC Comment	PI response
It is an Academic RCT but PI in SOP –Checklist In section-3-Clinical Trials –mentioned as NA-and ticked subsequent subsections - PI to justify	Correction done as advised
In Inclusion criteria - Age/ sex /Pregnant and lactating women criteria not given.	Added as adviced
Clinical Trial Registry document may be submitted to IEC as soon as registration is being done.	Clinical trial registry document will be submitted to IEC after receiving approval.
Tools-mentioned above are not submitted	Added as advised

The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer:- • As the inclusion criteria mention recruitment of subject of 15 to 60 years of age therefore Principal-Investigator is requested to submit Child Assent Form (E/H) also apart from regular ICF. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVIII-PGTSC-IIA/P14***
11-	Clarification of the proposal entitled ***"Comparative study on diagnostic yield in ultrasound-guided closed pleural biopsy versus thoracoscopic pleural biopsy in undiagnosed exudative pleural effusion"*** submitted by Dr. Anil Kumar Maurya, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 635/PCCM/23 dated 7th September, 2023. ***Previous PGTSC Comment:*** • This is a prospective study and a period of study is quoted as December 22 to October 23. Ethics clearance of prospective study should start before commencement of the work. Kindly correct the language of text in methodology that is either in past tense or future tense period. • Kindly present steps of sample size calculation. • Kindly summarise the outcome measures. • Kindly brief the anticipated statistics analytical methods. • Kindly include patient information sheet as per SOP of EC KGMU, both in English and Hindi. • Organise the description of proposal in PICO format ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P1***
12-	Clarification of the research proposal entitled ***"Evaluation of tumor budding as a promising prognostic marker in cervical squamous cell carcinoma using immunohistochemical staining"*** submitted by Dr. Santosh Kumar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 635/Patho/23 dated 30th August, 2023. ***Previous PGTSC Comment:*** • The scientific review committee has stated 'NA' regarding competency of investigation team. Kindly exclude the incompetent member and resolve the issue.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Kindly fill point 7 in annexure 1 properly as well as other vacant places.
- Is the risk not reasonable?
- What will be the adverse events (1)Patient 11 of annexure 1).
- Patient information sheet both in English and Hindi need to be submitted as per the SOP of EC KGMU
- The statistical analysis needs revision as per the aim ie survival analysis The investigator mentions breast cancer analysis- how to explain this. Again what is nestin expression kindly explain. The statistical analysis should be tailored for this study not made generic.
- Kindly include a data collecting protocol sheet to include all the clinical and radiological histological immunohistochemical data a two year survival study needs to be mentioned in aims.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- The Pi hs not addressed the fourth point in the table as wellk as no sheet is attached to clarify points 6 & 7 as stated by PI. Also regarding patients information sheet language correction/text rectifications need to be done in points 4,5,7,13,15,17,18,20.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

Second opinion of Primary reviewer:-

- The investigator has addressed the second point while annexure for rectification of the first point is missing.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P7

13- Clarification of the research proposal entitled ***"Outcome of marginal impaction injury of posterior wall of acetabulum fracture treated with kocher-langenback approach: A ambi study"*** submitted by Dr. Pranav Raghuwanshi, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 638/Ortho/23 dated 5th September, 2023.

Previous PGTSC Comment	PI response
Patient information sheet is missing.	Attached separately
At one place investigator says it is a prospective study while at 2 other places it seems to be a mixed of	This study is propective study (Attached separately)

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	prospective and retrospective study.	
	In ICF in study procedures, it seems a retrospective study from records-then why to take consent in prospective sense.	This study is propective study (Attached separately)
	Add Hindi version of ICF.	Attached separately
	Summarise methodology in PICO format.	Attached separately
	Are 7 Co-Investigotors from same department justified-one of them has superannuated- What will be his role from a different Institution-how data collection or Investigations are possible?	No, as per your advice 4 co-investigators included in the study (Attached separately)
	Annexure-fill in left blanks.	Attached separately

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P9

14- Clarification of the research proposal entitled ***"Assessment of residual cancer burden in breast cancer after neoadjuvant chemotherapy according to the subtypes and survival outcomes"*** submitted by Dr. Ananyaa, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 789/SY/23 dated 23rd August, 2023.

Previous PGTSC Comment:

- Blank spaces have to be filled in annexure 1.
- Is the risk not reasonable compare to benefit?
- Kindly elaborate sample size calculation
- Patient information sheet is not attached. Kindly attach in English and Hindi as per SOP of EC KGMU.
- If ICF is planned for retrospective work then study procedure in ICF should include a meaningful statement in the language that patient can understand. The idea is to obtain consent for this work/ publication and data about his survival include a case sheet to obtain the data as per the protocol.
- Innumerate all the outcomes needed for statistical analysis.
- Briefly summaries the anticipated statistical analysis.
- Re-organise description of proposal in PICO format and present a flowchart of approach.

The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer.

- Patient information sheet language correction/text rectifications need

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

to be in points 4,5,7,13,18,20.

The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P10

15- Clarification of the research proposal entitled ***"A study of ambulatory blood pressure monitoring in Medical Students in a tertiary care Hospital in North India"*** submitted by Dr. Arzoo Sharma, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2040/Med/23 dated 3rd May, 2023.

Previous PGTSC Comment	PI response
Title reflects study amongst medical students, but annexure 1 point 4 states patients	All medical students included in the study, attached separately.
Is the risk reasonable compare to anticipated benefit (annexure 1 point 10)	No risk involved in the study, attached separately.
What are the anticipated adverse events (annexure 1 point 11)- should be included in ICF	No adverse events included in the study, attached separately.
Patient information sheet both in English and Hindi needs to be attached as per SOP of EC KGMU.	Attached separately

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

Second opinion of reviewer:-

- Minor rectification in point's 5 & 7 patient information sheet both in English and Hindi versions.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P13

16- Clarification of the research proposal entitled ***"Study of serum homocysteine levels in various chronic complications of type2 diabetes mellitus"*** submitted by Dr. Radha Raman Pattanayak, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1175/Med/23 dated 30th August, 2023.

Previous PGTSC Comment	PI response

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	There are two co-supervisors mentioned on page 3 while four co-supervisors on page their names are also not the same. Kindly finalise the list in annexure 1 it is stated 'NO' against "where subjects from both sexes be recruited". Now which gender is to be taken? Kindly indicate and include in inclusion criteria.	Both sexes included in the study attached separately.
	Annexure 1 point 7 states 'NO' against use of body fluids but methodology involves blood sampling.	Attached separately
	What are the anticipated adverse effects (annexure 1 point11)- they need to be added in ICF.	No adverse events included in the study, attached separately.
	Patient information sheet both in English and Hindi needs to be submitted as per SOP of EC KGMU in annexure 1, 120 sample is required. While sample size calculation is 174. Why so?	Attached separately
	What are the various complications of type two diabetes mellitus as per the aims kindly indicate. It is not even indicated in inclusion criteria	----
	What is the outcome measures needed for analysis?	Attached separately
	Kindly summarise anticipated statistical analysis.	-----
	The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer. ***Second opinion of Primary reviewer:-*** • Anticipated statistical analysis summary not attached • Patient Information sheet very carelusly framed. Kindly revised point nos. 5,7,13,14,15,16,17,18, 20. ***The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P14***	
17-	Clarification of the research proposal entitled ***"Relationship of serum Vitamin D levels with viral replication and Hepatic Fibrosis in patients of***	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	chronic Hepatitis B and Chronic Hepatitis C" submitted by Dr. Pahul Ahuja, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1155/Med/23 dated 23rd August, 2023. ***Previous PGTSC Comment:*** • Please rectify the ICF, as per standard guidelines. • Please provide a properly filled Patient Information Sheet. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P17***
18-	Clarification of the research proposal entitled ***"Study of mechanism of injury, pattern of injury and mode of transport influencing outcome of trauma patients at level I trauma center: A retrospective and prospective observational study"*** submitted by Dr. Vishal Bisan Bedi Gammey, JRI, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. 415/TS/23 dated 19th August, 2023. ***Previous PGTSC Comment:*** • Sample size calculation not provided. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P32***
19-	Clarification of the research proposal entitled ***"Postmortem analysis of electrolytes (Na+, K+, Ca+2) in synovial fluid and cerebrospinal fluid for determination of time since death: A comparative study"*** submitted by Dr. Tauheed Anwar, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 314/FMT/23 dated 4th September, 2023. ***Previous PGTSC Comment:*** • Consent form both in English and Hindi needs to be corrected as it is in first person, although the consent is to be taken for blood collection from the corpse. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P35***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

20- Clarification of the proposal proposal entitled ***"Correlation of CSF and blood serotonin level with suicide"*** submitted by Dr. Harshita, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 334/FMT/23 dated 18th September, 2023.

Previous PGTSC Comment	PI response
For supervision of biochemical investigation no Co-Guide is there.	I have made a co-guide from IITR for supervision of biochemical investigation and have attached the collaboration letter here within on first.
The method for estimation of serotonin level not provided.	Method of estimation of serotonin is attached here withink on page no.2
There is no bibliography or references.	References are there on page no.3
Consent form both in English and Hindi needs to be corrected as it is in first person, although the consent is to be taken for blood collection from the corpse.	New consent form is attached here within on page no.4

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P36

21- Clarification of the proposal proposal entitled ***"Association of posterior tibial slope and functional outcome after total knee arthroplasty: An observational study in Indian population"*** submitted by Dr. Prakhar Verma, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1275/23 dated 4th September, 2023.

Previous PGTSC Comment:

- It is mentioned that the study will be conducted between September, 2022 to August, 2023. So it seems that the study has already been completed without Ethical clearance?

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P42

22- Clarification of the proposal proposal entitled ***"Study of nestin expression across spectrum of various native renal diseases and its association with progression/remission of disease"*** submitted by Dr. Shashi Nandini, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 739/23 dated 19th June, 2023.

Previous PGTSC Comment:

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Methodology for immunohistochemistry and electron microscopy including reference of method not provided.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P43

23- Clarification of the proposal entitled ***"Evaluation of functional outcomes of unstable intertrochanteric fractures managed by proximal femur nailing using modified harris HIP score"*** submitted by Dr. Ritesh Chaloo, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1256/Ortho/23 dated 8th September, 2023.

Previous PGTSC Comment	PI response
The study is very similar to another study from the same department by Dr. Krishna Mani Shukla under Dr. Devarshi Rastogi. Please reconsider either of the two studies.	Thesis of Dr. Krishna Mani Shukla is based on comparative studyk pertaining to hip replacement surgery (hemireplacement). On the other hand thesis of Dr. Ritesh is based on a broader aspect of hip preservation surgery only.(PFN)
There are nine Investigators in the study with overlapping roles.	Attached separately (4 Co-Investigators remove) New attached separately.
Several sections of the IEC proforma have been left incomplete.	Attached separately
Kindly limit to cases those are not elderly? Specify the age range, so that there is no overlap with the theses of Dr. Krishna Mani.	Age range between 40-70 years both male and female will be recruited in the study.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P45

24- Clarification of the proposal entitled ***"Comparative analysis of glenohumeral and subacromial steroid injection in primary frozen shoulder: A prospective, randomized short term comparision study"*** submitted by Dr. Namkumpeung Lungalang, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1257/Ortho/23 dated 8th September, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

Previous PGTSC Comment	PI response
Several sections of the IEC proforma are left incomplete.	New IEC proforma attached separately.
There are eight Investigators with overlapping roles.	Attached separately (4 Co-Investigator remove) New attached separately.
Sample size calculated is 50 but that mentioned in the IEC proforma is 70	Total sample size 50. IEC proforma attached separately.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P46

25- Clarification of the research proposal entitled ***"Analysis of expression of therapeutic biomarkers in gall bladder carcinoma"*** submitted by Dr. Arina Alam, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1251/23 dated 1st September, 2023.

Previous PGTSC Comment	PI response
Use of biological materials has been ticked 'No'	Ticked Yes now
Vulnerable subjects not mentioned.	Ticked yes now and includes elderly and severely ill patients

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P48

26- Clarification of the proposal entitled ***"To study the role of B-regulatory cells in development of inhibitors in hemophilia a patients"*** submitted by Dr. Sana Parveen, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1299/23 dated 11th September, 2023.

Previous PGTSC Comment	PI response
Section on Consent is incompletely filled.	Completely filled now
Use of organs/body fluids is ticked 'No' but blood sample is being drawn.	Ticked Yes now

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to Principal-Investigator was reviewed by reviewer. • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P49***
27-	Clarification of the research proposal entitled ***"Ultrasound guided erector spinae plane block in Paediatric patient undergoing meningomyelocoelesurgery: A prospective, randomized controlled study"*** submitted by Dr. Akanksha Gupta, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/599/23 dated 24th May, 2023. ***Previous PGTSC Comment:*** • Sample size is mentioned 80 at one place and 70 at another where sample calculation has been done. • Children are not ticked in the section on vulnerable population. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P54***
28-	Clarification of the research proposal entitled ***"Study of single nucleotide polymorphisms in pik3ca gene and it's role in cervical cancer"*** submitted by Dr. Harshi Srivastava, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1242/23 dated 28th August, 2023. **Previous PGTSC Comment** / **PI response** Section on Use of Biological Materials is ticked as 'No' / Ticked Yes now ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P53***
29-	Clarification of the research proposal entitled ***"Histopathological mapping of nodal status in patients of carcinoma gallbladder undergoing curative intent surgery: A combined retrospective and prospective study"*** submitted by Dr. Era Parasar, SR, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1444/23 dated 26th August, 2023. **Previous PGTSC Comment** / **PI response** Seven Investigators are from one / Investigator from Pathology

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	department. No Investigator from Pathology department even though HPE will be needed for patients in the prospective arm.	Department was already included in the study but was mistakenly missed from the list of Co-PI.
	Sample size calculation has not been done.	Sample size calculation is done and explained in detail.
	Section on Privacy and Confidentiality mentions use of indirect identifier. In such as case retrospective consent will be required from the patients. For consent waiver the data has to be completely anonymous.	Under section of privacy and confidentiality, the study will be completely anonymised/delinked.
	End point of the study has not been defined.	Primary objective is modified. 1-To describe incidence of nodal disease in patients undergoing curative intent surgery for carcinoma gallbladder. 2- To describe stationwise distribution of nodal disease in patients undergoing curative intent Surgery for carcinoma gallbladder.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P58

30- Clarification of the research proposal entitled ***"Survival outcomes for non-metastatic rectal cancer in patients undergoing treatment at a tertiary care centre: A retrospective and prospective study"*** submitted by Dr. Mandeep Singh, SR, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1445/23 dated 26th August, 2023.

Previous PGTSC Comment	PI response
The study design is retrospective as well as prospective. It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. It has to be split into two different parts.	Retrospective study (case series, from January, 2015 till December, 2022)[Point 3.3. and in synopsis]

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Each type shall use different subjects.	
The sample size calculation is not given. The number 60 is arbitrary.	Based on the number of rectal cancer patients managed in Department of Surgical Oncology at KGMU yearly, we estimate to have approximately 60 patients in this study. [Point 3.4]
Statistical analysis section is not given	Statistical analysis now given under separate heading as point 3.6

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P59

31- Clarification of the research proposal entitled ***"Caregiver burden in chronic obstructive pulmonary disease patients"*** submitted by Dr. Theepan Kumar S, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 611/CM/23 dated 2nd September, 2023.

Previous PGTSC Comment	**PI response**
Nothing is said about the reliability and validity of the instrument to be used.	Zarit caregiver burden assessment scale is a validated tool with Cronbach's alpha 0.646. It has a mean Kappa value of 0.961. (Sinha A et.al)
Can the scale be completed in a reasonable amount of time?	Yes, the scale can be completed in a reasonable amount of time.
How much training is needed to learn how to administer it?	Before administering the Zarit burden scale, individuals can typically become proficient in its administration within a relatively short amount of time with the provision of basic instructions and practice.
Sample size calculation is for prevalence study. It will use measurement scale methods.	Zarit burden interview contains 22 questions, scoring from (0-88).

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		0-21: No burden-Mild burden 22-40: Mild-moderate burden 41-60: Moderate-severe burden 61-88: Severe burden. In this study we will calculate the mean burden score

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P62

32- Clarification of the proposal entitled ***"Epidemiology of pediatric trauma victims admitted to the trauma centre of KGMU: A prospective observational study"*** submitted by Dr. Durga Krishna, SRI, Department of Pediatric Orthopedics, King George's Medical University, U.P., Lucknow vide letter no. 2606/PaedOrtho/23 dated 3rd October, 2023.

Previous PGTSC Comment	PI response
The objective is not clear. It just says: To describe victim related factors like age, sex,……..	The objectives have been rewritten as 1. To study time, place and person. distribution of Paediatric trauma among patients admitted to trauma center of KGMU. 2. To describe certain factors related to treatment of Paediatric trauma patients admitted to the trauma centre of KGMU 3. To do a subgroup analysis based on age and sex.
What is the use of these variables?	DEMOGRAPHIC CHARACTERISTICS- Analysis of variables like age and sex can help us identify age and sex specific trends in injury mechanism and injury severity. INJURY RELATED CHARACTERISTICS- Analysing variables like mode of injury, site of injury, severity of injury and pattern of injury will help in identifying prevalence in each category, which type of injuries are more severe at presentation.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Identifying such patterns will help in formulating policies to minimise/ prevent such occurrences. TREATMENT RELATED FACTORS Analysing variables like time since injury to presentaion, vehicle used for transport, referral from other centres and outcome of admission will help in identifying the efficacy/ any lacunae in emergency medical services.
	Proper research hypothesis should be formulated after identifying the study parameters.	Research hypothesis: Demographic factors like age and sex may have an effect on injury mechanism, severity of injury and outcome of admisson. Null hypothesis: Demographic factors like age and sex do not have an effect on injury mechanism of injury, injury severity and outcome of admission.
	Sample size calculation, statistical analysis should be in coherence with research hypothesis.	A previous study has reported the incidence of rate for paediatric injury to be 10460 per one lac per one year. (7) Sample size= 160 was calculated used the formula $n \geq \frac{NZ^2_{1-\alpha/2}p(1-p)}{d^2(N-1)+Z^2_{1-\alpha/2}p(1-p)}$ 95% CI per 5% margin error per 144+ 10% drop out = 160 patients Alpha- Type 1 error rate p: expected proportion d: marginal error rate N: Population size

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P64

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

33- Clarification of the proposal entitled ***"Study of microsatellite instability expression in gallbladder cancer and its clinicopathological correlation"*** submitted by Dr. Ankit Kumar, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1481/23 dated 1st September, 2023.

PGTSC Comments	Previous Proposal	Response
The study design is retrospective as well as prospective. It cannot be both. Each type of study uses different methodology and analysis and sample size calculation It has to be split into two different parts Each type shall use different subjects.	The present study is a retrospective and prospective analysis to be conducted in the Department of Surgical Oncology,KGMU, Lucknow	It is modified under heading AIM AND OBJECTIVES, in section **Methods** (Page No. 12) The present study is a observational study to be conducted in the Department of Surgical Oncology in collaboration with Department of Pathology , KGMU, LUCKNOW to look for MSI expression in Gall bladder cancer . It will include Data of patients of which tissue blocks are available (Jan 2017 to December 2022) and Patients of Gallbladder carcinoma who will undergo surgery (January 2023 to December 2024)
Sample size	This study is being	It is modified under

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	calculations are not given.	done as a combined retrospective and prospective analysis, in the Department of Surgical Oncology, KGMU, Lucknow. We Expect to recruit about 120 patients in combined retrospective and prospective arms.	heading AIM AND OBJECTIVES, in section **Sample Size** (Page No. 13) Based on the number of Gall Bladder cancer patients (40-50 yearly) managed in Department of Surgical Oncology at KGMU yearly, we estimate to have approximately 120 patients in this study.
	Statistical analysis section is very general. It should be specific to the study objectives.	The data would be analyzed using SPSS software version 16.0. The categorical variables will be mentioned as number and percentage. The Kaplan-Meier survival analysis will be done to find out the survival	It is modified under heading AIM AND OBJECTIVES, in section **Statistical Technique** (Page No. 12) Clinicopathological factors will be identified by univariable Cox regression analysis. The following covariates will include: gender, age, family history, MSI status , depth of infiltration tumor histology, lympho-vascular invasion, perineural invasion

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			and necrosis stage positive lymph nodes. Covariates with a p-value of ≤ 0.1 will subsequently include in a multivariable analysis. A p-value ≤0.05 will note as significant.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P67

34- Clarification of the research proposal entitled ***"A study of clinicopathological profile and survival outcome of adult extremity soft tissue sarcoma after curative surgery"*** submitted by Dr. Monika Shekhawat, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1486/23 dated 1st September, 2023.

Previous PGTSC Comment	PI response
-The study design is retrospective as well as prospective. -It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. -It has to be split into two different parts. -Each type shall use different subjects.	The study will be conducted 8 years retrospectively (2015-2023)
The sample size calculation is not given. The number 96 is arbitrary	As this is a retrospective observational study a formal sample size calculation was not done. We operate about 20-25 case of extremity soft tissue sarcoma per year. Based on this figure we estimate to recruit about 160 patients in the study.
Statistical analysis section is not given.	Statistical analysis now given under separate heading.

The above comment forwarded to Principal-Investigator was reviewed by

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P68

35- Clarification of the research proposal entitled ***"Study of factors predicting regional lymph nodes metastasis in marjolin's ulcer"*** submitted by Dr. Prabhat Shukla, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1482/23 dated 1st September, 2023.

PGTSC Comments	Previous Response	Response
In the aim it is supposed to be a prevalence study.	Aim of the study is to find out the proportion of patients having nodal metastasis in Marjolin's Ulcer and factors predicting Lymph nodes Metastasis	It is modified under heading AIM AND OBJECTIVES, in section AIM (Page No. 01) **Aim of the study is to find out the proportion of patients having regional nodal metastasis in Marjolin's Ulcer.**
The primary objective is to find a predictive model. The two are completely different objectives. The objective should be well defined and study should be planned accordingly.	Primary: • To study the factors predicting Regional Lymph nodes Metastasis in Marjolin's Ulcer. Secondary: • To assess short term outcomes	It is modified under heading AIM AND OBJECTIVES, in section OBJECTIVES (Page No. 01) **Primary:** • **To study the proportion of patients having regional nodal metastasis in Marjolin's Ulcer.** **Secondary:** • **To study the clinico-pathological factors associating with**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		and long term outcomes (recurrence, disease free survival and overall survival) in patient undergoing surgery for Marjolin's Ulcer.	**regional lymph node metastasis.**
	• The study design is supposed to be retrospective as well as prospective. • This is also a contradiction.	• The present study is a retrospective and prospective analysis to be conducted in the Department of Surgical Oncology in collaboration with Department of Pathology,	It is modified under heading AIM AND OBJECTIVES, in section MATERIALS AND METHODS • **The present study is a observational study to be conducted in the Department of Surgical Oncology in collaboration with Department of Pathology, KGMU, LUCKNOW. It will include-** • **Data of previously treated patient- This will be extracted**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		KGMU, LUCKNOW. • In retrospective aspect Patient's data will be extracted from case record for period of 8 yrs (2015-2022) from date of registration to assess factors determining Lymph nodes Metastasis. • In prospective aspect Patient of proven cases of Marjolin's Ulcer who will undergo surgery, for a period of 2 years.	**from case record for period of 8 yrs (2015-2022) from date of registration to assess clinico-pathological factors determining regional lymph nodes metastasis.** • **Data of newly admitted Patient-Patient of proven cases of Marjolin's Ulcer who will undergo surgery, for a period of 2 years.** (Page No. 01)
	• Statistical analysis	The data would	It is modified under heading

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	section is vague.	be analyzed using SPSS software version 16.0. The categorical variables will be mentioned as number and percentage. The Kaplan-Meier survival analysis will be done to find out the survival.	AIM AND OBJECTIVES, in section STATISTICAL TECHNIQUE (Page No. 02) **The data would be analyzed using SPSS software version 16.0. The categorical variables will be mentioned as number and percentage. Clinico-pathological factors will identify by univariable Cox regression analysis. The following covariates will include: gender, age, family history, addiction history, size, site, duration of scar, cause of marjolin's ulcer, thickness, tumor histology, lympho-vascular invasion, perineural invasion and differentiation grade of the primary tumor, resection margin, immunosuppression, postoperative radiotherapy, extracapsular spread, differentiation grade, size and number of positive lymph nodes. Covariates with a p-value of ≤ 0.1 will subsequently include in a multivariable analysis. A p-value ≤0.05 will note as significant**

The above comment forwarded to Principal-Investigator was reviewed by P reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P69

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

36- Clarification of the proposal entitled ***"Study of clinicopathological profile and survival outcomes of patients following curative surgical treatment for a second primary oral cancer"*** submitted by Dr. Priyanka Khilari, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1484/23 dated 1st September, 2023.

PGTSC Comments	Previous Response	Modification
The study design is retrospective as well as prospective. It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. It has to be split into two different parts. Each type shall use different subjects.	Retrospective and prospective study Retrospective for upo to 10 years (January 2013-December, 2022) and prospective up to Janaury 2023-September, 2024)	Observational study (Case series, 2013 till September, 2024)
The Sample size calculation is missing.The number 96 is arbitrary.	Formal sample size calculation has not been done. We estimate to have approximately 96 patients in this study.	Based on the number of second primary oral cancer patients managed in Department of Surgical Oncology at KGMU yearly, we estimate to have approximately 96 patients in this study.
• Statistical analysis section is missing.	Statistical analysis was meged with methodology and mentioned.	Statistical analysis now given under separate heading.
• Aim and objectives	Aims and objectives are not properly defined.	It is modified under heading aim and objectives.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XIX-PGTSC-IIA/P70

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

37- Clarification of the research proposal entitled ***"Survival outcomes of locally advanced (T4D) oral squamous cell cancers involving masticator space in patients undergoing surgical treatment"*** submitted by Dr. Pritesh P. Gaonkar, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1483/23 dated 1st September, 2023.

PGTSC Comments	Previous Response	Modification
• The study design is retrospective as well as prospective • It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. • It has to be split into two different parts • Each type shall use different subjects	Retrospective and prospective study .Retrospective for up to 10 years (January 2013-Decsember 2022) and prospective up to (January 2023- September 2024).)	Retrospective study (case series, 2012 till september 2022)
• The sample size calculation is not given. The number 80 is arbitrary.	Formal sample size calculation has not been done. We estimate to have approximately 80 patients in this study	Based on the number of locally advanced (T4b) Oral Squamous Cell Cancers involving masticator space patients Operated in Depatment of Surgical Oncology at KGMU yearly, we estimate to have approximately 80 patients in this study
• Statistical analysis section is not given	Statistical analysis was merged with methodology and mentioned	Statistical analysis now given under separate heading
• From the case series form , it is not clear , how the disease free survival shall be measured		Necessary changes have been made under the heading "statistical technique and method of collection"in page no.8 Disease-free survival is defined as the duration of time

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	between surgery to the first recurrence of the disease.
	The above comment forwarded to Principal-Investigator was reviewed by reviewer. • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P71***
38-	Clarification of the research proposal entitled ***"Surgical outcomes in cancer of the esophagus and gastroesophageal junction (Siewert's type 1&2)"*** submitted by Dr. Akshat Mishra, SRI, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/1485/23 dated 1st September, 2023. ***Previous PGTSC Comment:*** • The study design is retrospective as well as prospective. • It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. • It has to be split into two different parts. • Each type shall use different subjects. • Sample size calculation is missing. • From the Case series form, it is not clear: How the disease free survival shall be measured. • Statistical analysis section is very general. It should be specific to the objectives of the study. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P72***
39-	Clarification of the research proposal entitled ***"Correlation of L-Type fatty acid binding protein levelswith acute kidney injury in critically ill obstetrics patients and its association with fetomaternal outcome"*** submitted by Dr. Arunima Shukla, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1094/23 dated 25th August, 2023. ***Previous PGTSC Comment:*** • SOP Check list should be revised as Point no-5,7,8 ,10 not marked appropriately • Structured questionnaire, APACHE Score II and CRF not attached • Text component in MS Word file not appropriate, words are intermingled-Protocol should be revised. ***The above comment forwarded to Principal-Investigator was reviewed by***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Primary reviewer. ***Second opinion of Primary reviewer:-*** • But APACHE score and case record form still has not been given. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P75***
40-	Clarification of the research proposal entitled ***"Implementing heat stable carbetocin in treatment of atonic post partum hemorrhage-A pilot study"*** submitted by Dr. Aradhya Garg, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1177/23 dated 26th August, 2023. ***Previous PGTSC Comment:*** • SOP Check list should be revised as Point no- 8 & 10 not marked appropriately • In Scientific Review Committee name of one of the Co-guide (Prof. S P Jaiswar) is also included-Please justify or revise SRC. • CRF-not attached ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P76***
41-	Clarification of the research proposal entitled ***"Comparison of ultrasound guided suprainguinal and infrainguinal approaches of fascia iliaca compartment block for postoperative analgesia after total knee replacement: A prospective randomized trial"*** submitted by Dr. Adarsh Kumar Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1011/23 dated 4th September, 2023.

Previous PGTSC Comment	PI response
Scientific Review Committee– should be revised as name of one of the Co-PI (Prof. Vinita Singh) is there in SRC document	New SRC attached separately
SOP Check list should be revised as Point no- 6 & 8 not marked appropriately	Attached separately
The Study design in Protocol is Prospective randomized	As per your advice this study is prospective randomized trial

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	comparative study ,the Title may be corrected accordingly (in which Prospective randomized trial is written)	
	In methodology Flow chart is not given – please add flow chart	Attached separately
	VAS Score and CRF –Not attached	Attached separately
	The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer. ***Second opinion of Primary reviewer:-*** • Kindly provide CTRI registration as soon possible ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P78***	
42-	Clarification of the research proposal entitled ***"Role of dexmedetomidine in reduction of arrhythmias post long cardiopulmonary bypass exposure"*** submitted by Dr. Kamna Nagar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/578/23 dated 26th Auugst, 2023. ***Previous PGTSC Comment:*** • SOP Check list should be revised as Point no- 5 & 8 not marked appropriately –Please revise SOP Check list • In Inclusion criteria, Sex /Pregnancy & lactating women criteria not mentioned • Case record form (CRF)-not attached ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P81***	
43-	Clarification of the research proposal entitled ***"Prospective, randomized comparison of LMA protector versus LMA blockbuster for laparoscopic surgery"*** submitted by Dr. Sharon Shiu, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/933/23 dated 25th August, 2023. ***Previous PGTSC Comment:*** • SOP Check list should be revised as Point no- 10 (Risk and benefit) not marked appropriately • In methodology, Flow chart is not given–please include as it is a	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	randomized controlled study • CRF -not attached ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P84***
44-	Clarification of the research proposal entitled ***"Comparison of opioid free and opioid based anaesthesia in patient undergoing thyroid surgery on post operative outcome: a prospective randomized study"*** submitted by Dr. Garima, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/746/23 dated 16th August, 2023. ***Previous PGTSC Comment:*** • SOP Check list should be revised as Point no- 6 and 11 (ADR) not marked appropriately –(PI mentioned in Protocol that ADRs to be monitored-Please revise SOP Check list • In methodology Flow chart is not given-please include as it is randomized controlled study • ICF -attached (but Hindi version is incomplete)-PI to attach Complete Hindi version of ICF • CRF and VAS Score -not attached ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P85***
45-	Clarification of the research proposal entitled ***"Evaluation of different bedside clinical tests in predicting difficult laryngoscopy and intubation in oral cancer surgery patients- An observational study"*** submitted by Dr. Smita Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/585/23 dated 24th May, 2023. ***Previous PGTSC Comment:*** • SOP Check list should be revised as Point no-5 (vulnerability) and 10 (Risk and benefit) not marked appropriately • Study design- Prospective observational study (but written in Protocol as Prospective longitudinal study) -PI to clarify • In inclusion criteria -Pregnant & lactating women criteria -not mentioned • CRF -not attached ***The above comment forwarded to Principal-Investigator was reviewed by***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	reviewer. • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P86***
46-	Clarification of the research proposal entitled ***"To determine role of methylene blue in septic shock as a vasopressor sparing agent: A prospective randomized controlled study"*** submitted by Dr. Aditya Parmar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/955/23 dated 19th August, 2023. ***Previous PGTSC Comment:*** • In Inclusion criteria-Sex specificity and Lactating women criteria not mentioned • In methodology-Flow chart to be attached as it is a randomized controlled study • APACHE, n SOFA score and CRF -not attached. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIA/P87***
47-	Clarification of the research proposal entitled ***"IL-23 expression in subjects with ankylosing spondylitis: a case control study"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Mr. Timil Suresh, MBBS 2020 through his Mentor Dr. Arpit Singh, Associate Professor, Department of Orthopedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 11049/OS/23 dated 21st August, 2023.

Previous PGTSC Comment	PI response
Patient information sheet both in English and Hindi need to be submitted as per SOP of EC KGMU	It is attached herewith
Details about where, how and under whom will the IL-23 expression be conducted needs to be submitted	The expression of IL-23 will be done using ELISA kit and will be conducted under the guidance of Dr. Mili Jain, Additional Professor in the Department of Pathology, KGMU

The above comment forwarded to Principal-Investigator was reviewed by reviewer.
• Approved
PGTSC Decision: Approval ratified
Ref. code: XIX-PGTSC-IIB-IMR-S/P3

(Hardeep Singh) Malhotra
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

48-	Clarification of the research proposal entitled ***"Monitoring of anxiety, pain, and cardiovascular changes during root canal treatment: an observational clinical study"*** sponsored by ICMR STS submitted by Mr. Rishabh Pandey, BDS through his Mentor Dr. Pragya Pandey, Associate Professor, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. nil dated 4th September, 2023. ***Previous PGTSC Comment:*** • In Hindi ICF language to be modified. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX -PGTSC-IIB-STS/P1***
49-	Clarification of the research proposal entitled ***"A comparative analysis of histopathological findings in optic nerve in poisoning and snake bite cases"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Anup Kumar Raipuria, JRI through his Mentor Dr. Shiuli, Associate Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 155/FMT/23 dated 22nd May, 2023. ***Previous PGTSC Comment:*** • In scientific review committee CO-PI is also a member. • Objective: The objective of the study is to find and compare the histopathological changes in the optic nerve between different type of poisoning cases and different types of snake bite cases; types need to be clarified. • Sample size: The researcher assumes prevalence of poisoning 0.03% a basis for the assumption may give more clarity. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-II B IMR-R/P1***
50-	Clarification of the research proposal entitled ***"Estimation of time since death of human cadaver in view of cellular changes in cerebrospinal fluid"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Tauheed Anwar, JRI through his Mentor Dr. Anshu Priya, Assistant Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	vide letter no. 314/FMT/23 dated 4th September, 2023. ***Previous PGTSC Comment:*** • In scientific review committee CO-PI is also a member. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-II B IMR-R/P2***
51-	Clarification of the research proposal entitled ***"Diagnosis of early myocardial infarction by histochemical staining on autopsy"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Fathima Harsha P M, JRI through her Mentor Dr. Raja Rupani, Additional Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 309/FMT/23 dated 2nd September, 2023. ***Previous PGTSC Comment:-*** • The third objective seems like a directive for creating policy; it might be regarded as a secondary objective. • Is the study started? As the first sentence is written in present tense. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-II B IMR-R/P4***
52-	Clarification of the research proposal entitled ***"Study of sexual dimorphism on cranial Index in King George Medical University"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Abhipsa Senapati, JRI through his Mentor Dr. Raja Rupani, Additional Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 308/FMT/23 dated 4th September, 2023.

Previous PGTSC Comment	PI response
The purpose of this study is to evaluate the cranial index. However, it is worth mentioning that the researcher intends to examine the correlation between body statures and hand and foot dimensions in the statistical analysis. This particular aspect is not explicitly mentioned in the proposal or objectives.	I am removing the correlation between body and stature part from the data analysis of my project. As it is not part of my project **Correction:** correlation coefficient will be used to analyse the sexual dimorphism of cranial index with significance at P<0.05

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to Principal-Investigator was reviewed by reviewer. • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-II B IMR-R/P5***
53-	Clarification of the research proposal entitled ***"Assessment of correlation between biofilm adhesion on different archwires with their surface roughness"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Maheshwar Singh, JRII through his Mentor Prof. Gulshan Kumar Singh, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1647/Ortho/23 dated 12th September, 2023. ***Previous PGTSC Comment:*** • Is the work done? As description written in quantiitative biofilm measurement are in past tense. . • Hindi ICF needs to be modified with simple and understandable words so that the participant could comprehend it. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-II B IMR-R/P6***
54-	Clarification of the research proposal entitled ***"Correlation between intraoperative quantitative assessment of parathyroid gland perfusion during total thyroidectomy after gland excision using indocyanine green with post-operative hypocalcemia-a prospective interventional study"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Ashwinee Rahalkar, SR through her Mentor Prof. Anand Kumar Mishra, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSURG/353/23 dated 20th September, 2023. ***Previous PGTSC Comment:*** • Only 2 experts are there in the scientific review committee of the project. • The items of checklist are not ticked. • Time line is written as 1 Dec 2022 to 30 June 2024, is the study started? • In the consent form, the aim of the study needs to be written in simple language.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to Principal-Investigator was reviewed by reviewer. • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-II B IMR-R/P9***
55-	Clarification of the research proposal entitled ***"An in-vivo study on release of metal Ions and DNA damage in buccal mucosa during fixed orthodontic treatment"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Chandana Himanshu, JRII through her Mentor Prof. Amit Nagar, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1650/Ortho/23 dated 13th September, 2023. ***Previous PGTSC Comment:*** • In checklist section the type of study is not ticked. • In inclusion criteria, Indian population is to be targeted; this may be written as patient population consulting KGMU, OPD. • Sentences of investigative procedures indicate that proceudure are already one. • Language of Hindi ICF need to be rechecked. ***The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-II B IMR-R/P10***
56-	Clarification of the research proposal entitled ***"Assessment of sleep quality using Pittsburgh sleep quality index and it' correlation with anxiety level in undergraduate medical student"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Ms. Prachi, MBBS 2021 & Mr. Pragyesh Mishra, MBBS 2021 through thier Mentor Prof. Sandeep Bhattacharya, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3382/PHY/23 dated 26th September, 2023. ***Previous PGTSC Comment:-*** • Sample size calculation not done –Please include • Patient information sheet–not related to study. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIX-PGTSC-IIB-IMR-S/P6***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

57-	Clarification of the research proposal entitled ***"Prevalence of sleep related breathing disorder in heart failure patients and its correlation with ejection fraction, natriuretric peptide levels and diastolic dysfunction"*** submitted by Dr. Manoj Kumar Rai, SR, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1705/Cardio/23 dated 20th September, 2023. ***Previous PGTSC Comment:*** • The duration of study is mentioned as 1st August 2022 to 30th October 2023. Has the study been already undertaken without IEC approval? ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XX-PGTSC-IIA/P7***
58-	Clarification of the research proposal entitled ***"To study the role of T-REGULATORY cells in development of inhibitors in hemophilia a patients"*** submitted by Dr. Shada Bari, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1355/23 dated 22nd September, 2023. ***Previous PGTSC Comment:*** • Method for modified Bethesda Assay has not been provided in the material and methods section. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XX-PGTSC-IIA/P9***
59-	Clarification of the research proposal entitled ***"Early efficacy of oral lipid lowering therapy in achieving LDL-C targets following acute coronary syndrome"*** submitted by Dr. Ambresh Kumar Gautam, SR, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1711/Cardio/23 dated 19th September, 2023. ***Previous PGTSC Comment:*** • It is mentioned that 500 cases will be recruited but on what basis this number of cases are going to be taken is not mentioned. Sample size calculation needs to be provided. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XX-PGTSC-IIA/P10
60-	Clarification of the research proposal entitled ***"Profiling of T cells in newly diagnosed ITP patients and their correlation with response to steroid therapy"*** submitted by Dr. Radhika Singh, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1375/23 dated 25th September, 2023. ***Previous PGTSC Comment:*** • In Inclusion criteria-Age range and sex specificity of patients -not mentioned. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XX-PGTSC-IIA/P15***
61-	Clarification of the research proposal entitled ***"Elevated selenoprotein p levels in thalassemia major patients"*** submitted by Dr. Aashi Singhal, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1398/23 dated 29th September, 2023.

Previous PGTSC Comment	PI response
In Inclusion criteria – Cases and control pts and Pregnant and lactating women criteria not mentioned.	CASES: Patients above 10 years of age, males and females (excluding pregnant and lactating women) with thalassemia major/intermedia, receiving regular treatment, will be included in this group. CONTROLS: Healthy individuals (females and males) without anemia and chronic diseases will be included in the control group.
Study design is given as Prospective study but it seems to be Prospective case control study-PI to clarify and modify in protocol.	Prospective case control study Thalassemia patients will be labeled as cases and diseased free will be labeled as controls and then level of Selenoprotein P will be compared.
In Methodology- grouping of patients not described and Flow chart of the study not given-PI to give detailed methodology with Flow chart.	Attached

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	CRF-not attached | Attached ***The above comment forwarded to Principal-Investigator was reviewed by Primary reviewer.*** ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XX-PGTSC-IIA/P16***
62-	Clarification of the research proposal entitled ***"Early exposure to screen in children presenting with autistic symptoms: An observational study"*** submitted by Dr. Shivank Tomer, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1680/Psy/23 dated 21st September, 2023. ***Previous PGTSC Comment:*** • Guardian consent form instead of regular ICH in both English /Hindi version should be attached. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XX-PGTSC-IIA/P21***
63-	Clarification of the research proposal proposal entitled ***"Therapeutic effect of ketamine nebulization in acute respiratory distress syndrome: A randomized controlled trial"*** submitted by Dr. Amna Khatoon, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/588/23 dated 24th May, 2023. ***Previous PGTSC Comment:*** • Kindly provide a properly filled Patient Information Sheet. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XX-PGTSC-IIA/P23***
64-	Clarification of the research proposal entitled ***"Prospective cohort study to determine the safety of direct discharge to home from Indian ICU"*** submitted by Dr. Shikha Yadav, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1223/23 dated 29th September, 2023. ***Previous PGTSC Comment:*** • Kindly provide a properly filled Patient Information Sheet. ***The above comment forwarded to Principal-Investigator was reviewed by***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	reviewer. • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XX-PGTSC-IIA/P24***
65-	Clarification of the research proposal proposal entitled ***"To compare the impact of mccoy, mcintosh and video laryngoscope on intracranial pressure in supratentorial tumor surgery using ultrasonography measurement of optic nerve sheath diameter: A randomized control study"*** submitted by Dr. Sunanda Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/583/23 dated 24th May, 2023. ***Previous PGTSC Comment:*** • Kindly provide a properly filled Patient Information Sheet. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XX-PGTSC-IIA/P25***
66-	Clarification of the research proposal entitled ***"Socioeconomic problems of ICU survivors identified by structured follow up critical care clinic: a prospective observation study"*** submitted by Dr. Namrata Shukla, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1237/23 dated 3rd October, 2023. ***Previous PGTSC Comment:*** • Kindly provide properly filled patient Information Sheet. Please provide detailed information about the procedure to patient in the Informed Consent form. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XX-PGTSC-IIA/P29***
67-	Clarification of the research proposal entitled ***"Prevalence and correlates of obsessive compulsive symptoms and obsessive compulsive disorder in patients of schizophrenia"*** submitted by Dr. Rahul, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 940/Psy/23 dated 19th September, 2023. ***Previous PGTSC Comment:*** • Null hypothesis is not properly defined. The correlation is measured between two continuous variables, not between "prevalences". • The sample size calculation is not clear. The right formula is required. • The statistical section is very general. It should be specific to the

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

<table>
<tr><td></td><td>hypothesis and objectives.
The above comment forwarded to Principal-Investigator was reviewed by reviewer.
• Approved
PGTSC Decision: Approval ratified
Ref. code: XX-PGTSC-IIA/P32</td></tr>
<tr><td>68-</td><td>Clarification of the research proposal entitled "Additive effect of nitroglycerine spray with lignocaine spray lignocaine spray alone on haemodynamic responses to laryngoscopy and endotracheal intubation a comparative study" submitted by Dr. Vasioullah Khan, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1224/23 dated 29th September, 2023.
<table>
<tr><th>Previous PGTSC Comment</th><th>PI response</th></tr>
<tr><td>Title should be: ""Additive effect of nitroglycerine spray with lignocaine spray and lignocaine spray alone on haemodynamic responses to laryngoscopy and endotracheal intubation: a comparative study".</td><td>Yes</td></tr>
<tr><td>The study design is "prospective cohort study".</td><td>Yes</td></tr>
<tr><td>The patients will be divided randomly among two cohorts.</td><td>Yes</td></tr>
<tr><td>Give the details of randomization.</td><td>Computer generated random number table method.</td></tr>
<tr><td>Sample size calculation is not clear. Explain the different parameters (standard deviation, mean etc.) used in the formula. What are the variables whose mean and standard deviations are used? Actually the research hypothesis should be stated in terms of parameters of the study design.</td><td>Attached separately</td></tr>
<tr><td>The statistical section is very general. It should be specific to the hypothesis and objectives.</td><td>Attached separately</td></tr>
</table>
The above comment forwarded to Principal-Investigator was reviewed by reviewer.
• Approved</td></tr>
</table>

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

PGTSC Decision: Approval ratified

Ref. code: XX-PGTSC-IIA/P33

69- Clarification of the research proposal entitled ***"Impact of left bundle branch area pacing vs right ventricular apical pacing on cardiac function on intermediate (3 Month) term"*** submitted by Dr. Usha Kiran Kurrey, SR, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1840/Cardio/23 dated 25th September, 2023.

Previous PGTSC Comment	PI response
It is a prospective cohort study.	Yes, this study is prospective cohort study
Two groups (cohorts) are being compared.	Yes
The study variables (including outcome variable "LV systolic function") and study parameters should be exclusively defined.	Attached separately
The primary objective should be converted into research hypothesis using the study parameters.	Ok, as per your advice added
The sample size calculation is arbitrary. It should be specific to the research hypothesis.	Attached separately
The statistical analysis section is general. It should be specific to the research hypothesis.	Attached separately

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XX-PGTSC-IIA/P35

70- Clarification of the research proposal entitled ***"Clinical audit on peripartum and postpartum hysterectomy at a tertiary care center and its outcome"*** submitted by Dr. Ananya Verma, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1185/23 dated 18th September, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous PGTSC Comment	PI response
The primary objective is not clear. It says to find "incidence" and "risk factors"	As per your advice correction done (Attached separately)
The two objectives are completely different paradigms. Both require different kinds of study designs and methods.	Attached separately
The primary objective should be specific and converted into a proper research hypothesis involving study variables and study parameters.	Attached separately
In the absence of proper hypothesis, sample size calculation, methodology etc. has no meaning.	Attached separately

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XX-PGTSC-IIA/P38

71- Clarification of the research proposal entitled ***"To evaluate the additional diagnositic role of thoracoscopic pleural lavage and brush in undiagnosed exudative pleural effusion"*** submitted by Dr. Ravi Kant Pandey, SR, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 835/PDCC/23 dated 29th September, 2023.

Previous PGTSC Comment	PI response
In the title word "additional" is not clear. IN addition to "what"?	No Additional as per your adv change the title ***"To study the role thoracoscopic pleural lavage brush in undiagnosed exuda pleural effusion"***
Aim and objective is not clear. How "diagnostic role of thoracoscopic pleural lavage and pleural brush" is measured?	Yes, attached separately
The study variables and parameters should be exclusively identified.	Yes, attached separately
Research hypothesis should be formulated in terms of the study	Yes, attached separately

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	parameters.		
	Sample size calculation is arbitrary. It should be done in accordance to the proper research hypothesis.	Yes, attached separately	
	Methodology and statistical analysis section should be properly explained.	Yes, attached separately	

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XX-PGTSC-IIA/P39

72- Clarification of the research proposal entitled ***"A comparative study of maternal serum lactate level during pregnancy and after delivery and it's correlation with fetomaternal outcome"*** submitted by Dr. Pratibha Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1480/23 dated 30th September, 2023.

Previous PGTSC Comment	PI response
Aims & Objectives gives a list of measuring different maternal lactate levels.	Attached separately
No proper research hypothesis is formulated.	Attached separately
In the absence of research question, everything does not seem into proper place.	Attached separately

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XX-PGTSC-IIA/P40

73- Clarification of the research proposal entitled ***"To compare opioid free and opioid based anaesthesia techniques for intraoperative hemodynamic stability and overall outcome in patients undergoing supratentorial craniotomy"*** submitted by Dr. Prachi, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1176/23 dated 19th September, 2023.

Previous PGTSC Comment	PI response
It is a prospective cohort comparative study	This study is prospective randomized controlled study (Attached separately)

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Two groups are being compared. These groups should be exclusively defined. Randomization will be performed in allotting the subjects to the two groups. Method of randomization should be explained.	Yes, Two groups are compared. Randomized will be done by computer generated random number table (Attached separately)
	Research Hypothesis shluld be defined in terms of the parameters after identifying these from the study.	Attached separately
	Sample size calculation is arbitrary. It can be formulated only after formulating the proper research hypothesis.	Attached separately
	The statistical analysis section is very general. It should be specific to the research hypothesis.	Attached separately

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XX-PGTSC-IIA/P41

74- Clarification of the research proposal entitled ***"Comparative study between analgesic effect of conventional radio freouency vs pulsed radio frequency lesioning of glossopharyngeal nerve in patients of oropharyngeal cancer suffering from orofacial pain"*** submitted by Dr. Yashika Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1140/23 dated 15th September, 2023.

Previous PGTSC Comment	PI response
It is a prospective cohort comparative study	This study is prospective randomized controlled study (Attached separately)
Two groups are being compared. These groups should be exclusively defined. Randomization will be performed in allotting the subjects to the two groups. Method of randomization should be explained.	Yes, Two groups are compared. Randomized will be done by computer generated random number table (Attached separately)
Research Hypothesis shluld be	Attached separately

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	defined in terms of the parameters after identifying these from the study.	
	Sample size calculation is arbitrary. It can be formulated only after formulating the proper research hypothesis.	Attached separately
	The statistical analysis section is very general. It should be specific to the research hypothesis.	Attached separately

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XX-PGTSC-IIA/P42

75- Clarification of the research proposal entitled ***"To compare the efficacy of intravenous ketamine, fentanyl and dexmedetomidine infusions on hemodynamic controland overall outcome in paediatric infraumbilical surgeries: prospective randomized controlled study"*** submitted by Dr. Abdul Haseed, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1136/23 dated 15th September, 2023.

Previous PGTSC Comment	PI response
Section on subject selection/biological material/patient information sheet/risks and benefits incompletely filled.	Attached separately
Assent form for children not attached.	Attached separately
Study does not have any co-supervisor from General Surgery/Paediatric Surgery.	Dr. Sudhir Singh, Additional Profes Paediatrics Surgery included as a supervisor (Attached separately)

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XX-PGTSC-IIA/P43

76- Clarification of the research proposal entitled ***"The prognostic value of lactate albumin ratio and prob natriuretic peptide for predicting 28 days mortality in burn patients presenting to the burn intensive care unit: A prospective study"*** submitted by Dr. Surabhi, JRI, Department of

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1135/23 dated 14th September, 2023.

Previous PGTSC Comment	PI response
Section on Vulnerable subjects incorrectly filled.	Attached separately
Section on biological material ticked as 'No' but blood samples being collected.	Yes 5 ml venous blood sample wil used.
Section on patient information sheet/risks and benefits incomplete.	Attached separately
Who will bear the cost of the Investigators?	Principal Investigator bear the cost.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XX-PGTSC-IIA/P44

77- Clarification of the research proposal entitled ***"Comparison of IL-6, procalcitonin and CRP in the post-operative courses after lung decoricatio"*** submitted by Dr. R. Sankara Narayanan, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1201/23 dated 22nd September, 2023.

Previous PGTSC Comment	PI response
Scientific review committee signatures incomplete.	Scientif review committee f attached separately.
Use of body fluids is ticked as 'No' but serum markers are being used.	Sorry, Body fluids-Yes 5ml blood will be taken for se markers.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XX-PGTSC-IIA/P45

78- Clarification of the research proposal entitled ***"Effect of musical therapy on hemodynamic parameters and inflammatory markers in patients undergoing surgery for varicose veins under spinalanaesthesia"*** submitted by Dr. Mohd Pervez Alam, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1186/23 dated 21st September, 2023.

Previous PGTSC Comment:-

- IEC form incompletely filled

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above comment forwarded to Principal-Investigator was reviewed by reviewer. • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XX-PGTSC-IIA/P47***
79-	Clarification of the research proposal entitled ***"Clinico-pathological study of cases of oropharyngeal squamous cell carcinoma at a tertiary care centre with evaluation of human papilloma virus status"*** submitted by Dr. Suteerth Vajpeyi, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. nil dated 26th September, 2023. ***Previous PGTSC Comment:-*** • In a clinicopathological study, 'Use of Biological material' is ticked as 'No. Use of organs/body fluids is ticked as 'No' ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XX-PGTSC-IIA/P48***
80-	Clarification of the research proposal entitled ***"To study national quality assurance standards compliance in O.T. of Urology Department in a tertiary care Government teaching Hospital, Lucknow"*** submitted by Dr. Nabila Asif through her guide Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/2023/515 dated 3rd October, 2023. ***Previous PGTSC Comment:-*** • Sample size for patient interview/staff interview not mentioned. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XX-PGTSC-II B-MHA/P2***
81-	Clarification of the research proposal entitled ***"A descriptive study to assess the knowledge and attitude towards organ donation among care givers in OPD KGMU Lucknow"*** submitted by Ms. Manorama, Ms. Mahima, Ms. Nainsi, Ms. Nisha, Ms. Oppja Sikdar, Ms. Pratibha, Ms. Puja Maurya, Ms. Renu Kumari, Ms. Sarita, Ms. Shabnam through their guide Mrs. Shikha Malik, Clinical Instructor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1465/X.51/23 dated 30th September, 2023. ***Previous PGTSC Comment:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

- Kindly provide patient Information Sheet as per EC SOP and analysis plan of association study as stated in objective.

The above comment forwarded to Principal-Investigator was reviewed by reviewer.

- Approved

PGTSC Decision: Approval ratified

Ref. code: XX-PGTSC-IIC/P4

82- Clarification of the research proposal entitled ***"Hemodynamic assessment in newborn infant with sepsis: A prospective observational study"*** submitted by Dr. Tapan Singh, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 75/Ped/23 dated 12th April, 2023.

Previous PGTSC Comment	PI response
There are 5 Co-PIs from the same department with overlapping roles.	There are 3 Co-PIs from sa department and 1 Co-PI fi Cardiology department, define r attached separately.
Sample size is mentioned as 53 in the IEC form and as 288 in the synopsis.	New IEC form attached separately.
Sponsor is mentioned as Government; however, details of expenditure are not given.	None, New IEC form attac separately.
'Devices' is ticked in the Clinical Trial saction of the IEC form.	New IEC form attached separately.
Which devisce is being tested?	New IEC form attached separately.
Use of body fluids is not ticked in the IEC form but blood and spinal fluids are being used.	New IEC form attached separately.
Section on compensation in the IE is not filled.	New IEC form attached separately.
Direct identifiers are being used.	New IEC form attached separately.
Contact details of PI are not present on the IC form.	New IEC form attached separately.

The above comment forwarded to Principal-Investigator was reviewed by

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Primary reviewer. ***Second opinion of reviewer:-*** 1. Use of body fluids is mentioned as 'No' but blood and body spinal fluids are being used. Please make appropriate changes. 2. Contact details of PI not present on informed consent form. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XIV-PGTSC-IIA/P54***
83.	Clarification of the research proposal entitled ***"Evaluation of release of various metal ions during fixed orthodontic treatment and their genotoxicity: An in-vivo study"*** submitted by Dr. Chandana Himanshu, JRII, Department of Orthodontics & Dentofacial Orthopedics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1651/Ortho/23 dated 13th September, 2023. ***Previous PGTSC Comments:*** 1. It is a before and after treatment study. There are two kinds of treatments. So basically, there are three groups for comparison. 2. The study should be planned accordingly, and the hypothesis formulated properly. 3. Sample size calculation and statistical analysis section shall be done in accordance with the hypothesis formulated. ***The above comment forwarded to Principal-Investigator was reviewed by reviewer.*** • Approved **PGTSC Decision:** Approval ratified ***Ref. code: XVIII-PGTSC-IIA/P5***
I-B	**Expedited review**
1-	Research proposal entitled ***"A study of sendory processing in late-life depression"*** submitted by Dr. Shubha Joshi, SR Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 349/DGMH dated 7th October, 2023. ***The above research proposal forwarded to two Primary reviewers*** ***Recommendation of First Primary reviewer:-*** 1. Information from of healthy subject in English & Hindi. 2. Consent for health subjects in English & Hindi. ***Recommendation of Secondary reviewer:-*** • Approved **PGTSC Decision:** Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XXI-PGTSC-IB/P1
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"Prospective randomized study to evaluate the therapeutic effect of high volume v/s low volume caudal epidural injections in lumbar PIVD"*** submitted by Dr. Nilesh Kumar Singh, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1069/Ortho/23 dated 17th June, 2023. ***Recommendation of reviewer:*** 1. There are eleven (11) investigators in the projects with 10 from the same department with overlapping roles. 2. Vulnerable subjects have been ticked 'No' but elderly has also been ticked. Please clarify. 3. Section on Consent is incomplete. 4. Sample size calculation has not been done. 5. Patient information sheet is incomplete/incorrect. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Comparative evaluation of superficial and deep serratus anterior plane block for postoperative analgesia following modified radical mastectomy: A randomized controlled study"*** submitted by Dr. Shivendra Pratap Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/584/23 dated 24th May, 2023. ***Recommendation of reviewer:*** 1. Patient information sheet is incomplete/incorrect filled. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XXI-PGTSC-IIA/P2***
3.	Research proposal entitled ***"To study the effect of curcumin on inflammatory markers and microbial flora in hemimaxillectomy patients with obturator prosthesis: A randomized controlled trial"*** submitted by Dr. Yangchin Drema, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 241/23 dated 4th August, 2023. ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	1. As stated in Annexure 1 this study involves a (herbal) medicine of Indian system of medicine. So it would be better to include an ayurvedic co investigator. 2. This is stated to be double blind RCT. Kindly mention the technique of allocation, randomization & double blinding. Is placebo not indicated here? 3. Who will bear the cost of curcumin & tests. Do you plan to register this RCT.?? 4. Summarize the anticipated outcome variables and anticipated statistical analysis of the same. 5. Kindly mention the dose, duration , brand and mode of administering curcumin. 6. No need to submit the SOP guidelines of Pt information sheet. Instead kindly submit the actual patient information sheet both in English & Hindi accordingly. 7. Kindly revise "purpose of study" & "Study procedure" in ICF in such a language that the patient may understand. 8. In annexure 1 regarding use of biological specimen it is indicated as "NA" while lower down 'Yes' in indicated for the use of infectious & biohazardous specimen. This is contrasting statement. Also no indication of blood collection is mentioned for IL &TNF? 9. Kindly refer to CONSORT guidelines for RCT before resubmitting **PGTSC Comment:** As above **PGTSC Decision:** Modify & Re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Effect of dexmedetomidine, propofol, and midazolam on diaphragm function assessed by ultrasound in postoperative patients: A randomized comparative study"*** submitted by Dr. Jyoti Sharma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/573/23 dated 24th May, 2023. ***Recommendation of reviewer:*** 1. Scientific review committee should be revised as the name and signature of Chief Guide (Prof. G. P. Singh) is there in present SRC report. 2. SOP-Checklist point no.-10 ,Risk & benefit –marked as risk is not reasonable –please clarify and properly mark the section -10. 3. In Inclusion/ Exclusion criteria- Pregnant & lactating women criteria not mentioned 4. As this is randomized study, PI must mention the method of randomization and attach the Flow chart of the study. 5. Case record form–not attached

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	PGTSC Comment: As above **PGTSC Decision:** Modify & Re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P4***
5.	Research proposal entitled ***"PRE-operative 6-minute walk test for prediction of post-operative pulmonary complications in major abdominal surgeries"*** submitted by Dr. Abhijeet Kumar Patro, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/581/23 dated 24th May, 2023. ***Recommendation of reviewer:*** 1- Methodology mentions random allocation of patients in two groups, but the groups mentioned are one with post operative complications and one group without them. How will this be random? 2- Sample size calculation should be based on the prevalence of the problem which is not mentioned. 3- Is there a control group in the study? This is not clear from the methodology. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Analgesic efficacy of ultrasound guided intre-semispinal plane block in lower cervical spine surgery: A randomized controlled study"*** submitted by Dr. Priyanshi Garg, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/592/23 dated 24th May, 2023. ***Recommendation of reviewer:*** 1. SRC should be revised as the name & signature of one of the Co-guide (Dr. Manish Singh) is there in present SRC report. 2. In Inclusion/ Exclusion criteria- Pregnant & lactating women criteria not mentioned 3. As this randomized study, PI must attach the Flow chart of the study. 4. In sample size – in the section of subject PI mentioned the age group of recruited subjects as 20-65 yrs. which is different than in Inclusion criteria (18-60 yrs.)-please rectify 5. Case record form–not attached **PGTSC Comment:** As above **PGTSC Decision:** Modify & Re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P6***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

7.	Research proposal entitled ***"Effectiveness of prophylactic tranexamic acid for reducing blood loss in children undergoing wilms tumour surgery: A randomized control study"*** submitted by Dr. Shraddha Agarwal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/593/23 dated 24th May, 2023. ***Recommendation of reviewer:*** 1. Study design is mentioned as Prospective randomized controlled study,however In study title PI mentioned only randomized controlled study - please correct the discrepancy. 2. As children of age below 10 years will be recruited therefore Guardian consent and Child Assent form should be attached instead of regular ICF in both English and Hindi version. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Study of role of PRP (Platelet rich plasma) in thin endometrium in patients with infertility: An open label randomized controlled trial"*** submitted by Dr. Payal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. 225/OG/23 dated 30th June, 2023. ***Recommendation of reviewer:*** • In the consent form it is mentioned that there will be no complications. It needs to be corrected as the procedure will be performed and serum infused so there are chances of complications and the subject's needs to be informed. • Kindly modify the Inform Consent Form & Patient information sheet, Hindi & English both version. **PGTSC Comment:** • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P8***
9.	Research proposal entitled ***"An analysis of factors affecting intracranial pressure during laparoscopic cholecystectomy using ultrasonography measurement of optic nerve sheath diameter: An observational study"*** submitted by Dr. Asma Fatima Rizvi, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/587/23 dated 24th May, 2023. ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	1. Please inform, who among the investigators will perform ultrasonic evaluation for ONSD? 2. Sample size calculated is 108, whereas in IEC proforma it is mentioned as 80. Kindly explain the discrepancy. 3. ICF: Kindly explain the procedure in simple and understandable language, addressing the patient. 4. Kindly improve Patient Information Sheet. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Study of lung functions in construction workers exposed to cement dust: A cross sectional study"*** submitted by Dr. Maneesh Kumar Yadav, JR, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 201/PHY/23 dated 10th July, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** As above ***Ref. code: XXI-PGTSC-IIA/P10***
11.	Research proposal entitled ***"A comparative evaluation of the clinical & biological outcome of different provisional crowns on immediate loaded implant in maxillary esthetic zone-A randomized controlled trial"*** submitted by Dr. Deepak Verma, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 242/23 dated 4th August, 2023. ***Recommendation of reviewer:*** 1. Kindly provide the cost of two types of implants. The cost of the Implant, if borne by the patient, may be a concern for its blind selection. 2. Patient Information sheet: Kindly fill it properly. **PGTSC Comment:** 3. Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P11***
12.	Research proposal entitled ***"A comparative evaluation of biological marker and prosthodontic compliocation in splinted and nonsplinted implant supported prostheses: A split mouth study"*** submitted by Dr. Divya Dharshini M, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	letter no. 244/23 dated 4th August, 2023. ***Recommendation of reviewer:*** • Patient Information sheet: Kindly fill it properly. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XXI-PGTSC-IIA/P12***
13.	Research proposal entitled ***"A pilot randomized controlled trial comparing visually aided nicotine replacement therapy and standard nicotine replacement therapy in smokeless tobacco users"*** submitted by Dr. Aman Rajput, JRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 451/PHD/23 dated 1st August, 2023. ***Recommendation of reviewer:*** 1. It seems to be well planned study. Why it is being called pilot study? 2. If it is really, RCT, all the fundamentals are missing. 3. For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. 4. The sample size calculation is arbitrary in the absence of proper research hypothesis. The different quantities used in the formula are not clear. There is no design effect for this study. It is for cluster-randomized trial. 5. The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. 6. How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P13***
14.	Research proposal entitled ***"To determine prevalence of suboptimal levels of Vitamin D in preterm very low birth weight neonates in an NICU and to monitor response to treatment with Vitamin D"*** submitted by Dr. Abiya Nabi, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2084/Ped/23 dated 9th August, 2023. ***Recommendation of reviewer:*** 1. The role of PI is not provided.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	2. Annexure 1… the title of the proposal to be corrected as there is no space between words. 3. The patient information sheet needs to be revised as per the needs of the protocol. 4. The proposal aimed to enroll and assesse the newborn at age 4-10 days and at 38+2 wks after supplementation with 1000 IU/day Vit D levels or on discharge of the newborn. How the PI will approach for assessment after 38+2 wks, if the newborn will discharge much before 38+2 wks? Will she visit newborn place for final assessment? **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P14***
15.	Research proposal entitled ***"Evaluation of ozone therapy in comparison with occlusal splint in treating internal derangement of temporomandibular joint: A randomized controlled trial"*** submitted by Dr. Satyendra Pratap Singh, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 245/23 dated 4th August, 2023. ***Recommendation of reviewer:*** 1. If it is really, RCT, all the fundamentals are missing. 2. For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. 3. The sample size calculation is arbitrary in the absence of proper research hypothesis. The different quantities used in the formula are not clear. There is no design effect for this study. It is for cluster-randomized trial. 4. The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. 5. How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **PGTSC Comment:** • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P15***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

16.	Research proposal entitled ***"Effect of adjunctive photodynamic therapy on inflammatory markerslevel in patients with apical periodontitis-A randomized control trial"*** submitted by Dr. Monika Kumari, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 237/Coms&Endo/23 dated 11th August, 2023. ***Recommendation of reviewer:*** 1. Inclusion criteria and flow chart indicate **healthy patients;** an explanation for the term to be given. **PGTSC Comment:** • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P16***
17.	Research proposal entitled ***"A prospective study to compare perioperative and quality of life outcomes of hernioplasty versus herniorrhaphy for complicated primary vertral"*** submitted by Dr. Amit Pandey, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 323/SY/23 dated 10th August, 2023. ***Recommendation of reviewer:*** 1-Patient information sheet is incomplete. 2- Patient information sheet in Hindi is not attached. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P17***
18.	Research proposal entitled ***"Study of sentinel lymph node in gallbladder cancer using indocyanine green dye- A pilot study"*** submitted by Dr. Shiva, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 315/SY/23 dated 2nd August, 2023. ***Recommendation of reviewer:*** 1. Annexure 1 indicates that risk is not reasonable - Explain 2. Elaborate regarding DSMB as per annexure 1. What are the anticipated adverse events that need to be reported to IEC. 3. Kindly revise 'purpose of study' & 'Study 'procedure' in ICF in such a way for the patient to understand (simple Language) 4. Revise patient information sheet for the patient to understand esp points 4,6,7,9,13,14, 17. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XXI-PGTSC-IIA/P18
19.	Research proposal entitled ***"Detection of KPC, NDM, OXA-48, IMP,VIM carbapenemases/genes among carbapenem resistant klebsiella pneumonia isolated from endotracheal aspirate of patients on ventilator"*** submitted by Dr. Shivani Baranwal, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 539/23 dated 28th July, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved *Ref. code: XXI-PGTSC-IIA/P19*
20.	Research proposal entitled ***"Comparative evaluation of amniotic membrane and platelet-rich fibrin membrane on osseous healing post direct maxillary sinus lift augmented with graft around dental implants: A randomized controlled trial"*** submitted by Dr. Sonali Kaundal, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 243/23 dated 4th August, 2023. ***Recommendation of reviewer:*** • Patient Information sheet: Kindly fill it properly. **PGTSC Comment:** • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **PGTSC Decision:** Approval subject to modification *Ref. code: XXI-PGTSC-IIA/P20*
21.	Research proposal entitled ***"Assessment of osteoprotegerin (OPG) and implant stability through the topical application of UV irradiated " Vitamin D" on implant surface during placement: A randomized controlled clinical trial"*** submitted by Dr. Ruby Singh, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 240/23 dated 4th August, 2023. ***Recommendation of reviewer:*** • Spelling of ELISA needs to be corrected. • Vitamin D estimation technique not mentioned. **PGTSC Comment:** • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **PGTSC Decision:** Revise & re-submit *Ref. code: XXI-PGTSC-IIA/P21*

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

22.	Research proposal entitled ***"Role of injection optineuron on serum lactate levels in a patient undergoing surgery on cardio Pulmonary bypass machine"*** submitted by Dr. Nisah Razvi, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/589/23 dated 24th May, 2023. ***Recommendation of reviewer:*** • English and Hindi both patient information sheets to be prepared in a simplified and understandable language. **PGTSC Comment:** As above **PGTSC Decision:** Re-submit English and Hindi both patient information sheets. ***Ref. code: XXI-PGTSC-IIA/P22***
23.	Research proposal entitled ***"Prediction of peri operative outcomes using modified kingsnorth score in endoscopic repair of inguinal hernia"*** submitted by Dr. Jyoti Krishnamurty, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 234/SY/23 dated 23rd July, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P23***
24.	Research proposal entitled ***"Analysis of outcome amongst survivors of isolated moderate and severe head injury patients managed conservatively and surgically- A retrospective comparative stud-your experience"*** submitted by Dr. Biman Chandra Sinha, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 817/SY/23 dated 24th July, 2023. ***Recommendation of reviewer:*** 1. In Annexure 1 the sample size indicated is 80, while the sample size mentioned inside is 900-1000. Kindly resolve the discrepancy . 2. Kindly present the steps of sample size calculation. 3. In annexure 1 the duration of study is stated as 1yr while inside it is stated as 2yrs - kindly rectify. 4. This is retrospective study. Will retrospective records also be analyzed.? If prospective analysis is to be done then how can it be considered only respective study. Kindly submit a flowchart of patient recruitment with study procedure (Methodology) so as to make methodology more clear. 5. Kindly revise patient information sheet (esp point 13,15,17,18) and include language that patient can easily understand. 6. In scientific review committee the HOD seal is missing.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	7. As per annexure1, is the risk not reasonable as compared to anticipated benefits (point no. 10) ? 8. Kindly elaborate the role of DSMB (point No.11). What sort of adverse events are anticipated that need to be submitted to IEC. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P24***
25.	Research proposal entitled ***"A comparison between solitary IMF dental cleat technique with ersnt ligatures and conventional erich arch bars for intermaxillary fixations: a randomized controlled trial"*** submitted by Dr. Rangeet Bhadra, JRI, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 417/OMSD/23 dated 12th April, 2023. ***Recommendation of reviewer:*** 1. It this is RCT kindly elaborate technique of allocation & randomization. 2. Kindly refer CONSORT guidelines for better refinement. 3. Elaborate about DSMB. What about adverse events Kindly indicate in annexure 1(point 11). 4. If sample size of each group is 17 then why only 15 cases will be recruited in 1st group. 5. Summarize the anticipated statistical analysis. 6. Kindly submit Pt information sheet both in English & Hindi. 7. Kindly indicate the various outcome variables and that should reflect in case sheet. 8. The ICF should include study procedure in simple language understandable to the patient. It should also include the follow-up protocol. 9. If this study is of 3yrs duration then kindly include time line of action in terms of Pt recruitment, data collection, follow-up , analysis etc. **PGTSC Comment:** • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P25***
26.	Research proposal entitled ***"Comparative evaluation of effect of PFR and dehydrated human derived membrane on bone healing post endodontic Surgery: An ultrasonographic randomized controlled trial"*** submitted by Dr. Mamidala Jyothi, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 247/Coms&Endo/23 dated 17th August, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer: • Approved **PGTSC Decision:** As above ***Ref. code: XXI-PGTSC-IIA/P26***
27.	Research proposal entitled ***"A study of adverse drug effects/adverse drug reactions in patients with Psychosis taking antipsychotics"*** submitted by Dr. Surya, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 585/Pharm/23 dated 9th August, 2023. ***Recommendation of reviewer:*** 1. In Inclusion/Exclusion criteria-Sex specificity & Pregnant & lactating women criteria not mentioned. 2. In Tools-Brief Psychiatric Rating Scale and Hartwig's Severity assessment scale – not attached **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P27***
28.	Research proposal entitled ***"Morphological and morphometric analysis of coronary vessels in relation to atrioventricular annuli: A cadaveric study"*** submitted by Dr. Keerthy. L. K, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 247/ANAT/23 dated 3rd August, 2023. ***Recommendation of reviewer:*** 1. In SOP-Checklist – Point no.-1- Type of study – should be Basic Science 2. -Pont no. -5- Subject selection –PI should mention cadaveric autopsied hearts 3. -Point no. -8- ICF- mentioned as written oral consent ,but as the study is on Cadaveric autopsied heart – PI – should tick and mention it accordingly 4. Study design- mentioned-Cross sectional study but as this is a Cadaveric study on autopsied Hearts, Study Design may be changed to Prospective cross -sectional analytical cadaveric study / or PI to justify. 5. ICF-H/E –Attached- but as the study is on Cadaveric autopsied heart specimens and no living subject is involved therefore PI to submit Human Subject Review Waiver Form (HSRWF) instead of regular ICF). **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Dr. Anita Rani did not take part in the discussion and making decision. ***Ref. code: XXI-PGTSC-IIA/P28***
29.	Research proposal entitled ***"A comparative study of endoxifen and divalproex in patients with bipolar disorder (Manic Episode)"*** submitted by Dr. Alisha Raj, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 561/Pharm/23 dated 27th July, 2023. ***Recommendation of reviewer:*** 1. In Inclusion criteria -Sex specificity has not been mentioned. 2. How evaluation of pharmacological actions and efficacy of the drug (with single dose) will be done as written in Aims and objective-PI to explain. 3. Study design –mentioned as Prospective, parallel groupcomparative study, but PI has mentioned in Methodology section that the grouping will be done by randomization – PI to clarify and correct it in the Title of the study. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P29***
30.	Research proposal entitled ***"An observational prospective cohort study to evaluate different drugs used in viral hepatitis and adverse drug reactions associated with those drugs in patient coming to Gastroenterology and Medicine OPD KGMU"*** submitted by Dr. Shilpi Rani Biswas, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 584/Pharm/23 dated 9th August, 2023. ***Recommendation of reviewer:*** 1. Study design in protocol is mentioned as Prospective observational study , But in title the study design is mentioned as prospective observational cohort study- PI to clarify or correct 2. In Inclusion/ Exclusion criteria- Pregnant & lactating women criteria not mentioned. 3. Methodology section is missing, only flow chart of the study is given. PI should include detailed methodology. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P30***
31.	Research proposal entitled ***"Iron profile of very low birth weight preterm neonates in an NICU before and after iron supplementation"*** submitted by

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Dr. Anu Shree Chaudhary, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2041/Ped/23 dated 8th August, 2023. ***Recommendation of reviewer:*** 1. This seems to be a pretest-posttest study design. The same set of subjects is being used before and after supplementation. 2. Everything should be planned for this design, including primary objective and corresponding research hypothesis. 3. There are too many secondary objectives. Actually, these are the data which will be collected during the study. 4. Sample size calculation is missing. Only a number (88) is given without any justification. 5. The statistical analysis section is very general. It should be specific to the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P31***
32.	Research proposal entitled ***"Effect of customized oral health awareness program on knowledge and practice of oral hygiene maintenance among institutionalized visually impaired people of Lucknow city: A prospective interventional study"*** submitted by Dr. Mohit Kumar Kanoujia, JRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 450/PHD/23 dated 1st August, 2023. ***Recommendation of reviewer:*** 1. This seems to be a cluster randomized study. There are three intervention groups. 2. Everything should be planned and stated for the above study including the primary objective and corresponding research hypothesis. 3. The sample size calculation is missing. 4. After identifying the unit of analysis, how will the cluster-level analysis be done. 5. How the individual-level analysis will be done? **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P32***
33.	Research proposal entitled ***"Serial estimation of carboxypeptidase 1 & 2 in patient of acute pancreatitis: A new Diagnostic and prognostic Marker"*** submitted by Dr. Mohit Dilip Singh Verma, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	204/23 dated 8th July, 2023. ***Recommendation of reviewer:*** 1. There are too many objectives. 2. Identify one primary objective, and the rest should be listed as secondary objectives. 3. The primary objective should be converted into a proper research hypothesis, which will be defined in terms of the study variables and study parameters. 4. Sample size calculation is arbitrary. It should be specific to the research hypothesis defined in Step 3. 5. The method for grading the severity status should be explained. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P33***
34.	Research proposal entitled ***"Study assessment and comparison of no-reflow phenomena in patients with ST-segment-elevation myocardial infarction undergoing pharmacoinvasive strategy versus primary percutaneous coronary intervention"*** submitted by Dr. Awdhesh Yadav, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1653/Cardio/23 dated 14th August, 2023. ***Recommendation of reviewer:*** 1. In Inclusion criteria -Sex specificity has not been mentioned. 2. Flow chart of comparative study is required 3. ICF-E/H –Attached -but English version is incomplete –Please give full English version of ICF 4. Please submit only one Patient information sheet (E/H) related to study in prescribed format. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P34***
35.	Research proposal entitled ***"Study to compare fluorography versus cineangiography at reducing radiation exposure during single vessel PCI"*** submitted by Dr. Pawan Kumar Chaudhary, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1231/Cardio/23 dated 30th July, 2023. ***Recommendation of reviewer:*** 1. Pages of proposal are disorganized and page nos. are also missing, Pages need to be arranged in an order and protocl to be written following the IEC form point no 4 i.e. Brief description of the proposal.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	2. In material and methods section text needs to be modified as at some of the sentences are written in past tense. 3. Pt. Information sheet to be adapted and submitted as per the proposal. 4. ICF to be written in simple and understandable language. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P35***
36.	Research proposal entitled ***"Impact of newer heart failure therapies on health related quality of life (hrQOL)"*** submitted by Dr. Sidharth Sharma, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1659/Cardio/23 dated 14th August, 2023. ***Recommendation of reviewer:*** • The patient information sheet needs to be modified as per the study protocol. **PGTSC Comment:** As above **PGTSC Decision:**Re-submit ***Ref. code: XXI-PGTSC-IIA/P36***
37.	Research proposal entitled ***"To assess CT scan parameters of patients of severa aortic stenosis aged more than 60 years planned for TAVI"*** submitted by Dr. Harsh Vardhan, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1658/Cardio/23 dated 14th August, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P37***
38.	Research proposal entitled ***"Prevalence of dental anxiety and effect of School oral health education programe on anxiety level among 10 to 15 years old School Children in Lucknow. U.P."*** submitted by Dr. Deepak. S, JRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 449/PHD/23 dated 1st August, 2023. ***Recommendation of reviewer:*** • Hindi Title of Annexure 7 needs to be translated appropriately. **PGTSC Comment:** As above **PGTSC Decision:**Approval subject to modification ***Ref. code: XX-PGTSC-IIA/P38***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

39.	Research proposal entitled ***"MRI-based three-dimensional morphometic evaluation of the maxillary, sphenoid, ethmoidal and frontal sinuses to estimate age and gender"*** submitted by Dr. Ayushi Jain, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1820/OP/23 dated 23rd August, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P39***
40.	Research proposal entitled ***"A study to identify potential vitamin a responsive OPMDs patients via prame immunohistochemical expression"*** submitted by Dr. Sakshi Deorah, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1821/OP/23 dated 23rd August, 2023. ***Recommendation of reviewer:*** 1. Project is sketchy. 2. Protocol for Vitamin A prescription not given. 3. Inclusion and Exclusion of controls not defined. 4. Hindi consent form needs to be re-formatted as one is unable to read it. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P40***
41.	Research proposal entitled ***"Evaluation of postoperative outcomes of advanced electrosurgical devices v/s conventional clamp and tie technique for neck dissection- A randomized control trial"*** submitted by Dr. Aryan Dwivedi, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 212/SY/23 dated 23rd July, 2023. ***Recommendation of reviewer:*** 1- Will suggest changing 'Randomized controlled trial' to 'Randomized controlled study'. A trial will need CTRI registration and DCGI approval and will need to be submitted separately for full committee approval. 2- IEC form is incorrectly/incompletely filled. 3- Short forms should not be used in the consent form (English). 4- Section on sample size calculation is incomplete. Sample size calculation should be based on the prevalence of the disease rather than operative time taken.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	5- Patient information sheet is incomplete. **PGTSC Comment:** • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P41***
42.	Research proposal entitled ***"Comparative evaluation of MTA, emdogain and human biological membrane as A pilpotomy agents in permanent teeth with irreversible pulpitis: A randomized controlled trial"*** submitted by Dr. Zoya Kidwai, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 246/Coms&Endo/23 dated 17th August, 2023. ***Recommendation of reviewer:*** • Methodology incomplete, neither number of subjects to be taken in the study given nor that in different groups mentioned. Sample size calculation not provided. **PGTSC Comment:** • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P42***
43.	Research proposal entitled ***"Analysis of interllectual property rights reforms in India among health-care professionals in Lucknow Uttar Pradesh: A cross-sectional study"*** submitted by Dr. Atrey J. Pai Khot, SRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 514/PHD/23 dated 22nd August, 2023. ***Recommendation of reviewer:*** • There are some misprints before point no 5 of the IEC. • Patient information sheet will not required for this protocol. And, if it is needed it may be participants information sheet. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P43***
44.	Research proposal entitled ***"Assessment of prevalence and distribution of congenital missing teeth patients visiting tertiary care Hospital: A radiographic study"*** submitted by Dr. Khushboo Arif, SRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 519/PHD/23 dated 24th August,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:**Approved ***Ref. code: XXI-PGTSC-IIA/P44***
45.	Research proposal entitled ***"Evaluation of placental thickness and its correlation to pregnancy outcome"*** submitted by Dr. Alankriti Maurya, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1065/23 dated 31st July, 2023. ***Recommendation of Primary reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P45***
46.	Research proposal entitled ***"Cyanoacrylatevs tacker for mesh fixation in laparoendoscopic inguinal hernia repair-double blinded, randomized control trial"*** submitted by Dr. Vivek Vishwakarma, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 214/SY/23 dated 28th July, 2023. ***Recommendation of reviewer:*** 1-Will suggest changing 'Randomized controlled trial' to 'Randomized controlled study'. A trial will need CTRI registration and DCGI approval and will need to be submitted separately for full Committee approval. 2- There are ten investigators in the study from the same department with overlapping roles. Please decrease the number of Co-PI or define their unique roles. **PGTSC Comment:** • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P46***
47.	Research proposal entitled ***"Clinico-radiological and outcome study of spinal dysraphism cases admitted in last 10 years: A retrospective study"*** submitted by Dr. Pankaj Pawar, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 140/NeuroSurg/23 dated 25th July, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P47***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

48.	Research proposal entitled ***"Comparison of efficacy of two prophylactic antibiotic regiments for PPROM-A randomized controlled trial"*** submitted by Dr. Jyoti, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1082/23 dated 1st August, 2023. ***Recommendation of reviewer:*** 1. In SOP-Checklist-Point no-7 –Use of biological/hazardous materials–mentioned–No, but Blood, Urine, Vaginal fluid will be taken from patients for investigation- PI to correct. 2. In Title Abbreviations should be avoided–as PPROM in the present title-Please correct it. 3. In Inclusion criteria–Age specificity has not been mentioned. 4. Review literature with references in Protocol is missing–Please include. 5. CRF- not attached **PGTSC Comment:** • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P48***
49.	Research proposal entitled ***"Correlation of tumour infilterating lymphocytes (TIL's) as a potential predictive marker for response to neoadjuvant chemotherapy in breast cancer"*** submitted by Dr. Rajat Qanoongo, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 202/SY/23 dated 24th July, 2023. ***Recommendation of reviewer:*** 1. While the samples will be collected from 2015 to 2022, as indicated in sample analysis, the study sample duration is mentioned till 2023. Kindly resolve the discrepancy. 2. What is P1 and P2 in sample size? Kindly include the steps of sample size calculation. 3. Kindly include a copy of semi structured self administered proforma that will be used to extract details. 4. Kindly explain the short-term survival and how does it include febrile neutropenia / chemo toxicity 5. How and when will you assess febrile neutropenia and chemo toxicity? Kindly incorporate in your submission. 6. In point 10 of annexure 1, do you think that the risk here is not reasonable as compare to anticipated benefits. 7. Kindly elaborate on DSMB. What are the anticipated adverse events that need to be reported to IEC. 8. If patient information sheet is attached then where is informed consent

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	form? How will you obtained informed consent retrospectively? There is no consent waiver application either. 9. Kindly revise the patient information sheet specially points 479 13 14, 1517 and submit English and Hindi version both 10. By which parametres will you assess the response to neo adjuvant chemotherapy? Is it just the pathological response? Also includes the RECIST criteria. 11. Kindly summarize the anticipated continuous variables and proportional data that would be analyzed. 12. The scientific review committee report has not does not have a seal of chairperson. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P49***
50.	Research proposal entitled ***"Use of clinical nomogram with ICG based iymph node yield assessment in inguinal lymph node dissection in patients of carcinoma penis: A prospective observational study"*** submitted by Dr. Harsh, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 210/SY/23 dated 27th July, 2023. ***Recommendation of reviewer:*** 1- Section on 'Biological/hazardous material' is ticked as 'No' but lymph node dissection/biopsy is part of the project. 2- Patient information sheet is incomplete. 3- No Patient information sheet in Hindi has been attached. **PGTSC Comment:** As above **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P50***
51.	Research proposal entitled ***"Efficacy of early versus expectant artificial rupture of membranes in reducing induction delivery interval following cervical ripening by combined misoprostol and mechanical method: A randomized controlled trial"*** submitted by Dr. Arti Verma, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/081/23 dated 1st August, 2023. ***Recommendation of reviewer:*** 1. In SOP-Checklist point no-3, clinical trial–marked as NA (As this study is RCT, please correct, Point no.5 Vulnerability–marked as–No, but pregnant women are to be recruited-Please revise SOP Checklist *2.* CRF-Not attached **PGTSC Comment:** • Kindly modify the title ***"A randomized control study"*** in place of

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	"Randomized control trial" **PGTSC Decision:** Modify & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P51***
52.	Research proposal entitled ***"Lesion characterstics using IVUS imaging in diabetic individuals undergoing PCI and its impact on plaque modifying strategies"*** submitted by Dr. Rajesh Prasad Sharma, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1641/Cardio/23 dated 11th August, 2023. ***Recommendation of reviewer:*** 1-The study has eight investigators from the same department with overlapping roles. Please reduce the number of Co-PIs or define their unique roles. 2-Sample size has not been calculated. Number of participants has not been mentioned. **PGTSC Comment:** • Kindly modify the title ***"Randomized control study" in place of "Randomized control trial"*** **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P52***
53.	Research proposal entitled ***"A comparative study between acenocoumarol versus apixaban anticoagulants used in treatment of deep vein thrombosis patients at KGMU, a tertiary care centre- A prospective observational study"*** submitted by Dr. Madhulika Tiwari, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 623/Pharm/23 dated 25th August, 2023. ***Recommendation of reviewer:*** 1. It may not be proper for the lay-patient to decide which particular anticoagulant drug to choose for himself and that too without giving any information of the drug profile to the patient. This is unethical. 2. Both the drugs have different pharmacokiinetics and pharmacodynamics, different risk profiles and side-effects, different requirements for compliance and patient monitoring. Only the investigator can decide which drug is to be given in a particular patient depending upon the patient profile itself. 3. How many cases of deep vein thrombosis are encountered in one year? Will the patient be admitted or treated on OPD basis? 4. Has pharmaco-economic-consideration been thought of? Who will fund this study? Patient or KGMU? 5. While dreaded complications like pulmonary embolism is anticipated by investigator apart from recurrence of DVT and requirement of regular liver function / kidney function tests, then why there is no plan to inform adverse events to IEC as per annexure.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	6. The informed consent form is not as per the SOP of ethics committee kgmu- kindly re-write both English and Hindi versions. 7. Patient information sheet provides incomplete and wrong information. Kindly revise and resubmit both English and Hindi versions. 8. It is comparison of two drugs then why does investigator state not applicable in drug trial section of annexure 1 despite clearly stating that it is not an investigational drug 9. It is understood that the investigator team will administer the drug in proper dosage as established and accepted only. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P53***
54.	Research proposal entitled ***"A study on evaluating the role of cfDNA (Cell Free DNA) in prognosis of different histopathological grades of oral cancer"*** submitted by Dr. Akanchha Singh, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1824/OP/23 dated 23rd August, 2023. ***Recommendation of reviewer:*** 1. Study protocol is not clear as after cfDNA amplification without further processing by other techniques how grading will be carried out. It is not mentioned. 2. Hindi consent form needs to be re-formatted as one is unable to read it. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P54***
55.	Research proposal entitled ***"Patient perceptions regarding treatment following an adverse drug event"*** submitted by Dr. Avanish Kumar, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 588/Pharm/23 dated 11th August, 2023. ***Recommendation of reviewer:*** 1. In Title of the study Adverse drug event is mentioned but in Inclusion criteria /Flow chart –Adverse drug response/ Adverse drug reaction is mentioned –PI to clarify or correct. 2. In Inclusion/ Exclusion criteria-Age, sex specificity and Pregnant & lactating women criteria not mentioned. 3. Questionnaires are self prepared–please give proof (or reference) for authentication of Questionnaires.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P55***
56.	Research proposal entitled ***"Comparative evaluation of efficacy of boswellia serrata extract and eggshell membrane in the management of osteoarthritis of the knee"*** submitted by Dr. Rashmi Chandra, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 610/Pharm/23 dated 22nd August, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P56***
57.	Research proposal entitled ***"Effects of platelets rich fibrin & normal saline dressing in chronic wounds- A prospective randomized control trail"*** submitted by Dr. Dheerendra Kumar Mishra, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 5252/23 dated 5th June, 2023. ***Recommendation of reviewer:*** 1. If it is really, RCT, all the fundamentals are missing. 2. For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. 3. The sample size calculation is arbitrary in the absence of proper research hypothesis. The different quantities used in the formula are not clear. 4. The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. 5. How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **PGTSC Comment:** • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P57***
58.	Research proposal entitled ***"Study to evaluate role of serum β-hCG and cystatin C as a predictive biochemical marker for preeclampsia"*** submitted by Dr. Manvi Tyagi, JRI, Department of Obstetrics & Gynecology, King

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. OG/1150/23 dated 30th July, 2023. ***Recommendation of reviewer:*** 1. Methodology incomplete Biochemical estimations (hormones) protocol not provided. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P58***
59.	Research proposal entitled ***"Effect of counseling and call recall on post treatment surveillance in Gynacological cancers"*** submitted by Dr. Shristi Upadhyay, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1157/23 dated 30th July, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P59***
60.	Research proposal entitled ***"A study of fasting and postprandial total serum bile acids (TSBA) levels in term pregnant women and it's associated neonatal outcome"*** submitted by Dr. Anshu Choudhary, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1165/23 dated 31st July, 2023. ***Recommendation of reviewer:*** 1- Vulnerable subjects has been ticked a no and pregnant women as yes. 2-Resonable risk has been ticked as No. 3. Sample size is mentioned as 120 cases in IEC form and 200 cases in the synopsis. 4.Patient information sheet is incomplete. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P60***
61.	Research proposal entitled ***"Comparison of LMA proseal, ambu aurgagain, baska mask and LMA protector for airway management in laparoscopic surgeries: A randomized comparative, an open label study"*** submitted by Dr. Ayur Verma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/597/23 dated 24th May, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer: 1. The ICF should be modified specially with respect to study procedure that needs to be in a simple language for the patient to understand. 2. Pt information sheet should re-written specially for the pts 7,8,9,13,14,16,17. 3. Also mention the anticipated adverse events that need to be reported to IEC. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P61***
62.	Research proposal entitled ***"Comparison of incidence, risk factors, and outcome of spontaneous vs iatrogenic preterm deliveries in a tertiary care center"*** submitted by Dr. Syed Misbah Masood, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1127/23 dated 16th August, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P62***
63.	Research proposal entitled ***"Evaluating the serum calprotectin and endotrophin as novel biomarker for women with PCOS"*** submitted by Dr. Shashibala, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/915/23 dated 13th July, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:**Approved ***Ref. code: XXI-PGTSC-IIA/P63***
64.	Research proposal entitled ***"Role of fetal myocardial performance index as predictor of adverse fetal outcome in women with gestational diabetes mellitus"*** submitted by Dr. Vaishali Billtoria, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1127/23 dated 16th August, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:**Approved ***Ref. code: XXI-PGTSC-IIA/P64***
65.	Research proposal entitled ***"Evaluation of psychological symptoms and quality of life amongst women with natural menopause versus surgical menopause-A cross sectional study"*** submitted by Dr. Khushtar Jabeen, JRI,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1153/23 dated 30th July, 2023. ***Recommendation of reviewer:*** 1. IEC form to be filled properly. 2. The introduction of the study needs to be written properly along with appropriate references. 3. Psychological symptoms include a broad range of indicators that need to be defined. 4. Will there be any criteria for menopausal patients or any of the female patients consulting OBG/ psychiatry OPD will be taken? And, if so why in exclusion criteria pt. with psychiatric disorders will to be excluded? 5. The study description needs to be written as point no 4 of the IEC proforma. 6. The Hindi consent form need to be written in a simple and understandable language. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P65***
66.	Research proposal entitled ***"Knowledge, attitude and practices of hereditary Gynaecological cancer among high risk women"*** submitted by Dr. Bhavya Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1167/23 dated 21st August, 2023. ***Recommendation of reviewer:*** 1. The Hindi consent form need to be written in a simple and understandable language. **PGTSC Comment:** As above **PGTSC Decision:**Revise & re-submit ***Ref. code: XXI-PGTSC-IIA/P66***
67.	Research proposal entitled ***"Study of fever in pregnancy at a tertiary care teaching Hospital"*** submitted by Dr. Deep Shikha, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1180/23 dated 22nd August, 2023. ***Recommendation of reviewer:*** 1. The inclusion criteria include all pregnant females with fever on any occasion while HPE of placenta will be done in selected cases with fever in any trimester. So what are those selected indications? 2. Summarize all the outcome variables and brief the anticipated

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	statistical annulus. 3. Rewrite the patient information sheet specially points 11,13,14,15. 4. Elaborate on DSMB as indicated in Annexure 1. What are the anticipated adverse events that need to be reported to IEC. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P67***
68.	Research proposal entitled ***"Memory T cell targeted immune response in patients of liver cirrhosis and immunocompetent recipient of ChAdOx1nCov-19 vaccine (Covishield): A cohort study"*** submitted by Dr. Mohd Faizan, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 315/Med/23 dated 30th July, 2023. ***Recommendation of reviewer:*** 1. Identify one primary objective. Identify the study variables and study parameters. 2. Convert the primary objective into proper research hypothesis in terms of study parameters identified in step 1. 3. Is there one cohort (group) only? 4. Sample size calculation is missing. The number 55 is given without any justification. 5. The statistical analysis section is very general. It should be specific to the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P68***
69.	Research proposal entitled ***"A critical analysis of maternal mortality using three-delay model at tertiary care centre in the Northern India"*** submitted by Dr. Manvi Garg, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1188/23 dated 1st August, 2023. ***Recommendation of reviewer:*** 1. Case record form–not attached **PGTSC Comment:** As above **PGTSC Decision:**Kindly provide case record form-Approved ***Ref. code: XXI-PGTSC-IIA/P69***
70.	Research proposal entitled ***"A retrospective study of clinicoradiological profile and outcome of medulloblastoma at KGMU, Lucknow for the last five years"*** submitted by Dr. Jason, SRI, Department of Neurosurgery, King

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. 316/NS/23 dated 20th August, 2023. ***Recommendation of reviewer:*** 1. The study duration in annexure 1 is quoted as 1yr while in methodology section it is quoted as 2yrs? Kindly resolve. 2. Kindly elaborate regarding DSMB for this retrospective study as mentioned in annexure 1. What are the anticipated adverse events that may be reported to IEC. 3. The stamp of HOD in annexure1 (last page) in missing. 4. While annexure 1 indicates written informed consent and ICF is attached accordingly, the data collection section in methodology indicated only "telephone consent "- Kindly resolve. 5. ICF needs to be revised as text mentioned in " purpose of study." and "study procedure." does not make sense. Kindly revise in the language understandable to the patient. 6. Kindly re-write the patient information sheet as per SOP of EC KGMU and specially consider points 2,3,4,5,7,9,11,13,14,17 that do not make any sense. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P70***
71.	Research proposal entitled ***"A prospective study to determine indications, procedures and outcome of gynecological endoscopic surgeries"*** submitted by Dr. Km. Juhi Meena, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1189/23 dated 1st August, 2023. ***Recommendation of reviewer:*** 1. There are too many objectives. 2. Identify one primary objective, and the rest should be listed as secondary objectives. 3. The primary objective should be converted into a proper research hypothesis, which will be defined in terms of the study variables and study parameters. 4. Sample size calculation is arbitrary. It should be specific to the research hypothesis defined in Step 3. 5. Statistical analysis section is missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P71***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

72.	Research proposal entitled ***"To study oxidative stress and antioxidant status in adolescents and young women with primary dysmenorrhea"*** submitted by Dr. Monika Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1190/23 dated 1st August, 2023. ***Recommendation of reviewer:*** 1. Methodology incomplete Biochemical estimations (oxidative stress parameters) protocol not provided. **PGTSC Comment:** As above **PGTSC Decision:**Approval subject to modification ***Ref. code: XXI-PGTSC-IIA/P72***
73.	Research proposal entitled ***"Association of frailty assessment tools and postoperative outcomes in elderly patients undergoing elective surgery: A prospective observational study"*** submitted by Dr. Kaushal Kasaudhan, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/596/23 dated 24th May, 2023. ***Recommendation of reviewer:*** 1. The primary objective should be rephrased as "To find prevalence of abnormal results……..". 2. The sample size calculation is not clear. The parameter p should be explicitly defined. 3. Statistical analysis section is very general. It is a prevalent study. There is lot of statistical tests mentioned here. Will they really be done here? **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P73***
74.	Research proposal entitled ***"Effect of prophylactic selective serotonin reuptake inhibitors on incidence of acute delirium in intensive care unit and neuropsychiatric illness in intensive care unit survivors"*** submitted by Dr. Apoorva Jaiswal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/571/23 dated 24th May, 2023. ***Recommendation of reviewer:*** 1. In Inclusion/ Exclusion criteria- Pregnant & lactating women criteria not mentioned. 2. As this is RCT study PI should include in methodology section-the method of randomization and Flow chart of the study. 3. CRF, Richmond Agitation Sedation Score and Sequential organ failure assessment score –not attached.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	4. Clinical trial registry document is also missing. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P74***
75.	Research proposal entitled ***"Evaluation of differential expression of MUC20 and SPRR1B in oral squamous cell carcinoma and oral potentially malignant disorder"*** submitted by Dr. Payal Panwar, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1823/OP/23 dated 23rd August, 2023. ***Recommendation of reviewer:*** 1. The primer to be used for qRT-PCR has not been mentioned. It may be provided. Otherwise it is fine. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P75***
76.	Research proposal entitled ***"Unlocking stature: hand and handprint insights in estimating stature among North Indians"*** submitted by Dr. Priya Devi, JRIII, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1822/OP/23 dated 23rd August, 2023. ***Recommendation of reviewer:*** 1. There is no cohesion between the title, aim and objectives. 2. The title says: Estimating Stature…. 3. The aim says: Generate population specific regression models…. 4. The objectives describe taking different kind of measurements. 5. In the absence of proper research hypothesis, a study can not be planned. 6. Identify primary objective, identify the study variables and parameters. 7. Formulate the research hypothesis in terms of study parameters. 8. Everything should be centered around the research hypothesis, including sample size calculation, methodology and statistical analysis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P76***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

77.	Research proposal entitled ***"Prospective randomized controlled single centre study to assess efficacy and safety of over the wire mammoth ballon percutaneous mitral balloon valvotomy in patients with mitral stenosis"*** submitted by Dr. Rahul Sahu, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1691/Cardio/23 dated 14th August, 2023. ***Recommendation of reviewer:*** 1. If it is really, RCT, all the fundamentals are missing. 2. The two groups to be compared for efficacy should be defined exclusively. 3. For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. 4. The sample size calculation is arbitrary in the absence of proper research hypothesis. The different quantities used in the formula are not clear. 5. The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. 6. How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P77***
78.	Research proposal entitled ***"An observation study to estimate the efficacy of statins for LDL-C reduction in acute coronary syndrome and non-acute coronary syndrome patients Indian population"*** submitted by Dr. Saket Ramraika, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1669/Cardio/23 dated 17th August, 2023. ***Recommendation of reviewer:*** 1. In annexure 1. the duration of study in 18 m as well as 2yr. Kindly resolve and finalize. 2. Kindly submit the steps of sample size calculation. 3. In undertaking by PI, the other members of research team are missing. 4. In plan of study the follow-up at one place is after 3 months (as per NICE guidelines) While at other place it is stated as monthly for

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	3mths. Kindly make this clear. 5. Summarize the anticipated outcome variables. 6. The ICF does not mention the contact of investigator. 7. The Hindi version of ICF should be retyped and hind text needs to be corrected. 8. The patient information sheet should be as per SOP of EC KGMU only. 9. No need to attached SOP guidelines for patient information sheet. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P78***
79.	Research proposal entitled ***"Lymphatic function and arm morbidity after mini-LD flap reconstruction post modified radical mastectomy (MRM)"*** submitted by Dr. Pankaj Kumar, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 325/SY/23 dated 18th August, 2023. ***Recommendation of reviewer:*** 1. Sample size justification/calculation has not been done. 2. Patient information sheet is incomplete **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XXI-PGTSC-IIA/P79***
80.	Research proposal entitled ***"Outcome analysis and clinic-radiological profile of patients with intraventricular tumours treated at KGMU"*** submitted by Dr. Mohit Mangla, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 230/NS/23 dated 28th July, 2023. ***Recommendation of reviewer:*** 1. Kindly define the roles of guides & co guides as per protocol . 2. If no side effects are expected then what is the role of DSMB, or reporting of adverse events and interim analysis as per annexure 1. 3. If the aim is to study patients of last 12 years then how can it be a prospective study and how will the consent be obtained - Will the patient be called to decide his/her participation? and rest others excluded ?. 4. Pt information sheet indicates that it is both retrospective & prospective. Kindly indicate the inclusion of patients (retrospective & prospective) in methodology preferably via flow chart. 5. Ethical approval is primarily for prospective intervention and not for past procedures. 6. What is the anticipated sample size (not indicated in annexure 1)-

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	kindly show sample size calculation. 7. Kindly rectify language for points 5,6,13,15,17 in patient information sheet. 8. Kindly rectify language in ICF for patient participation as per design of study (prospective or retrospective.) **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P80***
81.	Research proposal entitled ***"Effect of mindful meditation an anxiety, haemodynamic parameters and inflammatory markers on patients undergoing surgery for varicose veins"*** submitted by Dr. Chaitanya Gahlot, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/579/23 dated 24th May, 2023. ***Recommendation of reviewer:*** 1. The project is written in a sketchy way. To write a proposal a proper description of the problem statement along with a relevant review of literature, existing research gap, relevance of the study along with objectives to be there, which is missing? Further, there is a need for suitable methods to address the concerns. The introduction of the study barely talks about the research gap as per the topic chosen for the study. Methodology also not gives any clue about the strategy that is to be adopted for mindful meditation. 2. Who will guide modification techniques? **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P81***
82.	Research proposal entitled ***"A retrospective study of epidemiology, clinical presentation, surgical intervention and outcome of patients who underwent surgery for aneurismal SAH from 2015 till 2023"*** submitted by Dr. Shubhrit Tyagi, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 320/SY/23 dated 18th August, 2023. ***Recommendation of reviewer:*** 1. The Study design indicates that it is a retrospective study & ethical approval is primarily for prospective interception & not for post procedures. 2. Kindly define the roles of guides & co guides as per protocol . 3. If no side effects are expected then what is the role of DSMB, or reporting of adverse events and interim analysis as per annexure 1. 4. If the aim is to study patients of last 8 years then how can it be a

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	prospective study and how will the consent be obtained - Will the patient be called to decide his/her participation? and rest others excluded ?. 5. Kindly rectify language for points 5,7,13,15,16,17 in patient information sheet. 6. Kindly rectify language in ICF for patient participation as per design of study (prospective or retrospective.) **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P82***
83.	Research proposal entitled ***"Effect of dexmedetomidine as an adjuvant in superficial cervical plexus block, for perioperative analgesia in patients undergoing thyroidectomy surgery under TIVA"*** submitted by Dr. N. Narasimhan, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/606/23 dated 24th May, 2023. ***Recommendation of reviewer:*** 1. In Title of the study abbreviations should be avoided, please write full form of TIVA in the title. 2. In Inclusion/ Exclusion criteria-Sex specification and Pregnant & lactating women criteria not mentioned. 3. In methodology section, method of blinding and randomization and Flow chart of the study is missing. 4. In tools- CRF, VAS score and Brussels sedation score–not attached - Please attach. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P83***
84.	Research proposal entitled ***"Comparison of i gel versus I gel plus in adult patients under controlled ventilation under general anesthesia: Randomised observational study"*** submitted by Dr. Shambhavi Jha, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/590/23 dated 24th May, 2023. ***Recommendation of reviewer:*** 1. There is nothing like randomized observational study. 2. This is prospective cohort study, where two groups (cohorts) will be compared. 3. Define primary objective properly. It should be research question, not "Time for successful insertion". 4. Identify the study variables and study parameters. 5. Convert the primary objective into a proper research hypothesis using

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	the study parameters of step 4. 6. Sample size calculation, methodology and statistical analysis should be in coherence to the research hypothesis. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P84***
85.	Research proposal entitled ***"Association of bacterial vaginosis and asymptomatic urinary tract infection in pregnant women attending a tertiary care Hospital"*** submitted by Dr. Annpurna Pal, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 538/23 dated 28th July, 2023. ***Recommendation of reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P85***
86.	Research proposal entitled ***"Incidence of drug induced peripheral neuropathy in patients with drug susceptible and drug resistant pulmonary tuberculosis"*** submitted by Dr. Jay Prakash Shukla, JRI, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 870/Res/23 dated 23rd August, 2023. ***Recommendation of reviewer:*** 1. In Scientific review committee report, the name and signature of one of the Co-PI (Prof. Surya Kant) is there- please revise SRC. 2. In SOP-Checklist--point no.7-use of biological /hazardous material–is ticked as NO-, but according to protocol , investigations will be done with the help of blood sample –please revise the point-7 of SOP-Checklist. 3. In Inclusion/ Exclusion criteria- Sex specification and Pregnant & lactating women criteria not mentioned. 4. Study design mentioned is Case control study–where are the control subjects ,both are the cases and Duration of study mentioned is from September 2022 to August 2023 – whether it is retrospective or prospective study–PI to clarify the study design and duration period of the study. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P86***
87.	Research proposal entitled ***"Clinical, demographic, psychological and molecular profile in patients of pre-extensively drug resistant pulmonary***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	tuberculosis" submitted by Dr. Anjali, JRI, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 869/Res/23 dated 23rd August, 2023. ***Recommendation of reviewer:*** 1- Sample size calculation has to be done. There can be no 'Pilot Study' in a dempgraphic cross-sectional study. 2- Inclusion criteria seem to be incorrect. Please check **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-IIA/P87***
II-B	**IMR- Resident**
1-	Research proposal entitled ***"Study of CDKN2A mutation in gliomas eith cytohistological correlation"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Aisha Mahmood, JRI, Through her Mentor Dr. Madhu Kumar, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1005/23 dated 1st January, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:**Approved ***Ref. code: XXI-PGTSC-II B IMR-R/P1***
2.	Research proposal entitled ***"Extensive lymph node dissection in predicting survival in patients with Gallbladder cancer-preliminary data from a tertiary care Hospital in Northern India"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Shiva, JRI through his Mentor Prof. A.A. Sonkar, Head, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 322/SY/23 dated 10th August, 2023. ***Recommendation of reviewer:*** 1-IEC form is improperly filled. 2-Use of biological/hazardous material is ticked as 'No' 3-Sample size calculation has not been done. 4-Methods sections mentions the design as retrospective, but patient information sheet mentions the study as prospective. Please clarifiy? 5- Patient information sheet is incomplete. 6- Informed consent form in Hindi is incompletely attached. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XXI-PGTSC-II B IMR-R/P2
II-B	**MHA**
1.	Research proposal entitled ***"A study on level of compliance with disabled friendly Hospital guidelines in urology, Pharmacology Department and SFAR in a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Rajnish MP Singh, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/393/23 dated 3rd August, 2023. ***Recommendation of reviewer:*** 1. IEC needs to be filled properly. 2. Topic of the study is written as the aim. 3. How objective 3 of the will be addressed. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI-PGTSC-II B-MHA/P1***
2.	Research proposal entitled ***"To evaluate the disinfectant hazard profile in a tertiary care Government Teaching Hospital, Lucknow"*** submitted by Dr. Sairaj Subhash Chodankar, JRII, under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/412/23 dated 16th August, 2023. ***Recommendation of reviewer:*** • Scientific review committee report and tools of the study are not enclosed. **PGTSC Comment:** As above **PGTSC Decision:** Kindly provide above documents ***Ref. code: XXI-PGTSC-II B-MHA/P2***
3.	Research proposal entitled ***"To study the cost of disinfectants being used in high-risk areas of a tertiary care Government Teaching Hospital, Lucknow"*** submitted by Dr. Sairaj Subhash Chodankar, JRII under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/413/23 dated 16th August, 2023. ***Recommendation of reviewer:*** 1- Recommendations of Departmental Scientific Review Committee not attached. Human subjects consent waiver may be granted.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Comment: As above **PGTSC Decision:** Waiver approved, Kindly provide above document. ***Ref. code: XXI-PGTSC-II B-MHA/P3***
II-B	**Research proposal for STS grant**
1.	Research proposal entitled ***"Comparative evaluation of periodontal health status in patients with interstitial lung diseases (ILD)"*** sponsored by ICMR STS submitted by Ms. Sakshi Khokhar, BDS through her Mentor Prof. Umesh Pratap Verma, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1362/P/23 dated 5th September, 2023. ***Recommendation of reviewer:*** 1. Total number of subjects need to replace 22 in annexure 1 pt5. 2. What will be the source of control subjects.? 3. Separate ICF & Patient information sheet for controls should also be enclosed both in English & Hindi. 4. Kindly summarize & categorize the anticipated outcome variables as per the 3 objectives of study. 5. Kindly elaborate the anticipated statistical analysis as per the 3 objectives of study. 6. In ICF kindly revise the language of 'study procedures' in the way a patient or control subject can understand. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI -PGTSC-IIB-STS/P1***
2.	Research proposal entitled ***"Perceived clinical competence of undergraduate dental students in rendering complete denture services to edentulous patients"*** sponsored by ICMR STS submitted by Ms. Shivangi Singh, BDS through her Mentor Prof. Saumyendra Vikram Singh, Department of Prosthodontics & Crowns and Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 283/23 dated 4th September, 2023. ***Recommendation of reviewer:*** • IEC form to be filled correctly. • Hindi ICF needs modification. अनियंत्रित उपचार may be replaced with स्वतंत्र उपचार .... मरीजों to be replaced as सहभागियों **PGTSC Comment:** As above **PGTSC Decision:**Approal subject to modifiction

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XXI -PGTSC-IIB-STS/P2
3.	Research proposal entitled ***"Occupational hazards hampering the Health of Dentists- A survey"*** sponsored by STS submitted by Miss. Shivangi Dubey, BDS through her Mentor Dr. Dipti Shastri, Additional Professor Department of Orthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1603/Ortho/23 dated 29th August, 2023. ***Recommendation of reviewer:*** 1. Sample size calculation not provided. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XXI -PGTSC-IIB-STS/P3***
4.	Research proposal entitled ***"Evaluation of effect of periodontal treatment during III trimester on prevention of PT-LBW": A case control study"*** sponsored by CIMR-STS submitted by Ms. Shivani Belani, BDS III year student through her Mentor Prof. Anjani Kumar Pathak, Department of Perodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1358/P/23 dated 2nd September, 2023. ***Recommendation of reviewer:*** 1. Kindly fill up point no11 in annexure 1. 2. In annexure 1 'Yes' is indicated for compensation of injury while indicated otherwise in ICF. 3. Kindly revise the contribution of investigators. Who will do patient recruitment & who will collect data. Also clarify as what do you mean by "conception.' (conception of idea or what?). 4. Regarding sample size calculation what is the criteria of RR being 4.21. 5. The para of "Ethical consideration" before reference section is confusing. It seems that some retrospective concent has been taken- if yes then for what? Kindly explain. **PGTSC Comment:** As above **PGTSC Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXI -PGTSC-IIB-STS/P4***
III-A	**Additional Document**
1-	Additional of research proposal entitled ***"Study of circulating cell free tumor human papillomavirus dna in cervical cancer"*** submitted by Dr. Apoorva

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Gangwar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1271/23 dated 2nd September, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:**Approved ***Ref. code: XVI-PGTSC-IIA/P41***

The next Meeting shall be held on 08th December, 2023 from 10.00 AM to 01.30 PM in hybrid mode in the Board Room, Administrative Block, KGMU UP, Lucknow.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 127th ECM held on 25th October, 2023

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the 127th Institutional Ethics Committee Meeting in *hybrid mode* held on **25th October, 2023 from 11:30 A.M. till 02.45 P.M.** in the Committee Room, Administrative Block King George's Medical University, U.P., Lucknow.

The following Members were present in the Meeting:-

1. Dr. Alok Dhawan -Chairman
2. Dr. G.G. Agarwal -Member
3. Dr. A.A. Mahdi -Member
4. Dr. Akash Agarwal -Member
5. Mrs. Akansha Dubey -Member
6. Mrs. Vasundhara Kumari -Member
7. Mr. Ujjawal Krishna -Member
8. Dr. Rajendra Nath -Member
9. Dr. Nisha Mani Pandey -Member
10. Dr. Anupam Mishra -Member
11. Dr. D.N. Upadhyaya -Additional Member-Secretary, IEC
12. Dr. Hardeep Singh Malhotra -Member-Secretary, IEC, ex-officio

The following Member was not present in the Meeting:-

1. Dr. K..K.Yadav -He has given his comments
2. Dr. Anita Rani -She has given her comments
3. Dr. Shubha R Phadke

I	**Minutes of previous Meeting held on 01-09-2023.** **The following documents have been brought from the last meeting because the quorum was incomplete.**
	Attendance
	The following Members were present in the Meeting:- 1. Dr. Alok Dhawan -Chairman 2. Dr. Akash Agarwal -Member 3. Dr. Anita Rani - Member 4. Dr. K.K. Yadav -Member 5. Dr. D.N. Upadhyaya - Member 6. Dr. Anupam Mishra -Member 7. Dr. Rajendra Nath -Member 8. Dr. G.G. Agarwal -Member 9. Dr. Shally Awasthi -Member-Secretary, IEC *Dr. Shally Awasthi superannuated on 6th September, 2023.*

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 126th ECMIIB-Ph.D/P2
31	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 25th October, 2023 from 11:00 a.m. till 12:30 p.m. ***physically as well as virtually*** in the Committee Room, Administrative Block, KGMU, U.P., Lucknow. ***The following Members were present in the Meeting:*** 1. Dr. Alok Dhawan -Chairman 2. Dr. Rajendra Nath -Member 3. Dr. Nisha Mani Pandey -Member 4. Mrs. Akansha Dubey -Member 5. Mr. Ujjawal Krishna -Member 6. Dr.D.N. Upadhyaya -AdditionalMember-Secretary, IEC 7. Dr. Hardeep Singh Malhotra-Member-Secretary, IEC, ex-officio ***The following Member was not present in the Meeting:*** 1. Mrs. Vasundhara Kumari
	DCGI
Ia-	ADR of research proposal entitled CKJX839B12302 entitled "*A randomized, double-blind, placebo-controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT)*" sponsored by M/s Novartis Healthcare Pvt. Ltd. submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 358/Cardio/Res/23 dated 20th September, 2023 & **preliminary email dated 9th September, 2023 at 4:04 p.m.** **Death** **Patient ID & age and gender:** K-1014042/59 yrs. Male **Patient Diagnosis:** Death **Patient enrollment date:** 20-10-2022 **Patient follow up under study**-Randomization (Day 1), M-3, M-9, M-15, M-21, M-27, M-33, M-39, M-45, M-51, M 57 to M-69.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Follow up visit completed-Randomization (Day-1) **Planning on visit-** 9th Month, 16 July (2023) **SAE reported on date:** 09th June, 2023 **Follow up visits remaining:** M-15, M-21, M-27 to M-69 **24 hours, notified to EC, Sponsor**-09-09-2023 **14 days analysis report submitted to EC**-09-09-2023 **Subject History:** A letter was received in the Office of the Ethics Committee on 21st September, 2023 from PI informing that the Subject's LAR had informed on 9th September, 2023 that the Subject passed away on 9th June, 2023 around 01:30 hrs. As per patient's LAR the patient was having complaints of loss of appetite and generalized weakness. The patient was not hospitalized and passes away at home on 9th June, 2023 at 01:30 PM. and a local practitioner visited to his place and confirmed subject's death. No autopsy was done. **Death Certificate has not been provided by the patient's LAR.** *Recommendation of Primary reviewer:-* • SAE (Death) on 09-05-2023 is likely due to disease the outcome (FTC of Ant. wall MI) and not due to intervention (Inclisiran) as patient was randomized on 20-10-22 and more than 7 months had elapsed after intervention when SAE occurred. Patient died at home on 9th June, 2023 at 01:30 PM. • Therefore causal relationship can not be established and no compensation is required as death occurred at home and no autopsy was done. • (Death certificate has not been provided by the patient's LAR) **ADR sub Committee Decision:** Noted as above ***Ref. code: 114th ECM IIC/P4***
32	**Non-DCGI**
	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 25th October, 2023 from 11:00 a.m. till 11:30 a.m. ***physically as well as virtually*** in the Committee Room, Administrative Block, King George's Medical University, U.P., Lucknow.***The following Members were present in the Meeting:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	1.Dr. Alok Dhawan -Chairman 2.Dr. Rajendra Nath -Member 3.Dr. Nisha Mani Pandey -Member 4.Mrs. Akansha Dubey -Member 5.Mr. Ujjawal Krishna -Member 6.Dr.D.N. Upadhyaya -Additional Member-Secretary, IEC 7.Dr. Hardeep Singh Malhotra-Member-Secretary, IEC, ex-officio *The following Member was not present in the Meeting:* 1.Mrs. Vasundhara Kumari
33	**Non-DCGI**
I	**The following documents have been brought from the last meeting held on 1st September, 2023 because the quorum was incomplete.**
	Attendance -01-09-2023 *The following Members were present in the Meeting:* 1. Dr. Alok Dhawan -Chairman 2. Dr. Rajendra Nath -Member 3. Dr.D.N. Upadhyaya -Additional Member-Secretary, IEC 4. Dr.Shally Awasthi -Member-Secretary, IEC *The following Members were not present in the Meeting:* 1. Dr. Nisha Mani Pandey 2. Mrs. Akansha Dubey 3. Mrs. Vasundhara Kumari 4. Mr. Ujjawal Krishna

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

34	Previous-Non-DCGI
Ia-	ADR of research proposal entitled *"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial* submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 237/Cardio/Res/2023 dated 22nd July, 2023 & preliminary email dated 10th July, 2023 at 10:46 AM. Hospitalization **Patient ID & age and gender:** 127/42 year/female **Patient Diagnosis:** RHD/Sev-MS/MVA 1.7 ccm **Patient enrollment date:** 14-06-2023 **Patient enrollment arm-**Digoxin **Patient follow up under study-**6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed-**Enrolment & Baseline Follow-up **Planning on visit-** 6th Month **SAE detected on date:** 08th July, 2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours Notified to EC, Sponsor-**10-07-2023 **14 days analysis report submitted to EC-**23-07-2023 **Subject History:** A letter was received in the Office of the Ethics Committee on 22nd July, 2023 from PI informing that the Subject's LAR has informed on 9th July, 2023 that the Subject was having complaint of breathlessness since night, for which she was hospitalized in the ICU on 8th July, 2023. The patient was managed conservatively and got stabilized. She got discharged on 11th July, 2023. The patient has been advised to go for MVR Surgery. Hence, She has been advised to temporary discontinue the IP. *Recommendation of reviewer:-* • SAE (Hospitalization) is likely due to disease outcome (RHD/Sev.-MS/MVA 1.7) and not due to intervention (Tab Digoxin) as patient was randomized in enrolment arm-on 14-06-2023 and SAE occurred on 08-07-2023, more than 20 days have elapsed after intervention. Patient was admitted in ICU due to breathlessness on 8th July, 2023 and managed conservatively and got stabilized. Patient was discharged on 11th July, 2023. • Causal relationship can not be established and as the patient was

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	treated successfully and discharged on stable condition therefore no compensation is required. **Previous ADR sub Committee Decision:** Defer to the next Meeting because quorum was incomplete **ADR sub Committee Decision:** Noted as above ***Ref. code: 102nd ECM IIA/P24***
Ib	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lueknow vide letter no. 266/Cardio/Res/2023 dated 1st August, 2023 & preliminary email dated 19th July, 2023 at 10:19 AM. **Death** **Patient ID & age and gender:** 063/39 year/Female **Patient Diagnosis:** RHD/Sev-MS/MVA 0.8cm **Patient enrollment date:** 07-12-2022 **Patient enrollment arm-**Digoxin **Patient follow up under study-**6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed-**Enrolment & Baseline Follow-up **Planning on visit-** 6th M **SAE detected on date:** 04th May-2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Notified to EC, Sponsor-**19th July-2023 **14 days analysis report submitted to EC-**1st August, 2023 **Subject History:** A letter was received in the Office of the Ethics Committee on 1st August, 2023 from PI informing that the subject's LAR has informed to the PI repeated reminder calls for 6 months follow-up, but, the telephonic calls were not answered by the subject. The subject's LAR informed to PI on 18th July, 2023 that the patient had complaints of acute excruciating pain in abdomen on 3rd May, 2023 for which she underwent a few Investigations and was referred to some higher treatment centre. The subject could not be hospitalized anywhere and she passed away on 4th May 2023 morning around 6:30 AM at her home. As per the previous consultation and reports of ultrasound submitted by the LAR, it seems that the subject had gross ascites with absent peristalsis and intestinal perforation that might be the cause of the subject's death. The death of the subject is not related to the Investigational

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Bhawan)
Chairman, IEC

drug. No autopsy was done.

Recommendation of reviewer:-

- Patient enrolment date 07-12-2022. Skipped 6 month follow up in May, 2022. SAE occurred-04-05-2023. SAE detected on 18-07-2023. Notification to EC-19-07-2023.
- Patient was suffering from ascites and possible ileus and passed away due to this-The SAE doesn't appear to be related to the drug under study.

ADR sub Committee Comment:

- Letter asking for explanation that why 6th month visit was skipped and the SAE was detected on 18th July. 2023.

ADR sub Committee Decision: Defer to the next Meeting because quorum was incomplete.

DR sub Committee Decision: Approval subject to response reviewed from PI.

Ref. code: 102nd ECM IIA/P24

Minutes of -25-10-2023

35 **Non-DCGI**

IIa- ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 333/Cardio/Res/2023 dated 4th September, 2023 & preliminary email dated 22nd August, 2023 at 01:40 p.m.

Death

Patient ID & age and gender: G-D-93/49 year/female
Patient Diagnosis: RHD/Sev-MS/MVA 1.0cm
Patient enrollment date: 15-02-2023
Patient enrollment arm-Digoxin
Patient follow up under study-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month.
Follow up visit completed-Enrolment & Baseline Follow-up
Planning on visit- 6th Month
SAE detected on date: 09th May-2023
Follow up visit remaining: 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month.
Follow up visit completed: Enrolment & Baseline Follow-up
Planning on Visit: 6th month

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 25th October, 2023

	24 hours, notified to EC, Sponsor-22-08-2023 **14 days analysis report submitted to EC**-04-09-2023 **Subject History:** A letter was received in the Office of the Ethics Committee on 4th September, 2023 from PI informing that the Subject's LAR has informed on 22nd August, 2023 that the Subject was having complaint of severe pain in abdomen, urinary retention and inability to pass stools since 30th July, 2023. The pain in her stomach deteriorated on 31st July, 2023 (Morning). The subject passed away on 31st July 2023 evening around 4:45 PM at her home, she could not was hospitalized anywhere and a local practitioner visited to her place and confirmed subject's death. No autopsy was done. *Recommendation of reviewer:-* 1. Enrolment date- 15-02-2023. 2. The SAE occurred on 31-07-2023. 3. SAE detection date is mentioned as 31st July at one place and 9th May at another place. In the letter of Causality assessment by Investigator the SAE detection date in 22-08-2023. 4. SAE reporting date is 22nd August which is not within 24 hrs. 5. Patient complained of abdominal distention and urinary retention and died at home. No Autopsy was done. 6. The SAE appears to be unrelated to the drug being used in the trial (Digoxin) 7. The dates of SAE detection need to be clarified/corrected in records. **ADR sub Committee Decision:** Approval subject to modification. ***Ref. code: 102nd ECM IIA/P24***
IB	**Expedited review**
1-	Research proposal entitled ***"Targeting epigenetic modulators of EZH2 and SGLT to mitigate renal toxicity and chronic kidney disease progression"*** submitted by Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 451/Nephro/23 dated 12th October, 2023. ***The above research proposal was forwarded to two Primary reviewers:-***

Recommendation of First Primary reviewer	**PI response**
Reporting of adverse events has been ticked as 'No'. Adverse events	We had changed the status of adverse event from "No" to "Yes"

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 128th ECM held on 8th December, 2023

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the 128th Institutional Ethics Committee Meeting *hybrid mode* held on **8th December, 2023 from 10:30 A.M. till 1.00 P.M.** in the Board Room, King George's Medical University, U.P., Lucknow.

The following Members were present in the Meeting:-

1. Dr. Alok Dhawan -Chairman
2. Smt. Akansha Dubey -Member
3. Mr. Ujjawal Krishna -Member
4. Dr. A.A. Mahdi -Member
5. Dr. Rajendra Nath -Member
6. Dr. Anupam Mishra -Member
7. Dr. Nisha Mani Pandey -Member
8. Dr. Hardeep Singh Malhotra -Member

The following Members were not present in the Meeting:-

1. Dr. G.G. Agarwal -He has given his written Comments
2. Dr. Shubha R Phadke -She has given her written Comments
3. Dr. Akash Agarwal -He has given his written Comments
4. Dr. K.K. Yadav -He has given his written Comments
5. Smt. Vasundhara Kumari
6. Dr. D.N. Upadhyaya -He has given his written Comments
7. Dr. Anita Rani -She has given her written Comments

IA	Action Taken
1-	Clarification of research proposal entitled ***"Elucidate the role of miRNA mediating epithelial to mesenchymal transition in chronic myeloid leukemia"*** sponsored by DST Inspire Fellowship submitted by Ms. Surbhi Gupta, under the guidance Dr. Nitu Nigam, Associate Professor, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 190/CFAR/23 dated 20th September, 2023.

Previous EC Comment	PI response
The objectives are unclear, vague.	To analyze differential micro RNA in peripheral blood mononuclear cells (PBMC) of chronic myeloid leukemia patients for epithelial to mesenchymal transition. 2. Validation of differential differentially expressed (DE) genes in CML patients through qPCR. 3. To explore the role of screened miRNA in CML pathobiology and disease course.
What is the primary objective?	The primary objective of the study is to identify the different differential microRNA and to investigate their expression in chronic myeloid leukemia

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		mediating through epithelial to mesenchymal transition.
	Sample size calculation is based on which objective?	It is based on the first objective in which different micro RNA will be determined through sequencing. After that expression of selected miRNA having vital role in chronic myeloid leukemia mediating through epithelial to mesenchymal transition (EMT). Then the identified miRNA will be validated in all the CML patient samples through RT-PCR Finally, the pathobiology and disease course will be analyzed in CML modulating through epithelial to mesenchymal transition. Therefore the miRNA that has impact in CML regulating through epithelial to mesenchymal will work as biomarkers for disease diagnosis.
	Sample size of 30, appears to be too little for this type of research.	The study is not related to population of India but the population of chronic myeloid leukemia epithelial cases in India whose prevalence is very small and we are studying the status of miRNA expressions in these cases. The CML in correlation with epithelial to mesenchymal transition (EMT) is yet more to explore. The new sample size for the proposed study is 55.
	The above comments were forwarded to the Principal-Investigator which was put-up in the Meeting:- **Previous Decision:** A Sub-Committee will be constituted & call to PI with her guide for discussion. **Comment:** • The existing short-coming were informed in person and asked for rectification. **Decision:** Research proposal to be re-submitted ***Ref. code: 124thECM II B-FS/P1***	
2-	Clarification of research proposal entitled ***"Elucidate the regulatory role of miRNAs in epithelial to mesenchymal transition in cervical cancer patients"*** submitted by Mr. Praveen Kumar, Ph.D. Scholar under the guidance Dr. Nitu Nigam, Associate Professor,	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 187/CFAR/23 dated 16th September, 2023.

Previous EC Comment	PI response
The account of budget not indicated and sponsor is indicated as NA. Kindly specify the total budget (split up) and kindly specify the source of funding.	Corrected included the budget and the source of funding included. Page No. 1
Attach the CSIR-JRF papers pertaining to the candidate.	The JRF-NET Certificate has been enclosure
Kindly fill up the left blanks in annexure-1	Corrected. Page No. 1-4
'National significance with rational' indicates the detail about prostate cancer (in male) while the project is for cervical cancer in females.	Corrected Page No. 6
Patient information sheet in Hindi is to be included.	Patients information sheet in Hindi has been attached Page No.12-13
Name and contact of Guide to be included in informed consent form.	Name and contact of guide included in informed consent form. Page No. 14 and 16.
All study procedures undertaken on patient's sample need to be briefed in informed consent form to the patient and not labeled as NA.	I have mentioned briefly about the study procedure. Page No. 14 and 16.
The second and third aims pertain to the progression of cervical cancer and prognostic aspects of cervical cancer respectively, but there is neither indication of any clinical data been collected nor any follow-up data. Kindly attach a case sheet to record the clinical findings and specify which specific clinical prognostic marker is intended be correlated with molecular outcomes.	Socio-demographic and clinical data were added and patients case sheet were attached in methodology. Page No.27.
It is indicated that 60 normal cervical samples will be collected. Does it mean from normal subject? What will be the indication to take samples from normal person??Kindly specify.	Corrected, methodology Page No. 27
It is further indicated that patients will be included on the basis of well-defined inclusion and exclusion criteria. Those	Changes done, inclusion and exclusion criteria has been modified. Page No.26 and 27

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

criteria included both cervical cancer and other serious uncontrollable medical conditions, decreasing life expectancy please clarify. Inclusion and exclusion criteria may be modified accordingly.	
The study design is case control and experimental if any control is included then kindly mention the inclusion criteria and include informed consent form as well as in information sheet for control.	This study is only case and control, inclusion and exclusion criteria is mention according controls. Page No. 27
How will clinical validation be done as shown in last flowchart? Also specify some tentative micro RNA and EMT markers.	Changes done in flowchart. Some tentative miRNA and EMT markers already show in Review of literature and mention in the methodology also Page No. 31 and 32

The above comments were forwarded to the Principal-Investigator and the response was reviewed by Primary reviewer:-

Second opinion	**PI response**
Split budget need to be added.	Total budgets have been added Column No.04 and CSIR-JRF/SRF award letter attached on page no.45
Regarding patients 9 & 11- Kindly enclosed ICF & information sheet for health controls both in English & Hindi	We have to take 2ml blood sample from patients which do not have to be reported, Column 11 ICE got tick by mistake and information sheet for health controls both English and Hindi are attaché. Page no.05 and 37 to 42.

The above comments were forwarded to the Principal-Investigator and the response was reviewed by Primary reviewer:-

Third opinion of Primary reviewer:-

- Split budget needs to be indicated in term of manpower and contingency, including consumables & needed instrument etc if needed.
- Total budget as indicated is 2,42,646/- While the letter quoted in Annexure indicates 4,40,000/-? Why this discrepancy? There is no indication for contingency.
- The above quoted letter suggest stipend for only one year (Nov 22 to Oct 23) While duration of prospective project is quoted as 3 yrs. What will be the source of funding after October, 2023. Kindly clarify through proper documents.
- Mention the source of funding for laboratory work through proper documentation

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

	form funding agency. • Hence a three yr prospective funding should be submitted for this 3 yr prospective study. • Kindly rectify your mistake in annexure 1. ***The above comments forwarded to the Principal-Investigator vide this office letter no.1744/Ethics/2023 dated 27th September, 2023.*** **Previous IEC Decision:** Comments to be forwarded to PI to seek her in the forthcoming IEC Meeting **Comment:** • Are there enough funds to conduct the research, if not, contingency may be used. • No charge should be levied to the subjects for the tests performed. • The IEC assumes that no intervention are involved **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 124thECMIIB-Ph.D/P3***
3-	Clarification of research proposal entitled ***"Association of advanced glycation end products with microvascular and neurodegenerative changes in diabetic retinopathy"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Dr. Nibha Mishra, Assistant Professor, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 7759/OPH/23 dated 2nd November, 2023. **Previous EC Comment:** • Please resend full proposal. Only IEC form is attached in this and preceding mail. ***The above comment was forwarded to the Principal-Investigator was forwarded to reviewer:*** *Reply awaited from reviewer side.* ***Ref. code: 125thECM II B-IMR-F/P1***
4-	Clarification of research proposal entitled ***"Impact of awareness of menstrual hygiene and identification of premenstrual dysphoric disorder on quality of life among adolescent Girls in Rural and Urban Area, Lucknow"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Dr. Rashmi P. John, Assistant Professor, Department of College of Nursing, King George's Medical University, U.P., Lucknow vide letter no. 1686/PF/23 dated 27th October, 2023. ***Previous IEC Comments:*** • Objectives are not specific and well defined. It is unclear whether the investigator will try to find out level or something else in the awareness of menstrual hygiene. Similarly, in the second objective what will be your objective like diagnosis, burden of symptoms for PMS and PMDD is not clear. • Statististical Analysis of various scores/answers/scales is not given.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Since the study population is adolescent girls from the school question number 20 and 21 (How satisfied are you with your personal life and How satisfied are you with your sex life) are not permissible in school environments. Moreover, we need a child's Assent form and parents ICF prior to recruitment in the study. ***The above comment was forwarded to the Principal-Investigator: Reply awaited*** **Decision:** Reminder to be sent to PI ***Ref. code: : 125th ECM II B-IMR-F/P3***
5-	Clarification of research proposal entitled "***Establishment of genetic diagnostic unit (NIDAN Kendra) at King George's Medical University under the DBT-UMMID initiative***" **Component 1: Prenatal testing for genetic disorders: Beta thalassemia, sickle cell disease and other hemoglobinopathies Component 2: New-born screening for relatively common treatable genetic metabolic disorders- [BT/PR4087/MED/12/900/2021]** submitted by Dr. Mili Jain, Additional Professor, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1533/23 dated 11th November, 2023. ***Recommendation of reviewer:*** May be / Provisionally Approved **Decision:** Approved ***Ref. code: : 126th ECM IB/P1***
6-	Clarification of research proposal entitled "***Effect of flipped classroom teaching as an addon to the routine Teaching in understanding of Anatomy during first professional Teaching***" submitted by Prof. Rakesh Kumar Diwan, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 515/ANAT/23 dated 29th November, 2023.

Previous EC Comment	PI response
They are trying to compare two different teaching methods	Yes, Lectures will be taken using traditional method (didactic) and flip classroom methodology. A comparative analysis of flip classroom teaching method with lecture based session will be done by obtaining the score of the students.
This is prospective Cohort study	Yes, it is repeated measures designed and prospective experimental comparative study.
The two groups should be explicitly defined.	Total first year MBBS students are 250, that are divided into two groups A and cConsist of 125 students each.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The questionnaire is required. Its detail of construction (including items) is required.	This is a pilot study. A structured questionnaire to assess the learner's perceptions about Flipped Classroom Teaching will be obtained from the participants. A sample (questionnaire) has been attached for reference.
	The method of assessment of the questionnaire should be outlined.	Each group will teach the class by traditional and flipped classroom method and after completion of the class post session assessment MCQ will be conducted. A structured questionnaire to assess the learner's perception about flipped classroom teaching methodology will be obtained from the participants. A sample (MCQ format) has been attached for reference.
	How the reliability and validity of the Questionnaire would be assess.	This is a pilot study, questionnaire is validated by internal and external experts of our Anatomy Department. A structured questionnaire to assess the learner's perception about flipped classroom teaching methodology will obtain from the participants. This validated questions for reference (Aristotle, et al: Flipped classroom methodology vs traditional didactic lectures in undergraduate medical students) The kappa statistic is frequently used to test interrater reliability. The importance of rater reliability lies in the fact that it represents the extent to which the data collected in the study are correct representations of the variables measured. After Collecting the scores of flipped and traditional class methodology, this test will be done.
	How much training is needed to learn how to administer it.	Questionnaire is in simple English language. Therefore, no training is required.
	Sample size calculation and statistical analysis section is required.	Sample Size: The sample size for the present study was estimated for repeated

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		measures between factors ANOVA using G*Power software. Considering a minimum clinical significant difference of 2 units between any two duration groups, the minimum number of participants required in each duration group was estimated as 103 for 95% power and 5% level of significance, assuming the within standard deviation to be 5. After accounting for the attrition of 10%, the final sample size would be 114 in each duration group. Statistical Analysis: Continuous and categorical variables related to patient's demographic, and clinical data will be presented as mean and SD and percentages, respectively.[AD1] Student's t-test will be used for continuous variables and Chi-square test for categorical variables to analyse the significant difference between groups. A p-value < 0.05 will be considered statistically significant. Multivariate analysis will be performed using repeated measures ANOVA to assess the group differences and multiple linear regression to find the significant predictors of outcome variables.

Recommendation of reviewer:
May be / Provisionally Approved
Decision: Approved

Ref. code: 127th ECM IIA/P7

Action taken-PGTSC

7- Clarification of research proposal entitled ***"Evaluation of postoperative outcomes of advanced electrosurgical devices v/s conventional clamp and tie technique for neck dissection- A randomized control trial"*** submitted by Dr. Aryan Dwivedi, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 855/SY/23 dated 23rd July, 2023.

Previous PGTSC Comment:

- Will suggest changing 'Randomized controlled trial' to 'Randomized controlled study'. A trial will need CTRI registration and DCGI approval and will need to be

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	submitted separately for full committee approval. • IEC form is incorrectly/incompletely filled. • Short forms should not be used in the consent form (English). • Section on sample size calculation is incomplete. • Sample size calculation should be based on the prevalence of the disease rather than operative time taken. • Patient information sheet is incomplete. • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** ***The above comment was forwarded to the Principal-Investigator which was forwarded to reviewer:-*** ***Recommendation of reviewer:*** • The PI has changed the title of the study from 'Randomized Control Trial' to 'Randomised Control Study' but has applied for CTRI registration. If indeed it is a trial, the proposal needs to be accompanied with a CONSORT statement and needs to be put-up in the full committee meeting. **Comment:** • Candidate to explain the nature of the proposal-"Trial versus Study" **Decision:** Proposal to be resubmitted ***Ref. code: XXI-PGTSC-IIA/P41***
8-	Clarification of research proposal entitled ***"Cyanoacrylatevs tacker for mesh fixation in laparoendoscopic inguinal hernia repair-double blinded, randomized control trial"*** submitted by Dr. Vivek Vishwakarma, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 855/SY/23 dated 2nd November, 2023. ***Previous PGTSC Comments:*** • Will suggest changing 'Randomized controlled trial' to 'Randomized controlled study'. A trial will need CTRI registration and DCGI approval and will need to be submitted separately for full Committee approval. • There are ten investigators in the study from the same department with overlapping roles. Please decrease the number of Co-PI or define their unique roles. • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** • Please resend full proposal. Only IEC form is attached in this and preceding mail. ***The above comment was forwarded to the Principal-Investigator which was forwarded to reviewer:-*** ***Recommendation of reviewer:*** • The PI has changed the title of the study from 'Randomized Control Trial' to 'Randomised Control Study' but has applied for CTRI registration. If indeed it is

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	a trial, the proposal needs to be accompanied with a CONSORT statement and needs to be put-up in the full committee meeting. **Comment:** • As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: XXI-PGTSC-IIA/P46***
9-	Clarification of the research proposal entitled ***"Perceived clinical competence of undergraduate dental students in rendering complete denture services to edentulous patients"*** submitted by ICMR, New Delhi for STS grant under supervision of Ms. Shivangi Singh, BDS student under the guidance of Prof. Saumyendra Vikram Singh, Department of Prosthodontics, FODS, KGMU, UP, Lucknow vide letter no.559/23 dated 21st November, 2023. ***Recommendation of reviewer:*** • IEC form to be filled correctly. • Hindi ICF needs modification अनियंत्रित उपचार may be replaced with स्वतंत्र उपचार .... मरीजों to be replaced as सहभागियों *The above comments was reviewed by the Member-Seretary, IEC.* *Recommendation of Member-Secretary, IEC* Provisionally approved subject to ratification by IEC *Recommendation of reviewer received by email dated 4th December, 2023 at 2:56 PM* May be / Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIB-STS/P2***
10-	Clarification of the research proposal (Under the expedited review) entitled ***"To study effect of examination stress on autonomic functions and salivery pH among medical students"*** submitted to ICMR, New Delhi for STS grant under supervision of Ms. Pragati Maurya, MBBS batch 2021 student under the guidance of Prof. Dileep Kumar Verma, Department of Physiology, K.G's Medical University, U.P., Lucknow vide letter no.3473/PHY/23 dated 8th November, 2023. ***The above research proposal was forwarded to two reviewers, for review Recommendations of both reviewers have been approved.*** May be / Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IB/P1***
11-	Clarification of research proposal (Under the expedited review) entitled ***"Relationship between dental anxiety and oral health awareness in patients visiting dental school in North India"*** submitted to ICMR, New Delhi for STS grant under supervision of Ms. Samreen Hussain, BDS through her Mentor Prof. Deeksha Arya, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 385/23 dated 16th September, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above research proposal was forwarded to two reviewers:- **Recommendation of First reviewer:-** • Gone through the proposal. Overall it is fine. But as anxiety is going to be assessed therefore it will be better if a Co-PI is included from the Department of Psychiatry. That will help in better evaluation of the anxiety score. *The above comments forwarded to Principal-Investigator, response has given by the Primary reviewer Principal-Investigator which was forwarded to Primary reviewer:-* **Recommendation of first reviewer:-** • May be / Provisionally Approved **Recommendation of Secondary reviewer:-** • May be / Provisionally Approved **PGTSC Decision:** Provisionally approved **Decision:** Approved *Ref. code: XXII-PGTSC-IB-STS/P2*
12-	Clarification of research proposal entitled ***"Occupational hazards hampering the Health of Dentists- A survey"*** sponsored by STS submitted by Miss. Shivangi Dubey, BDS through her Mentor Dr. Dipti Shastri, Additional Professor Department of Orthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1603/Ortho/23 dated 29th August, 2023. ***Previous PGTSC Comment:*** 1. Sample size calculation not provided. *The above comment was forwarded to the Principal-Investigator which was forwarded to reviewer:-* *Recommendation of reviewer:* May be / Provisionally approved **Decision:** Approved *Ref. code: XXI -PGTSC-IIB-STS/P3*
13-	**Minutes of ADR Subcommittee Meeting**
A-	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 21st November, 2023 from 02:00 p.m. in the Committee Room, Administrative Block, KGMU, U.P., Lucknow ***in hybrid mode.*** ***The following Members were present in the Meeting:-*** • Dr. Alok Dhawan — Chairman • Dr. Rajendra Nath — Member • Mrs. Akansha Dubey — Member • Mr. Ujjawal Krishna — Member • Dr. Nisha Mani Pandey — Member • Dr. D.N. Upadhyaya — Additional Member-Secretary, IEC • Dr. Hardeep Singh Malhotra — Member-Secretary, IEC, ex officio

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	DCGI-Hospitalization
I-	ADR of research proposal entitled INVICTUS: entitled ***"Investigation of rheumatic AF Treatment using vitamin K antagonists, rivaroxaban or aspirin studies"*** M/s Gilead Sciences Inc submitted by Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 1645/Cardio/Res/2021 dated 2nd July, 2021. **SAE term:** Hospitalized for valve replacement **Patient ID & age and gender:** R-M-010-0084, 47/Male **Patient diagnosis:** RHD/Sev MS/Post-BMV/in AF/EF-42%/NYHA III/Fuc of MVR with 31 M **Patient enrolled date:** 15-11-2018 **Patient enrolled in Arm-**Rivaroxaban 20 mg OD **Patient follow up under study-** 1st Month, 6th Month, 12th Month & every 6th Month till 5 year **Follow up visit Completed-** 1st Month, 6th Month, 12th Month, 18th Month, 24th Month, 30th Month (completed by telephonic visit-07-Jun-2021) **Planning on Visit-** No planning on visit **SAE detected on Date:** 24th June, 2021 (Hospitalization) **Follow up visit remaining:** 36th Month, 42nd Month, 48th Month, 54th Month, 60th Month **24 Hrs. Notified in EC, Sponsor & DCGI by Email:** 24th June, 2021 **14 Days analysis report submitted EC & DCGI:** 03rd July, 2021 **Subject History:** A letter was received in the Office of the Ethics Committee on 2nd July, 2021 from PI informing that the Subject was hospitalized for 11 days i.e. from 27th January, 2021 to 6th Feb, 2021 in the CTVS department for valve replacement, subject's last visit was done on 7th June, 2021 (30th Month visit) telephonically and the subject had not disclosed about this event at that time. Subject's unscheduled visit was done on 24th June, 2021 and then while reviewing his medical records, we became aware about the event. ***Recommendation of Primary reviewer:-*** SAE (Hospitalization) is due to disease outcome (RHD/ Sev. MS/ P-BMV / in AF/EF-42%/NYHA III/ Fuc MVR with 31M valve) and not due to intervention (Rivaroxaban) as patient was taking VKA for more than 2 year 7 months and completed 30th Month visit without any complaint. Subject made an unscheduled visit on 24th June, 2021 due to breathlessness. While scrutinizing his medical record PI came to know about subject's SAE (Hospitalization from 27th January, 2021 to 6th February, 2021 for visit in CTVS department for valve replacement surgery). Therefore, causal relationship cannot be established and no compensation is warranted as the subject was successfully treated and discharged from the hospital. **Comment:- Besides aforementioned, nothing further.** **Decision: Approved**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 83rd ECM IIC/P6
2	Research Protocol no. EX9536-4773 entitled "***Effect of semaglutide 2.4 mg once-weekly on function and symptoms in subjects with obesity related heart failure with preserved ejection fraction, and type 2 diabetes***" sponsored by M/s Novo Nordisk India Pvt. Ltd. submitted by Dr. Pravesh Vishwakarma, Professor Junior Grade, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no.372/Cardio/Res/2022 dated 22nd October, 2022. **SAE term:** Hospitalized for valve replacement **Patient ID & age and gender:** 377006, 54 yr/Female **Patient diagnosis:** ACS NSTEMI **Patient screening date:** 27-07-2022 **Patient follow up under study-** Randomization visit Month 2, Month 3, Month 4, Month 5, Month 6, Month 8, Month 9, Month 10, Month 11, Month 12, **Follow up visit Completed-** Randomization Month 2, Month 3, Month 4 **Planning on Visit:** Site visit **SAE detected on Date:** 11-10-2022 **Follow up visit remaining:**, Month 5 to Month 12 **24 Hrs. Notified in EC, Sponsor & DCGI by Email:** 11-10-2022 **14 Days analysis report submitted EC & DCGI:** 22-10-2022 **Subject History:-** A letter was received in the Office of the Ethics Committee on 22nd October, 2022 from PI informing that the Subject came to emergency with chest pain, radiating to back and left shoulder with sweating and anxiety since 04:00 am 10th October, 2022. Subject was promptly attended by Senior resident on duty, diagnosed as ACS-NSTEMI; he underwent CART followed by emergency PCI to LM-LAD and LCX with two drug eluting stents on 10th October, 2022. Site staff became aware of the event on 11th October, 2022. The subject stabilized with treatment and was discharged on 12th October, 2022. ***Recommendation of Primary reviewer:-*** a- Enrolment date-27-07-2022 b-The SAE occurred on 10-10-2023. c-SAE detected on 11-10-2023 d-Patient discharged from hospital 12-10-2023. e- 24 hrs notification by email 11-10-2023. f- 14 day analysis submitted on 22-10-2023. g- Causal relationship of SAE with SAE cannot be established and no compensation is warranted. **Comment:- Besides aforementioned, nothing further.** **Decision: Approved** *Ref. code: 113th ECM IIC/P4*

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

3-	Research Protocol no. EX9536-4773 entitled "***Effect of semaglutide 2.4 mg once-weekly on function and symptoms in subjects with obesity related heart failure with preserved ejection fraction, and type 2 diabetes***" sponsored by M/s Novo Nordisk India Pvt. Ltd. submitted by Dr. Pravesh Vishwakarma, Professor Junior Grade, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 489/Cardio/Res/22 dated 12th December, 2022. **Subject initial:** Y-D **Subject No.** 377006 **Hospital/OPD record number:** 20220157891 **Randomization No.** 377006 **Gender :** Female **Age and/or date of birth:** 54 year 01/01/1968 **Weight:** 78.0 kg **Height:** 150.0 cm **Subject History:-** A letter was received in the Office of the Ethics Committee on 12th December, 2022 from PI. Subject came to hospital emergency with complaints of severe chest pain from back to left shoulder since 04:00 am 10th October, 2022. In the emergency Senior Resident attended the patient and informed PI about this SAE. Subject hospitalized with the diagnosis- follow up case of ACS/NSTEMI/P/PCI-RCA/LCX. ***Recommendation of Primary reviewer:-*** a- Enrolment date-27-07-2022 b-The SAE occurred on 10-10-2023. c-SAE detected on 11-10-2023 d-Patient discharged from hospital 12-10-2023. e- 24 hrs notification by email 11-10-2023. f- 14 day analysis submitted on 22-10-2023. g- Causal relationship of SAE with the intervention cannot be established and no compensation is warranted. **Comment:- Besides aforementioned, nothing further.** **Decision: Approved** ***Ref. code: 113th ECM IIC/P4***
4-	Research Protocol no. CTQJ230A12301 entitled "***A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease***" sponsored by Novartis Health Care Pvt. Ltd. submitted by Prof. S.P. Verma, Department of Clinical Heamatology, K.G's Medical University, U.P., Lucknow vide letter no. 209/Cardio/Res/21 dated 30th December, 2021.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	SAE term: Hospitalized for valve replacement **Patient ID & age and gender:** 1178-079,61 yr/Male **Patient diagnosis:** Acute Coronary Syndrome/Non ST Elevation MI **Patient screening date:** 26-10-2021 **Patient follow up under study-** Randomization visit Month 1, Month 2, Month 3, Month 4, Month 5, Month 6, Month 9, Month 12, Month 13, Month 15, month 18, month 21, month 24, month 27 and every three month Follow up till 4 year. **Follow up visit Completed-** Randomization visit **Planning on Visit:** Month 1 visit due on 27th December, 2016 **SAE detected on Date:** 16-12-2021 **Follow up visit remaining:** Month 1, Month 2, Month 3, Month 4, Month 5, Month 6, Month 9, Month 12, Month 13, Month 15, Month 18, Month 21, Month 24, Month 27 and every three month Follow up till 4 year. **24 Hrs. Notified in EC, Sponsor & DCGI by Email:** 17-12-2021 **14 Days analysis report submitted EC & DCGI:** 30-12-2021 A letter was received in the Office of the Ethics Committee on 31st December, 2021. Subject came to emergency with complaints of weakness and dizziness. Subject had tested glucose level at home and random glucose level was noted to be low. In the emergency, Senior Resident attended the patient and informed PI about this SAE. Subject was hospitalized with the diagnosis of hypoglycemia and gastroenteritis. Subject was managed conservatively and discharged in a stable condition on 18th December, 2021. *Recommendation of Primary reviewer:-* • SAE (Hospitalization) was due to the subject's complaint of weakness, dizziness and diarrhea which was detected by the site staff on 16-12-2021. The subject was diagnosed having hypoglycemia and gastroenteritis that occurred 20 days after randomization. The subject was managed conservatively and discharged in a stable condition on 18-12-2021. • Causal relationship of SAE with the intervention cannot be established and no compensation is warranted as the subject was successfully treated and discharged from the hospital on 18-12-2021. **Comment:- Besides aforementioned, nothing further.** **Decision: Approved** ***Ref. code: 101stECMIIC/P18***
5-	Research Protocol no. LTE 15174 ATLAS-OLE entitled ***"An open label long term safety and efficacy study of Fitusiran in patients with Hemophilia A or B with or without***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	inhibitory antibodies to factor VIII or IX sponsored by Novartis Health Care Pvt. Ltd. submitted by Prof. S.P. Verma, Department of Clinical Hematology, K.G's Medical University, U.P., Lucknow vide letter dated 1st August, 2023, 15th August, 2023, 12th September, 2023 & 18th November, 2023. **Sub.:** 356000505004 Event term **As per the subject, he fell down on the road after** being hit by some vehicle on July 25, but he did not inform anybody in his family or the site. On July 29, the subject experienced a severe headache and vomiting, so his mother went to the local hospital and the local doctor advised a CT scan. As per the CT scane report, the subject experienced a CNS bleed and the local doctor advised the subject take some medication. As per the advice, PI-500 IU Factor VIII was administered on July 29, 2023. PI advised the subject to visit the site with all the reports. On July 31, the subject came to the site with reports and met with PI. PI advised some medication to the subject and as per the standard of care, 500 IU of factor VIII was advised OD for 7 days. After 7 days, repeat the CT. Hospitalization is not required. After 07 days from 29th July, 2023.The CT scan was performed on 4th August, 2023 and as per the CT report subject intracranial hematoma was reducing but not resolved and as per the subject the pain is also reducing and vomiting was stopped. So PI advised to repeat CT scan after 7 days and continue the 500 IU factor administration for more 7 days. Prescribed medications were stopped on 4th August, 2023. Only 500 IU factor VIII was continuing for more 07 days and Valprol-CR 300 (Sodium Valproate (200mg) + Valproic Acid (87mg) OD continue for more 03 months. Factor administration was stopped on 12-08-23 PI advised to Subject for repeat CT scan after 02 days. Subject CT scan was done on 16th August, 2023 and as per the report size of hematoma was reducing. For safety purpose PI advised to subject 250 IUfactor VIII administration for more 07 days. Factor administration was start on 16th August, 2023 to 22nd August, 2023. ***Recommendation of Primary reviewer:-*** SAE (Hospitalization) was due to severe headache and vomiting because of CNS bleed, which was detected by CT Scan and this was the result of accidental injury and fall of the subject after being hit by some vehicle. Therefore SAE is not related to clinical trial intervention. Subject was treated successfully for this accidental injury and had recovered is no casual relationship between the SAE & the intervention; no compensation is, therefore, warrented. **Comment:- Besides aforementioned, nothing further.** **Decision: Approved** ***Ref. code: 101stECMIIC/P18***
B-	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Committee" held on 8th December, 2023 from 10:00 a.m. till 10:30 p.m. ***in hybrid mode.*** ***The following Members were present in the Meeting:-*** • Dr. Alok Dhawan — Chairman • Dr. Rajendra Nath — Member • Mrs. Akansha Dubey — Member • Mr. Ujjawal Krishna — Member • Dr. Nisha Mani Pandey — Member • Dr. Hardeep Singh Malhotra — Member-Secretary, IEC, ex officio ***The following Member were not present in the Meeting:-*** • Dr. D.N. Upadhyaya -He has given his written comment • Mrs.Vasundhra Kumari
Ia-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. /Cardio/Res/23 dated & preliminary email dated 27th September, 2023 at 3:23 p.m. **Death** **Patient ID & age and gender:** J-P-105/46 year/Male **Patient Diagnosis:** RHD/Sev-MS/MVA 0.6 cm **Patient enrollment date:** 27-03-2023 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit**- 6th Month **SAE detected on date:** 26th September, 2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed:** Enrolment & Baseline Follow-up **24 hours, notified to EC, Sponsor**-27-09-2023 **14 days analysis report submitted to EC**- 10-10-2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 10th October, 2023 from PI. The subject's LAR informed on 26th September that the patient had complaints of loss of appetite and breathlessness since 22nd September, 2023 for which he got hospitalized on 23rd September, 2023 and he was managed conservatively. The subject's condition got worsened on 2nd October, 2023 and he died at 7:30 PM due to cardiogenic

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	shock in hospital (As per the death summary provided by the subject) The above information was provided by the subject's LAR on 26th September, 2023. *Recommendation of reviewer:* **a- Enrolment date**-27-03-2023 **b-Hospitalized on:** 23-09-2023. **c-LAR information :** 26-09-2023 **d**-The SAE date occurred on 02-10-2023 **e-Details of Event:** Patient managed conservatively for breathlessness and vomiting in hospital from 23-09-2023 but died on 02-10-2023 due to cardiogenic shock (as mentioned in PI report) and which is because of disease progression and is not related to intervention. **f- 24 hrs notification by email:** 27-09-2023 **g- 14 day analysis submitted on :** 10-10-2023. **h- Causal relationship and Compensation:** The causal relationship of SAE with intervention cannot be established and no compensation is warranted. **Comment:-** Reply received from PI has been reviewed. **Decision:** Approved ***Ref. code: 102nd ECM IIA/P24***
Ib-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 464/Cardio/Res/23 dated 1st November, 2023 & preliminary email dated 20th October, 2023 at 10:49 p.m. **Death** **Patient ID & age and gender:** M-84/23 year/Male **Patient Diagnosis:** RHD/Sev-MS/MVA 0.99.cm **Patient enrollment date:** 16-01-2023 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit-** 6th Month **SAE detected on date:** 20th October-2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed:** Enrolment & Baseline Follow-up **24 hours, notified to EC, Sponsor**-20-10-2023 **14 days analysis report submitted to EC**-01-11-2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

Subject History:

A letter of PI was received in the Office of the Ethics Committee on 2nd November, 2023 from PI & email dated 20th October, 2023 at 10:49 AM. The subject was enrolled on 16th January, 2023 in the Digoxin study.

The subject was contacted on 14th April, 2023 for the 3 months telephonic follow-up, but the subject's contact numbers were not reachable and switched off. The subject was repeatedly contacted on reminder calls for 6 month visit calls (window period till 16th September, 2023) but the calls were not answered.

The subject was again contacted 20th October, 2023 when the subject's LAR informed that the subject was having complaint of breathlessness and dyspnea since 29th January, 2023.

The subject was not able to reach the hospital and he died on the way on 31st January, 2023.

A follow up scheduled visit M-3 call was made to the Patient on 20th October, 2023 that the subject's LAR received the call on 20th October, 2023 and informed that the subject was having a complaint of breathlessness and dyspnoea since 29th January, 2023. The subject was not able to reach the hospital and he died on the way on 31st January, 2023. A local practitioner came and confirmed the patient's death and no autopsy was done. Despite multiple reminders the subject's LAR was unable to provide the death certificate of the subject. The SAE is not related to the investigational drug.

Recommendation of reviewer:

- Enrolment date – 16.01.2023. TAVI insertion was done on 05.10.2023.
- SAE occurred on 12.10.2023. Complete Heart Block
- SAE detected on 13.10.2023 when patient reported to hospital with syncope. Patient was hospitalized and Pacemaker implantation wad done on 14.10.2023. Patient was discharged on 16.10.2023.
- 24-hour report on 17.10.2023 (late – 4/5 days after SAE occurrence and after patient discharge from hospital)
- 14-day analysis report on 30.10.2023 (late)
- CHB is one of the complications of TAVI. But PI has reported that the SAE is not due to the study. Explanation may be sought on this and the reason for late reporting.

Comment:- Reply received from PI has been reviewed.
Decision: Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Ref. code: 102nd ECM IIA/P24

Ic- ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 519/Cardio/Res/23 dated 21st November, 2023 & preliminary email dated 7th November, 2023 at 3:51 p.m.

Death

Patient ID & age and gender: C-D-107/51 year/Female
Patient Diagnosis: RHD/Sev-MS/MVA 0.8cm
Patient enrolled date: 08-04-2023
Patient enrollment arm-Digoxin
Patient follow up under study-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month.
Follow up visit completed-Enrolment & Baseline Follow-up
Planning on visit- 6th Month
SAE detected on date: 6th November-2023
Follow up visit remaining: 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month.
24 hours, notified to EC, Sponsor-07-11-2023
14 days analysis report submitted to EC-21-11-2023
Subject History:

A letter of PI was received in the Office of the Ethics Committee on 22nd November, 2023 from PI & preliminary email dated 7th November, 2023 at 03:51 PM .A follow up scheduled visit M-3 telephonic follow-up and 6 months actual follow-up visit at the PI's site, the call were not answered. The subject's LAR informed on 6th November, 2023 that the subject was admitted for MVR surgery on 28th June that the subject was admitted for MVR surgery and was kept under observation as she had complaints of post-surgery fever and delirium. The subject passes away on 5th July, 2023 in the hospital around 6.28 AM due to sudden cardiac arrest and postoperative delirium. The SAE is not related to the investigational drug.

- The SAE documents for the above subject was sent on 21st November, 2023 around 2:00 PM (within the 14 days time limit) at the EC office but because of some meeting there was no staff available to receive the SAE documents and they were returned back so we recent the documents on the very next day i.e. 22nd November, 2023.

Recommendation of reviewer:

a- Enrolment date-08-04-2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	b- SAE detected on : 06-11-2023 **c- The SAE (Death) occurred on:** 05-07-2023 **d- Details of Event :** Patient was admitted for MVR surgery on 28-06-2023 but developed post-surgical fever & delirium and died (SAE) on 05-07-2023 due to cardiac arrest and postoperative delirium (as mentioned in PI report) and is not related to intervention. **e- 24 hrs notification by email:** 07-11-2023. **f- 14 day analysis submitted on :** 21-11-2023. **g- Causal relationship and Compensation:** The causal relationship of SAE with Intervention cannot be established and no compensation is warranted. **Comment:-** Besides aforementioned, nothing further **Decision:** Approved ***Ref. code: 102nd ECM IIA/P24***
1d	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 520/Cardio/Res/23 dated 21st November, 2023 & preliminary email dated 7th November, 2023 at 2:59 p.m. **Death** **Patient ID & age and gender:** S-C-075/54 year/Male **Patient Diagnosis:** RHD/Sev-MS/MVA 0.8.cm **Patient enrolled date:** 27-12-2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit-** 6th Month **SAE detected on date:** 6th November-2023 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor**-07-11-2023 **14 days analysis report submitted to EC**-21-11-2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 22nd November, 2023 from PI & preliminary email dated 7th November, 2023 at 03:51 PM .A follow up scheduled visit at Month 6. (actual follow-up visit at the PI's site) but, the calls were not answered. The subject's LAR informed on 6th November, 2023 that the subject had complained of breathlessness since 5th August, 2023 for which he consulted in the emergency department on 6th August, 2023, where he was treated conservatively and he passed away on the way to the home from the hospital on 6th August, 2023 around 9:30

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PM. A local practitioner came and confirmed the patient's death and no autopsy was done. Despite multiple reminders the subject's LAR was unable to provide the death certificate of the subject. As per the information provided by the patient's LAR, it seems to be a case of new onset of heart failure. **The SAE is not related to the investigational drug.** • There was an inadvertent delay of 1 day in submitting the 14 day report; therefore, it was submitted on the 15th day i.e. on 22nd November, 2023. • Patient enrollment date must be 27th December, 2022. • The SAE is not related to the Investigational drug. *Recommendation of reviewer:* a) Enrolment date – incorrectly mentioned as 27.12.2023 b) The SAE occurred on 06.08.2023. c) SAE detected on 06.11.2023 (3 months after SAE occurrence). d) SAE reporting date mentioned is 07.11.2023 (e-mail copy not attached). e) 14-day analysis report sent on 21.11.2023 (late) f) Patient had complaints of breathlessness since 05.08.2023, for which he consulted emergency department (Where?). Subject died on 06.08.2023 on the way from hospital to home. No Death certificate has been furnished. g) The SAE appears to be unrelated to the drug being used in the trial (Digoxin). • h):- E-mail copy of 24-hour notification needs to be furnished. • Date of enrolment/randomization in the trail needs to be corrected in the records. • 14-day reporting is late. **Comment:-** Reply received from the PI has been reviewed. **Decision:** Approved ***Ref. code: 102nd ECM IIA/P24***
1e	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 521/Cardio/Res/23 dated 21st November, 2023 & preliminary email dated 7th November, 2023 at 3:06 P.M. **Death** **Patient ID & age and gender:** H-N-094/37 year/Male **Patient Diagnosis:** RHD/Sev-MS/MVA 1.1cm **Patient enrolled date:** 20-02-2023 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up **Planning on visit-** 6th Month **SAE detected on date:** 6th November-2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

	Follow up visit remaining: 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor**-07-11-2023 **14 days analysis report submitted to EC**-21-11-2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 22nd November, 2023 from PI & preliminary email dated 7th November, 2023 at 03:06 PM .A follow up scheduled visit at Month 6 (actual, follow-up visit at the PI's site) but, the calls were not answered. Despite multiple reminders the subject did not answer the calls. The subject's LAR informed on 6th November, 2023 that the subject had complained of breathlessness and cough since 24th August, 2023 and he passes away on 26th August, 2023 at home around 1:30 PM. As per the information given by the patient's LAR, it seems to be a case of worsening of Heart failure. A local practitioner came and confirmed the patient's death and no autopsy was done. Despite multiple reminders the subject's LAR was unable to provide the death certificate of the subject. **The SAE is not related to the investigational drug.** • The SAE documents for the above subject was sent on 21st November, 2023 around 2:00 PM (within the 14 days time limit) at the EC office but because of some meeting there was no staff available to receive the SAE documents and they were returned back so we recent the documents on the very next day i.e. 22nd November, 2023. ***Recommendation of reviewer:*** a- Enrolment date-20-02-2023 b-The SAE occurred on: 26-08-2023. c- **SAE detected on** : 06-11-2023 d- **Details of Event**: The Subject was hospitalized on 24-08-2023 due to breathlessness and cough and died (SAE) on 26-08-2023 apparently due to progression of Disease and is not related to intervention. No autopsy was done e- **24 hrs notification by email**: 07-11-2023. f- **14 day analysis submitted on** : 21-11-2023. g- **Causal relationship and Compensation :** Causal relationship of SAE with Intervention cannot be established and no compensation is warranted. **Comment:-** Besides aforementioned, nothing further. **Decision:** Approved ***Ref. code: 102nd ECM IIA/P24***
II	ADR of research proposal entitled ***"GENESIS II: A clinical evaluation of the HYDRA self expanding transcatheter aortic valve"*** submitted by Prof. Sharad Chandra, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 458/Cardio/Res/23 dated 30th October, 2023 & preliminary email dated 17th October, 2023 at 12:05 P.M.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Hospitalization **Patient ID & age and gender:** K-L-K/ G-02-002, 79 year/Male **Patient Diagnosis:** F/U/C Degenerative Severe AS with Symtomatic **Patient enrollment date:** 04-10-2023 and procedure (TAVI) was done on 5th October, 2023. **Follow up visit completed-**Enrolment **Planning on visit-** 1st Month **SAE detected on date:** 13th October-2023 **Follow up visit remaining:** 1st Month & 6th Month **Follow up visit completed:** Enrolment & Baseline Follow-up **24 hours, notified to EC, Sponsor-**17-10-2023 **14 days analysis report submitted to EC-**30-10-2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 30th October, 2023 from PI & email dated 17th October, 2023 at 12:05 PM. The Subject came in the Department of Cardiology, KGMU UP, Lucknow in emergency on 13th October, 2023 with the complaint of Syncope from last 1 day, he got admitted for the stabilization. His Permanent Pacemaker Implantation (DDDR) was done on 14th October, 2023. Patient was discharged in stable condition without any complication on 16th October, 2023. He was hospitalized for medical management. *Recommendation of reviewer:* • Enrolment date – 04.10.2023. TAVI insertion was done on 05.10.2023. • SAE occurred on 12.10.2023. Complete Heart Block. • SAE detected on 13.10.2023 when patient reported to hospital with syncope. Patient was hospitalized and Pacemaker implantation wad done on 14.10.2023. Patient was discharged on 16.10.2023. • 24-hour report on 17.10.2023 (late–4/5 days after SAE occurrence and after patient discharge from hospital) • 14-day analysis report on 30.10.2023 (late) • CHB is one of the complications of TAVI. But PI has reported that the SAE is not due to the study. Explanation may be sought on this and the reason for late reporting. **Comment:-** Besides aforementioned, nothing further. **Decision:** Approved ***Ref. code: 109th ECM IIC/P2***
IB	**Expedited review**
1-	Expedited review of research proposal entitled ***"Unravelling the diagnostic power of novel biomarkers ad microbial profiling with genotyping and whole-genome sequencing for early and late-onset sepsis diagnosis and outcome prediction in preterm neonates"*** submitted by Dr. Sheetal Verma, Additional Professor, Department of Microbiology, K.G's Medical University, U.P., Lucknow vide letter no. 839/2003 dated 5th October, 2023. ***The above research proposal was forwarded to two reviewers, for review.***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of both reviewers : May be / Provisionally approved **Decision:** Approved ***Ref. code:128th IEC IB/P1***
2-	Expedited review of research proposal entitled ***"Optical coherence tomography (OCT) and its brain volume correlated in Alzheimer's disease: A cross-sectional study"*** submitted by Dr. Shailendra Mohan Tripathi, Additional Professor, Department of G.M.H., K.G's Medical University, U.P., Lucknow vide letter no. nil dated 14th October, 2023. ***The above research proposal was forwarded to two reviewers, for review.*** *Recommendation of First reviewer :* Provisionally approved *Recommendation of Secondary reviewer :* • The researcher has mentioned in point 10, that the risks outweigh the benefits. Such a study is unethical. Such protocols should not be considered for review leave alone. **Decision:** Approved ***Ref. code:128th IEC IB/P2***
3-	Expedited review of research proposal entitled ***"Development of artificial intelligence (A1) for screening, early diagnosis and treatment of oral potentially malignanat disorders (OPMDs) through population-based registry"*** submitted by Prof. Uma Shanker Pal, Department of Oral & Maxillofacial Surgery, FODS, K.G's Medical University, U.P., Lucknow vide letter no. 1018/OMSD/23 dated 29th November, 2023. ***The above research proposal was forwarded to two reviewers, for review.*** *Recommendation of first reviewer :* The project looks fine just two things in certain places e.g. in the first point of the research question language needs improvement, Moreover, references are cited in the text but are not listed. *Recommendation of Secondary reviewer :* • The title mentions the word 'registry' which registry is being used? • In the section on Sponsor, National Industry is ticked. Which Industry is the sponsor of the study? • Subject selection/calculation-How will a population of 5,69,117 be surveyed? Or will the actual sample size be smaller? • Section on 'Special Group Subjects' mentions 'Any other'. Please specify. • Section on 'Risk' - Risk is reasonable has been ticked as No. Minimal Risk has been ticked. • Advertising for the project has been ticked as 'Yes'. Please furnish advertisement material which will be used for the same. • Section on 'Risk' - Risk is reasonable has been ticked as No. Minimal Risk has

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	been ticked. • Reporting of adverse events is ticked as 'yes' - to Sponsor/IEC. Please mention what adverse events are expected in the PIS/ICF. • Patient information sheet in Hindi not attached. • PI proposes to use an AI algorithm based App for diagnosis, screening etc. Details about the App and its developer are missing. How will the photos /data generated by the App be stored? Will it be stored in the App, servers? Who will ensure safety of the data generated by the App? ***The above comments were forwarded to the Principal-Investigator which was forwarded to Secondary reviewer:-*** ***Recommendation of Secondary reviewer:*** • The title mentions the word 'registry'. Which registry is being used? The response to this query still mentions a 'population-based registry' without details of which registry is being used. • In the section on sponsor, National Industry is ticked. Which Industry is the sponsor of the study?-ICMR has been mentioned as sponsor which is not an 'Industry'. This needs changes in the IEC form. • Section on 'Risk' –Risk is reasonable has been ticked as No. Minimal risk has been ticked-Needs changes in the IEC form as per the response of the PI. • Reporting of adverse events is ticked as 'Yes'-to Sponsor/IEC-Needs changes in the IEC form. ***The above comments were forwarded to the Principal-Investigator:*** Provisionally approved **Decision:** Approved ***Ref. code:128th IEC IB/P3***
4.	Expedited review of research proposal entitled "***Improved data on dengue covering differences in epidemiological surveillance, patient demographics, the health seeking behavior of patients and standards of care***" under supervision of Prof. Avinash Agrawal, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1950/DCCM/23 dated 2nd November, 2023. ***The above research proposal was forwarded to two reviewers, for review.*** ***Recommendation of first reviewer:-*** • This is a multi-centre study. • There are certain guidelines for multi-centre studies. These must be followed. Only a list of potential sites is given. The name of participating centres is required. • What will be the common protocol? • Which will be a coordinating centre to collect, process and analyze the data? • The number of field sites varies greatly across studies according to their size, complexity and purpose. How will this be handled?

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

	• Sample size calculation is arbitrary. This is due to the fact that there are too many objectives. • Identify one primary objective and put the rest into secondary objectives. The primary objective should be converted into a proper research hypothesis in terms of the study variables and parameters. • Sample size calculation will be based on the research hypothesis defined in step 7. • Data analysis plan is very general. It should be specific to the research hypothesis. • The reliability and validity of instruments have to be assessed. • Can the scale be completed in a reasonable amount of time? • How will it be scored/evaluated? ***Recommendation of Secondary reviewer:-*** May be / Provisionally approved **Decision:** Approved subject to incorporation/inclusion of responses wherever applicable in the revised proposal. ***Ref. code: 128th ECM IB/P4***
5-	Expedited review of research proposal entitled "***A cytogenetic study of suspected cases of chromosomal in Uttar Pradesh region of North India***" under supervision of Prof. Rakesh Kumar Verma, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 497/ANAT/23 dated 24th November, 2023. ***The above research proposal was forwarded to two reviewers, for review.*** ***Recommendation of First reviewer:-*** • This is a prospective multicentric project conditionally approved for funding by ICMR. • The submitted project lacks scientific committee report that may be considered with the approval by project selection committee of ICMR. Still scientific committee report is necessary to assess the technical aspects of this project. • IRB of a centre (AIIMS Rishikesh) has approved the project subject to mandatory reporting of adverse events. But in this submission there are no anticipated adverse events (Annexure 1 point II). Why this confusion? • Is the risk not reasonable compared to anticipated benefits. (Annexure 1 point 10) • The patient information sheet (English & Hindi version) need to be re-written as per SOP of EC KGMU. • In ICF the email of, PI needs to be added. Also the 'study procedure' and 'Benefits of study' need to be elaborated and in a language that patient can understand. Kindly revise. • There is no indication of funding for KGMU. It seems that full budget will given to the nodal centre (AIIMS Gorakhpur). How will the budget be allocated to KGMU and for what purpose kindly enclose split budget as well for KGMU including institutional overhead. • The background states that chromosomal anomalies are "most significant" cause

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	of genetic disorders in human which actually is not correct. They may be common but certainly not the 'most significant'. Hence a scientific review committee needs to assess the entire project. • Regarding expected out-comes what are the anticipated determinants of chromosomal disorders? • Where will the chromosomal study be under taken? Which laboratory? Which department? Who will under take this lab work. (Individual or team?) ***Recommendation of secondary reviewer:*** • The researcher has mentioned in point 10, that the risks outweigh the benefits. Kindly clarify. **Comment:** • Patient enrolment, budget & initiation of project only after formal IEC approval. **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 128th ECM IB/P5***
II-A	**New Proposal**
1.	Research proposal entitled "***On normal brain sparing approach using objective function for radiosurgery of single brain targets with static and rotational intensity-modulated planning techniques***" under supervision of Prof. Navin Singh, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 931/RT/23 dated 3rd October, 2023. ***Recommendation of reviewer:*** • The researcher has mentioned in point 10, that the risks outweigh the benefits. Kindly clarify. **Comment:** • As above **Decision:** Approval subject to modification ***Ref. code: 128th ECM IIA/P1***
2.	Research proposal entitled "***Usefulness of receiving prepared cytology smears over those prepared under direct vigilance of a Pathologist***" under supervision of Prof. Riddhi Jaiswal, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1414/23 dated 4th October, 2023. ***Recommendation of reviewer:-*** **(i)** As title of the study suggests usefulness of a method over other but criteria or definition of usefulness is not defined. It should be clearly defined. **(ii)** Study type and design is not clearly mentioned in the proposal under respective headings though it has been declared as retrospective study in the covering letter of EC review and clearance. **(iii)** There is ICF form in the proposal. The PI should fill the form of consent waiver form. **(iv)** After reading whole proposal it seems to be done already. The proposal should be

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	revised in a manner that it reflects that the study will be done after getting ethical approval. **EC Comment:** As above **EC Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 128thECM IIA/P2***
3.	Research proposal entitled "***Association of bedtime procrastination with sleep behavior and subjective well-being in the Indian population- A cross-sectional study***" under supervision of Dr. Sujit K Kar, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1582/Psy/23 dated 3rd October, 2023. ***Recommendation of reviewer:-*** • The reliability and validity of instruments have to be assessed. • Can the scale be completed in a reasonable amount of time? • How will it be scored/evaluated? • Give the exclusive list of social media platforms to be used in the study. • Why do you want to choose convenient sampling? It is a non-probability sampling method. • The non-probability samples cannot depend upon the rationale of probability theory. At least with a probabilistic sample, we know the odds or probability that we have represented the population well. We are able to estimate confidence intervals for the statistic or do the testing of hypotheses. With non-probability samples, we may or may not represent the population well, and it will often be hard for us to know how well we've done so. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 128thECM IIA/P3***
4.	Research proposal entitled "***Functional and radiological outcome of combined PRIF with plate osteosynthesis and percutaneous screw fixation of pelvic ring fracture and/or acetabulum fractures: experience at tertiary care centre***" under supervision of Dr. Ravindra Mohan, Assistant Professor, Department of Orthopedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 14022/OS/23 dated 12th October, 2023. ***Recommendation of reviewer:-*** • Annexure 1 is grossly incomplete. Kindly complete. • Enumerate all the outcome variables & accordingly describe anticipated statistical analysis. • Kindly submit patient information sheet as per SOP of EC KGMU. • Under taking by PI indicates the possibility of unexpected & serious adverse

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	events. Is it just a generic statement? What are those events-kindly specify & add in ICF & patient information sheet. • If this is a retrospective project then it seems that these patients will be called for follow-up evaluation? **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 128th ECM IIA/P4***
5.	Research proposal entitled "***Efficacy of Hyper Baric Oxygen Therapy (HBOT) in management of Diabetic Foot Ulcer-A Randomized control trial***" under supervision of Prof. Vijay Kumar, Head, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1269/23 dated 6th October, 2023. ***Recommendation of secondary reviewer:*** • The researcher has mentioned in point 10. that the risks outweigh the benefits. Kindly clarify. **Comment:** • As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 128th ECM IIA/P5***
6.	Research proposal entitled "***Primary obstructive megaureter with urolithiasis: 20 years' single centre experience***" submitted by Prof. Apul Goel, Head, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 879/URO/23 dated 18th October, 2023. ***Recommendation of reviewer:-*** May be / Provisionally Approved **Decision:** Approved ***Ref. code: 128th ECM IIA/P6***
7.	Research proposal entitled "***Development of patient derived organoid bio-bank as a resource for drug response studies and precision medicine application in triple negative breast cancer***" sponsored by ICMR, New Delhi submitted by Prof. Pooja Ramakant, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. EndoSurg/374/23 dated 29th September, 2023. ***Recommendation of reviewer:-*** No ethics issues. But the information brochures need to explain 'tumor organoids' and system to validate. ' A small piece of breast tumor taken from the biopsy will be grown in a tube / bottle and as it develops similar to a tumor mass, it will be used to study the effects/ efficacy of the medicine.' Something like this.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Comment: • Issues associated with Bio safety & Bio banking alongwith commercialisation of the material. • Needs detailed clarification. **Decision:** Revise & Re-submit with response to comments in tabular format. *Ref. code: 128thECM IIA/P7*
8.	Research proposal entitled "*To evaluate the variables in mouth opening among the population of northern India: An observational study*" under supervision of Prof. Pavitra Rastogi, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. nil dated 6th October, 2023. ***Recommendation of reviewer:-*** May be / Provisionally Approved **Decision:** Approved *Ref. code: 128thECM IIA/P8*
9.	Research proposal entitled "*Diagnostic evaluation of index molecular test lit (s) compared to the microbiological reference standard for detection of adult pulmonary tuberculosis*" submitted to ICMR New Delhi under supervision of Dr. Parul Jain, Associate Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 813/23 dated 13th October, 2023. ***Recommendation of reviewer:-*** • Project incomplete • Review of literature not provided • No references **Comment:** Approved subject to incorporation of reviewer's concern. Ethical clearance of other Centre's. Names of Participating Centres. **Decision:** Revise & re-submit *Ref. code: 128thECM IIA/P9*
10.	Research proposal entitled "*Centre of Excellence for adolescent Health and Development in KGMU, Lucknow*" submitted to NHM (National Health Mission) under supervision of Prof. Sujata Deo, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1642/23 dated 27th October, 2023. ***Recommendation of reviewer:-*** • Title should be "Justification for establishment of Centre of Excellence for adolescent Health and Development in KGMU, Lucknow." • Identify one primary objective and the rest should be clustered into secondary objectives. • Identify study variables and population parameters.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Convert the primary objective into "research hypothesis" using the study variables and parameters of step 3. • Sample size calculation is arbitrary. It should be specific to the research hypothesis of Step 4. • The statistical analysis section is very general. It should be in tune with the research hypothesis and other objectives of the study. **Comment:** As above **Decision:** Re-submit with clarification ***Ref. code: 128th ECM IIA/P10***
11.	Research proposal entitled "***Evaluation of clinico-pathological characteristics, prognostic factors and treatment outcomes in patients with ewing sarcoma in children and young adults***" under supervision of Dr. Nishant Verma, Additional Professor, Department of Pediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3437/Ped/23 dated 31st October, 2023. ***Recommendation of reviewer:-*** May be / Provisionally Approved **Decision:** Approved ***Ref. code: 128th ECM IIA/P11***
12.	Research proposal entitled "***Effectiveness of continuing nursing education on knowledge regarding intellectual property right among nursing professionals working in various states of India***" under supervision of Mrs. Sudha Mishra, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no. 1738/23 dated 2nd November, 2023. ***Recommendation of reviewer:-*** • The IEC format needs to be filled out properly; please look at point no.8 and the checklist. • Please check ICF statement and correct no. of participants. • Proposal description:- a. Title states that the study is on nursing professionals working in various states of India; but the study protocol does not reflect. b. Methodology to be written properly. c. Subject inclusion/ exclusion criteria should be there. d. Procedure of the study is missing **Comment:** • As above **Decision:** Revise & Re-submit with response to comments in tabular format. ***Ref. code: 128th ECM IIA/P12***
13.	Research proposal entitled "***Development of psychological assessment tool for the***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	assessment of problematic internet use (PIU) among adults" under supervision of Prof. Shweta Singh, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1816/Psy/23 dated 2nd November, 2023. ***Recommendation of reviewer:-*** • No ethics issues. • It should be made clear that how many times the questionnaire will be filled. The study is said to last for 5 months. **Comment:** As above **Decision:** Provisionally approved with condition to kindly explain that how many times the questionnaire will be filled. The study is said to last for 5 months. ***Ref. code: 128th ECM IIA/P13***
14.	Research proposal entitled "***Comparative evaluation of carbamazepine and botox treatment of trigeminal neuralgia***" under supervision of Dr. Akhilanand Chaurasia, Associate Professor, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 523/PM&R/23 dated 28th October, 2023. ***Recommendation of reviewer:-*** • Approved with suggestion: The number of subjects calculated are 169 + 10% drop outs. But only 50 patients will be enrolled in each group leading to a total of 150. Therefore, number of patients in each group shall be increased. **Comment:** • Kindly include a Co-Investigator from the Department of Neurology, KGMU, UP, Lucknow. **Decision:** Approval subject to modification. ***Ref. code: 128th ECM IIA/P14***
15.	Research proposal entitled "***Role of urinary monocyte chemoattractant protein-1 (MCP-1), plasminogen activator inhibitor-1 (PAI-1), neutrophil gelatinase- associated lipocalin (NGAL) and liver-type fatty acid binding protein (L-FABP) as urinary biomarkers for early detection of renal damage in posterior urethral valves (PUV)***" under supervision of Prof. Archika Gupta, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 927/PedSY/23 dated 7th November, 2023. ***Recommendation of reviewer:-*** • No ethics issues. But the patient information brochure does not mention, whether blood or urine or both or any other sample will be collected. Needs to be clear. • The information brochure should be for the parents as the patient will be a child. The language needs improvement .e.g. , 'WHY HAVE I BEEN CHOSEN? - SINCE YOUR PATIENT IS HAVING POSTERIOR URETHRAL VALVE SO YOUR CHILD IS CHOSEN'

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Whether micturating cystourethrography will be done for the research or it is a part of the routine follow up and management? • Hindi brochure mentions that serum creatinine will be done while English brochure mentions only urine and MCU. • Need to improve Hindi and English patient info brochures. **Comment:** As above **Decision:** Approved subject to incorporation of reviewer's comments. ***Ref. code: 128th ECM IIA/P15***
16.	Research proposal entitled "***Evaluating the efficacy of oblique of oblique osteotomy and uniplanar distraction in TMJ ankylosis patients***" under supervision of Prof. Geeta Singh, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 960/ONSD/23 dated 1st November, 2023. ***Recommendation of reviewer:-*** • It is not a proposal. • Here they are presenting the results of a study already conducted on 10 patients with TMJ ankylosis in the period between January 2021 and January 2023. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format. ***Ref. code: 128th ECM IIA/P16***
17.	Research proposal entitled "***Feedback collection for the modified postpartum intrauterine device (PPIUD) (Tcu380A) with inserter in postparum women who underwent vaginal delivery***" submitted by Pregna International Ltd. under supervision of Prof. Anjoo Agarwal, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1757/23 dated 10th November, 2023. ***Recommendation of reviewer:-*** May be / Provisionally Approved **Decision:** Approved ***Ref. code: 128th ECM IIA/P17***
18.	Research proposal entitled "***Designing and implementation of health care model in patients with stage 2 breast cancer***" under supervision of Prof. Pooja Ramakant, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. 427/EndoSurg/23 dated 3rd November, 2023. ***Recommendation of reviewer:-*** • I'm one of the co-investigators of this project.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	King George's Medical University, U.P., Lucknow vide letter no. 943/PedSY/23 dated 8th November, 2023. ***Recommendation of reviewer:-*** May be / Provisionally Approved for waiver **Decision:** Approved for waiver ***Ref. code: 128th ECM IIA/P20***
II-B	**IMR-Faculty**
1.	Research proposal entitled ***"Comparison of self collected cervicovaginal smears with clinician collected cervical smears for human papillomavirus testing to detect high grade cervical intraepithelial lesions: A North Indian cross sectional study"*** submitted by Office of Dean, Research & Development, KGMU Lucknow under supervision of Dr. Shilpa Singh, Associate Professor, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1745/23 dated 8th November, 2023. ***Recommendation of secondary reviewer:*** • The researcher has mentioned in point 10, that the risks outweigh the benefits. Kindly clarify. **Comment:** • As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 128th ECM II B-IMR-F/P1***
II-B	**New Ph. D Proposal**
1.	Research proposal entitled ***"Implementation of LASER based cost effective motion monitoring system for left breast cancer radiotherapy: Application of python programming for automation"*** under supervision of Mr. Shriram A. Rajurkar, Ph.D Scholar, under the guidance Prof. Teerthraj Verma, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 916/RT/23 dated 29th September, 2023. ***Recommendation of reviewer:-*** • Project incomplete • Review of literature not provided • No references **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 128th ECMIIB-Ph.D/P1***
2.	Research proposal entitled ***"Association of BDNF and apoE gene polymorphism with their circulatory levels, biochemical and physiologic markers in geriatric population***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	with early and late onset depression" under supervision of Mr. Kaxmi Rani Gupta, Ph.D Scholar, under the guidance Dr. Ausaf Ahmad, Assistant Professor, Amity Institute of Biotechnology, Amity University Uttar Pradesh, Lucknow Campus: Lucknow Through Co-Guide Prof. Shrikant Srivastava, Head, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 346/DGMH/23 dated 6th October, 2023. ***Recommendation of reviewer:-*** May be / Provisionally Approved **Decision:** Approved ***Ref. code: 128thECMIIB-Ph.D/P2***
3.	Research proposal entitled ***"Dietary profile, cognitive status and Vitamin B12 level in aging individuals with type 2 diabetes mellitus: A cross sectional Hospital comparative study"*** under supervision of Ms. Vidya Priya, Ph.D. Scholar under the guidance Dr. Nisha Mani Pandey, Professor Jr. Grade, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 354/DGMH/23 dated 13th October, 2023. ***Recommendation of reviewer:-*** • Although in the title it is mentioned that the B12 levels will be assessed but neither its methodology is given nor it is mentioned where it will be estimated? Moreover, it is mentioned in the materials and methods section that no biochemical estimations will be carried out. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 128thECMIIB-Ph.D/P3***
II-B	**Fellowship**
1.	Research proposal entitled ***"Evaluation of the effect of a functional electrical stimulation device on walking speed and functional gait dynamics in footdrop patients-An exploratory pilot study"*** under supervision of Mr. Prithu Prasad & Mr. Kushagra Asthana, under the guidance Prof. Anil Kumar, Head, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 5749/23 dated 9th October, 2023. ***Recommendation of reviewer:-*** • Project incomplete • Review of literature not provided • Methodology not provided • No references

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer:- • Project incomplete • Review of literature not provided • Methodology not provided • No references **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format *Ref. code: 128th ECM II B-FS/P1*
II-C	**Review of New Drug Trial**
1.	Research protocol no.GPL/CT/2022/011/1V entitled *"An open label single arm, multicentric, prospective, post marketing study to evaluate the safety and effectiveness of fluticasone Furoate/Vilanterol (FF/VI) DPI in the management of asthma patients (Promise OD)"* submitted by M/s Glenmark Pharmaceuticals Ltd under supervision of Dr. Ankit Kumar, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow, vide letter no. CT/RM/18/2023 dated 4th October, 2023. *Recommendation of reviewer:-* May be / Provisionally Approved *The following documents were reviewed in the Meeting:-*

S.No.	Document Name	Version No.	Date
1-	Protocol	1.0	27-Apr-2023
2-	Draft Case Report Form	1.0	07-Aug-2023
3-	Subject Diary Visit -1	1.0	26-Jul-2023
4-	Subject Diary Visit 1 Hindi	1.0	25-Aug-2023
5-	Subject Diary Visit 1 Hindi Translation Certificate	NA	25-Aug-2023
6-	Subject Diary Visit 1 Hindi to English Back Translation	1.0	28-Aug-2023
7-	Subject Diary Visit 1 Hindi Back Translation Certificate	NA	28-Aug-2023
8-	Subject Diary Visit -2	1.0	26-Jul-2023
9-	Subject Diary Visit 2 Hindi	1.0	25-Aug-2023
10-	Subject Diary Visit 2 Hindi Translation Certificate	NA	25-Aug-2023
11-	Subject Diary Visit 2 Hindi to English Back Translation	1.0	28-Aug-2023
12.	Subject Diary Visit 2 Hindi Back	NA	28-Aug-2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Translation Certificate		
13.	Insurance Policy (Certificate No. 4066 - GPL/CT/2022/011/IV-23-24)	NA	Valid From: 01 July 2023 To: 30 June 2024
14.	Patient Information Sheet and Informed Consent Form–English	1.0	09-May-2023
15.	Patient Information Sheet and Informed Consent Form- Translation_English to Hindi	1.0	25-Aug-2023
16.	Patient Information Sheet and Informed Consent Form- Translation Certificate_English to Hindi	NA	25-Aug-2023
17.	Patient Information Sheet and Informed Consent Form- Back Translation_Hindi to English	1.0	28-Aug-2023
18.	Patient Information Sheet and Informed Consent Form- Back Translation Certificate_Hindi to English	NA	28-Aug-2023
19.	Assent Form–English	1.0	09-May-2023
20.	Assent Form-Translation_English to Hindi	1.0	25-Aug-2023
21.	Assent Form-Translation Certificates_English to Hindi	NA	25-Aug-2023
22.	Assent Form-Back Translation_Hindi to English	1.0	28-Aug-2023
23.	Assent Form- Back Translation Certificate_Hindi to English	NA	28-Aug-2023
24.	Investigator's Undertaking_ Dr. Ankit Kumar	NA	24-May-2023
25.	Curriculum Vitae_ Dr. Ankit Kumar	NA	24-May-2023
26.	Medical Registration Certificate_Dr. Ankit Kumar	MRC Certificate No. 62953	24-May-2023
27.	GCP Certificate_Dr. Ankit Kumar	NA	24-May-2023
28.	Protocol Signature Page_ Dr. Ankit Kumar	1.0	24-May-2023
29.	CT NOC	NA	28-Jul-2023
30.	Draft CTA	NA	NA
31.	Product Leaflet	NA	NA
32.	Draft CTRI Registration	NA	NA

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

	33.	DCGI Submission Letter	NA	08-Jun-2023

Decision: Approval subject to fulfilment & Administrative formalities

Ref. code: 128thECMIIC/P1

2. Research protocol no. #: R3918-PNH-2021 entitled "***A randomized, open-label, C5 inhibitor-controlled study to evaluate the efficacy and safety of pozelimab and cemdisiran combination therapy in patients with paroxysmal nocturnal hemoglobinuria who are complement inhibitor treatment-naïve or have not recently received complement inhibitor therapy*** " submitted by M/s Regeneron Pharmaceuticals Inc under supervision of Prof. Shailendra Prasad Verma, Principal Investigator, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow, vide letter no. CH/CT/13/2023 dated 3rd October, 2023.

Recommendation of reviewer:-

- In SOP-Checklist -Point no.-3 -vaccine is ticked-? and subdivision (ii) & (iii) -not ticked.
- Point no.-7–(ix) -necessary clearance for sending samples abroad – ticked as yes, but clearance letter is missing-PI to clarify.
- No other Ethical issues.

Comment:

As above

Decision: Approval subject to modification

Ref. code: 128thECMIIC/P2

3. Research protocol no. D7830C00004/Site-3520 entitled "***A randomized, double-blind, placebo-controlled, multi-centre phase 2b study to evaluate the efficacy, safety and tolerability of AZD2693 in participants with non-coirrhotic non-alcoholic steatohepatitis (NASH) with fibrosis who are carriers of the PNPLA3 rs 738409 148M risk allele***" submitted by M/s The Executive Centre Lavel 7, M-Far Greenheart, Manyate Embassy Tech Park under supervision of Dr. Ajay Kumar Patwa, Principal Investigator, Department of Medicine, King George's Medical University, U.P., Lucknow, vide letter no. MED/CT/18/2023 dated 20th July, 2023.

Recommendation of reviewer:-

- Sponsor address mentions two sponsors – one in Sweden, one in Japan.
- Consolidated budget approved as per CTA must be mentioned in the IEC form.
- Please mention type of study –clinical/epidemiological etc.
- Special group subjects (any other) is ticked Yes. Please specify.
- Collection for banking/future research has been ticked No, but consent for baking and future research is being taken. Please explain/correct.
- Samples are being sent outside the country for tests. Please specify which tests are being conducted inside the country and which are being sent outside. Has necessary clearance been obtained?
- DCGI approval does not list KGMU site, and the approval is subject to

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	submission of Phase-I, results to the Central Licensing Authority. • Certificate of Insurance coverage is not present in the proposal. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 128th ECMIIC/P3***
4.	Research protocol no. DRL-IND-NDA08-TEG/2022 entitled "***Multi-national, multi-centric, prospective, randomized, double-blind, active-controlled, parallel-group study to evaluate the efficacy and safety of tegoprazan in patients with erosive gastroesophageal reflux disease***" submitted by M/s Dr. Reddy's Laboratories Ltd, under supervision of Dr. Ajay Kumar Patwa, Principal Investigator, Department of Medicine, King George's Medical University, U.P., Lucknow, vide letter no. MED/CT/24/2023 dated 17th November, 2023. ***Recommendation of reviewer:-*** • The SRC of the department has not commented on the content of the proposal, but merely written 'Attached in Dossier'. The SRC has to affirm the scientific validity of the study. • Specific budget is not mentioned either in the IEC form or the CTA. • DCGI Approval letter attached to the application is protocol amendment approval letter. Please attach original letter. • No approval letter mentions KGMU as a site. • Insurance is valid only up to March 2024 which will lapse soon. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 128th ECMIIC/P4***
III A-	**Additional Document**
1.	Additional of research protocol no. TILD-19-07 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF experienced subjects with active psoriatic arthritis I (INSPIRE 1)*** submitted by M/s Sun Pharmaceutical Industries Limited under supervision of Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/116/23 dated 10th October, 2023. ***Recommendation of reviewer:-*** May be / Provisionally Approved ***The following documents were reviewed:-***

Sl	Documents	Version number / Date/details

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

No.		
A	English	Master Pregnant Partner PIS-ICF, Version 01 dated 25-Jul-2023 adapted from Master Global Pregnant Partner ICF version 1.1 dated 11-May-2022 Protocol TILD-19-07, Sun Pharmaceutical Industries Limited.
2	**Pregnant Partner PIS-ICF (Translation)**	
A	Hindi to English	Master Pregnant Partner PIS-ICF, Version 01 dated 25-Jul-2023 adapted from Master Global Pregnant Partner ICF version 1.1 dated 11-May-2022 Translation from English to Hindi: 03 Aug 2023 Protocol TILD-19-07, Sun Pharmaceutical Industries Limited, backtranslated Hindi to English on 17 Aug 2023.
4	**Pregnant Partner PIS-ICF (Translation/Back Translation) Certificates**	
A	English to Hindi	03 Aug 2023
B	Hindi to English	17 Aug 2023
5	**Patient ID Card**	
A	English	Project Version No. 1.0 Project Effective Date: 10 Feb 2020 Subject ID Card
6	**Patient ID Card (Translation)**	
A	English to Hindi	Patient Id card_V1_10 Feb 2020_Hindi_ 18 Aug 2023
7	**Patient ID Card (Back Translation)**	
A	Hindi to English	Patient Id card_V1_10 Feb 2020_Hind

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			i to English_18 Aug 2023
	8	**Patient ID Card (Translation/Back Translation) Certificates**	
	A	English to Hindi	18 Aug 2023
	B	Hindi to English	18 Aug 2023
	9	**eCRF Completion Guidelines**	

Decision: Approved

Ref. code: 122nd ECMIIC/P5

2. Additional of research protocol no. TILD-19-19 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF naive subjects with active psoriatic arthritis II (INSPIRE 2)***" submitted by M/s Sun Pharmaceutical Industries Limited under supervision of Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/115/23 dated 10th October, 2023.

Recommendation of reviewer:-

May be / Provisionally Approved

The following documents were reviewed in the Meeting:-

Sl. No.	Documents	Version number / Date/details
1	**Pregnant Partner PIS-ICF**	
A	English	Master Pregnant Partner PIS-ICF, Version 01 dated 25-Jul-2023 adapted from Master Global Pregnant Partner ICF version 1.1 dated 11-May-2022 Protocol TILD-19-19, Sun Pharmaceutical Industries Limited.
2	**Pregnant Partner PIS-ICF (Translation)**	
A	English to Hindi	Master Pregnant Partner PIS-ICF, Version 01 dated 25-Jul-2023 adapted from Master Global Pregnant Partner ICF version 1.1 dated 11-May-2022 Protocol TILD-19-19, Sun Pharmaceutical Industries Limited, English toHindi-Translation date 03 Aug 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

3	**Pregnant Partner PIS-ICF (Back Translation)**	
A	Hindi to English	Master Pregnant Partner PIS-ICF, Version 01 dated 25-Jul-2023 adapted from Master Global Pregnant Partner ICF version 1.1 dated 11-May-2022 Translation from English to Hindi: 03 Aug 2023 Protocol TILD-19-07, Sun Pharmaceutical Industries Limited, backtranslated Hindi to English on 17 Aug 2023.
4	**Pregnant Partner PIS-ICF (Translation/Back Translation) Certificates**	
A	English to Hindi	
B	Hindi to English	
5	**Patient ID card**	
A	English	Project Version No. 1.0 Project Effective Date: 10 Feb 2020Subject ID Card
6	**Patient ID card (Translation)**	
A	English to Hindi	Patient Id card_V1_10 Feb 2020_Hindi _20 Jul 2023
7	**Patient ID card (Back Translation)**	
A	Hindi to English	Patient Id card_V1_10 Feb 2020_Hindi to English_30 Jul 2023
8	**Patient ID card (Translation/Back Translation) Certificates**	
A	English to Hindi	20 Jul 2023
B	Hindi to English	30 Jul 2023
9	**eCRF Completion Guidelines**	Version: 5.0, Version Effective Date: 19 Jan 2023

Decision: Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 122nd ECMIIC/P6
3.	Additional of research protocol no. 18F-MC-GPIJ entitled "***A phase 3, randomized, double-blind, placebo-controlled study to investigator the effects of tirzepatide on the reduction of morbidity and mortality in adults with obesity***" submitted by M/s Eli Lilly Company Legal Registered under supervision of Prof. Gaurav Chaudhary, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no.427/Cardio/Res/2023 dated 14th October, 2023. ***Recommendation of reviewer:-*** May be / Provisionally Approved ***The following documents were reviewed:-*** **1. Recruitment and retention materials:** **English:** 1.1 Making Healthy food choices VI_IN EN 1.2 Staying fit through and active lifestyle VI_IN EN 1.3 Translation certificate **Hindi:** 1.4 Making Healthy food choices VI_IN HI 1.5 Staying fit through an active lifestyle VI_IN HI 1.6 Translation certificate **Decision:** Approved ***Ref. code: 122nd ECMIIC/P1***
4.	Additional of research protocol no. CTIN816A12201 entitled "***A randomized, multi-centric, placebo-controlled, participant, and investigator blinded study to evaluate the safety, tolerability and efficacy of TIN816 in adult patients at risk for acute kidney injury following cardiac surgery***" submitted by M/s Novartis Healthcare Private Limited under supervision of Dr. Sarvesh Kumar, Professor Junior Grade, Department of Cardiovascular & Thoracic Surgery, King George's Medical University, U.P., Lucknow, vide letter no. 963/CVTS/2023 dated 27th October, 2023. ***Recommendation of reviewer:-*** May be / Provisionally Approved **Decision:** Approved ***Ref. code: 127th ECMIIC/P1***
III-B	**Modification**
1.	Modification of research protocol no. 18F-MC-GPIJ entitled "***A phase 3, randomized, double-blind, placebo-controlled study to investigator the effects of tirzepatide on the reduction of morbidity and mortality in adults with obesity***" submitted by M/s Eli Lilly Company Legal Registered under supervision of Prof. Gaurav Chaudhary, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

no.400/Cardio/Res/2023 dated 10th September, 2023.

Recommendation of reviewer:-

May be / Provisionally Approved

The following documents were reviewed in the Meeting:-

S.No.	Documents
1.	**Protocol Amendment (a) dated 02-Mar-2023**
2.	IB dated 22 Feb 2023
3.	**Patient Informed Consent Form:** **2.1** India Specific ICF Version 3.0, English dated 10 Mar 2023 **2.2** India Specific ICF Version 3.0, Hindi Translation dated 30 Mar 2023 with Certificate of Translation
4.	Hibbert Appreciation items for Subjects

Decision: Approved

Ref. code: 122nd ECMIIC/P1

2. Modification of research protocol no. LTE15174 entitled "***ATLAS-OLE: An open label long term safety and efficacy study of fitusiran in patients with Hemophilia A or B, with or without inhibitory antibodies to factor VIII or IX***" under supervision of Dr. S.P. Verma, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. CH/CT/14/23 dated 5th October, 2023.

Recommendation of reviewer:-

May be / Provisionally Approved

The following documents were reviewed:-

Sr. No.	Document/Language	Document Details/Versions
1-	Investigator's Brochure (Clean copy)	Investigator's Brochure Edition 13 07 June 2023 (Controlled Copy No: PPD/ LTE15174/ Investigator's Brochure/Edition 13/Dated 07 June 2023/004-005) 1.1 Investigator's Brochure Edition 12 dated 24 May 2023 (Controlled Copy No: PPD/ LTE15174/ Investigator's Brochure/Edition 12/Dated 24 May 2023 /004 – 005)
2-	Investigator's Brochure (Track change copy)	Investigator's Brochure Edition 13 dated 07 June 2023 2.1 Investigator's Brochure Edition 12 dated 24 May 2023
3-	Investigator's Brochure (Summary of changes)	Investigator's Brochure Edition 13 dated 07 June 2023 3.1 Investigator's Brochure Edition 12 dated 24 May

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

			2023
	4.	DCGI Acknowledgment for Submission Email and Screenshot_Investigator's Brochure Edition 12 Sep 2023	Email acknowledgement dated 12 Sep 2023
	5.	Memo Justification for IB Ed 13	Justification for replacement of Investigator's Brochure version 12 with version 13_07Aug2023_signed

Decision: Approved

Ref. code: 90th ECMIIC/P2

3. Modification of research proposal entitled "***A prospective, interventional, single-arm post-marketing clinical follow-up study evaluating copper IUD insertion procedure using Yanae® associated with crossGlide™ technology in women desiring long-term contraception***" submitted by Mr. Ranjit Gaikwad Pregna International Limited under supervision of Prof. Anjoo Agarwal, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1546/23 dated 10th October, 2023.

Recommendation of reviewer:-

May be / Provisionally Approved

Decision: Approved

Ref. code: 121st ECM IIA/P6

4. Modification of research proposal entitled "***To evaluate the bone mineral status in children with type 1 diabetes mellitus-a hospital based case-control study***" submitted by Dr. Arpita, Associate Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.3485/Ped/2023 dated 9th November, 2023.

Recommendation of reviewer:-

(i) The proposal were revised and revisions are enlisted as study design has been changed from case control to cohort study while in the revised proposal there is still exclusion and inclusion criteria for the controls in the revised protocols.

(ii) Bifurcation of budget is well described but from where the researchers will get the fund/budget is not given.

(iii) Since, I was not the primary reviewer for the unrevised proposal and the current revised proposal doesn't have ICF forms, KGMU specific proforma, departmental approval etc. So, I would not able to comment on these.

Comment:

As above

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Decision: Full proposal to be sent to reviewer. ***Ref. code: 114thECMIB-IMR-F/P6***
5.	Modification of research protocol no. RVP-30-001 RECOVER entitled "***Brilaroxazine (RP5063), phase 3, randomized, 28 days, double-blind, placebo-controlled, multicenter study to assess the safety and efficacy of brillaroxzine (RP5063) in subjects with an acute exacerbation of schizophrenia, followed by a 52-week open-label extension***" submitted by M/s Revive Pharmaceuticals Holdings. Inc. under supervision of Prof. Adarsh Tripathi, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1695/Psy/2022 dated 17th October, 2023. ***Recommendation of reviewer:-*** • This is a request for protocol amendment where in the sample size is to be increased for screening & enrollment from 156 & 117 to 375 & 300 respectively. • This amendment has been accepted by DCGI. -The earlier clearance has not been attached. -No Consent from is attached. -The participant information sheet, subject information sheet caregiver/partner information sheet all mention the name of Dr. Shally Awasthi as contact person in IEC. Since she has superannuated the necessary modification is needed. • Also attach documents pertaining to insurance if any. **Comment:** • As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 121st ECMIIC/P1***
6-	Modification of research protocol no. NN9838-4942 entitled "***Re-REDEFINE 3: The cardiovascular safety of cagrilintide 2.4 mg.s.c. in combination with semaglutide 2.4 mg s.c. (CagriSema 2.4 mg/2.4 mg.s.c.) once-weekly in participants with obesity and established cardiovascular disease***" sponsored by M/s Novartis Healthcare Private Limited submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 438/Cardio/Res/23 dated 20th October, 2023. ***Recommendation of reviewer:-*** • Clarity on amount-Institutional overhead. ***The following documents were reviewed in the Meeting:-***

Sl. No.	Documents
1.	Protocol Version 3.0 dated 14 Apr 2023
2.	a. Protocol Version 4.0 dated 13 Jun 2023 b. Protocol signature Page for Page for Protocol version 4.0

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	3.	CagriSema IB ed 9- error in table 1-1 statement 25Apr2023
	4.	**SIIC** **English:** **NN9838-4942**, Subject Information/Informed Consent Form – Main Version 2.0_IN_EN Dated 05 Jul 2023, Status: Final **Hindi:** **a-NN9838-4942**, Subject Information/Informed Consent Form – Main Version 2.0_IN_HI Dated 06 Jul 2023, Status: Final **b-NN9838-4942**, Subject Information/Informed Consent Form – Main Version 2.0_IN_BT Dated 06 Jul 2023, Status: Final **c-** Translation certificate 2.0_IN_HI **d.**Translation certificate 2.0_IN_HI_BT **a.** NN9838-4942, Subject Information/Informed Consent Form – Main Version 2.0_IN_BT Dated 06 Jul 2023, Status: Final **b.** Translation certificate 2.0_IN_HI Translation certificate 2.0_IN_HI_BT
	5.	Patient Recruitment Material (Cooler Bag)
	Decision: Approved ***Ref. code: 123rd ECMIIC/P3***	
IV	**Other Matter with the permission of Chair**	
1-	Reg. request to change in Principal-Investigator because after superannuation of Prof. Shally Awasthi, ex-Principal-Investigator, Prof. Chandra Kanta, Department of Paediatrics, KGMU, UP, Lucknow will now be Principal-Investigator of the same project under the research proposal entitled ***"Electronic capture and machine learning analysis of data pertaining to childhood tuberculosis from tertiary hospitals in India"*** vide letter no.3559/Ped/23 dated 25th November, 2023. **Comment:** • The letter should have from the PI. **Decision:** As above	
V	**Brought to Ethics Committee after XXII-PGTSC held on 21st November, 2023**	
	Minutes of the XXII-PGTSC of IEC Meeting held on **21st November, 2023 from 11:00 till 1:00 P.M.** in the Board Room, King George's Medical University, U.P., Lucknow.*(in*	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	mode) *The following Members were present in the Meeting:-* 1. Dr. G.G. Agarwal -Member 2. Dr. A.A. Mahdi -Member 3. Dr. Rajendra Nath -Member 4. Dr. Anupam Mishra -Member 5. Dr. Nisha Mani Pandey -Member 6. Dr. D.N. Upadhyaya -Additional Member-Secretary, IEC 7. Dr. Hardeep Singh Malhotra -Convener *The following Member was not present in the Meeting:-* 1. Dr. Anita Rani -She has given her written Comment
IA	**Action Taken**
1	Clarification of research proposal entitled ***"Co-incidence of liver fibrosis with OSMF in areca nut habituals-An observational study"*** submitted by Dr. Karina Hyanki, JRI, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 483/OM&R/22 dated 4th October, 2023.

Previous PGTSC Comments	PI response
There are four sections: Research question, research hypothesis, aims and objectives. They do not syndromes.	1- **Dr. Anurag Tripathi** B.D.S, M.D.S. Additional Professor, Department of Oral Medicine and Radiology Faculty of Dental Sciences, King George's Medical University, U.P. Lucknow 2- **Prof. (Dr). Ranjit Kumar Patil** Professor and Head, Department of Oral Medicine and Radiology, Faculty of Dental Sciences, King George's Medical University U.P.,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Lucknow. 3- **Prof (Dr.) Sumit Rungta** D.M (Gastroenterology) Professor (Jr. Grade) & Head, Department of Medical Gastroenterology, King George's Medical University, U.P., Lucknow.
The statements under these sections are contradictory and confusing.	Is there any co relation between fibrosis in osmf and liver fibrosis in osmf patients having areca nut ? Comparison of liver fibrosis in control group of OSMF patients with OSMF patients having areca nut habit?
There should be one primary research hypothesis clearly stated. Everything thing else should be subjected to secondary objectives.	To find the degree oif hepatic changes in OSMF patients having areca nut, using Elastography amd Liver Function Test (LFT) To find the incidence of liver fibrosis in various grades of fibrosis occurring in OSMF patients having areca nut habitual.
Aim	To find the degree of hepatic changes in OSMF patients having areca nut, using Elastography and Liver Function Test (LFT)
Objective	To find the incidence of liver fibrosis in various grades of fibrosis occurring in OSMF patients having areca nut habitual.
Methodology	Enclosed
Budget	Self-funded
Sample size	32

The above comments forwarded to the Principal-Investigator were reviewed by the reviewer:-
Provisionally approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approved ***Ref. code: XIII-PGTSC-II***
2	Clarification of research proposal entitled ***"Non-alcoholic fatty liver disease in patients of hypothroidism"*** submitted by Dr. Tushar Rajoura, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1541/Med/23 dated 30th September, 2023. ***Previous PGTSC Comment:*** • The methodology needs to be revised and clearly sub-categorised in intervention, comparison, and outcome in order to make it more clear. • The statistical tools are stated in past tense and it would be better to brief the various outcome parameters used in analysis. • The patient information sheet needs to be submitted both English and Hindi as per the • SOP of EC KGMU. ***The above comments forwarded to the Principal-Investigator were reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XIX-PGTSC-IIA***
3	Clarification of research proposal entitled ***"Fall risk assessment among lower limb prosthesis user-A cross-sectional study"*** submitted by Dr. Mohd Farid Ahamad, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 841/23 dated 10th October, 2023. ***Previous PGTSC Comment:*** • Please attach properly filled Patient Information Sheet ***The above comments forwarded to the Principal-Investigator were reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XIX-PGTSC-IIA***
4	Clarification of research proposal entitled ***"Study of outcome & efficacy of genicular nerve block versus saphenous nerve block in osteoarthritis of knee: A prospective randomized controlled trial"*** submitted by Dr. Arun Kumar Ojha, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 840/23 dated 10th October, 2023. ***Previous PGTSC Comment:*** • Please attach properly filled Patient Information Sheet ***The above comments forwarded to the Principal-Investigator were reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XIX-PGTSC-IIA/P26***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

5 Clarification of research proposal entitled *" An exploratory study on knowledge, attitude" To study knowledge, attitude and practice with respect to infection control among healthcare workers of intensive care units in a tertiary care Government teaching Hospital, Lucknow"* submitted by Dr. Garima Jaiswal, JRI, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/538/23 dated 14th October, 2023.

Previous PGTSC Comment:

- It can be a pilot study. Title may be changed accordingly.

The above comments forwarded to the Principal-Investigator were reviewed by the reviewer:-

Provisionally approved

PGTSC Decision: Approved

Ref. code: : XIX-PGTSC-IIA/P37

6 Clarification of research proposal entitled *"Intramedullary nailing vs hemireplacement arthroplasty in unstable intertrochanteric femur fracture in elderly"* submitted by Dr. Krishna Mani Shukla, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 1290/Ortho/23 dated 17th October, 2023.

Previous PGTSC Comments	PI response
The study is very similar to another study from the same department by Dr. Ritesh Chakoo under Dr. Mayank Mahendra. This will result in a salami study. Please reconsider either of the two studies.	Thesis of Dr. Krishna Mani Shukla is based on a broader aspect of hip preservation surgery only (PFN). On the other hand thesis of thesis of Dr. Krishna Mani Shukla is based on comparative study pertaining to hip replacement surgery (hemireplacement)
IEC proforma is incompletely filled.	Attached separately
Sample size is mentioned as 100 at one place and 80 at another.	Sample size attached separately
No clinical end point is given when the scoring will be done.	Modified Harris hips score will be used. Age range between 40-070 years both male and female will be recruited in the study.

The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-

Second opinion of reviewer	PI response
Typing errors in clarification of point no.1	Yes, Thesis of Dr. Ritesh Chako is based on a broader aspect of hip preservation surgery only (PFN). On the other hand thesis of thesis of Dr. Krishna Mani Shukla is based

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

		on comparative study pertaining to hip replacement Surgery (hemireplacement)

The above comment forwarded to the Principal-Investigator was reviewed by the Primary reviewer:-
Provisionally approved
PGTSC Decision: Approved

Ref. code: XIX-PGTSC-IL

7 Clarification of research proposal entitled ***"Clinical outcome of idiopathic congenital talipes equinovarus treated with ponseti method"*** submitted by Dr. Nitin Jeenjwadia, SRI, Department of Pediatric Orthopedics, King George's Medical University, U.P., Lucknow vide letter no. 2466/PaedOrtho/23 dated 4th July, 2023.

Previous PGTSC Comments	PI response
Some details should be given about Pirani scoring method.	The Pirani Score is a simple and reliable system to determine severity and monitor progress in the Assessment and Treatment of Clubfoot. It is an easy to use tool, developed to assess the severity of each of the individual components of Clubfoot. It is used both as a means to assess the severity of the Clubfoot at initial presentation and for ongoing monitoring of the patient's progress. The Pirani Clubfoot Score documents the severity of the deformity and sequential scores are an excellent way to monitor progress.
How the numbers/scores would be extracted from this scale.	In Pirani score 6 well described clinical signs of clubfoot. Three of these signs indicate primarily Hind Foot Contracture (HFC) and three signs indicate primarily Mid Foot Contracture (MFC). Hind Foot Contracture (HFC) - 1. Posterior crease (PC), 2. Rigid Equinus(RE), 3. Empty Heel (EH) Mid Foot Contracture (MFC) -

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	1. Curved lateral border, 2. Medial crease, 3. Coverage of the talar head Each component will be scored as 0 (normal), 0.5 (mildly abnormal), or 1 (severely abnormal). Pirani scoring of each component and the total scores will be maintained at each visit on a weekly interval. The least total score for all categories combined will be 0 and the maximum score as 6.
It seems to be a pre-post study done on a single sample.	Assessment of pre-correction and post-correction of deformity is done following the same process on weekly visits of the patient till full correction is achieved. Pirani scoring at initial presentation (Pre correction) and follow same process in every weekly visit till achieving full correction (post correction)
The sample size calculation is incorrect as it is for two independent samples.	Corrected sample size statistical al calculation is enclosed herewith.
Statistical analysis section is missing.	Data will be recorded on Microsoft excel sheet. Categorical variables will be described using frequency table of histograms. Continuous variables will be described using measures of central tendency (mean, median and mode) and measures of dispersion like SD. Correlation and a test for correlation will be used to find the significant correlation between the Pirani score and the total number of casts. A probability value of 0.05 will be accepted as the level of statistical significance.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

	The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:- Provisionally approved **PGTSC Decision:** Approved *Ref. code: XIX-PGTSC-IIA/P63*
8	Clarification of research proposal entitled ***"CT guided evaluation of rotational deformity in femoral shaft fractures in Children treated by flexible elastic intra medullary nailing: A prospective cohort study"*** submitted by Dr. Praseeth K.R, SRI, Department of Pediatric Orthopedics, King George's Medical University, U.P., Lucknow vide letter no. 2612/PaedOrtho/23 dated 5th October, 2023.

Previous PGTSC Comments	PI response
Some details of evaluating Scales are required including their reliability and validity.	Attached separately
How are these scored?	These are measured in the axial view CT scan taken in the final follow-up of the patient after the fracture has united. The torsion angle of the femur is compared to the opposite normal side and the difference is noted in degrees using standard CT scan axial slices. It' there is a difference then it is counted to be in the category of rotational malalignrrient of'the fenatll following TENS surgery.
Sample size calculation is for prevalence study, not for measurement scale.	Attached separately
The statistical analysis section is very general. It should be specific to the research hypothesis.	Statistical analysis will be done by finding outthe number of patients with malrotation (asmeasured by the Torsion angle of ie femw of the operated side compared to the normal side añer complete fracture union) following the surgery expressed as a per-centage out of ie total number of patients studied. Data ofpatients with malrotation will be entered in Microxoñ Excel and chi-

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		square analysis will be done for categorical variables, T-test and ANOVA analysis will be done for continuous variables usiclg IBM Corp.'s SPSS version. 27. Statistical significance was defined as a p value<0.05

The above comments forwarded to the Principal-Investigator were reviewed by the reviewer:-
Provisionally approved
PGTSC Decision: Approved

Ref. code: XIX-PGTSC-IIA/P65

9	Clarification of research proposal entitled ***"Efficacy of pre-operative lugol's lodine in reducing peri-operative complications in patients with graves' disease following thyroidectomy- A randomized control trial"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow KGMU UP, Lucknow submitted by Dr. Mithum Raam, SR, Through his Mentor Prof. Anand Kumar Mishra, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ENDOSORSG/364/23 dated 26th September, 2023. ***Previous PGTSC Comment:*** • The study mentions that IEC & RC approval: Nov 2022; Time line is incorrect. Study period is written as Dec 2022, is the study started? ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XIX-PGTSC-II B IMR-R/P7***
10	Clarification of research proposal entitled ***"Study on association of circulatory homocysteine, LP(a) and triglyceride-glucose index in young adult (age<45 years) of acute coronary syndrome subjects: A case control study"*** submitted by Dr. Deeksha Chaurasiya, SR, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1368/23 dated 25th September, 2023. ***Previous PGTSC Comment:*** • In the consent form it is given that 3-5 ml of the blood sample will be collected while in the project it is mentioned that 10 ml of fasting blood samples will be collected. Please seek clarification. ***The above comment forwarded to the Principal-Investigator was reviewed by the***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	reviewer:- Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIA/P1***
11	Clarification of research proposal entitled ***"Retraction clefts as a prognostic marker in breast cancer- A study from tertiary care center of Northern India"*** submitted by Dr. Fatima Khan, SR, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1358/23 dated 22nd September, 2023. ***Previous PGTSC Comment:-*** • It is mentioned that 200 cases will be recruited but on what basis this number of cases are going to be taken is not mentioned. Sample size calculation needs to be provided. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIA/P2***
12	Clarification of research proposal entitled ***"Study of expression of CD24 IHC marker in breast cancer cells and its clinic-pathological correlation"*** submitted by Dr. Mantasha Mukhtar, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1369/23 dated 25th September, 2023. ***Previous PGTSC Comment:-*** • IHC methodology not mentioned ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIA/P3***
13	Clarification of research proposal entitled ***"Clinicopathological study of bone tumors with expression of DEPDC1 in osteosarcoma"*** submitted by Dr. Harshpreet Kaur Sall, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1384/23 dated 13th October, 2023. ***Previous PGTSC Comment:-*** • It is a retrospective as well as prospective study. It is mentioned that 106 cases will be taken but how many of them will be for retrospective and how many are for prospective study is not mentioned. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

<table>
<tr><td></td><td>Ref. code: XX-PGTSC-IIA/P5</td></tr>
<tr><td>14</td><td>Clarification of research proposal entitled "Study to assess the morphological characteristics of left main coronary artery in patients undergoing percutaneous coronary intervention using intravascular ultrasound" submitted by Dr. Somya Mahalawat, SR, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 2145/Cardio/23 dated 22nd September, 2023.
Previous PGTSC Comment:-
• Although the aim of study is mentioned, objectives have not been properly defined. Needs clarification.
The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-
Provisionally approved
PGTSC Decision: Approved
Ref. code: XX-PGTSC-IIA/P6</td></tr>
<tr><td>15</td><td>Clarification of research proposal entitled "Immunohistochemical expression of col11A1 & KI67 breast carcinoma and its correlation with tumor infiltrating lymphocytes and clinicopathological parameters" submitted by Dr. Somya Agarwal, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 1427 dated 7th October, 2023.
<table>
<tr><th>Previous PGTSC Comments</th><th>PI response</th></tr>
<tr><td>In Inclusion criteria-Age specificity & Pregnant and lactating women criteria not mentioned.</td><td>All ages, pregnant, lacting, nulliparous women and men are included.</td></tr>
<tr><td>How PI will assess/take consent for Retrospective part of the study which will be done on previous 1 year registered patients or PI will attach HSRWF for this patients–PI to clarify.</td><td>Consent is taken through phone calls or informed consent</td></tr>
<tr><td>CRF has not been attached-please attach.</td><td>CRF has been attached separately</td></tr>
</table>
The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-
Provisionally approved
PGTSC Decision: Approved
Ref. code: XX-PGTSC-IIA/P14</td></tr>
<tr><td>16</td><td>Clarification of research proposal entitled "Screening for CCR5 ΔA 32 variant mutation in exposed uninfected spouse of HIV-1 patients: a potential target of hematopoietic stem cell transplantation in HIV" submitted by Dr. Sahivangi Nayak, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 947/23 dated 18th July, 2023.</td></tr>
</table>

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous PGTSC Comments: In Scientific Review Committee, the name of one of the Co-guides (Prof. U S Singh) is there-please clarify or revise SRC. • In Inclusion criteria - Age specificity & Pregnant and lactating women criteria not mentioned • Case record form is incomplete –Please attach proper CRF ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIA/P13***
17	Clarification of research proposal entitled ***"Safety and efficacy of azathioprine in the treatment of paradoxical reaction in patients with tuberculous meningitis: A randomized clinical trial"*** submitted by Dr. Saritesh Kumar Thakur, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 299/Neuro/23 dated 9th October, 2023.

Previous PGTSC Comments	PI response
In SOP-Checklist -Point-6 -confidentiality statement- ticked as No, Point-7 -use of body organ /fluids not ticked for taking CSF -Please revise.	6. Privacy and confidentiality i. Study Involves Direct identifiers [×] Indirect Identifiers/Coded [✓] Completely Anonymized / Delinked [×] ii. Confidential handling of data by staff Yes[✓] No[ ] 7. Use of biological / hazardous materials i. Use of fetal tissue of aborts. If yes provide details Yes [ ] No [✓] ii. Use of organs or body fluids. If yes provide details Yes[✓] No [ ] Details – CSF samples will be collected at the time of diagnosis and follow up. iii. Use of recombinant / gene therapy products Yes[ ] No [✓] if yes, has Department of Biotechnology

(Hardeep Singh) Malhotra
Member-Secretary, IEC

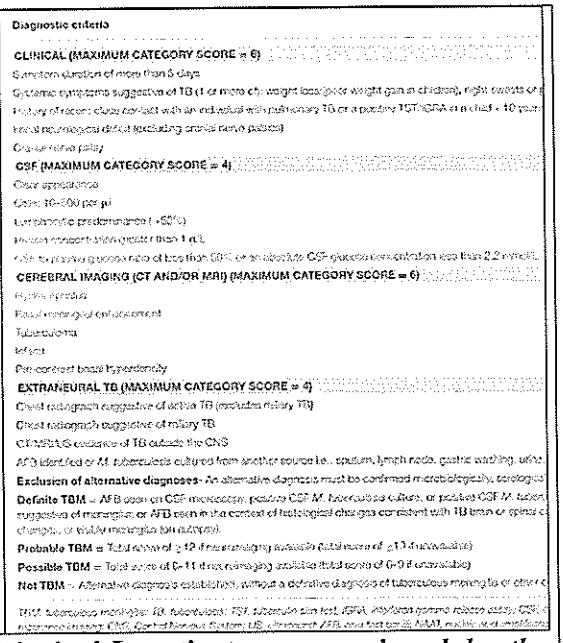
(Alok Dhawan)
Chairman, IEC

		(G01) approval for rDNA products been obtained"? Yes[ ] No [ ] iv. Use of pre-existing/stored/left over samples Yes[ ] No [✓] v. Collection for banking / future research Yes[ ] No[✓] vi. Use of ionizing radiation /radioisotopes' Yes[ ] No [✓]
	Detailed sample size calculation -not done (written that calculation will be done by sample size calculator along with reference)-please give calculated sample size.	Total Sample size = 126 Group A = 63 Group B = 63 Two-sided significance level(1-alpha): 95 Power(1-beta, % chance of detecting): 80 Ratio of sample size, Unexposed/Exposed 01 Percent of Unexposed with Outcome: 30
	CTRI document after registration should be send to office of Ethics Committee as soon as it will get registered (as it is RCT study)	Applied for CTRI registration. Approval of Institutional Ethics committee is needed for completion of application process.

CONTINUED ON NEXT PAGE

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC



	Please attach diagnostic criteria for TBM according to Marais et al.	**Diagnostic criteria** **CLINICAL (MAXIMUM CATEGORY SCORE = 6)** Symptom duration of more than 5 days Systemic symptoms suggestive of TB (1 or more of: weight loss (poor weight gain in children), night sweats or History of recent close contact with an individual with pulmonary TB or a positive TST/IGRA in a child < 10 years Focal neurological deficit (excluding cranial nerve palsies) Cranial nerve palsy **CSF (MAXIMUM CATEGORY SCORE = 4)** Clear appearance Cells: 10–500 per µl Lymphocytic predominance (>50%) Protein concentration greater than 1 g/L CSF to plasma glucose ratio of less than 50% or an absolute CSF glucose concentration less than 2.2 mmol/L **CEREBRAL IMAGING (CT AND/OR MRI) (MAXIMUM CATEGORY SCORE = 6)** Hydrocephalus Basal meningeal enhancement Tuberculoma Infarct Pre-cerebral basal hyperdensity **EXTRANEURAL TB (MAXIMUM CATEGORY SCORE = 4)** Chest radiograph suggestive of active TB (excludes miliary TB) Chest radiograph suggestive of miliary TB CT/MRI/US evidence of TB outside the CNS AFB identified or *M. tuberculosis* cultured from another source i.e., sputum, lymph node, gastric washing, urine **Exclusion of alternative diagnoses**- An alternative diagnosis must be confirmed microbiologically, serologic **Definite TBM** = AFB seen on CSF microscopy, positive CSF *M. tuberculosis* culture, or positive CSF *M. tuber* suggestive of meningitis, or AFB seen in the context of histological changes consistent with TB brain or spinal c changes, or visible meningitis (on autopsy). **Probable TBM** = Total score of ≥ 12 if neuroimaging available (total score of ≥ 13 if unavailable) **Possible TBM** = Total score of 6–11 if neuroimaging available (total score of 6–9 if unavailable) **Not TBM** = Alternative diagnosis established, without a definitive diagnosis of tuberculous meningitis or other c TBM, tuberculous meningitis; TB, tuberculosis; TST, tuberculin skin test; IGRA, interferon gamma release assay; CSF, c cerebrospinal fluid; CNS, Central Nervous System; US, ultrasound; AFB, acid fast bacilli; NAAT, nucleic acid amplification

The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-

Second opinion of Primary reviewer:-

- SOP-Checklist-again not ticked properly-please attach SOP-Checklist separately.
- Give a complete calculated sample size with the method.
- The tool-Diagnostic criteria for tuberculosis meningitis are attached but not readable-Please send it again.
- Review the CONSORT statement.
- DCGI approval/repurposing of Azathioprine.

The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-

Provisionally approved

PGTSC Decision: Send to regular IEC:-

- DSMC to periodically review the progress/protocols
- Who would bear the cost of treatment/adverse events/ insurance etc.
- Provisionally approval has cancelled.

Ref. code: XX-PGTSC-IIA/P17

18-	Clarification of research proposal entitled ***"Role of metal alloy impregnated foley's catheter in catheter associated urinary tract infection in ICU patients: A prospective randomized comparative study"*** submitted by Dr. Naman Gupta, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1330/23 dated 21st October, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous PGTSC Comment:- • Kindly provide properly filled Patient Informed Sheet. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIA/P30***
19	Clarification of research proposal entitled ***"Role of soluble triggering receptor expressed on myeloid cells-1 (sTREM-1) in neonates with early and late-onset neonatal sepsis"*** submitted by Dr. Shradha Gupta, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 501/23 dated 22nd July, 2023. ***Previous PGTSC Comment:-*** • It is not clear whether it is a comparative study (Comparison between sTerM-1 levels of two kinds of neonates) or correlation study (Correlation or association between SterM-1 level and severity of infection). • The severity of infection has to be defined. • The sample size formula is for prevalence study. Anyway, it can be formulated after clarification of "primary objective" as in point 1. • Statistical analysis section is missing. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIA/P34***
20	Clarification of research proposal entitled ***"Efficacy of microvascular couplers for venous microanastomosis in the reconstruction of oral defects"*** submitted by Dr. Ranjeet Singh, JR, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 918/OMFS/23 dated 12th October, 2023.

Previous PGTSC Comments	PI response
EC Comment 1 This seems to be comparative study	This is not a comparative study, this is an interventional study with the results of those compared with previous literature data.
EC Comment 2 The control group should be properly defined.	As this is not an comparative study & results where compared with previous published literature, there is no need of control group.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	EC Comment 3 The null hypothesis is not properly defined. It should be defined in terms of study parameters and variables, which should be identified for the study.	The null hypothesis is properly defined and corrections done as advised and attached in proforma.
	EC Comment 4 The sample size is for prevalence study. It should be specific to research hypothesis.	Sample size was calculated on the basis of efficacy of coupler in venous anastomosis and not for the prevalence. Which is appropriate for the research hypothesis?
	EC Comment 5 The statistical analysis section is general. It should be specific to research hypothesis.	Continuous variables conforming to a normal distribution will be expressed as mean ± standard deviation. Counting data will be expressed as number and percentages. The independent-samples t-test will be used for inter-group analysis of quantitative data. The $\chi 2$ test will used to find association between study variables. In all of the statistical analyses, $P < 0.05$ will be considered to be statistically significant. SPSS latest available version and MS Excel will be used for statistical analysis of the data.
	The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:- Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIA/P36***	
21	Clarification of research proposal entitled ***"A study of weekly brief telephonic intervention in patients with alcohol Dependence"*** submitted by Dr. Shobhit Nain, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 940/Psy/23 dated 13th October, 2023. ***Previous PGTSC Comments:*** • The outcome "Cumulative abstinence duration" should be exclusively defined. Its method of measurement should be outlined. • The null hypothesis is defined in terms of the parameter (e.g. mean, proportion	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	etc.) not the variables. • How the controls are selected. The detail is required. • Sample size calculation is arbitrary. It can be defined after properly defining the research hypothesis. • Statistical analysis section is missing. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIA/P37***
22	Clarification of research proposal entitled ***"A descriptive study to assess the perception regarding nursing profession among intermediate students of Lucknow, U.P."*** submitted by Ms. Shashi Gautam, Ms. Shikha Mall, Ms. Shikha Pal, Mr. Shiv Kumar Kushwaha, Ms. Shivani Verma, Ms. Shivanshi Srivastava, Mr. Shubham Pal, Ms. Sneha Verma, Mr. Subodh Kumar, Ms. Sushmita Tadav through their Guide Ms. Aditi Mecarty & Mrs. Jyoti Grace Masih, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1473/51/23 dated 4th October, 2023. ***Previous PGTSC Comment:*** • Kindly provide Patient Information Sheet as per EC SOP. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIC/P1***
23	Clarification of research proposal entitled ***"A study to assess the social stigma and familial attitudes related to infertility among women with infertility attending infertility clinic at Queen Mary Hospital, KGMU, Lucknow"*** submitted by Ms. Swati Mishra, Ms. Sweta Yadav, Ms. Tanu Yadav, Mr. Tanveer Rashid, Mr. Vaibhav Singh, Ms. Vibha Yadav, Mr. Sandeep Kumar through their guide Ms. Sarita Singh & Mrs. Mathivathani M, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1477/51/23 dated 4th October, 2023. ***Previous PGTSC Comment:*** • Kindly provide Patient Information Sheet as per EC SOP and brief plan of statistical analysis regarding establishing association & correlation between variables as stated in objectives of study. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIC/P2***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

24	Clarification of research proposal entitled ***"A study to assess the level of stress and coping strategies adopted by primigravida Mother admitted in antenatal ward, department of Obstetrics and Gynecology KGMU, Lucknow"*** submitted by Ms. Pratibha, Ms. Preeti Yadav, Ms. Priya Mishra, Ms. Priyanka Ghauhan, Ms. Priyanka Ghosh, Ms. Priyanshi Patel, Mr. Ravi Kumar, Ms. Reema, Ms. Rekha Singh, Ms. Renu Verma through their guide Mrs. Suman Lata, Clinical Instructor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1529/23 dated 11th October, 2023. ***Previous PGTSC Comment:*** • Kindly provide Patient Information Sheet as per EC SOP and brief summary of statistical analysis regarding establishing association & Plan analysis. • A Co-guide from Obst. & Gynecology may facilitate the project. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIC/P3***
25	Clarification of research proposal entitled ***"A study to assess the effectiveness of planned teaching programme on knowledge regarding prevention of coronary artery disease among obese patients at Medicine OPD of K.G.M.U., Lucknow, U.P."*** submitted by Ms. Ganga, Ms. Jyoti Agrahari, Ms. Jyoti Yadav, Mr. Kalishanker, Ms. Karuna Kushwaha, Ms. Anuradha Kushwaha, Ms. Apoorva Singh, Ms. Asha, Ms. Garima, Ms. Kanchan through their Guide Mr. Migron Rubin, Clinical Instructor, & Mrs. Priyanka Singh, Nursing Tutor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1500/51/23 dated 6th October, 2023. ***Previous PGTSC Comment:*** • Kindly provide the Patient Information Sheet as per EC SOP and anticipated plan of analysis descriptive and inferential statistics as mentioned in objectives. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XX-PGTSC-IIC/P9***
26.	Clarification of research proposal entitled ***"Prospective randomized study to evaluate the therapeutic effect of high volume v/s low volume caudal epidural injections in lumbar PIVD"*** submitted by Dr. Nilesh Kumar Singh, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1560/Ortho/23 dated 30th October, 2023. ***Previous PGTSC Comment:*** • There are eleven (11) investigators in the projects with 10 from the same department with overlapping roles.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Vulnerable subjects have been ticked 'No' but elderly has also been ticked. Please clarify. • Section on Consent is incomplete. • Sample size calculation has not been done. • Patient information sheet is incomplete/incorrect. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P1***
27	Clarification of research proposal entitled ***"Comparative evaluation of superficial and deep serratus anterior plane block for postoperative analgesia following modified radical mastectomy: A randomized controlled study"*** submitted by Dr. Shivendra Pratap Singh, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1771/23 dated 31st October, 2023. ***Previous PGTSC Comment:*** • Patient information sheet is incomplete/incorrect filled. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P2***
28	Clarification of research proposal entitled ***"Effect of dexmedetomidine, propofol, and midazolam on diaphragm function assessed by ultrasound in postoperative patients: A randomized comparative study"*** submitted by Dr. Jyoti Sharma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1745/23 dated 6th November, 2023. ***Previous PGTSC Comment:*** • Scientific review committee should be revised as the name and signature of Chief Guide (Prof. G. P. Singh) is there in present SRC report. • SOP-Checklist point no.-10, Risk & benefit–marked as risk is not reasonable – please clarify and properly mark the section -10. • In Inclusion/ Exclusion criteria- Pregnant & lactating women criteria not mentioned • As this is randomized study, PI must mention the method of randomization and attach the Flow chart of the study. • Case record form–not attached ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approved ***Ref. code: XXI-PGTSC-IIA/P4***
29	Clarification of research proposal entitled ***"Analgesic efficacy of ultrasound guided intre-semispinal plane block in lower cervical spine surgery: A randomized controlled study"*** submitted by Dr. Priyanshi Garg, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/592/23 dated 24th May, 2023. ***Previous PGTSC Comment:*** • SRC should be revised as the name & signature of one of the Co-guide (Dr. Manish Singh) is there in present SRC report. • In Inclusion/ Exclusion criteria- Pregnant & lactating women criteria not mentioned • As this randomized study, PI must attach the Flow chart of the study. • In sample size – in the section of subject PI mentioned the age group of recruited subjects as 20-65 yrs. which is different than in Inclusion criteria (18-60 yrs.)- please rectify • Case record form–not attached ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P6***
30	Clarification of research proposal entitled ***"Effectiveness of prophylactic tranexamic acid for reducing blood loss in children undergoing wilms tumour surgery: A randomized control study"*** submitted by Dr. Shraddha Agarwal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1744/23 dated 6th November, 2023. ***Previous PGTSC Comment:*** • Study design is mentioned as Prospective randomized controlled study, however In study title PI mentioned only randomized controlled study - please correct the discrepancy. • As children of age below 10 years will be recruited therefore Guardian consent and Child Assent form should be attached instead of regular ICF in both English and Hindi version. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P7***
31	Clarification of research proposal entitled ***"Study of role of PRP (Platelet rich plasma)***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	in thin endometrium in patients with infertility: An open label randomized controlled trial" submitted by Dr. Payal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1935/23 dated 6th November, 2023. ***Previous PGTSC Comment:*** • In the consent form it is mentioned that there will be no complications. It needs to be corrected as the procedure will be performed and serum infused so there are chances of complications and the subject's needs to be informed. • Kindly modify the Inform Consent Form & Patient information sheet, Hindi & English both version. • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** • Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P8***
32	Clarification of research proposal entitled ***"Effect of adjunctive photodynamic therapy on inflammatory markerslevel in patients with apical periodontitis-A randomized control trial"*** submitted by Dr. Monika Kumari, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 428/Coms&Endo/23 dated 8th November, 2023. ***Previous PGTSC Comment:*** • Inclusion criteria and flow chart indicate **healthy patients;** an explanation for the term to be given. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** • Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P16***
33	Clarification of research proposal entitled ***"Role of injection optineuron on serum lactate levels in a patient undergoing surgery on cardio Pulmonary bypass machine"*** submitted by Dr. Nisah Razvi, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1790/23 dated 2nd November, 2023. ***Previous PGTSC Comment:*** • English and Hindi both patient information sheets to be prepared in a simplified and understandable language. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P22***
34	Clarification of research proposal entitled ***"Comparative evaluation of MTA, emdogain and human biological membrane as A pilpotomy agents in permanent teeth with irreversible pulpitis: A randomized controlled trial"*** submitted by Dr. Zoya Kidwai, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2246/Coms&Endo/23 dated 14th November, 2023. ***Previous PGTSC Comment:*** • Methodology incomplete, neither number of subjects to be taken in the study given nor that in different groups mentioned. Sample size calculation not provided. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** • Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P42***
35.	Clarification of research proposal entitled ***"Comparison of efficacy of two prophylactic antibiotic regiments for PPROM-A randomized controlled trial"*** submitted by Dr. Jyoti, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/2001/23 dated 10th November, 2023. ***Previous PGTSC Comment:*** • In SOP-Checklist-Point no-7 –Use of biological/hazardous materials–mentioned–No, but Blood, Urine, Vaginal fluid will be taken from patients for investigation-PI to correct. • In Title Abbreviations should be avoided–as PPROM in the present title-Please correct it. • In Inclusion criteria–Age specificity has not been mentioned. • Review literature with references in Protocol is missing–Please include. • CRF- not attached ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** • Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P48***
36.	Clarification of research proposal entitled ***"Use of clinical nomogram with ICG based iymph node yield assessment in inguinal lymph node dissection in patients of carcinoma penis: A prospective observational study"*** submitted by Dr. Harsh, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	letter no. 2972/SY/23 dated 4th November, 2023. ***Previous PGTSC Comment:*** • Section on 'Biological/hazardous material' is ticked as 'No' but lymph node dissection/biopsy is part of the project. • Patient information sheet is incomplete. • No Patient information sheet in Hindi has been attached. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** • Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P50***
37.	Clarification of research proposal entitled ***"Efficacy of early versus expectant artificial rupture of membranes in reducing induction delivery interval following cervical ripening by combined misoprostol and mechanical method: A randomized controlled trial"*** submitted by Dr. Arti Verma, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/2002/23 dated 10th November, 2023. ***Previous PGTSC Comment:*** • In SOP-Checklist point no-3, clinical trial–marked as NA (As this study is RCT, please correct, Point no.5 Vulnerability–marked as–No, but pregnant women are to be recruited-Please revise SOP Checklist • CRF-Not attached ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** • Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P51***
38.	Clarification of research proposal entitled ***"Knowledge, attitude and practices of hereditary Gynaecological cancer among high risk women"*** submitted by Dr. Bhavya Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1824/23 dated 2nd November, 2023. ***Previous PGTSC Comment:*** • The Hindi consent form needs to be written in a simple and understandable language. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** • Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P66***
39.	Clarification of research proposal entitled ***"A prospective study to determine indications,***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	procedures and outcome of gynecological endoscopic surgeries" submitted by Dr. Km. Juhi Meena, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1922/23 dated 8th November, 2023. ***Previous PGTSC Comment:*** • There are too many objectives. • Identify one primary objective and the rest should be listed as secondary objectives. • The primary objective should be converted into a proper research hypothesis, which will be defined in terms of the study variables and study parameters. • Sample size calculation is arbitrary. It should be specific to the research hypothesis defined in Step 3. • Statistical analysis section is missing. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P71***
40	Clarification of research proposal entitled ***"Association of frailty assessment tools and postoperative outcomes in elderly patients undergoing elective surgery: A prospective observational study"*** submitted by Dr. Kaushal Kasaudhan, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1835/23 dated 4th November, 2023. ***Previous PGTSC Comment:*** • The primary objective should be rephrased as "To find prevalence of abnormal results……..". • The sample size calculation is not clear. The parameter p should be explicitly defined. • Statistical analysis section is very general. It is a prevalent study. There is lot of statistical tests mentioned here. Will they really be done here? ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P73***
41	Clarification of research proposal entitled ***"Unlocking stature: hand and handprint insights in estimating stature among North Indians"*** submitted by Dr. Priya Devi, JRIII, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1922/OP/23 dated 3rd November, 2023. ***Previous PGTSC Comment:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• There is no cohesion between the title, aim and objectives. • The title says: Estimating Stature…. • The aim says: Generate population specific regression models…. • The objectives describe taking different kind of measurements. • In the absence of proper research hypothesis, a study can not be planned. • Identify primary objective, identify the study variables and parameters. • Formulate the research hypothesis in terms of study parameters. • Everything should be centered around the research hypothesis, including sample size calculation, methodology and statistical analysis. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P76***
42	Clarification of research proposal entitled ***"Lymphatic function and arm morbidity after mini-LD flap reconstruction post modified radical mastectomy (MRM)"*** submitted by Dr. Pankaj Kumar, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 297/SY/23 dated 4th November, 2023. ***Previous PGTSC Comment:*** • Sample size justification/calculation has not been done. • Patient information sheet is incomplete ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P79***
43	Clarification of research proposal entitled ***"Effect of dexmedetomidine as an adjuvant in superficial cervical plexus block, for perioperative analgesia in patients undergoing thyroidectomy surgery under TIVA"*** submitted by Dr. N. Narasimhan, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1791/23 dated 2nd November, 2023. ***Previous PGTSC Comment:*** • In Title of the study abbreviations should be avoided, please write full form of TIVA in the title. • In Inclusion/ Exclusion criteria-Sex specification and Pregnant & lactating women criteria not mentioned. • In methodology section, method of blinding and randomization and Flow chart of the study is missing. • In tools- CRF, VAS score and Brussels sedation score–not attached - Please

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

	attach. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P83***
44.	Clarification of research proposal entitled ***"Comparison of i gel versus I gel plus in adult patients under controlled ventilation under general anesthesia: Randomised observational study"*** submitted by Dr. Shambhavi Jha, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1780/23 dated 30th October, 2023. ***Previous PGTSC Comment:*** • There is nothing like randomized observational study. • This is prospective cohort study, where two groups (cohorts) will be compared. • Define primary objective properly. It should be research question, not "Time for successful insertion". • Identify the study variables and study parameters. • Convert the primary objective into a proper research hypothesis using the study parameters of step 4. • Sample size calculation, methodology and statistical analysis should be in coherence to the research hypothesis. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P84***
45	Clarification of research proposal entitled ***"Comparative evaluation of periodontal health status in patients with interstitial lung diseases (ILD)"*** sponsored by ICMR STS submitted by Ms. Sakshi Khokhar, BDS through her Mentor Prof. Umesh Pratap Verma, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 3067/P/23 dated 7th November, 2023. ***Previous PGTSC Comment:*** • Total number of subjects need to replace 22 in annexure 1 pt5. • What will be the source of control subjects.? • Separate ICF & Patient information sheet for controls should also be enclosed both in English & Hindi. • Kindly summarize & categorize the anticipated outcome variables as per the 3 objectives of study. • Kindly elaborate the anticipated statistical analysis as per the 3 objectives of study.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• In ICF kindly revise the language of 'study procedures' in the way a patient or control subject can understand. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI -PGTSC-IIB-STS/P1***
46	Clarification of research proposal entitled ***"Evaluation of effect of periodontal treatment during III trimester on prevention of PT-LBW": A case control study"*** sponsored by CIMR-STS submitted by Ms. Shivani Belani, BDS III year student through her Mentor Prof. Anjani Kumar Pathak, Department of Perodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 3055/23 dated 6th November, 2023. ***Previous PGTSC Comment:*** • Kindly fill up point no11 in annexure 1. • In annexure 1 'Yes' is indicated for compensation of injury while indicated otherwise in ICF. • Kindly revise the contribution of investigators. Who will do patient recruitment & who will collect data. Also clarify as what do you mean by "conception.' (conception of idea or what?). • Regarding sample size calculation what is the criteria of RR being 4.21. • The para of "Ethical consideration" before reference section is confusing. It seems that some retrospective concent has been taken- if yes then for what? Kindly explain. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI -PGTSC-IIB-STS/P4***
47	Clarification of research proposal entitled ***"A study of adverse drug effects/adverse drug reactions in patients with Psychosis taking antipsychotics"*** submitted by Dr. Surya, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 831/Pharm/23 dated 9th November, 2023. ***Previous PGTSC Comment:*** • In Inclusion/Exclusion criteria-Sex specificity & Pregnant & lactating women criteria not mentioned. • In Tools-Brief Psychiatric Rating Scale and Hartwig's Severity assessment scale – not attached ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-***

(Hardeep Singh) Malhotra
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P27***
48	Clarification of research proposal entitled ***"Serial estimation of carboxypeptidase 1 & 2 in patient of acute pancreatitis: A new Diagnostic and prognostic Marker"*** submitted by Dr. Mohit Dilip Singh Verma, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 940/SY/23 dated 31st October, 2023. ***Previous PGTSC Comment:*** • There are too many objectives. • Identify one primary objective, and the rest should be listed as secondary objectives. • The primary objective should be converted into a proper research hypothesis, which will be defined in terms of the study variables and study parameters. • Sample size calculation is arbitrary. It should be specific to the research hypothesis defined in Step 3. • The method for grading the severity status should be explained. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P33***
49	Clarification of research proposal entitled ***"Effects of platelets rich fibrin & normal saline dressing in chronic wounds- A prospective randomized control trail"*** submitted by Dr. Dheerendra Kumar Mishra, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 2240/PMR/23 dated 3rd November, 2023. ***Previous PGTSC Comment:*** • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary in the absence of proper research hypothesis. The different quantities used in the formula are not clear. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. ***The above comment forwarded to the Principal-Investigator was reviewed by the***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	reviewer:- Provisionally approved **PGTSC Decision:** Approved *Ref. code: XXI-PGTSC-IIA/P57*
50	Clarification of research proposal entitled ***"Incidence of drug induced peripheral neuropathy in patients with drug susceptible and drug resistant pulmonary tuberculosis"*** submitted by Dr. Jay Prakash Shukla, JRI, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 870/Res/23 dated 23rd August, 2023. ***Previous PGTSC Comment:*** • In Scientific review committee report, the name and signature of one of the Co-PI (Prof. Surya Kant) is there- please revise SRC. • In SOP-Checklist--point no.7-use of biological /hazardous material–is ticked as NO-, but according to protocol , investigations will be done with the help of blood sample –please revise the point-7 of SOP-Checklist. • In Inclusion/ Exclusion criteria- Sex specification and Pregnant & lactating women criteria not mentioned. • Study design mentioned is Case control study–where are the control subjects ,both are the cases and Duration of study mentioned is from September 2022 to August 2023 – whether it is retrospective or prospective study–PI to clarify the study design and duration period of the study. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer:-*** Provisionally approved **PGTSC Decision:** Approved *Ref. code: XXI-PGTSC-IIA/P86*
IB	**Expedited review**
1	Expedited review research proposal entitled ***"To study effect of examination stress on autonomic function and salivary pH among medical Students"*** submitted by Ms. Pragti Maurya, MBBS through her Mentor Prof. Dileep Kumar Verma, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3358/PHY/23 dated 18th September, 2023. ***The above research proposal was forwarded to two reviewers:-*** **Recommendation of Primary reviewer:-** • Name of person responsible in biochemistry for pH measurement. • The level of examination needs to be mentioned such as lab viva, terminal examination, formative assessment etc. • Kindly attach PSQI form. **Recommendation of Secondary reviewer:-** • It is advisable that the name of person (faculty or technician) responsible for

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	salivary pH estimation from the Department of Biochemistry, KGMU should be given in the project-PI to justify. • Tool-Pittsbrug sleep quality index chart-not attached. ***The above comments were forwarded to* Secondary reviewer, *for review.*** ***Recommendation of Secondary reviewer:-*** • Provisionally approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IB-STS/P1***
2-	Expedited review research proposal entitled ***"Relationship between dental anxiety and oral health awareness in patients visiting dental school in North India"*** submitted by Ms. Samreen Hussain, BDS through her Mentor Prof. Deeksha Arya, Department of Prosthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 385/23 dated 16th September, 2023. ***The above research proposal was forwarded to two reviewers:-*** **Recommendation of Primary reviewer:-** • Gone through the proposal. Overall it is fine. But as anxiety is going to be assessed therefore it will be better if a Co-PI is included from the Department of Psychiatry. That will help in better evaluation of the anxiety score. ***The above comments forwarded to Principal-Investigator, response has given by the Primary reviewer Principal-Investigator which was forwarded to Primary reviewer:-*** **Recommendation of Primary reviewer:-** Reply awaited for **Recommendation of Secondary reviewer:-** • Approved **PGTSC Decision:** Provisionally approved ***Ref. code: XXII-PGTSC-IB-STS/P2***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"Evaluation of aloe vera loaded nanofibrous scaffold in vital pulp therapy: A randomized controlled trial"*** submitted by Dr. Anjali Mall, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 311/Cons&Endo/23 dated 14th September, 2023. ***Recommendation of reviewer:*** • The title mentions that the study is an RCT. If it is a Trial, it will need a CTRI registration, a CONSORT statement and submission for a full Committee meeting. Otherwise please change the title to Randomization Control study. • Sample size mentions 20 patients in each group but the total sample size is also 20. Please correct this. • Section on Consent is incomplete. • Age group in Material and Methods is 18-40 years and that in the inclusion

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	criteria is 17-57 years. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P1***
2.	Research proposal entitled ***"To determine the antivasoplegic effect of intervenous ketamine in septic shock in ICU patients: A prospective comparative trial"*** submitted by Dr. Yogesh Kumar M, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/601/23 dated 24th June, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Microbiological & histopathological study of chronic dacryocystitis at a tertiary care centre in Northern India"*** submitted by Dr. Niraj Kumar Yadav, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 7525/23 dated 19th September, 2023. ***Recommendation of reviewer:*** • Section on Biological material is marked as NA, whereas the title is microbiological and histopathological study. • Sample size calculation has not been done/shown. • Patient Information Sheet is incomplete. • Risk mentioned as 'Unacceptable' in IEC form. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Study of perception of respectful maternity care amongst post natal women before and after training of healthcare workers"*** submitted by Dr. Monika Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1190/23 dated 22nd August, 2023. ***Recommendation of reviewer:*** • Identify one primary objective and the rest should be marked as secondary objective. • Convert the primary objective, which is based on pretest posttest design, into proper research hypothesis in terms of study variables and parameters. • The sample size calculation is incorrect. It is for prevalence study. • The statistical analysis section is incomplete. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P4***
5.	Research proposal entitled ***"Study of adverse cardiac events and interventions in***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

	pregnant women with heart disease" submitted by Dr. Shashi, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1184/23 dated 22nd August, 2023. ***Recommendation of reviewer:*** • Identify one primary objective and the rest should be marked as secondary objective. • Identify the study variables and study parameters. • Convert the primary objective, into proper research hypothesis in terms of study variables and parameters. • Sample size is mentioned as approximately 186 patients. Then at another place it is calculated as 120 patients. What are the different quantities in sample size calculation? Clarify it. • The statistical analysis section is general. It should be specific to the primary and secondary objectives of the study. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Observational study of acceptability compliance and side effects of contraceptives antara (Depot Medroxyprogesterone Acetate) and chhaya (Centchroman) at a tertiary care centre"*** submitted by Dr. Namita, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1185/23 dated 22nd August, 2023. ***Recommendation of reviewer:*** • Sample size calculation not done (only total sample size-356 is given) • In Inclusion criteria –Age group of the patients not mentioned. • Case record form not included. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P6***
7.	Research proposal entitled ***"A study of 24 hr ambulatory blood pressure, salivary cortisol and urinary melatonin in subjects with acute stroke"*** submitted by Dr. Isha Atam, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3366/PHY/23 dated 19th September, 2023. ***Recommendation of reviewer:*** • Methodology for biochemical estimations (Salivary cortisol/urinary melatonin) not provided. • Consent form in Hindi is written in first person (Stroke patients may not be able to give consent) • Consent form in English is incomplete. **PGTSC Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Apparently, there is **"Conflict of interest"** between the JR-I & Co-PI, Kindly modify. **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Role of biomarkers angiopoietin 1 and 2 in prediction of malaria illness"*** submitted by Dr. Unnati Chaudhary, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 491/23 dated 19th July, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P8***
9.	Research proposal entitled ***"An observational study on drugs causing liver injury, its clinical patterns and severity in a tertiary care Hospital in Northern India"*** submitted by Dr. Fatima Rani, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 596/Pharm/23 dated 16th August, 2023. ***Recommendation of reviewer:*** • Identify one primary objective, and the rest should be marked as secondary objective. • Identify the study variables and study parameters. • Convert the primary objective into proper research hypothesis in terms of study variables and parameters. • The objectives mentioned do not pose a research question. These looks to be statements only. • The Sample size calculation is arbitrary. It should be specific to the research hypothesis formulated in step 3. • The statistical analysis section is general. It should be specific to the primary and secondary objectives of the study. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P9***
10.	Research proposal entitled ***"An observational study to monitor antimicrobial prescribing drug pattern and associated adverse drug reaction among the patients admitted in intensive care units of a tertiary care Hospital in Northern India"*** submitted by Dr. Shubham Biswas, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 724/Pharm/23 dated 18th September, 2023. ***Recommendation of reviewer:*** • Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	PGTSC Decision: Approved ***Ref. code: XXII-PGTSC-IIA/P10***
11.	Research proposal entitled ***"An observational study on comparison of efficacy, safety, cost effectiveness and Impact on quality of life of montelukast levocetirizine combination vs montelukast-bilastine combination therapy in patients of allergic rhinitis"*** submitted by Dr. Debendra Suman, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 726/Pharm/23 dated 18th September, 2023. ***Recommendation of reviewer:*** • Identify one primary objective, and the rest should be marked as secondary objective. • Identify the study variables and study parameters. • Convert the primary objective into proper research hypothesis in terms of study variables and parameters. • This is a prospective cohort comparative study. Everything should be planned accordingly. • The Sample size calculation is arbitrary. It should be specific to the research hypothesis formulated in step 3. • The statistical analysis section is general. It should be specific to the primary and secondary objectives of the study. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P11***
12.	Research proposal entitled ***"Clinical audit of maternal and fetal outcome in pregnancies following artificial reproductive Technology"*** submitted by Dr. Shweta Priya, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/ 1181/23 dated 22nd August, 2023. ***Recommendation of reviewer:*** • Study involves pregnant women and their fetuses. The section on vulnerable participants does not mention this. • Patients Information Sheet is incomplete/improperly filled. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P12***
13.	Research proposal entitled ***"Mullerian anomalies diagnosis, management, with its impact on the quality of life-A retrospective study"*** submitted by Dr. Nivedita Prakash, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/ 1188/23 dated 22nd August, 2023. ***Recommendation of reviewer:*** • Seal of Chairperson in Scientific review committee is absent.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The study period in annexure 1 patient 5 states is 1.5 years while elsewhere it is year. Kindly resolve the confusion. • Is the risk not reasonable compared to anticipated benefits? (Annexure 1 patient 10) • What are the anticipated adverse events that need to be reported to IEC? (Annexure 1 patient 11) • While study design is reported as "Retrospective", the inclusion criteria includes all new cases in the upcoming year. Why this confusion? • The outcomes are confusing. Kindly indicate all the primary & secondary out-comes point wise. • Kindly brief the statistical analyses in reference to out come variables. • Kindly eneumerate the anticipated common association with mulleran anomalies. Elaborate their assessment. • Kindly provide the details of the questionnaire used for detailed assessment including the quality of life. • The methodology should include all the steps of data collection needed to achieve the desired outcomes. • In ICF 'Study procedures' & 'Benefits from study' need to be re-written, elaborated and in the language which patient can better understand. • Patient information sheet is to be carefully re-written completely in a customized fashion and excluding the pregnant women with heart disease. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P13***
14.	Research proposal entitled ***"Efficacy of epidural transforaminal injection of ozone in comparison with transforaminal PRP (Platelet Rich Plasma) injection in the management of chronic low back radicular pain: one year prospective randomized control study"*** submitted by Dr. Karthickraja, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/572/23 dated 24th June, 2023. ***Recommendation of reviewer:*** • Methodology for preparation of PRP not given. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XXII-PGTSC-IIA/P14***
15.	Research proposal entitled ***"Open label randomized control trial to compare efficacy of letrozole with misoprostol vs mifepristone with misoprostol for medical termination of pregnancy"*** submitted by Dr. Arusha Tiwari, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/315/23 dated 24th June, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

	Recommendation of reviewer: • Seal of Chairperson in scientific review committee is missing. • Annexure 1 patient 5 states that sample size is only 58 but sample size indicates 58 per group. Similarly the study period in annexure 1 patient 5 is 1.5 years while elsewhere it is 1 year. Kindly resolve the discrepancy. • Is the risk not reasonable compared to anticipated benefits? (Annexure 1 patient 10) • What are the anticipated adverse events that need to be reported to IEC? (Annexure 1 patient 11) • Kindly complete the check list part of Annexure 1. • If this a RCT then refer to CONSORT statement for further refirement. • The text in sample size calculation is printed carelessly. Kindly correct. • Being RCT, kindly mention about allocation & randomization method to be followed. Also submit the methodology in a flowchart format. • Are there only 2 outcome variables? If more mention them • Elaborate the anticipated statistical data management analysis as per the outcome variables. • In ICF the 'Study procedures' & 'Benefits of study' need to be re-written, elaborated & in the language that patient can better understand. • Patient information sheet is totally wrong and cannot be accepted. Regretfully the patient information sheet of another study from QMH (Dr. Nivedita Prakash) is identical with this submission. Kindly rewrite in a customized fashion, according to submitted project. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P15***
16.	Research proposal entitled ***"Preoperative factors predicting close/positive surgical margins in oral cancer-A retrospective cohort study"*** submitted by Dr. Akanksha Singh, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 745/SY/23 dated 30th July, 2023. ***Recommendation of reviewer:*** • Sample size calculation has not been done. Patient Information Sheet is incomplete/incorrectly filled. **PGTSC Decision:** Approval subject to modification. ***Ref. code: XXII-PGTSC-IIA/P16***
17.	Research proposal entitled ***"Evaluation of oral health care practice and awareness among health care Students in Lucknow"*** submitted by Dr. Mohit Kumar Kanoujia, JRI,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Department of Public Health Dentistry, King George's Medical University, U.P., Lucknow vide letter no. 606/PHD/23 dated 26th September, 2023. ***Recommendation of reviewer:*** • Both Co-guides has similar role. • No stamp on SRC. • Title of the study needs correction. • There are many objectives; it should be restricted to 1-2 objectives. • Sentences written in the inclusion/ exclusion criteria of the study are in present and past tense which needs to be recomposed. • In the study procedure it is written that *a pilot study on 30 subjects has been done for the validation and reliability of the study tool…* is the questionnaire developed by the investigator; if yes, what tests of reliability and validity were applied? • The flowchart written with procedure portrays selection of study population=Lko….and training and calibration of personnel …? Needs clarification. • There is no mention about how the study participants will be identified and recruited for the study? • As this study is to be done on students medical, dental and nursing students there will be no need to provide *guidelines for patient information sheet*, if PI wishes to provide any information to the participants it may be tailored as participant's information sheet. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P17***
18.	Research proposal entitled ***"Efficacy of bempedoic acid as an add on therapy for achieving LDL cholesterol goals in secondary prevention in atherosclerotic cardiovascular disease patients on maximally tolerated doses of statins"*** submitted by Dr. Gargi Gupta, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 725/Pharm/23 dated 18th September, 2023. ***Recommendation of reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P18***
19.	Research proposal entitled ***"Prevalence of aspergillus sensitization and ABPA in Asthmatic patient"*** submitted by Dr. Vishal Shukla, JRI, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 532/ResMed/23 dated 26th September, 2023. ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

	• The Scientific review committee does not have seal of Chairperson. • Annexure 1 point 7 states that 'no body fluids or tissue' is to be taken. Then how will 1gE be measured? • Is the risk not reasonable as compared to anticipated benefits? (Annexure 1 point 11) • What are the anticipated adverse events that need to be reported to IEC? (Annexure 1 point 11) • Revise the ICF so that patient may better understand specially the study procedures. • Patient information sheet is for pleural effusion (point 4 & 5)? What is the role of biopsy? If biopsy is to be under taken then kindly mention in annexure 1 point 6 does not make any proper sense. Kindly re-write the entire Patient information sheet (both English & Hindi version) • Kindly indicate in which body tissue 1gE will be estimated. • Kindly given details of ACT 7 GINA 16 ptom control. • Kindly summarize the various outcome variables and statistical analysis as those variables. • Kindly summarize methodology in PICO format. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P19***
20.	Research proposal entitled ***"To study the prognostic indicators for mortality in cases of acute exacerbation of COPD"*** submitted by Dr. Abhishek Shukla, JRI, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 533/ResMed/23 dated 26th September, 2023. ***Recommendation of reviewer:*** • Number of subjects is given as 100 in IEC form and 60 in the sample size calculation. Please specify. • Methodology mentions that the study is prospective but the data being collected is retrospective. • Patient Information Sheet is incomplete. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P20***
21.	Research proposal entitled ***"Role of fetal head circumference-to-maternal-height ratio in predicting cesarean section for labor dystocia"*** submitted by Dr. Garima Singh, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/210/23 dated 6th September, 2023. ***Recommendation of reviewer:*** • In the informed consent form under the heading benefits of study language is not

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	clear. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to modification ***Ref. code: XXII-PGTSC-IIA/P21***
22.	Research proposal entitled ***"Efficacy of Olanzapine versus Lorazepan for management of breakthrough chemotherapy induced vomiting in Childhood cancer patients: An open label, quasi randomized, pilot study"*** submitted by Dr. Meenakshi, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2956/Ped/23 dated 30th August, 2023. ***Recommendation of reviewer:*** • This is a prospective cohort comparative study. Everything should be planned accordingly. **PGTSC Comment:** Approval subject to modification ***Ref. code: XXII-PGTSC-IIA/P22***
23.	Research proposal entitled ***"Assessment of diaphragm and peripheral muscle using ultrasonography in extubation"*** submitted by Dr. Smriti Khare, SRI, Department of Pulmonary & Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. 884/PCCM/23 dated 3rd October, 2023. ***Recommendation of reviewer:*** • In Scientific review committee (SRC) the name and signature of one of the Co-PI (Dr. Ved Prakash) is also there. PI should revise the SRC • Sample size calculation not done (only total patient number -20 is given) • As the age of the recruited children given is 12 yrs. therefore Child Assent Form (E/H) instead of regular ICF should be attached • Case record form not attached. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P23***
24.	Research proposal entitled ***"Molecular screening for group B streptococci in pregnant women in a tertiary care Hospital"*** submitted by Dr. Rosalie Yekali Chishi, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 786/23 dated 29th September, 2023. ***Recommendation of reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P24***
25.	Research proposal entitled ***"Study of cognitive functions and heart rate variability in reproductive age group and post-menopausal women"*** submitted by Dr. Akansha, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3384/PHY/23 dated 29th September, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 8th December, 2023

	Recommendation of reviewer: Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P25***
26.	Research proposal entitled ***"Effect of androgen deprivation therapy on bone density in carcinoma prostate patients"*** submitted by Dr. Kaneeze Fatma, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3383/PHY/23 dated 27th September, 2023. ***Recommendation of reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P26***
27.	Research proposal entitled ***"Study the effect of high intensity interval training and moderate intensity continuous training on Pulmonary functions in College Students"*** submitted by Dr. Manish Kumar, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3384/PHY/23 dated 27th September, 2023. ***Recommendation of reviewer:*** Approved **PGTSC Comment:** As above **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P27***
28.	Research proposal entitled ***"Comparative analysis of mouth self-examination awareness amongst tobacco consumers in urban and rural populations of Lucknow"*** submitted by Dr. Aman Rajput, JRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 515/PHD/23 dated 22nd August, 2023. ***Recommendation of reviewer:*** • No stamp on covering and SRC. • Study aim should be re-framed as written in past tense. • Patients are to be taken from OPD of KGMU too, where patients come from different places. A clear mention in the inclusion criteria regarding patient recruitment would be better. • The study duration is only 3 months and 300 rural/ urban patients are to be recruited, will it be feasible for the PI to complete the task in the said period. • Consent form to be written in an understandable language. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P28***
29.	Research proposal entitled ***"Analysis of gait in type-2 diabetes milletus with sarcopenia and without sarcopenia"*** submitted by Dr. Seema Tewari, JRI, Department of

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3389/PHY/23 dated 3rd October, 2023. ***Recommendation of reviewer:*** • The name of the Department of Physical Medicine and Rehabilation needs to be corrected in the methodology as it is mentioned as Rehabilitation centre at two places. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to clarification ***Ref. code: XXII-PGTSC-IIA/P29***
30.	Research proposal entitled ***"To study the association of serum immunoglobulin G levels with outcome of Hospitalized cases of WHO defined severe community acquired pneumonia"*** submitted by Dr. Aaradhya Shukla, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3257/Ped/23 dated 4th October, 2023. ***Recommendation of reviewer:*** • The Scientific Committee report in unsigned. • The Principal guide Dr.S.Awasthi has superannuated and since Dr. Mala Kumar is new Principal-Investigator guide the submitted documents need to reflect the same. • The consent form in Hindi is incomplete. • The Patient information sheet needs to be submitted as per SOP of EC, KGMU. • The details of Patient Information Sheet need to be filled up in Annexure 1. • Kindly enclose details of PRISM -3 severity scoring. • Since this study on children involves even revise & re-submit of 2m age, an assent form needs to be submitted. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P30***
31.	Research proposal entitled ***"Study of P 100 wave latency of visual evoked potential test in persons with recently diagnosed type 11 diabetes mellitus as early diagnostic tool for diabetic retinopathy"*** submitted by Dr. Riya Raj, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3396/PHY/23 dated 3rd October, 2023. ***Recommendation of reviewer:*** • In Inclusion criteria the Age group of the patients not mentioned • Why not Co-PI from Ophthalmic department is included for better clinical interpretation - PI to justify. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XXII-PGTSC-IIA/P31
32.	Research proposal entitled ***"Effect of long-term use of electroacoustic devices on hearing of healthy young adults"*** submitted by Dr. Sunil Kumar Paharia, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 1303/23 dated 3rd October, 2023. ***Recommendation of reviewer:*** • Hypothesis and primary objective do not match. These are stating different statements. • Identify the study variables and study parameters. • Convert the primary objective into proper research hypothesis in terms of study variables and parameters. • The Sample size calculation is arbitrary. It is for prevalence study. It should be specific to the research hypothesis formulated in step 3. • The statistical analysis section is general. It should be specific to the primary and secondary objectives of the study. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format.
	Ref. code: XXII-PGTSC-IIA/P32
33.	Research proposal entitled ***"Efficacy of time restricted eating in patients of non-alcoholic fatty liver disease-A chronophysiological interventional study"*** submitted by Dr. Shaiphali Sharma, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3388/PHY/23 dated 3rd October, 2023. ***Recommendation of reviewer:*** • This is a prospective cohort comparative study. Everything should be planned accordingly. • Identify the study variables and study parameters. • Convert the primary objective into proper research hypothesis in terms of study variables and parameters. • The Sample size calculation is arbitrary. It should be specific to the research hypothesis formulated in step 3. • The statistical analysis section is missing. It should be specific to the primary and secondary objectives of the study. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format.
	Ref. code: XXII-PGTSC-IIA/P33
34.	Research proposal entitled ***"Effect of moderate intensity continuous training on heart rate variability in college students"*** submitted by Dr. Nupoor Srivastava, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3390/PHY/23 dated 3rd October, 2023. ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P34***
35.	Research proposal entitled ***"Brainstem evoked response audiometry in young adults with prolonged usage of ear phone"*** submitted by Dr. Ashutosh Singh, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. nil dated 3rd October, 2023. ***Recommendation of reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P35***
36.	Research proposal entitled ***"Application of molecular methods to detect common pathogens in patients presenting with sore throat"*** submitted by Dr. Prerna Singh, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 545/23 dated 31th July, 2023. ***Recommendation of reviewer:*** • In Scientific review committee (SRC) the name and signature of three Co-PIs (Prof. Amita Jain , Prof. Vimala Venkatesht and Dr. Sheetal Verma) is also there. PI should submit the revise SRC report • In Inclusion/ Exclusion criteria –Pregnant & lactating women criteria not mentioned • As the all age group patients to be recruited in the study therefore , Child Assent Form , Guardian consent form apart from regular ICF (in both E/H versions) to be submitted (Presently only regular ICF with mention of guardian consent only in English version has been submitted).Case record form –not attached **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P36***
37.	Research proposal entitled ***"Perceived social support, subjective well-being, coping styles, personality traits, and social media addiction among the patients with major depressive disorder-An observational study"*** submitted by Dr. Shubhra Pandey, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1112/Psy/23 dated 19th July, 2023. ***Recommendation of reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P37***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

38.	Research proposal entitled ***"A prospective study on serosurveillance of pertussis among healthcare worker at a tertiary care Hospital in Lucknow"*** submitted by Dr. Shoa Zehra, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 492/23 dated 19th July, 2023. ***Recommendation of reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P38***
39.	Research proposal entitled ***"Correlation of hand and foot dimensions with stature for their identification in age group between 19-30 years"*** submitted by Dr. Harshita, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 328/FMT/23 dated 15th September, 2023. ***Recommendation of reviewer:*** • As this study is on living subjects (ICFs are included) then why PI in exclusion criteria mentioned about decomposed bodies/unknown, unclaimed bodies. • Informed consent forms in English and Hindi versions are not similar. **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P39***
40.	Research proposal entitled ***"Utility of molecular over traditional diagnostic method in diagnosis and management of ventilator-associated pneumonia caused by gram negative bacteria in intensive care unit"*** submitted by Dr. Krishna Priya Agrawal, SRI, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1916/23 dated 16th October, 2023. ***Recommendation of reviewer:*** • While duration of study in Annexure 1 is indicated as 2 years while elsewhere it is 1 year. Kindly resolve/clarify. • Patient information sheet (both English & Hindi version) need to be re-written as per the SOP of K.G's Medical University. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P40***
41.	Research proposal entitled ***"Mechanical power (MP) as a predictor of outcome in patients with moderate to severe traumatic brain injury (TBI) a prospective observational study"*** submitted by Dr. Neeraj Kumar, SRI, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1830/23 dated 14th September, 2023. ***Recommendation of reviewer:*** • IEC form mentions selection of vulnerable subject like mentally challenged, illiterate and terminally ill patients. In this case the consent of an LAR will be required.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Section on Biological material mentions 'banking for future research'. What will be stored for future research? • Section on Data Monitoring mentions presence of DSMB. The University has no DSMB. Where will adverse events be reported? • Sample size in IEC form is mentioned as 80-120, whereas in the synopsis it is mentioned as 120. Please specify. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P41***
42.	Research proposal entitled ***"Prevalence, risk factors and outcomes of acute kidney injury in full term neonates admitted to NICU"*** submitted by Dr. Nitika Chauhan, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2778/Ped/23 dated 4th September, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P42***
43.	Research proposal entitled ***"To study frequency of delamanid resistance among multidrug resistant mycobacterium tuberculosis isolates from pulmonary samples"*** submitted by Dr. Pyare Lal Gupta, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 764/23 dated 26th September, 2023. ***Recommendation of reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P43***
44.	Research proposal entitled ***"Study of sexual dysfunction in clinically stable patients with bipolar affective disorder receiving valproate"*** submitted by Dr. Rishabh Tiwari, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1111/Psy/23 dated 19th July, 2023. ***Recommendation of reviewer:*** • Role of PI needs to be reconsidered, Chief supervisor and supervisor have similar role. • In IEC format no of participants to be written as provided in the proposal i.e. 110. • Hindi ICF needs to be written in a simple and understandable language. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P44***
45.	Research proposal entitled ***"A comparative evaluation of periodontal health and clinical success of prefabricated stainless steel crown, zirconia and edelweiss crowns in primary molars: A randomized clinical trial"*** submitted by Dr. Mayank Goel, JRI,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 292/23 dated 5th September, 2023. ***Recommendation of reviewer:*** Approved **PGTSC Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P45***
46.	Research proposal entitled ***"Assessment of awareness and attitude regarding early Childhood caries among parents of Pre-School Children attending Pediatric OPD:A cross-sectional study"*** submitted by Dr. Deepak S, JRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 560/PHD/23 dated 13th September, 2023. ***Recommendation of reviewer:*** • Both supervisors have similar role. • In the role of supervisors' sheet Dr. Sumit is given chief supervisor role but the Annexure: 1 RV confirms Dr. Gaurav Mishra as chief supervisor….needs clarification and correction. • There is no one from the pediatrics dept and participants are to be recruited from there. • Study procedure needs a re-check, as sentences are in past tense. • Study duration is 3 months, 500 participants are to be recruited; is it feasible? • Translation to Guidelines for Patient Informaion Sheet to be translated as मरीज की सूचना/ जानकारी हेतु दिशानिर्देश या मार्गदर्शिका not मार्गदर्शिका प्रिय प्रयोगशाला के .....Further, this study is neither a clinical trial nor to be done on patients so it can be removed. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P46***
47.	Research proposal entitled ***"A comparative evaluation of concentrated platelet rich fibrin and calcium silicate based cement in pulpotomy of permanent teeth using laser-A randomized control trial"*** submitted by Dr. Himi Rathore, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 334/Coms&Endo/23 dated 21st September, 2023. ***Recommendation of reviewer:*** • Seal of Chairperson in Scientific Committee report is missing. • Patient 4 of Annexure 1 should be elaborated as required in protocol-Kindly rewrite. • While patient age group is mentioned as 15-25 years, on the other hand age criteria are stated as 18-45 years-Kindly clarify.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

52.	Research proposal entitled ***"Effect of duration of type 2 diabetes mellitus on impairment of lung functions: A cross sectional study"*** submitted by Dr. Abhishek Kumar Singh, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3400/PHY/23 dated 4th October, 2023. ***Recommendation of reviewer:*** • Is the project already reviewed? There is a paper just after covering letter indicating PGTSC comment. • What method was applied to calculate the sample of the study? Sample size not provided in IEC. • Hindi consent to be written in an understandable language. **PGTSC Comment:** As above **PGTSC Decision:** Modified & re-submit with response to queries in tabular format. ***Ref. code: XXII-PGTSC-IIA/P52***
II-B	**IMR- Resident**
1-	Research proposal entitled ***"Sulfiredoxin levels in chronic periodontitis and healthy patients: A case control study"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow U.P submitted by Dr. Disha Dixit, JRI through her Mentor Prof. Shalini Kaushal, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1331/P/23 dated 2nd August, 2023. ***Recommendation of reviewer:*** • Sample size discrepancy in SOP-Checklist (30 Pts in each group) and in Protocol (20 Pts in each group)-PI to correct or clarify • How Plaque and Gingival index will be assessed–PI to clarify. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to clarification ***Ref. code: XXII-PGTSC-IIB-IMR-R/P1***
II-B	**MHA**
1.	Research proposal entitled ***"A study on radiation safety in Radiodiagnosis Department of a tertiary care Government Teaching Hospital, Lucknow"*** submitted by Dr. Stuti Mishra, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/445/23 dated 11th September, 2023. ***Recommendation of reviewer:*** • Methodology needs corrections as written in past tense. • Study required waiver that may be given. **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to clarification ***Ref. code: XXII-PGTSC-IIB-MHA/P1***
II-B	**Research proposal for STS grant**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

1.	Research proposal entitled ***"A study to estimate the level of total serum bile acids and delta bilirubin in intrahepatic cholestasis of pregnancy"*** sponsored by ICMR STS submitted by Ms. Apoorva Sharma, MBBS through her Mentor Dr. Kalpana Singh, Additional Professor & Head, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/651/23 dated 23rd September, 2023. ***Recommendation of reviewer:*** • In Inclusion criteria age group of pregnant women to be recruited is not mentioned • Sample size calculation not given (Only 40 cases & 40 control is given) **PGTSC Comment:** As above **PGTSC Decision:** Approval subject to clarification ***Ref. code: XXII -PGTSC-IIB-STS/P1***
III-A	**Additional Document**
1.	Additional of research proposal entitled ***"Measurement of changes in blood flow across coronary sinus using transoesophageal echocardiography post coronary artery bypass grafting: A single center observational study"*** submitted by Dr. Himanshu Sharma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1266/23 dated 23rd September, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XIV-PGTSC-IIA/P8***
III-B	**Modification**
1.	Modification of research proposal entitled ***"A cross sectional study of stress, self esteem, life satisfaction and subjective happiness in students of Medical Colleges of Lucknow"*** submitted by Dr. Divyansh Singh, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 814/CM/23 dated 14th October, 2023. ***Recommendation of reviewer:*** • Approved **PGTSC Decision:** Approved ***Ref. code: XVI-PGTSC-IIA/P59***

The next meeting shall be held on 12th January, 2024 in hybrid mode from 2.00 p.m. in the Board-Room, Administrative Block, KGMU, UP, Lucknow.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 129th IEC Meeting held on 12th January, 2024

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the 129th Institutional Ethics Committee Meeting held on **12th January, 2024 from 02:30 P.M. till 5:00 P.M.** in the Board-Room, Administrative Block, King George's Medical University, U.P., Lucknow in ***hybrid mode.***

The following Members were present in the Meeting:-

1. Dr. Alok Dhawan -Chairman
2. Smt. Akansha Dubey -Member
3. Mr. Ujjawal Krishna -Member
4. Dr. G.G. Agarwal -Member
5. Dr. Akash Agarwal -Member
6. Dr. K.K. Yadav -Member
7. Smt. Vasundhara Kumari -Member
8. Dr. A.A. Mahdi -Member
9. Dr. Rajendra Nath -Member
10. Dr. Anupam Mishra -Member
11. Dr. Nisha Mani Pandey -Member
12. Dr. Anita Rani -Member
13. Dr. D.N. Upadhyaya -Additional Member-Secretary, IEC
14. Dr. Hardeep Singh Malhotra -Member-Secretary, IEC, ex-officio

The following Member was not present in the Meeting:-

1. Dr. Shubha R Phadke

	Action Taken
1-	Clarification of modified research protocol version 3.1.2 entitled "***Evaluate the effectiveness, safety and tolerability of various doses of linezolid in combination with bedaquiline and pretomanid in adults with extensively drug-resistant (XDR),MDR with additional resistance to fluroquinolones or second line injectables, intolerant/non-responsive multidrug-resistant (MDR) pulmonary tuberculosis in India***" sponsored by ICMR, New Delhi submitted by Prof. Surya Kant, Department of Respiratory Medicine vide letter no. 009/24 dated 3rd January, 2024. ***Previous Comments:*** • The Iinvestigator has submitted an updated protocol version for approval but has not indicated if earlier version was ethically approved. • Although the new version is approved by the institutional ethics committee of the National Institute of Research in Tuberculosis, no evidence of KGMU approval is enclosed. • They need to submit annexure 1 and ICF as per SOP of EC IRB KGMU. • Since adverse effects include lethal life threatening consequences including death, a proper patient information sheet needs to be enclosed as per SOP of EC IRB KGMU. • The PI may think of incorporating co-investigators from other specialties if there is a high chance of such side effects such as cardiac events etc. This may further facilitate continuous monitoring.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Who will bear the cost of treatment and hospitalization of patients with adverse events: patient himself? or KGMU? or ICMR? • Where and how will the Whole Genome Sequencing be done? • Clear documents for Trial-Registration and insurance needs to be submitted. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** **Decision:** Approved ***Ref. code: 109th ECMIB/P7***
2-	Clarification of research proposal entitled ***"Lung oscillometry registry for patients with various Respiratory disorders and healthy subjects (LEAD Study)"*** submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 10/24 dated 3rd January, 2024.

Previous Comment	PI response
To attach the original proposal (Correspondence) of CREST and ARISE network	Annexure-1 (attached)
To attach the full designation of all the investigators involved	Annexure-2 (attached)
To attach patient information sheet both in English & Hindi	Annexure-3 (attached)
Kindly mention the names of various centers involved in the study (National & International) rather than referring the EC to link	Annexure-4 (attached)

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.
Recommendation of PR: Approved
Decision: Approved

Ref. code:115th ECM IIA/P13

3- Clarification of research proposal entitled ***"Effect of dopamine as VEGF antagonist on progression of sepsis to septic shock, ALI (acute lung injury) and AKI (acute kidney injury)"*** submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 263/CCU/2023 dated 19th December, 2023.

Previous Comment	PI response
Patient information sheet is not attached.	Revised & Attached
Methodology is grossly incomplete. Kindly elaborate the details of intervention, comparison & outcome.	Methodology is re-written intervention; comparison & outcome are described in detail.
Kindly revise methodology & data sheet	Methodology re-written & Data Sheet

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	in relevance the sepsis & septic shock.	Revised (attached)
	Anticipated adverse event is still not added in ICF.	Tachycardia
	Not complied. Methodology to be re-written as per the points rose earlier.	Methodology re-written

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Second opinion of reviewer:

- The submitted methodology is acceptable now.
- The left blanks in annexure 1 need to be completed such as number of subjects etc.
- The patient information sheet is incorrect; it should be as per the guidelines already attached with this revised submission.
- The consent form should detail 'study procedure' according to the patients understanding and relevant layman language.
- Kindly refer to the SOP of IEC (KGMU website).

The aforementioned comments were sent to the Principal-Investigator vide office letter no.2862/Ethics/2024 dated 5th January, 2024. Awaiting reply from the PI.

Decision: Reminder to be sent to the PI

Ref. code:119thECM IIA/P3

4- Clarification of research protocol no. DEN302 entitled ***"A randomized, double-blind, placebo-controlled, phase 3 trial to investigate the safety and immunogenicity of a dengue tetravalent vaccine (Live Attenuated) (TDV) administered subcutaneously to healthy subjects aged 4 to 60 years in India"*** sponsored by M/s Takeda Vaccines, Inc. submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/26/23 dated 7th December, 2023.

Previous comment:

- PI has sent the Declaration statement (given by Sponsor) regarding sample transportation to abroad, but permission from regulatory authorities for the same is missing -PI is requested to send the same or justify.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of PR: Approved

Decision: Approved

Ref. code:121stECMIIC/P2

5- Clarification of research proposal entitled ***"Effect of nutraceutical potential of pumpkin seeds on glycaemic and lipid profile in type 2 diabetes mellitus patients"*** submitted by Miss. Poonam Sahu, Ph.D. Scholar under the guidance Prof. Dileep Kumar Verma, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3602/PHY/23 dated 22nd December, 2023.

Previous Comment	PI response

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Provide UPCST proposal	I have submitted my PhD synopsis for ethical approval. Earlier I was employed as a Junior Research Assistant (JRA) in UP-CST project and the project tenure has ended on 5th July 2023. (Sanction letter and Appointment proof attached) Currently, I am employed as Junior Research Fellow (JRF) in ICMR Adhoc-project (Sanction letter and Appointment proof attached). The objectives of my Ph.D. synopsis and ICMR project are same. The Ph.D. guide and the Principal-Investigator of ICMR project is Dr. Dileep Kumar Verma in both the cases.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.
Recommendation of PR: Approved
Decision: Approved

Ref. code:124thECMIIB-Ph.D/P1

6- Clarification of research proposal entitled ***"Study on clinical outcomes and drug resistance profile (both phenotypic and genotypic) in MDR tuberculosis patients treated with bedaquiline containing regimen"*** submitted by Mrs. Rashmi Ratnam, Ph.D. 2021 Scholar through her guide Prof. R.A.S. Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1213/Resp/23 dated 6th December, 2023.

Previous Comment	PI response
Budget has to be mentioned in rupees, not by naming the funding agency?	150000/- Rs. As this is only a Ph. D. thesis work, no budget is provided by any funding agency. The TB testing consumables are supplied by National Tuberculosis Elimination Program (NTEP). The bedaquiline drug and other required items will be purchased by the scholar herself as the scholar is working at IRL TB LAB as a microbiologist.
No. of subjects to be recruited not mentioned?	90 MDR patients will be recruited in the study. The sample size and its estimation were already mentioned in the proforma attached with the checklist. Page No. 8.
Why Vulnerable Samples have been ticked?	As any of the mentioned vulnerable subjects can be a MDR patient if he/she found suitable for the study then only they will be included.
Bio-banking is being done: what will be	Sputum culture positive isolates are being

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	stored, for what purposes?	stored according to sample retention policy of NABL accredited lab, this is a routine T B Laboratory activity not only for the purpose for Ph.D. thesis.
	Hindi patient information sheet should be written properly. Google translate should not be used?	Amendment has been done accordingly. Page No.11
	Is the Ph.D. student will not work in the laboratory?	Student will work in laboratory as the student will enroll the patients from the dept. of respiratory medicine, collect sputum samples, process these samples in T.B. Laboratory and will conduct test MIC for bedaquiline, gene sequencing in the laboratory also maintain and analyze the results.
	What are the primary & secondary objective measures?	For primary objectives, outcome measures will be: Culture conversion Treatment outcome in terms of cured, died, treatment failure and lost to follow up Frequency of primary and secondary drug resistance in genotypic and phenotypic DST. For secondary objectives, outcome measures will be: Comparative efficacy of culture conversion and treatment outcome of all oral longer with shorter oral bedaquiline containing regimens. Page No.: 10
	How long will Patient be followed?	It will be done at intervals defined by the NTEP for both the regimens for maximum 6 months (Bedaquiline is given to the patients for a maximum period of 6 months).
	Why 2 groups have been included?	Two groups have been included because we want to know the frequency of primary and secondary Bedaquiline resistance.
	When and why will drug resistant profiling be done?	Drug resistant profiling will be done at the time of initial screening of patient samples and when any follow up sample will be culture positive. This will be done to check any change in drug resistant status of M. tuberculosis. Page No.: 9.
	Statistical tests and methodology need to	For primary objective outcome: Cox

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	be elaborated.	regression method for relationship between an event (death, recurrence) occurring over time. To study frequencies chi square test will be used. For secondary objective: Kappa statistics for agreement between two groups. Page No.: 12.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of reviewer:

- Formalities related to vulnerable subjects within the proposal as well as in the annexure (such as assent form; patient information sheet; etc.) to be completed.

Comment: As above

Decision: Revise and resubmit with response to comments in a tabular format.

Ref. code:126thECMIIB-Ph.D/P1

7- Clarification of research proposal entitled ***"To explore the relationship between periodontitis and preterm delivery with Fcγ receptor polymorphisms as genetic susceptibility factor"*** submitted by Dr. Iman Baig, Ph.D. 2019 Scholar through her guide Prof. Pavitra Kumar Rastogi, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 4026/P/23 dated 18th December, 2023.

Previous Comment	PI response
As is clear from the 1st subsection of the IEC, i.e., Sponsor information, it is for external funding agencies be they Indian or any other It needs to be filled out as none or not applicable, and then PI may declare that the expenses would be borne by him.	Sponsor information has been revised and re-filled as none or not applicable and the PI has then further declared that the expenses would be borne by her.
IEC point no. 7.iv PI chooses the option yes and states the collected samples will be stored. The point is about the use of pre-existing samples. So the option to be chosen is no.	The correct option has been selected and marked as no.
In Pt. Information Sheet (both English and Hindi) point no. 7 to be revisited, why to write you can drive, drink.....मदिरा का सेवन कर सकते हैं. ICF and Patient information sheets need to be written in simple language.	Patient information sheet (both English and Hindi) point no.7 has been revised and written in simpler language.

Second opinion of the reviewer:

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

<table>
<tr><td></td><td>

- The PI tried to modify the proposal as per observation; still, there are some font errors in the Hindi consent form; the patient information sheet and some sentences still contain difficult words.

The aforementioned comments were sent to the Principal-Investigator vide office letter no.2814/Ethics/2023 dated 30th December, 2023. Awaiting reply from the PI.

Decision: Reminder to be sent to the PI.

Ref. code:126thECMIIB-Ph.D/P2
</td></tr>
<tr><td>8-</td><td>

Clarification of research proposal entitled ***"Pan-India epidemiological, virological and genomic surveillance for Human Influenza, COVID 19 and RSV through DHR-ICMR VRDL Network"*** submitted by Dr. Shruti Radera, Assistant Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1137/2023 dated 12th December, 2023.

<table>
<tr><th>Previous Comment</th><th>PI response</th></tr>
<tr><td>Reply to comments of Primary reviewer</td><td></td></tr>
<tr><td>In the following project the consent form needs to be corrected. As the consent ID to be taken from parents for the children so it cannot be in first person. Both Hindi and English consent formats need to be corrected</td><td>Both Hindi and English consent formats have been changed as per suggestions (Annexure attached)</td></tr>
<tr><td>Title of the Project: "Pan-India epidemiological, virological and genomic surveillance for Human Influenza, RSV and COVID 19 through DHR-ICMR VRDL Network"</td><td>Title of project is "Pan-India epidemiological, virological and genomic surveillance for Human Influenza, COVID 19 and RSV through DHR-ICMR VRDL Network".</td></tr>
<tr><td>Reply to Comments of Secondary reviewer</td><td></td></tr>
<tr><td>Grant letter attached is not for the study. In such a case who will bear the cost of the investigations/treatment offered to the subjects enrolled in the study?</td><td>The submitted proposal is a part of DHR-ICMR-VRDL network. Therefore, no separate budget has been sanctioned, however one junior nurse will be appointed as an additional manpower (Sanction letter attached) A declaration has been signed and attached in annexure.</td></tr>
</table>

The above comments were forwarded to both reviewers:-
Recommendation of both reviewers:
Provisionally Approved

Decision: Approved

Ref. code: 127thECMIB/P2
</td></tr>
<tr><td>9-</td><td>Clarification of research proposal entitled ***"An analysis of the anomalous fissure of***</td></tr>
</table>

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

ligamentum teres hepatis: A morphological perspective in North Indian population" submitted by Dr. Heena Singh, Assistant Professor, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 543/ANAT/23 dated 11th December, 2023.

Previous Comment	PI response
Ph.D Scholar cannot be made a Co-PI	Name excluded from the study
Number of subjects not mentions	100 livers obtained from embalmed cadavers of donated bodies.
Other pts. of section 5	5. Subject selection: NA i. Number of subjects: 100 livers obtained form formalin fixed Cadavers of donated bodies ii. Duration of a) Study: 6 months b) Subject participation: NA iii. Will subjects from both sexes be recruited Yes √ No □ iv. Inclusion/exclusion criteria given Yes √ No □ v. Type of subjects - livers obtained from embalmed cadavers Volunteers □ Patients □ vi. Vulnerable subjects NA Yes □ No □ (Tick the appropriate boxes) Pregnant Women □ Children □ Elderly □ Fetus □ Illiterate □ Handicapped □ Terminally ill □ Seriously ill □ Mentally Challenged □ Economically & socially backward □ Any other □ vii. Special group subjects NA Yes □ No □ (Tick the appropriate boxes) Captives □ Institutionalized □ Employees □ Students □ Nurses / Dependent □ Armed Forces □ Any other □ Staff □
Section 6 not addressed	Privacy and confidentiality: NA i. Study Involves Direct Identifiers□ Indirect Identifiers/Coded □ Completely Anonymised / Delinked √ ii. Confidential handling of data by staff Yes √ No□
Section 8 Consent form whom/for what?	8. Consent: NA – consent form is not required as study is done on livers obtained from donated bodies in the department for study and research.(Waiver form Attached)
Section 10: If risk are not reasonable	10. Risks & benefits: NA i. Is the risk

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	compared to anticipated benefits: Unethical to do the study	reasonable compared to the anticipated benefits to subjects / community/country? Yes √No□ ii. Is there physical / social / psychological risk /discomfort? Yes □ √No□ if yes, Minimal or no risk □ More than minimum risk □ High risk □
		iii. Is there benefit a) to the subject? NA- as study done on liver specimens Yes □ No□ Direct□ Indirect □ b) to the society? √Yes □ No□

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Second opinion of reviewer:-

- Data Management cannot be NA.
- Part of the methodology has been written in past tense.

Comment:

- As above

Decision: Approval subject to appropriate modification of the current proposal.

Ref. code: 127th ECM IIA/P4

10- Clarification of research proposal entitled ***"Study of clinical outcomes of neuropsychiatric events in systemic lupus erythematosus patients attending Rheumatology clinic at a tertiary care centre"*** submitted by Dr. Kriti Kishor, Assistant Professor, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/998/23 dated 15th December, 2023.

Previous Comment	PI response
Comment 1/2/3: Study variables and Primary objectives	PRIMARY OBJECTIVE: To assess the impact of immunosuppression on clinical outcomes (Likert scale) and change in health related QOL in terms of SF-36 and Lupus QOL in a multidisciplinary assessed and prospectively followed up cohort of patients with Neuropsychiatric Lupus. SECONDARY OBJECTIVES: 1. To study the proportion of NPSLE patients achieving LLDAS and impact of LLDAS on HRQOL in terms of Lupus QOL and SF-36 at 1 year. 2. To study the proportion of NPSLE patients achieving remission as per

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	DORIS definition of SLE remission and impact of remission on HRQOL in terms of Lupus QOL and SF-36 at 1 year. 3. To assess damage accrual as measured by SDI (SLE damage index) at 1 year and its impact on HRQOL in NPSLE. 4. To study whether different pathophysiological mechanism (inflammatory/pro-thrombotic) impact HRQOL (SF-36 :PCS and MCS and Lupus QOL 8 domains) in NPSLE patients at 1 year 5.To study whether different pathophysiological mechanism (inflammatory/pro-thrombotic) impact NPSLE patients achieving LLDAS or remission as per DORIS definition of SLE remission . 6. To study the effect of SLE disease duration and duration of neuropsychiatric symptoms on HRQOL at 1 year. 7. To study the spectrum of autoantibody profile of patients of NPSLE. 8. To study the spectrum of radiological findings in patients of NPSLE.
Comment 4: Research hypothesis	Does immunosuppression in NPSLE improve clinical outcomes and impact HRQOL in terms of SF-36 and Lupus QOL at 1 year follow up
Comment 5: Sample size	Since there are no studies from India which have assessed Clinical outcomes and HRQOL in NPSLE patients followed up prospectively, considering this a pilot study all NPSLE patients enrolled over 1 year will be included with a minimum sample size of 20.
Comment 6: Statistical analysis	All data will be expressed as mean (±standard deviation), medians with interquartile range (IQR) or proportion if applicable. Independent associations between clinical- demographic variables

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Dated 12th January, 2024

		(age, gender, disease duration, duration of NP event, lag time between SLE diagnosis and NP event presentation, change in SLEDAI-2K [cSLEDAI-2K], SDI at first visit and 1 year, antiphospholipid syndrome diagnosis, NP SLE diagnosis and NP SLE pathophysiological phenotypes) will be investigated by univariate linear regression analysis, using the change in Likert scale, SF-36 MCS and PCS , Lupus QOL domains as the dependent variables. Variables with univariate associations with a p & lt; 0.20 will be retested in a multivariate model. Secondly, a multiple variable analysis will be performed in order to test for the contributory or confounding effect of several independent variables.
	The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer. ***Recommendation of reviewer:*** • Provisionally Approved **Decision:** Approved ***Ref. code: 127th ECM IIA/P6***	
11-	Clarification of research proposal entitled ***"Role of heavy metal toxicity in progression of bladder cancer and their effect on quality of life"*** sponsored by CST-UP submitted by Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 1097/URO/23 dated 29th December, 2023. ***Previous comments:-*** • In this case control study the sample size as indicated is 94 cases and 94 controls i.e. total 180. So kindly rectify the total sample size as 180 in your submission. (Annexure 1 and text) • If Controls are healthy subjects then kindly mention their source and inclusion criteria. • If healthy controls are to be sampled then separate informed consent and information sheets need to be re-submitted both English and Hindi. • Kindly indicate a split budget as submitted. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** **Comment:**	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• In information sheet for healthy subjects it is important to mention the process of blood sampling through venepuncture technique. The same to be indicated in ICF. • The 'Study procedure' section in ICF needs to be less technical & more as per patient-understandable language. • Kindly demarcate the ICF for patients and Healthy subjects separately. **Decision:** Approval subject to appropriate modification of the current proposal. ***Ref. code:127th ECM IIA/P10***
12-	Clarification of research proposal entitled ***"Ellipsoid zone restoration correlates with final visual outcome in diabetic macular edema and macular hole surgery: A comparative analysis"*** submitted by Prof. Sandeep Saxena, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 2213/OPH/23 dated 29th December, 2023. **Previous Comment:** • The methodology indicates that the study has already been done while the overall impression is that of a prospective study of retrospective records plus follow-up. Also the steps of sample size calculation need to be mentioned. ***The aforementioned comments were forwarded to the Principal-Investigator vide office letter no.2861/Ethics/2023 dated 5th January, 2024. Awaiting reply from the PI.*** **Decision:** Reminder to be sent to the PI ***Ref. code:127th ECM IIA/P12***
13-	Clarification of research proposal entitled ***"Nurse-led genetic counseling in improving awareness and implementation of screening services for hereditary women's cancer (NuGenA)"*** submitted by Govt. of West Bengal under supervision of Prof. Nisha Singh, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/2010/23 dated 14th December, 2023. ***Previous comment:*** • In IEC proforma each box has a question mark which is probably an inadvertent error; however, this needs to be deleted. • The letter of intent is in the form of an email, which was sent to the PI long back on 27th January 2023 for which a reply was solicited by 5th Feb. Also ethical approval letter from the study site is enclosed, which is very old i.e. 4-12-2020. There is no mention of KGMU. A fresh letter of intent along with details will be needed. • Is there any provision for compensation and/or insurance for healthy relatives of the Cancer patient? • KGMU is not mentioned as a study site not in the CTRI. It seems from the proposal that only samples will be taken from KGMU. • IEC subsection 5 reveals 30 subjects in a year will be recruited whereas the proposal of 100 women in the first 24 months (preparatory phase) will be identified.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Second opinion of reviewer	PI response
Question mark in each box	Corrected IEC proforma with errors deleted is enclosed.
LOI	New LOI with details dated 11 th Dec.23 is attached.
Provision for compensation	There is no provision of compensation or insurance included since the study involves counseling only.
KGMU as a site in CTRI	The CTRI was done at the start of study from the principal investigating site. KGMU received a letter of intent for inclusion in the study starting with training of nurses at KolGOTrg. Two permanent nurses from genital cancer control unit were thereby trained and study proposal is being sent now for starting the study with a new letter of intent dated 11th December 2023. After the ethics approval from KGMU it will be updated as study site in CTRI as mentioned in point number 10 of new letter of intent. Simultaneously a research advisory approval dated 24 th November 2023 is also being attached. The Ovarian and Breast cancer patients at high risk for hereditary cancers will be counseled for genetic testing and samples of those accepting the testing will be sent to KolGOTrg.
Sample size	Correction regarding subject recruitment done in both IEC subsection 5 as well as in proposal.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Third opinion of the reviewer:

- PI informed the collaborating PI of the referred project that, after getting ethical approval from each site, the names of the study sites would be updated (Point no.10).
- The Patient Information Sheet and consent forms (Hindi and English) need modifications.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

These need to be written in simple language so that the participant may understand the purpose and procedure of the study.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of the reviewer:

Provisionally approved

Decision: Approved

Ref. code:127th ECM IIA/P13

14- Clarification of research entitled ***"Introduction of hyperbaric oxygen therapy (HBOT) as an effective modality in management of hearing loss–A Randomized Trial"*** submitted by Prof. Vijay Kumar, Head, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 264/24 dated 8th January, 2024.

Previous EC Comment	PI response
Patient information sheet is missing	Patient information sheet is provided
The title reveals randomizes trial but the protocol does not follow the CONSORT guidelines. And study design states as an observational study.	The protocol is revised as per CONSORT guidelines. Study design is changed from "Observational study" to randomized trial.
The study indicates sample age between 10-65 years, as asset form is not provided	The participant's age is modified, only adult patients will be included in the study, with age 18-65 years.
Methodology section needs revision, if it is a prospective study, methodology needs to be written in future tense.	Methodology section is revised and re-written.
Hindi consent form needs revision.	Hindi consent form revised as per instructions.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Comment:

- Kindly modify the title to ***"A randomized clinical study"*** in place of ***"A randomized trial"***

Decision: Policy decision required on the conduct of randomized controlled trial/ academic trial/ investigator-initiated trial or their counterparts as "study" when there is no provision for the insurance of subjects involved.

Ref. code:127th ECM IIA/P18

15. Clarification of research entitled ***"Oral health practice of dental professionals towards self oral care"*** submitted by Dr. Sumit Kumar, Professor Jr. Grade, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P.,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Lucknow vide letter no.823/PHD/23 dated 22nd December, 2023. ***Previous comments:-*** • There are some primary guidelines, which should be followed in the construction of a scale. • Only some textual references are given for the questionnaire. It should be given explicitly, explaining where the items come from: (i) previous scale, (ii) clinical observations, (iii) expert opinion, (iv) patients' report, (v) research finding, (vi) theory. • Are they were assessed for (i) endorsement frequency, (ii) restriction in range, (iii) comprehensions, (iv) lack of ambiguity, (v) lack of value-laden or offensive content? • How is the scale checked for internal consistency? • Does it have good test-retest reliability? • What method is used to find the reliability coefficient? • How was the sample size calculated? • Does the scale have face validity? • Is there evidence of content validity? • Has it been evaluated for criterion validity? • With what groups has the scale been validated? • Can the scale be completed in a reasonable amount of time? • How much training is needed to learn how to administer it? • How the questionnaire will be evaluated to generate numerical score, so that it can be used in the assessment of the attitude and practices of the dental professionals? ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of the reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code:127th ECM IIA/P20***
16-	Clarification of research proposal entitled ***"Effectiveness of a School based health promotion intervention for prevention of non-communicable diseases among adolescents of Lucknow-A quasi experimental study"*** sponsored by ICMR New Delhi submitted by Dr. Sugandha Jauhari, Ph.D. Scholar under the guidance Prof. Monika Agarwal, Head, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1130/CM/23 dated 28th December, 2023. ***Previous Comments:-*** • All scientific committee members including chairman are CO PI in the Project. I request IEC members to kindly comment during discussion. • Roles allotted to all Co-PI are similar. Unique roles have to be specified.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Though ethically proposal is appropriate but certain issues like.
- Discrepancy in number of participants 303 written in flow charts and 333 decided with dropouts after calculating as 288 raises concern.
- Study participants are students of classes 6th to 8th, whereas in the inclusion criteria students of class 9th are included.
- Age parameter is also varying at places.
- Proforma defines MET but such parameter is never mentioned anywhere else in the project.
- Why the study will be registered with CTRI.
- Study proposal need re review from scientific review committee.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Second opinion of reviewer:

- Approved with suggestion that there is no need for registration with CTRI.

Decision: Approved

Ref. code:127thECMIIB-Ph.D/P2

17- Clarification of research entitled ***"Study the role of tumor suppressor genes as a biomarker for early detection of lung cancer"*** sponsored by M/s Climate Trends Limited Liability Partnerships submitted by Ms. Afreen Mehdi, Ph.D. Scholar under the guidance of Prof. Surya Kant, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1386/Res/23 dated 11th December, 2023.

Previous Comment	PI response
IEC needs to be fulfilled properly	We apologize for the same. Now, we have filled the IEC proforma correctly.
The project seems to be an industry – sponsored study but PI indicates it as a Govt. sponsored.	We are sorry for unintentional mistake and making confusion in funding information. Ms. Afreen Mehdi (Ph.D. Scholar) is working as a Research Assistant in the She will bear all the charges of laboratory experiments from her stipend. Also, here we would like to clear that current proposed project work is not sponsored from any funding agency.
Is the budget sanctioned in the name of the PI? Related documents to the same need to be enclosed.	Please refer to the 'Response 2.'
Patient information sheet needs to be filled Properly.	We are sorry for the same, now we have filled patient information sheet properly as per our best of knowledge.
Consent is to be written in simple and	The inadvertent mistake is regrated. We

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	comprehensive language.	have written the consenting the simple and easy language which is understandable to study participants.
	PI wishes to add healthy controls, inclusion, and exclusion criteria for the same to be included and separate ICF to be prepared.	Thanks for the suggestion we have enclosed the informed consent for cases and controls separately. Please find it in the revised IEC pro-Pharma.
	If healthy controls are to be added, who will pay for their investigations?	Healthy volunteers will not be charged for the same. PhD student will bear all the expenses.
	The study title and aim are to determine the role of tumour suppressor genes as a biomarker but in the objectives the first Objectives is to find the epidemiological status of lung cancer, which needs revision	Thanks for the suggestion; we have replaced it as secondary objective. Because for better understanding of disease burden and to find out the correlation between tumour suppressor gene and patients characteristics, we have to explore the symptoms, risk factors, and clinical features of the lung cancer patients.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Second opinion of the reviewer:

- As it is a Ph.D. research proposal, a thorough review of the literature, identified research gaps and proper rationale for the study would help in developing the protocol in a better way.
- In inclusion criteria, the PI writes: -
  All healthy people. Where this population will be identified should be described. Also, an operational definition of healthy individuals needs to be given.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to reviewer vide office letter no.2890/Ethics/2024 dated 10th January, 2024. Awaiting reply awaited from the reviewer.

Comment: MoU or CTA, as applicable needs to be deposited along with response to the aforementioned commen

Decision: Revise & re-submit with appropriate response to comments in a tabular format.

Ref. code:127thECMIIB-Ph.D/P4

18-	Clarification of research ***"Role of mitochondrial DNA and TLR 9 in endothelial cell activation and preeclampsia"*** submitted by ICMR under supervision of Ms. Sonam Gautam, Ph.D. Scholar under the guidance of Prof. Narayan Prased, Head, Department of

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Nephrology through Co-PI Prof. Renu Singh, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1997/23 dated 13th December, 2023.

Previous EC Comment	PI response
Age of the subjects to be taken in the study not mentioned	I have included age rnnge of subjects in the inclusion A revised Case Report Form has been attached
It is mainly a biochemical study and no co-guide has been taken from that background	The study has been designed as a molecular and translational study The biochemical parameters included in the study are general

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of the Reviewer:

Provisionally approved

Decision: Approved

Ref. code:127th ECMIIB-Ph.D/P5

19- Clarification of research proposal entitled ***"To investigate the potential source of DNA and its STR-DNA profiling for human identification from the most challenging body fluids in a medico-legal setting"*** submitted by Office of the Dean, Research & Development, KGMU Lucknow under supervision of Dr. Anshu Priya, Assistant Professor, Department of Forensic Finger Printing Lab (CFAR) King George's Medical University, U.P., Lucknow vide letter no. 385/FMT/23 dated 4th December, 2023.

Previous Comment	PI response
IEC form to be filled properly.	Filled and attached the IEC form
The study is to be done on corpses, who is going to give informed consent? If consent is to be taken from diseased relatives or LAR. She has to modify the ICF accordingly.	Consent will be given by close relatives of the deceased or LAR it has been modified as suggested
Who will be there to see the patient information sheet? If it is to be shown and given to the LAR/relative the texts of different subsections of the Information sheet need to be written as per the need of the study.	A close relative or LAR will be there. As our subject for this study is a corpse so patient information sheet has been modified as per the study design
In the role of the investigators' sheet-investigator-specific share for this particular study is not given which needs to be added.	Provided as you suggested

The aforementioned comments were sent to the Principal-Investigator, the response to

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	which was forwarded to the reviewer. *Second opinion of the Reviewer:-* • Approval subject to modification of ICF (English & Hindi) into simple language. *The aforementioned comment was sent to the PI; awaiting reply from the PI.* **Decision:** Reminder to be sent to the PI. *Ref. code:127th ECM II B-IMR-F/P1*
20-	Clarification of research protocol no. CTIN816A12201 entitled *"A randomized, multi-centric, placebo-controlled, participant, and investigator blinded study to evaluate the safety, tolerability and efficacy of TIN816 in adult patients at risk for acute kidney injury following cardiac surgery"* submitted by M/s Novartis Healthcare Private Limited under supervision of Dr. Sarvesh Kumar, Professor Junior Grade, Department of Cardiovascular & Thoracic Surgery, King George's Medical University, U.P., Lucknow, vide letter no. 1105/CVTS/2023 dated 18th December, 2023. *Previous Comment:-* • Section 3 (ii) of IEC form is incorrectly answered as NA. Please answer Yes or No. • IEC form section 3 (iii) please comment on DCGI permission. • IEC form section 3 (iv) Please comment on the Phase of the study and whether copy of DCGI application is attached. • IEC form Section 5 (vi) Pregnant women is not ticked whereas the protocol copy has ICF for pregnant women. Please clarify. • IEC form Section 7 mentions no samples will be collected. Protocol has ICF for exploratory genetic study and section 7 (ix) mentions samples being sent abroad. Please address this discrepancy. • Reasons for sending samples abroad are not clear. No clarify on what will happen to samples after the project is over. Will participants be informed if their tissue/samples are used for further research? • Samples size is 10. No justification of this sample size has been given. • No contact details are given in ICF. • Letter from sponsor (Novartis) to DCGI does not mention KGMU site. • Insurance certificate not attached. *The above comments were forwarded to Principal-Investigator was reviewed by reviewer:-* *Second opinion of reviewer:-* • IEC form section 5 (vi) response to Vulnerable subject is No and pregnant subject is still not ticked. • IEC form section 7 still mentions that no samples will be collected. *The above comments were forwarded to Principal-Investigator was forwarded to reviewer vide this office letter no.2860/Ethics/2024 dated 5th January, 2024:-*

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer:- • IEC form section 7 (I to VIII) are still mentioned as 'No', which means no samples are being collected. • Study may be approved after minor changes in the IEC form and subject to acknowledgement/approval from DCGI once it is obtained. Comment: As above Decision: Approval subject to appropriate response to comments. ***Ref. code:127th ECM II C/P1***
21-	Clarification of research proposal entitled "***On normal brain sparing approach using objective function for radiosurgery of single brain targets with static and rotational intensity-modulated planning techniques***" under supervision of Prof. Navin Singh, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 32/RT/24 dated 6th January, 2024. ***Previous comment:*** • The researcher has mentioned in point 10, that the risks outweigh the benefits. Kindly clarify. ***The above comment was sent to the Principal Investigator, the response to which was reviewed by the Member-Secretary, IEC.*** **Comment:** The title of the study may be modified as follows "Evaluation of normal brain sparing approach using objective function for radiosurgery of single brain targets with static and rotational intensity-modulated planning techniques" **Decision:** Approved with the said modification. ***Ref. code: 128th ECM IIA/P1***
22-	Clarification of research proposal entitled ***"Efficacy of Hyper Baric Oxygen Therapy (HBOT) in management of Diabetic Foot Ulcer-A Randomized control trial"*** under supervision of Prof. Vijay Kumar, Head, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 25/24 dated 8th January, 2024.

Previous Comment	PI response
The researcher has mentioned in point 10, that the risk outweighs the benefits. Kindly clarify	The procedure of hyperbaric oxygen therapy is safe and being done in plastic surgery department on daily basis. By mistake, point no 10 is ticked "no". There is no risk associated with the procedure. Kindly consider it "yes".

The aforementioned comment was sent to the Principal Investigator, the response to which was reviewed by the Member-Secretary, IEC.

Provisionally approved

Decision: Policy decision required on the conduct of randomized controlled trial/

(Hardeep Singh) Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	academic trial/ investigator-initiated trial or their counterparts as "study" when there is no provision for the insurance of subjects involved. ***Ref. code:128thECM IIA/P5***
23-	Clarification of research proposal entitled ***"Diagnostic evaluation of index molecular test lit (s) compared to the microbiological reference standard for detection of adult pulmonary tuberculosis"*** submitted to ICMR New Delhi (in response to a call for collaboration from the ICMR) under supervision of Dr. Parul Jain, Associate Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1202/Micro/23 dated 23rd December, 2023.

Previous Comment	PI response
Project incomplete	As this is a multi-centric study designed by ICMR of which KGMU is a site, the whole project as provided by them is provided.
Review of literature not provided	As this is a multi-centric study designed by ICMR of which KGMU is a site, the whole project as provided by them is provided. Review of literature has been provided.
No references	References are listed in the project on page no. 19.
Approved subject to incorporation of reviewer's concern	Thank You
Ethical clearance of other centers	Ethical clearance of 2 centers of the same project is provided:- 1. CMC, Vellore 2. ICMR- Regional Medical Research Center, Bhubaneswar
Names of participating centers	Participating centers are as follows: 1. ICMR- National Institute for Research in Tuberculosis, Chennai 2. ICMR- Bhopal Memorial Hospital & Research Centre, Bhopal 3. King George's Medical University, Lucknow 4. CMC, Vellore 5. National Institute of Tuberculosis & Respiratory Diseases, New Delhi 6. PGIMER, Chandigarh

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		7. ICMR-RMRC, Bhubaneswar 8. PD Hinduja Hospital & MRC, Mumbai These sites have been mentioned on pages 2 and 3 of the project.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of the Reviewer:

Provisionally Approved

Decision: Approved

Ref. code:128th ECM IIA/P9

24- Clarification of research proposal entitled ***"Comparative evaluation of carbamazepine and botox treatment of trigeminal neuralgia"*** under supervision of Dr. Akhilanand Chaurasia, Associate Professor, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 523/OMS/2/24 dated 8th January, 2024.

Previous Comment:-

- Approved with suggestion: The number of subjects calculated are 169 + 10% drop outs. But only 50 patients will be enrolled in each group leading to a total of 150. Therefore, number of patients in each group shall be increased.

The aforementioned comment was sent to the Principal Investigator, the response of which was reviewed by the Member-Secretary, IEC.

Provisionally approved

Decision: Approved

Ref. code: 128th ECM IIA/P14

25- Clarification of research entitled ***"Role of urinary monocyte chemoattractant protein-1 (MCP-1), plasminogen activator inhibitor-1 (PAI-1), neutrophil gelatinase- associatrd lipocalin (NGAL) and liver-type fatty acid binding protein (L-FABP) as urinary biomarkers for early detection of renal damage in posterior urethral valves (PUV)"*** under supervision of Prof. Archika Gupta, Department of Pediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1128/Ped.Sy/23 dated 28th December, 2023.

Previous Comment:-

- No ethical issues. But the patient information brochure does not mention, whether blood or urine or both or any other sample will be collected. Needs to be clear.
- The information brochure should be for the parents as the patient will be a child. The language needs improvement .e.g. , 'WHY HAVE I BEEN CHOSEN? - SINCE YOUR PATIENT IS HAVING POSTERIOR URETHRAL VALVE SO YOUR CHILD IS CHOSEN'
- Whether micturating cystourethrography will be done for the research or it is a part of the routine follow up and management?

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Hindi brochure mentions that serum creatinine will be done while English brochure mentions only urine and MCU. • Need to improve Hindi and English patient info brochures. ***The response to the aforementioned comments were reviewed by the Member-Secretary, IEC.*** Provisionally Approved **Decision:** Approved ***Ref. code:128thECM IIA/P15***
26.	Clarification of research proposal entitled "***Development of patient derived organoid bio-bank as a resource for drug response studies and precision medicine application in triple negative breast cancer***" sponsored by ICMR, New Delhi submitted by Prof. Pooja Ramakant, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. EndoSurg/2024/01 dated 2nd January, 2024. **Previous Comment:** • The information brochures need to explain 'tumor organoids' and system to validate. • 'A small piece of breast tumor taken from the biopsy will be grown in a tube / bottle and as it develops similar to a tumor mass, it will be used to study the effects/ efficacy of the medicine.' • Issues associated with Bio safety & Bio banking alongwith commercialisation of the material. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of the Reviewer:*** • The answer to comment one about organoids and 'validation' is too scientific to understand by a layperson who is required to give the consent? • Description in simple language in Hindi and English should be give, **Comment:** As above **Decision:** Approved with the said modification. ***Ref. code: 128thECM IIA/P7***
27.	Clarification of research proposal entitled "***Designing and implementation of health care model in patients with stage 2 breast cancer***" under supervision of Prof. Pooja Ramakant, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. 07/EndoSurg/23 dated 3rd January, 2024. ***Recommendation of secondary reviewer:-*** • Comments in Departmental Scientific Review absent. Stamp of Chairperson missing. • IEC form incomplete. The Check boxes have to be ticked. • Patient Information Sheet in Hindi not present.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the secondary reviewer vide office letter no.2887/Ethics/ 2024 dated 10th January, 2024. *Recommendation of secondary reviewer:-* Provisionally approved **Decision:** Approved *Ref. code: 128th ECM IIA/P18*
28-	Clarification of research proposal entitled *"Association of advanced glycation end products with microvascular and neurodegenerative changes in diabetic retinopathy"* sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Dr. Nibha Mishra, Assistant Professor, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 7759/OPH/23 dated 2nd November, 2023. **Previous EC Comment:** • Please resend full proposal. Only IEC form is attached in this and preceding mail. *The above comment was forwarded to the Principal-Investigator was reviewed by reviewer: Reply awaited for* *The above research proposal was allotted to Secondary reviewer:* **Recommendation of Secondary reviewer:-** • In SOP checklist, point no.7-use of biological samples-ticked as No but various blood test and serum bioassay is to be done-Please correct, Point no. 10- Risk and benefit-ticked that risk is reasonable-No-Please correct. • Sample size calculation discrepancy is there in inclusion criteria- three groups given-total subjects-128 and in sample size calculation-total subjects mentioned are 169-PI to clarify and correct. • Study design mentioned is Cross-sectional but comparative evaluation are to be done including control and other two groups, therefore clarify the study design, whether cross-sectional or case control study. • In Methodology please elaborate the grouping of the subjects/patients and include flow chart of the study. *The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.* *Recommendation of reviewer:-* Provisionally approved **Decision:** Approved *Ref. code: : 125th ECM II B-IMR-F/P1*
29-	**ADR Subcommittee**
	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 12th January, 2024 from 2:00 P.M. till 2:30 p.m. *in hybrid mode,*

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Administrative Block, K.G's Medical University, U.P., Lucknow. ***The following Members were present in the Meeting:-*** Dr. Alok Dhawan -Chairman Dr. Rajendra Nath -Member Dr. Nisha Mani Pandey -Member Mrs. Akansha Dubey -Member Mr. Ujjawal Krishna -Member Mrs. Vasundhara Kumari -Member Dr. D.N. Upadhyaya -Additional Member-Secretary, IEC Dr. Hardeep Singh Malhotra -Member-Secretary, IEC, ex-officio
1-	ADR of research protocol no. CTQJ230A12301 entitled "***A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease***" sponsored by M/s Novartis Health Care Pvt. Ltd. submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 548/Cardio/Res/2023 dated 14th December, 2023. **Death** **Site no. 1178** **Patient ID & age and gender:** S-113/52 year/Male **Patient Diagnosis:** Acute (1W+RV+PW) MI **Patient enrollment date:** 07-03-2022 **Patient follow up under study:** Randomization visit, Month 1, Month 2, Month 3, Month 4, Month 5, Month 6, Month 9, Month 12, Month 15, Month 18, Month 21, Month 24, Month 27 and every three month follow up till 4 year **Follow up visit completed**-Randomization visit, Month 1, Month 2, Month 3, Month 4, Month 5, Month 6, Month 9, Month 12, Month 15 & Month 16. **Planning on visit-** Month 17 **SAE detected on date:** 30th November, 2023 **Follow up visit remaining:** 17th Month, 18th Month, 21st Month, 24th Month, 27th and every three month follow up till 4 year **Follow up visit completed:** Enrolment & Baseline Follow-up **24 hours, notified to EC, Sponsor**-01-12-2023 **14 days analysis report submitted to EC-** 14-12-2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 15th December, 2023 from PI. PI tried to contact on alternate numbers but not answered. Many times his phone was found switched off and not reachable. Again site tried to contact on 30th November, 2023. The subject's LAR informed on 30th November, 2023 around 13:00

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	about the death of his father which occurred on 18th August, 2023. On detailed evaluation of records provided from patient's son it was found that patient has dizziness and became unconscious on 15th August, 2023 in the morning. Subject was taken to local hospital and referred to super specialty hospital with the diagnosis Right sided paralysis. He was hospitalized on 15th August, 2023 and his treatment started in the evening. Some primary investigations done and CT scan revealed the Left sided fronto-parietal infarct during the course of hospitalization. Subject expired on 18th August, 2023 in the hospital. No Autopsy was done. Most likely cause of death was not related to study drug as per the documents provided by the patient's LAR. **Death certificate provided.** ***Recommendation of reviewer:*** **a- Enrolment date**-07-03-2022 **b-The SAE (Death) occurred on:** 18-08-2023. **c-SAE detected on:** 30-11-2023 **d- Details of Event:** Patient has dizziness and became unconscious on 15th August ,2023, he was taken to local hospital and referred to super specialty hospital with diagnosis of Rt. sided paralysis, he died on 18th August due to left sided fronto-parietal infarct (revealed by CT Scan). This is likely due to disease progression (Acute (1W+RV+PW) MI) and not due to intervention (TQJ230) as he was taking it from more than 1 year and 8 months. No autopsy was done **e- 24 hrs notification by email:** 01-12-2023. **f- 14 day analysis submitted on :** 14-12-2023. **g- Causal relationship and Compensation:** The causal relationship of SAE (Death) with intervention cannot be established and no compensation is warranted. **Comment:-** Reply received from PI has been reviewed. **Decision:** Approved ***Ref. code: 101st ECM IIC/P18***
2-	ADR of research protocol ***ISCHEMIA*** entitled ***"International study of comparative health effectiveness with Medical and invasive approaches"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no.551/Cardio/Res/23 dated 18th December, 2023. **Death** **Site no. 091019** **Patient ID & age and gender:** R-S/131,63 years/Male **Patient Diagnosis:** Coronary Artery Disease/Chronic Stable Angina **Patient enrollment date:** 06-10-2017 **Patient follow up under study**-Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic Follow up till 5 year. **Follow up visit completed**-Randomization visit, Month 1.5, Month 3, Month 6, Month

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	12, Month 18 **Planning on visit-** Telephonic Follow-up Visit of month of December 2023. **SAE detected on date:** 11-Dec-2023 **Follow up visit remaining:** Telephonic Visits (Every Month) till 2025 **24 hours, notified to EC, Sponsor-**11-Dec-2023 **14 days analysis report submitted to EC-** 25-Dec-2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 18th December, 2023 from PI. Study Coordinator made a scheduled monthly follow up call to the subject on 11th December, 2023 at 11:00 A.M. Earlier to that many calls were made for monthly telephonic follow-up visits. PI tried to contact on alternate numbers but not answered. Many times his phone was found switched off and not reachable. The patient's son has informed about the death of his mother which occurred on 1st October, 2023 at around 03:00 PM. Subject's LAR informed that subject had loose motion from last 02 days and did not eat and on 1st October, 2023 around 12:30 PM in forenoon, subject did her routine activities and then slept, she didn't wake-up and found dead at 3.00 PM. As she was not admitted anywhere, hence no documents are available and No autopsy was done. **Death certificate provided by LAR.** ***Recommendation of reviewer:*** a. Enrolment date – 06.10.2017. Randomization date – 12.10.2017 b. SAE date – 01.10.2023 c. Patient was on regular monthly telephonic follow-up which were skipped. d. SAE detected on 11.12.2023. e. 24-hr notification to IEC by email on 11.12.2023. Date of awareness of SAE in email is written as 11.06.2023 which must be corrected. f. 14-day notification to IEC on 18.12.2023. No dates are present on the PI letter to IEC. g. The SAE (death) doesn't appear to be related to the study. The patient had loose motions for two days prior to the SAE and died at home. No autopsy was performed. **Comment:-** Reply received from PI has been reviewed. ***The above study follow-up extended till 2025 vide letter 1796/Ethics/19 dated 13th December, 2019.*** **Decision:** Approved ***Ref. code: 102nd ECM IIA/P24***
3	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial"*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

552/Cardio/Res/2023 dated 18th December, 2023 & preliminary email dated 5th December, 2023 at 4:05 PM.

Death

Site no.: 109
Patient ID & age and gender: P-036/ 21 years/Female
Patient Diagnosis: RHD/Sev-MS/MVA 1.3 cm.

Patient enrollment date: 10-08-2023

Patient enrollment arm-Digoxin
Patient follow up under study-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month.
Follow up visit completed-Enrolment & Baseline Follow-up
Planning on visit- 12th M
SAE detected on date: 04-12-2023
Follow up visit remaining: 12th Month, 18th Month, 24th Month, 30th Month, 36th Month.
24 hours, notified to EC, Sponsor-05-12-2023
14 days analysis report submitted to EC-18th December, 2023
Subject History:

A letter was received in the office of the Ethics Committee on 19th December, 2023 by PI, The subject had to visit the site on 10th September, 2023 for 12-month actual on site visit. The PI informed the patient regarding the visit on 6th September, 2023 as a reminder calls made to the subject, she did not answer the calls. The subject's LAR informed to PI on 4th December, 2023 that the subject had complained of breathlessness and dyspnoea since 22nd November, 2023. Her condition deteriorated on 23rd November, 2023 and she passed away on 23rd November, 2023 at home around 11:15 PM. As per the information given by the patient's LAR, it seems to be a case of worsening of Heart failure. A local practitioner came and confirmed the patient's death and no autopsy was done.

Recommendation of reviewer:

- Enrolment date –10.08.2023.
- Skipped 12-month follow-up which is given as 10.09.2023.
- SAE detected on 4th December 2023.
- Notification to IEC by email on 05.12.2023.
- 14-day notification on 18.12.2023.
- No date present on the causality letter attached by the PI.
- The SAE (death) doesn't appear to be related to the study, and appears to be an outcome of the disease process. The patient died at home and no autopsy was performed. However, the dates given in the documents are incorrect at several places which need to be corrected.

Comment:- Reply received from PI has been reviewed.
Decision: Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 102nd ECM IIA/P24
4	ADR of research protocol ***ISCHEMIA*** entitled ***"International study of comparative health effectiveness with Medical and invasive approaches"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no.576/Cardio/Res/23 dated 21st December, 2023. **Death** **Site no. 091019** **Patient ID & age and gender:** A-A/072,69 years, DOB 20-07-1947/Male **Patient Diagnosis:** Coronary Artery Disease/Chronic Stable Angina **Patient enrollment date:** 06-04-2017 **Patient follow up under study-** Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic Follow up till 5 year. **Follow up visit completed-**Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18 **Planning on visit-** Telephonic Visit of (Every month) till 2025 **SAE detected on date:** 13-Dec-2023 **Follow up visit remaining:** Telephonic Visits (Every Month) till 2025 **24 hours, notified to EC, Sponsor-**13-Dec-2023 **14 days analysis report submitted to EC-** 27-Dec-2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 21st December, 2023 from PI. The patient's LAR has informed to PI on 13th December, 2023 that the subject passed away on 24th August, 2023 at around 04:00 AM. Subject's LAR informed that on 23rd August, 2023 around 21:30 hr, subject had alteration of sensorium while sitting & did not respond to command for nearly 20 minutes. Then he became alright & had his dinner and medicine & slept after that subject did not awaken and in morning he found dead at 04:00 AM. Subject died at home hence no documents are available and no autopsy was done. **Death certificate provided by LAR.** *Recommendation of reviewer:* **a- Enrolment date-**06-04-2017 **b-The SAE (Death) occurred on:** 24-08-2023. **c-SAE detected on :** 13-12-2023 **d- Details of Event:** Patient's LAR informed that on 23rd August,2023 around 21:30 hr subject had alteration of sensorium and he did not respond to command for 20 minutes after that he became alright then slept and after that he did not awaken and found dead in the morning of 24-08-23 at 04.00 pm . SAE (death) is most likely due to disease

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	progression (CAD/Chronic Stable Angina) as subject was randomized in conservative arm on 06-04-2017 and more than 6 years 4 months has elapsed before the incidence. He died at home and no autopsy was done **e- 24 hrs notification by email:** 13-12-2023. **f- 14 day analysis submitted on :** 27-12-2023. **g- Causal relationship and Compensation:** The causal relationship of SAE with intervention cannot be established and no compensation is warranted. **Comment:-** Reply received from PI has been reviewed. ***The above study follow-up extended till 2025 vide letter 1796/Ethics/19 dated 13th December, 2019.*** **Decision:** Approved ***Ref. code: 102nd ECM IIA/P24***
5	ADR of research protocol ***ISCHEMIA*** entitled ***"International study of comparative health effectiveness with Medical and invasive approaches"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no.595/Cardio/Res/23 dated 29th December, 2023. **Death** **Site no. 091019** **Patient ID & age and gender:** R-M/097,75 years, DOB 01-01-1942/Male **Patient Diagnosis:** Coronary Artery Disease/Chronic Stable Angina **Patient enrollment date:** 15-06-2017 **Patient follow up under study-** Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic Follow up till 5 year. **Follow up visit completed-**Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18 **Planning on visit-** Telephonic Follow-up Visit of month of December 2023 **SAE detected on date:** 16-Dec-2023 **Follow up visit remaining:** Telephonic Visits (Every Month) till 2025 **24 hours, notified to EC, Sponsor-**16-Dec-2023 **14 days analysis report submitted to EC-** 30-Dec-2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 29th December, 2023. The subject was randomized in Conservative Arm. Study Coordinator made a scheduled monthly follow up call to the subject on 16th December, 2023 at 10:00 AM. Earlier to that in last week PI tried to contact him but his phone was not answered. The patient's LAR has informed to PI on 16th December, 2023 that the subject was feeling down since the

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	last few days and he was not able to perform his daily routine. On 19th November, 2023 at around 04:00 PM he was sleeping and his son tried to wake him up at 05:50 PM but found that subject expired. Subject expired at home hence no documents are available and No autopsy was done. **Death certificate provided by LAR.** *Recommendation of reviewer:* **a. Enrolment date – 15.06.2017.** **b. SAE occurred on 19.11.2023. SAE detected on 16.12.2023.** **c. Notification to IEC by email on 16.12.2023.** **d. 14-day notification on 29.12.2023** **e. No date present on the PI Narrative letter attached by the PI.** *f. The SAE (death) doesn't appear to be related to the study, and appears to be an outcome of the disease process. The patient died at home and no autopsy was performed.* **Comment:-** Reply received from PI has been reviewed. ***The above study follow-up extended till 2025 vide letter 1796/Ethics/19 dated 13th December, 2019.*** **Decision:** Approved ***Ref. code: 60th ECM IIA/P13***
6-	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial"*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 593/Cardio/Res/23 dated 26th December, 2023 & preliminary email dated 14th December, 2023 at 3:43 PM. **Death** **Site no.: 109** **Patient ID & age and gender:** S-D-095/ 42 years/Female **Patient Diagnosis:** RHD/Sev-MS/MVA 0.9 cm. **Patient enrollment date:** 22-02-2023 **Patient enrollment arm-**Digoxin **Patient follow up under study-**6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed-**Enrolment & Baseline **Planning on visit-** 6th M **SAE detected on date:** 14-12-2023 **Follow up visit remaining:** 16th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	24 hours, notified to EC, Sponsor-14-12-2023 **14 days analysis report submitted to EC-**28th December, 2023 **Subject History:** A letter was received in the office of the Ethics Committee on 28th December, 2023 by PI, The subject was visited the hospital at the time of SAE but didn't inform any of the site staff. Whenthe staff tried to contact the subject for follow-up calls and visits, none of the calls were answered and the subject became lost to contact till 14th December, 2023. As per the documents submitted by the patient's LAR the cause of the death was cardiogenic shock. ***Recommendation of reviewer:*** **a.** Enrolment date – 22.02.2023 **b.** SAE date – 06.03.2023. SAE detected on 14.12.2023 **c.** 24-hr notification to IEC by email on 14.12.2023. **d.** 14-day notification to IEC on 28.12.2023. No dates are present on the Causality assessment letter by PI to IEC. **e.** After randomization on 22.02.2023 the patient again made unscheduled visits to the site on 25.02.2023 and 03.03.2023 and died on 06.03.2023 in the emergency of KGMU which was not detected/reported to the site/PI. **f.** The SAE (death) doesn't appear to be related to the study. The patient had reported to the emergency of KGMC on the day of the death but the site was unaware of this. The subject died in KGMC on 06.03.2023 under department of Medicine and this was detected by the site on 14.12.2023, nine months after the incident which happened in KGMC premises. **Comment:-** Reply received from PI has been reviewed. **Decision:** Approved ***Ref. code: 102nd ECM IIA/P24***
7	ADR of research protocol ***ISCHEMIA*** entitled ***"International study of comparative health effectiveness with Medical and invasive approaches"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no.585/Cardio/Res/23 dated 26th December, 2023. **Death** **Site no. 091019** **Patient ID & age and gender:** A-A-006/074 years, DOB 26-08-1938/Male **Patient Diagnosis:** Coronary Artery Disease/Chronic Stable Angina **Patient enrollment date:** 04-12-2014 **Patient follow up under study-** Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic Follow up till 5 year. **Follow up visit completed-** Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Planning on visit- Telephonic Follow-up Visit of month of December 2023 **SAE detected on date:** 15-Dec-2023 **Follow up visit remaining:** Telephonic Visits (Every Month) till 2025 **24 hours, notified to EC, Sponsor-**15-Dec-2023 **14 days analysis report submitted to EC-** 29-Dec-2023 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 26th December, 2023. Subject was randomized in Invasive Arm. The study coordinator made a scheduled monthly follow up call to the subject on 15th December, 2023 at 13:00 hrs. After several monthly calls subject's LAR picked the call on 15th December, 2023 and informed to the PI that the subject suffered a sudden cardiac arrest while talking with his daughters and within 10 minutes and he expired on 9th October, 2023 at 11:30 AM. Subject expired at home hence no documents are available and No autopsy was done. **Death certificate provided by LAR.** ***Recommendation of reviewer:*** **a- Enrolment date-**04-12-2014 **b-The SAE (Death) occurred on:** 09-10-2023. **c-SAE detected on :** 15-12-2023 **d- Details of Event:** The Subject's LAR informed to PI that on 15th December, 2023 the subject suffered a sudden cardiac arrest while talking with his daughters and within 10 minutes he expired on 9th October, 2023 at 11:30 AM . SAE (death) is most likely due to disease progression (CAD /Chronic Stable Angina) as the subject was randomized in Invasive arm on 04-12-2014 and he remains alive for more than 8 years 10 months after randomization. He died at home and autopsy was not done. **e- 24 hrs notification by email:** 15-12-2023. **f- 14 day analysis submitted on:** 29-12-2023. **g- Causal relationship and Compensation:** The causal relationship of SAE with intervention cannot be established and no compensation is warranted. **Decision:** ***The above study follow-up extended till 2025 vide letter 1796/Ethics/19 dated 13th December, 2019.*** Approved ***Ref. code: 60th ECM IIA/P13***
8	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial"*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 593/Cardio/Res/23

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

dated 26th December, 2023 & preliminary email dated 14th December, 2023 at 3:43 PM.

Death

Site no.: 109

Patient ID & age and gender: S-50/ 39 years, DOB 15-07-1982/Female

Patient Diagnosis: RHD/Sev-MS/MVA 1.0 cm.

Patient enrollment date: 12-11-2022

Patient enrollment arm-Digoxin

Patient follow up under study-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month.

Follow up visit completed-Enrolment & Baseline Follow-up & 6 months Follow-up

Planning on visit- 12th Month

SAE detected on date: 20-12-2023

Follow up visit remaining: 12th Month, 18th Month, 24th Month, 30th Month, 36th Month.

24 hours, notified to EC, Sponsor-21-12-2023

14 days analysis report submitted to EC-04th January, 2024

Subject History:

A letter was received in the office of the Ethics Committee on 3rd January, 2024 by PI, The subject was visited the site on 6th June, 2023 for 6 months actual on site visit. The subject was last contacted telephonically on 6th September 2023 for 9 month telephonic follow-up call. The subject got hospitalized on 20th September, 2023 valve replacement Surgery and got discharged on 3rd October, 2023 after the procedure. The subject was contacted telephonically on 6th December, 2023 for 12th month visit follow-up reminder call, but, the subject didn't answer the call. The subject was again contacted on 20th January for reminder call. The subject's LAR picked the call and informed that the subject had complaints of breathless and discomfort on 30th November, 2023 and she passed away on the same day at home around 12:00 AM.

As per the informed given by the patient's LAR, it seems to be a case of sudden cardiac death. A local practitioner came and confirmed the patient's death and no autopsy was done. Despite multiple reminders the subject's LAR was unable to provide the death certificate of the subject. The SAE is not related to the investigational drug.

Recommendation of reviewer:

a- **Enrolment date-**12-11-2022

b- **The SAE (Death) occurred on:** 30-11-2023.

c- **SAE detected on :** 20-12-2023

d- **Details of Event:**. The subject's LAR after repeated calls picked the call on 20th December and informed that the subject had complaints of breathless and discomfort on 30th November, 2023 and she passed away on the same day at home around 12:00 AM. The SAE (death) is most likely due to disease progression (RHD/Sev-MS/MVA 1.0 cm-valve replacement surgery done on September ,2023) resulting in sudden cardiac arrest and not due to intervention (Digoxin),which he was taking for more than 1 year and 15 days. Death occurred at home and no autopsy was done.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	e- 24 hrs notification by email: 21-12-2023. **f- 14 day analysis submitted on:** 04-01-2024 **g- Causal relationship and Compensation:** The causal relationship of SAE with intervention cannot be established and no compensation is warranted. **Comment:-** Reply received from PI has been reviewed. **Decision:** Approved ***Ref. code: 102nd ECM IIA/P24***
IB	**Expedited review**
1-	Expedited review of research proposal entitled ***"Anant Muskaan: A Multi-site implementation research of primary school-based tooth brushing and oral health education in India"*** submitted by Prof. Vinay Kumar, Head, Department of Public Health Dentistry, Faculty of Dental Sciences, K.G's Medical University, U.P., Lucknow vide letter no. nil dated 14th October, 2023. ***The above research proposal was forwarded to two reviewers, for review.*** ***Recommendation of Primary reviewer: Awaiting reply from the primary Reviewer.*** ***Recommendation of Secondary reviewer :*** • The scientific review committee report needs to give specific comments such as acceptable/satisfactory or unacceptable/ not satisfactory. • The Chairman of scientific evaluation committee & principal investigator cannot be the same person. • In this implementation research project proposed by ICMR (with a grant of >2 crore split across the 3 phase of this study), kindly provide anticipated split of grant if available (contingency, manpower, transport etc.) • Kindly notify what efforts have been made by PI to identify the various private & public schools/manpower involved in this study. How would you plan for sampling to be done while selecting the research subject? • Kindly include patental information sheet & teacher's information sheet along with their respective consent forms as you have submitted. In this regard kindly follow the guidelines as per SOP of EC KGMU website. • In annexure 1 (point 10), is the risk not reasonable compared to anticipated benefits? What are the anticipated adverse events? Kindly make necessary incorporations. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of the IEC after discussion and considering the response received from the PI to comments raised by the secondary Reviewer:*** Approved **Decision:** Approved ***Ref. code:129th IEC IB/P1***
2-	Expedited review of research proposal entitled ***"Impression of tobacco related products for general and specific carcinogenicity and screening of patients with oral pre cancer***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	and cancer on genetic polymorphism involved in DNA base excision repair genes and risk of oral cancer and precancer" submitted by Prof. Shadab Mohammad, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, K.G's Medical University, U.P., Lucknow vide letter no. OMSD/047/23 dated 2nd November, 2023. ***The above research proposal was forwarded to two reviewers, for review.*** ***Recommendation of the primary Reviewer :*** Provisionally approved ***Recommendation of Secondary reviewer:*** ***Awaiting reply from the secondary Reviewer.*** ***Recommendation of the IEC after discussion and considering the response received from the PI to comments raised by the primary Reviewer:*** Approved **Decision:** Approved ***Ref. code:129th IEC IB/P2***
3-	Expedited review of research proposal entitled ***"Multiparametric MRI-based radiomics and machine learning models for diagnosis and classification of renal tumors"*** submitted by Dr. Durgesh Kumar Dwivedi, Additional Professor, Department of Radiodiagnosis, K.G's Medical University, U.P., Lucknow vide letter no. 1267/RD/23 dated 2nd December, 2023. ***The above research proposal was forwarded to two reviewers, for review.*** ***Recommendation of Primary reviewer :*** Provisionally approved ***Recommendation of Secondary reviewer :*** ***Awaiting reply from the secondary Reviewer*** ***Recommendation of the IEC after discussion and considering the response received from the PI to comments raised by the primary Reviewer:*** Approved **Decision:** Approved ***Ref. code:129th IEC IB/P3***
4-	Expedited review of research proposal entitled ***"Prognostic role of TBI-Indused white matter changes: A longitudinal advanced diffusion MRI study leveraging super-resolution and Artificial Intelligence"*** submitted by Dr. Durgesh Kumar Dwivedi, Additional Professor, Department of Radiodiagnosis, K.G's Medical University, U.P., Lucknow vide letter no. 1302/RD/2023 dated 13th December, 2023. ***The above research proposal was forwarded to two reviewers for review.*** ***Recommendation of Primary reviewer :*** • Section on Vulnerable subjects is incorrectly filled. • Section on benefits to the subject/society incomplete. • Budgetary details not submitted. ***The above comments were forwarded to the Principal-Investigator, reply has given by PI was forwarded to reviewer vide this office letter no. 2895/Ethics/2023 dated 10th January, 2024.***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer: Provisionally approved ***Recommendation of the secondary reviewer: Awaiting reply from the secondary reviewer.*** ***Recommendation of the IEC after discussion and considering the response received from the PI to comments raised by the primary Reviewer:*** Approved **Decision:** Approved ***Ref. code:129th IEC IB/P4***
5-	Expedited review of research proposal entitled ***"Uncovering the gene expression profile of programmed cell death ligand 1 (PD-L1) gene and its polymorphism and its association in regulation to platinum drug resistance in head and neck squamous cell carcinoma"*** submitted by Prof. Navin Singh, Department of Radiotherapy, K.G's Medical University, U.P., Lucknow vide letter no. 1204/RT/2023 dated 15th December, 2023. ***The above research proposal was forwarded to two reviewers for review.*** ***Comments of Primary reviewer:-*** • It is indicated clearly in annexure 1, that the samples will be sent abroad since facility is not available in India & its necessary clearance has been obtained. In this regard kindly submit. (a) Clearance formalities with Govt. of India regarding shipping the bio-specimen abroad. (b) In which overseas laboratory will the samples be shipped? © Who is the overseas collaborator? Kindly include his CV/details. What would be then change in patent policy as described by UPCST? • How & from where will the healthy controls be selected? There needs to be a separate comment form & information sheet for health subjects before any invasive procedure can be undertaken. • Is the risk not reasonable compared to benefits (annexure 1 point 10). Kindly rectify? • Kindly submit the details (steps) of sample size calculation that concluded a sample of 160 patients. Also the PI states that this is a 'pilot preliminary experiment' in this regard. • Kindly fill in the left blank spaces in annexure such as number of subjects etc. ***Comments of Secondary reviewer:-*** The IEC form needs to be filled out properly. • Please check point no. 5 of the IEC, which states 160 subjects and in the proposal total subjects seem to be double as written 160 pts and 160 controls. • Further, the proposal reveals healthy controls, again control (healthy individuals) …patients without chemotherapy, needs clarity. • 7.ii **'No'** is ticked whereas work methodology and research plan of the study point 2 states collection of tissue and blood samples to be extracted. • 7.ix yes is ticked are samples to be sent abroad..... now here in the proposal it is indicated

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	o 7.ix a & b what kind of clearance has been obtained? • 10.i ticked as **'No'** • The proposal portrays 2 kinds of study to be done, which need a proper description. • ICF for the control group is not given. • ICF and Patient information sheets should be written in simpler and more understandable language. ***The above comments were forwarded to the Principal Investigator:*** ***Awaiting reply from the PI.*** **Decision:** Reminder to be sent to the PI ***Ref. code:129th IEC IB/P5***
6-	Expedited review of research proposal entitled ***"A clinical evaluation of severity and management of peri-implantitis around dental implant in post COVID 19 patients-Randomized control trial"*** submitted by Dr. Mayank Singh, Prof. Jr. Grade, Department of Prosthodontics, Faculty of Dental Sciences, K.G's Medical University, U.P., Lucknow vide letter no. 665/23 dated 22nd December, 2023. ***The above research proposal was forwarded to two reviewers for review.*** ***Comments of Primary reviewer:-*** • This is a sanctioned RCT by UPCST. • As per annexure 1, healthy subjects will be recruited but no such indication is there in inclusion criteria, kindly resolve. • Since no DCGI clearance, copy of insurance policy or copy of CTA are attached, it is expected that PI will take care of formalities. • The PI has not mentioned as how will randomization & allocation be carried out? • Is the risk not reasonable as compared to benefit (see annexure 1 point 10). Kindly rectify. *Comments of Secondary reviewer:-* • The Chairperson of the SRC is one of the Co-Investigators. • Point no. 10.i needs to be ticked appropriately. • The Hindi patient Information sheet needs to be written clearly and more simply. ***The aforementioned comments were sent to the Principal Investigator, the response to which was reviewed by both reviewers:*** Approved **Decision: Policy decision required on the conduct of randomized controlled trial/ academic trial/ investigator-initiated trial or their counterparts as "study" when there is no provision for the insurance of subjects involved.** ***Ref. code:129th IEC IB/P6***
7-	Expedited review of research proposal entitled ***"Unraveling the role of salivary RxociRs in the regulation of immune evasion in prostate cancer"*** submitted by Dr. Shivali Duggal, DST-WOS A, through Prof. Kaleem Ahmad, Department of Biochemistry, K.G's Medical University, U.P., Lucknow vide letter no. Bio/2023/964 dated 22nd December, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The above research proposal was forwarded to two reviewers for review. *Recommendation of Primary reviewer*:- Provisionally approved *Awaiting reply of from the secondary Reviewer.* *Recommendation of the IEC after discussion and considering the response received from the PI to comments raised by the primary Reviewer:* Approved **Decision:** Approved *Ref. code:129th IEC IB/P6*
II-A	**New Proposal**
1.	Research proposal entitled "*Correlation between functional disability and Radiological severity in North Indian patients with osteoarthritis knee-A cross-sectional study*" submitted by Dr. Sandeep Kumar Gupt, Assistant Professor, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 5917/23 dated 28th November, 2023. *Recommendation of reviewer:* Approved **Decision:** Approved *Ref. code: 129th ECM IIA/P1*
2.	Research proposal entitled "*Oral sodium hyaluronate supplementation results in release of vitreomacular traction*" submitted by Prof. Sandeep Saxena, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 1049/OPH/23 dated 30th November, 2023. *Recommendation of reviewer:* • The study duration in annexure is mentioned as 2 months while elsewhere it is stated as 3 months. Kindly resolve. • As per annexure 1 point 10, is the risk not reasonable as compared to benefit? Kindly resolve. • As per annexure 1, if there is plan to report adverse events than kindly mention those anticipated adverse events and also state them in ICF & patient information sheet. • In ICF, the study procedure indicates that the work has already been done in a young male. Is this a retrospective case report for which ethical permission is sought? • The Hindi version of ICF does not reflect the English version and rather quotes some other pathology pertaining to macular hole. Kindly note that both English & Hindi versions of ICF need to communicate the same information. • While only 2 cases (One young & Other old) to be recruited in this study, the patient information sheet again mentions that young patient has already undergone this intervention. What about the older subject? Is this retrospective or prospective? • If adverse events are planned to be reported then why "no side effect" is mentioned in patient information sheet. **Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	As above **Decision:** Revise & re-submit with appropriate response to comments in a tabular format. ***Ref. code: 129th ECM IIA/P2***
3.	Research proposal entitled "***A randomized controlled trial of early valve replacement in severe asymptomatic aortic stenosis (EASY-AS)***" submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 409/Cardio/23 dated 6th December, 2023. ***Recommendation of reviewer:*** ◦ The IEC sponsor information column is to be ticked appropriately. Indian Institutional and International both cannot be ticked simultaneously. ◦ ICF is not as per standard format and Hindi is also hard to understand. ◦ This study is a Multicentric/ Multinational study which is to be coordinated by an external investigator from UK. The PI has the opportunity to be a coordinating center; however, no correspondence/ invitation related to the same is available. PI. check pg 3/61 to 6/61. ◦ If studies reveal that early valve replacement is beneficial, is randomization appropriate? As per my understanding before obtaining consent from the patient and randomization everything will be explained to him. In such a situation, after knowing everything, if a patient has been randomized to a particular group of treatment and he prefers to change his group, what will the researchers do? ◦ Protocol pg nos. 16-19 are missing. **Comment:** As above **Decision:** Revise & re-submit with response to comments in a tabular format ***Ref. code: 129th ECM IIA/P3***
4.	Research proposal entitled "***Partial penectomy under local anaesthesia: A retrospective review of our experience***" submitted by Dr. Madhur Anand, Assistant Professor, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 1013/URO/23 dated 30th November, 2023. ***Recommendation of reviewer:*** • The primary objective must be elaborated. It just says "Summarize our experience of performing partial penectomy under local anaesthesia." • You must express the objective in terms of study variables (e.g. clinical history, radiological and laboratory investigations) and population parameters. • The study design is not clear. It says "Retrospective observational study of prospective collected data". • Sample size calculation is not given. It is since research hypothesis is not properly

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	defined. • Statistical analysis is incomplete. It should be specific to the research hypothesis. **Comment:** As above **Decision:** Revise & Re-submit with response to comments in tabular format ***Ref. code: 129th ECM IIA/P4***
II-B	**New Ph. D. Proposal**
1.	Research proposal entitled "***Nutrigenomic insights into thalassemia: resveratrol's influence on HIF-1α and clock/BMAL1 genes expression, oxidative stress and bone mineral density (BMD) of North Indian thalassemia patients***" submitted by Ms. Neha Rawat, Ph.D Scholar under the guidance Dr. Nitu Nigam, Additional Professor, Department of Centre for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 284/CFAR/23 dated 7th December, 2023. ***Recommendation of reviewer:*** • Sample size calculation not mentioned. • The type of study to be conducted is not clear. • It has been mentioned that the subjects will be recruited from the Department of Paediatrics but the age group mentioned is 15-65 years. • The consent form needs to be corrected as for minors the consent has to be taken from the parents or the legal guardian. • Where the BMD will be carried out and the make of the instrument shall also be mentioned. • The dosage of Resveratrol is also not mentioned. **Comment:** As above **Decision:** Revise & re-submit with response to comments in a tabular format ***Ref. code: 129th ECMIIB-Ph.D/P1***
2.	Research proposal entitled "***The role of multi-parametric MRI-based surrogate biomarkers for specific gene mutations in the characterization of glioma***" submitted by Ms. Shweta Dubey, Ph.D. Scholar under the guidance Prof. Anit Parihar, Head, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 1241/RD/23 dated 22nd November, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: 129th ECMIIB-Ph.D/P2***
3.	Research proposal entitled "***A pharmacological approach to evaluate antifungal activity of bioactive compounds of medicinal plants against multi drug resistant candida***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	species" submitted by Mr. Shailendra Kumar Yadav, Ph.D Scholar, under the guidance Prof. D. Himanshu, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2339/MED/23 dated 22nd November, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: 129thECMIIB-Ph.D/P3***
III-B	**Modification**
1.	Modification of research protocol no. CKJX839D12302 entitled "***A randomized, double-blind, placebo-controlled multicenter study to evaluate the effect of inclisiran on preventing major adverse cardiovascular events in high-risk primary prevention patients (VICTORION-1 PREVENT)***" submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 529/Cardio/23 dated 28th November, 2023. ***Recommendation of reviewer:*** Approved ***The following documents were reviewed in the Meeting:-***

Sl.No.	Documents
1.	VICTORION-1 PREVENT_Patient ID_V1_001Feb23_English (India)
2.	VICTORION-1 PREVENT_Patient Information brochure V1_01Feb23_English (India)
3.	VICTORION-1 PREVENT_Poster_V1_01Feb23_English (India)
4.	VICTORION-1 PREVENT_Study visit guide_V1_01Feb23_English (India)
5.	VICTORION-1 PREVENT_Patient ID_V1_11Apr23_Hindi (India)
6.	VICTORION-1 PREVENT_Patient information brouchure_V1_11 Apr 23_Hindi (India)
7.	VICTORION-1 PREVENT_Poster_V1_11Apr23_Hindi (India)
8.	VICTORION-1 PREVENT_Study visit guide_V1_11Apr23_Hindi (India)
9.	VICTORION-1_Translation Certificate_Hindi (India): • VICTORION-1 PREVENT_Patient ID_V1_11Apr23_Hindi (India) • VICTORION-1 PREVENT_Patient information brouchure_V1_11Apr23_Hindi (India) • VICTORION-1 PREVENT_Poster_V1_11Apr 23_Hindi (India) VICTORION-1 PREVENT_Study visit guide_V1_11Apr 23_Hindi (India)
10	VICTORION-1 PREVENT _HCP_referral_fact_card_V1_15Feb23_English_(India)
11.	VICTORION- PREVENT _HCP_referral_fact_card_V1_31Mar 23_Hindi (India)_A4
12.	VICTORION-1 PREVENT_Transaltion Ceritificate_Hindi(India) of VICTORION-1 PREVENT_HCP referral fact card_V1_31Mar23_Hindi(India)_A4
13.	Clinical Trial Protocol Version 01 (Original Protocol) dated 14 Jul 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	14.	Summary of changes document: CKJX839D12302 – protocol amendment 01
	15.	Informed Consent Form: Core ICF V2.0 dated 16 Aug 2023 in English
	16.	Informed Consent Form: Core ICF V2.0 dated 16 Aug 2023 translated from English to Hindi on 24 Aug 2023
	17.	Informed Consent Form: Core ICF V2.0 dated 16 Aug 2023 back translated from Hindi to English 30 Aug 2023
	18.	Translation and Back translation certificate: Core ICF V2.0 dated 16 Aug 2023 Hindi

Decision: Approved

Ref. code: 123rd ECMIIC/P3

2. Modification of research protocol no. DEN302 entitled "***A randomized, double-blind, placebo-controlled, phase 3 trial to investigate the safety and immunogenicity of a dengue tetravalent vaccine (Live Attenuated) (TDV) administered subcutaneously to healthy subjects aged 4 to 60 years in India***" submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/19/23 dated 9th August, 2023.

Recommendation of reviewer:

- The Proposed changes (requested by CDSCO regarding blood draw at Day 30 removal) may kindly be approved.

The following documents were reviewed in its Meeting:-

1.1 DEN-302_Protocol V2.0 dated 15-Jun-2023
2.1 DEN-302_Protocol signature page dated 15 Jun 2023 for Dr. Himanshu Dandu for protocol V2.0 dated 17-Jul-2023
3.1 Main_V2.0IND(en) 1.0(23 Jun 2023)
3.2 Main_V2.0IND(hi) 1.0(23 Jan 2023)
3.3 Main_V2.0IND(hi) 1.0(23 Jan 2023)_Translation certificate_30 Jun 2023
3.4 Back translation of Main_V2.0IND (hi) 1.0 (23 Jan 2023)
3.5 Back translation of Main_V2.0IND(hi) 1.0(23 Jun 2023)_Back translation certificate_30 Jun 2023
4.1 PMain_V2.0IND(en) 1.0(23 Jun 2023)
4.2 PMain V2.0IND(hi) 1.0 (23 Jun 2023)
4.3 PMain_V2.0IND(hi) 1.0 (23 Jun 2023)Translation certificate_30 Jun 2023
4.4 Back translation of PMain_V2.0IND(hi)1.0(23 Jun 2023)
4.5 Back translation of PMain_V2.0IND(hi) 1.0(23 Jun 2023)_Back translation certificate_30 Jun 2023
5.1 Assent 7-11yrs_V2.0IND(en) 1.0(23 Jun 2023)
5.2 Assent 7-11yrs_V2.0IND(hi)1.0(23 Jun 2023)
5.3 Assent 7-11yrs_V2.0IND(hi)1.0(23 Jun 2023) Translation certificate_30 Jun 2023
5.4 Back Translation of Assent 7-11yrs_V2.0IND(hi)1.0(23 Jun 2023)
5.5 Back Translation of Assent 7-11yrs_V2.0IND(hi)1.0(23 Jun 2023)Back translation certificate 30 Jun 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

6.1 Assent 12yrs-Above_V2.0IND(en) 1.0(23 Jun 2023) 6.2 Assent 12yrs-Above_V2.0IND(hi)1.0(23 Jun 2023)

Decision: Approved

Ref. code: 121st ECMIIC/P2

3. Modification version-08 of research protocol no. GS-US-417-0304 entitled "*A multicenter, open-label, long-term extension study to assess the safety and efficacy of filgotinib in subjects with rheumatoid arthritis*" submitted by Prof. Puneet Kumar, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/153/23 dated 2nd December, 2023.

The following documents were reviewed in its Meeting:-

Sl. No.	Study Documents	Version No.	Date
1	Study Protocol	Amendment- 8	30 Jun 2023
2	Summary of Changes for study protocol amendment 8	NA	06 Jul 2023
3	Site Specific Main ICF- Subject Information and Informed Consent Form India (Dr. Puneet Kumar) Translation and Back Translation	Version- 13.2.1	Eng: 10 Oct 2023 Eng to Hin: 11 Oct 2023 Hin to Eng: 12 Oct 2023
4	Site Specific Main ICF- Subject Information and Informed Consent Form India (Dr. Puneet Kumar) Translation and Back Translation Certificates	Version- 13.2.1	Eng to Hin: 11 Oct 2023 Hin to Eng: 12 Oct 2023
5	Summary of Changes of Informed Consent Form From Version 12.1.0 To Version 13.2.0	NA	13 Sep 2023
6	Investigator Brochure	Version-18	12 Jun 2023
7	Summary of Changes of Investigator Brochure	NA	06 Jul 2023

Recommendation of reviewer:
Approved

Decision: Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 83rdECMIIC/P4
4.	Amended CTA of research protocol no. EX9536-4773 entitled "***Effect of semaglutide 2.4 mg once-weekly on function and symptoms in subjects with obesity related heart failure with preserved ejection fraction, and type 2 diabetes***" submitted by Dr. Pravesh Vishwakarma, Professor Junior Grade, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 546/Cardio/Res/23 dated 12th December, 2023. ***The following documents was reviewed in its Meeting:*** • Clause (3) obligation of the Institution and Principal-Investigator for no promotion to the public is included. ***Recommendation of reviewer:*** Approved **Decision:** Approved *Ref. code: 113thECMIIC/P4*
IV	**Re-approval**
1	Research proposal entitled "***To join Indian stroke clinical trial network phase II (INSTRuCT Network Phase II)***" to "***Establishment of Indian stroke clinical trial network phase II)***" submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 540/Neuro/23 dated 6th December, 2023. ***Recommendation of reviewer:*** • As per letter from Member secretary, KGMU (Ref. no.-472/Ethics/2022 dated 06-06 2022), the approved title of the study was "**Indian trial of tranexamic acid in spontaneous intracerebral haemorrhage (Intrinsic Trial)**".PI to clarify that whether above mentioned trial is changed into the trial entitled "**To join Indian stroke clinical trial network phase II (INSTRuCT Network Phase II)**" which has to be change to "**Establishment of Indian stroke clinical trial network phase II**". If so then PI to submit the Protocol with all other documents (e.g. SOP-Checklist, PI undertaking, List of CO-PIs if any with their role) as fresh. **There is no document sent, which correlates the two studies.** **Decision:** Seek response from PI with submission of required documents. *Ref. code: 115thECMIIA/P5*
IV	**Other Matter with the permission of Chair**
1-	Reg. request to change in Principal-Investigator because after superannuation of Prof. Shally Awasthi, ex-Principal-Investigator, Prof. Chandra Kanta, Department of Paediatrics, KGMU, UP, Lucknow will now be Principal-Investigator of the same project under the research proposal entitled ***"Electronic capture and machine learning analysis of data pertaining to childhood tuberculosis from tertiary hospitals in India"*** vide letter no.20/Ped/2024 dated 4th January, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous Comment: • The letter should have come from the PI. **Previous Decision:** Re-submit **Decision:** Approved *Ref. code: 118th ECMIB/P1*
2-	**As per advised by Prof. D.N. Upadhyaya, the following PGTSC research proposals will be discussed in the Full Ethics Committee Meeting:-**
a.	Clarification of the research proposal entitled *"Evaluation of postoperative outcomes of advanced electrosurgical devices v/s conventional clamp and tie technique for neck dissection- A randomized control trial"* submitted by Dr. Aryan Dwivedi, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1245/SU/23 dated 29th December, 2023.

Previous PGTSC Comment	PI response
The PI has changed the title of the study from Randomised control trial to Randomized control study but has applied for CTRI registration. If indeed it is a trial, the proposal needs to be accompanied with a CONSORT statement and needs to be put up in the full committee meeting.	As per your advice titled changed trial to Study. CTRI registration applied (attached separately) mandatory ethical approval. CONSORT statement attached separately.

The above comment was forwarded to the Principal-Investigator was reviewed by Dr. D.N. Upadhyaya:-

Recommendation of Dr. D.N. Upadhyaya:-

- The PI has changed the title of the study from *'Randomised Control trial' to 'Randomised Control Study'* but has applied for CTRI registration and has furnished a CONSORT STATEMENT.
- PI will need to supply details of funding and insurance for Serious Adverse Events.
- The project will need to be submitted for a Full IEC meeting for approval and not PGTSC meeting.

Comment:

Decision: Policy decision required on the conduct of randomized controlled trial/ academic trial/ investigator-initiated trial or their counterparts as "study" when there is no provision for the insurance of subjects involved.

Ref. code: XXI-PGTSC-IIA/P41

b.	Research proposal entitled *"Cyanoacrylatevs tacker for mesh fixation in laparoendoscopic inguinal hernia repair-double blinded, randomized control trial"* submitted by Dr. Vivek Vishwakarma, JRI, Department of General Surgery, King

(Hardeep Singh) Malhotra
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

George's Medical University, U.P., Lucknow vide letter no. 2141/SY/23 dated 29th December, 2023.

Previous PGTSC Comment	PI response
The PI has changed the title of the study from Randomised control trial to Randomized control study but has applied for CTRI registration. If indeed it is a trial, the proposal needs to be accompanied with a CONSORT statement and needs to be put up in the full committee meeting.	As per your advice titled changed Trial to Study. CTRI registration applied (attached separately) mandatory ethical approval. CONSORT statement attached separately.

The above comment was forwarded to the Principal-Investigator was reviewed by Dr. D.N. Upadhyaya:-

Recommendation of Dr. D.N. Upadhyaya:-

- The PI has changed the title of the study from ***'Randomised Control trial' to 'Randomised Control Study'*** but has applied for CTRI registration and has furnished a CONSORT STATEMENT.
- PI will need to supply details of funding and insurance for Serious Adverse Events.
- The project will need to be submitted for a Full IEC meeting for approval and not PGTSC meeting.

Comment:

Decision: Policy decision required on the conduct of randomized controlled trial/ academic trial/ investigator-initiated trial or their counterparts as "study" when there is no provision for the insurance of subjects involved.

Ref. code: XXI-PGTSC-IIA/P46

V **Brought to Ethics Committee after XXIII-PGTSC held on 5th January, 2024**

Minutes of the XXIII-PGTSC of IEC Meeting ***in hybrid mode*** held on **5th January, 2024 02:00 P.M. till 5:00 P.M.** in the Research Cell, Administrative Block, King George's M University, U.P., Lucknow.

The following Members were present it its Meeting:-

1. Dr. G.G. Agarwal -Member
2. Dr. A.A. Mahdi -Member
3. Dr. Anupam Mishra -Member
4. Dr. Rajendra Nath -Member
5. Dr. D.N. Upadhyaya -Member
6. Dr. Anita Rani -Member
7. Dr. Nisha Mani Pandey -Member
8. Dr. Hardeep Singh Malhotra -Member

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

IA	Action Taken
1-	Clarification of research proposal entitled ***"Effect of percutaneous supracondylar femoral osteotomy on body image & gait parameters in adolescents with genu valgum deformity at a tertiary care Hospital- A prospective study"*** submitted by Dr. Kunwar Utkarsh Yadav, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 5298/23 dated 20th December, 2022. **Previous PGTSC Comments:** • This is "One-group pretest-posttest design". • The research hypothesis should be accordingly stated after identifying the study variables and parameters. • Sample size calculation is missing. • Statistical analysis section should be properly discussed. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XIII-PGTSC-IIA/P6***
2-	Clarification of research proposal entitled ***"Capacity of Health and wellness centres to provide non-communicable disease services in Lucknow-A cross-sectional study"*** submitted by Dr. Kaustav Halder, JRII, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1092/CM/MD/2023 dated 22nd December, 2023. **Previous PGTSC Comments:** • The study requires construction of an instrument (questionnaire) to achieve the objective. It is missing. • After this the study can be planned and all the components of the study can be properly formulated/explained. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XVI-PGTSC-IIA/P3***
3-	Clarification of research proposal entitled ***"Coverage, utilization and impact of AB-PMJAY in rural areas of Lucknow-A cross-sectional study"*** submitted by Dr. Atul

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Verma, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1094/CM/MD/23 dated 22nd December, 2023. **Previous PGTSC Comments:** • The questionnaire is required to achieve the objective of the study. • Everything else will fall into the line according to the instrument. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XVI-PGTSC-IIA/P5***
4-	Clarification of research proposal entitled ***"A cross-sectional study on prevalence of depression, anxiety, stress, and suicidal thoughts among elderly population in Lucknow district"*** submitted by Dr. Akshay Kumar, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1093/CM/23 dated 22nd December, 2023. **Previous PGTSC Comments:** • Please attach the mentioned Tools. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XVI-PGTSC-IIA/P56***
5-	Clarification of research proposal entitled ***"Role of plasmapheresis in organophosphate poisoning"*** submitted by Dr. Sujeet Kumar, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1480/Med/23 dated 2nd December, 2023.

Previous PGTSC Comments	PI response
This is not cross-sectional study.	This is Prospective Observational study.
It seems to be pre & post treatment study. It should be clearly mentioned in the primary objective and accordingly research hypothesis formulated.	Attached separately
Sample size mentioned is 20. How is this figure arrived at? Actually, the sample size calculation can be done only after formulating the hypothesis. This can be a pilot study.	Total 28 cases included in the study. (Attached separately)

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Data analysis section is missing. | Attached separately *The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.* *Recommendation of reviewer:-* Provisionally approved **Decision:** Approved *Ref. code: XVIII-PGTSC-IIA/P3*
6-	Clarification of research proposal entitled ***"Spectrum of bacteria in infected pancreatic fluid collection in severe acute pancreatitis and their association with clinical outcome"*** submitted by Dr. Nyuwisie R Nyuwi, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1436/Med/23 dated 17th November, 2023. **Previous PGTSC Comments:-** • Please rectify the ICF, as per standard guidelines. • Please provide a properly filled Patient Information Sheet. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XIX-PGTSC-IIA/P19*
7-	Clarification of research proposal entitled ***"Effect of USG guided intra-articular prolotherapy versus steroid injection for sacroiliac joint dysfunction- A prospective randomized control trial"*** submitted by Dr. Ruth Kikon, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 781/PMR/23 dated 16th November, 2023. **Previous PGTSC Comments:-** • Please attach properly filled Patient Information Sheet ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Kindly modify the title to ***"randomized controlled study"*** instead of ***"randomized control trial"*** *Ref. code: XIX-PGTSC-IIA/P27*
8-	Clarification of research proposal entitled ***"A study to assess the knowledge and attitude on self care among Mothers diagnosed with PIH attending department of Obstetrics &***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Gynaecology, KGMU, Lucknow U.P." submitted by Ms. Shashikala, Ms. Shiva, Ms. Sunita, Ms. Swati Ranjan, Ms. Uttara, Ms. Pooja Singh, Ms. Anjali Pandey, Ms. Lalita Chaudhari, Mr. Manish Yadav, Ms. Manju Devi through their guide Mrs. Tanima Verma, Clinical Instructor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.3067/23 dated 18th December, 2023. **Previous PGTSC Comments:-** • Kindly provide Patient Information Sheet as per EC SOP and summary of association analysis. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XX-PGTSC-IIC/P7***
9-	Clarification of research proposal entitled ***"A descriptive study to assess the depression anxiety and burden of care among caregivers of oral cancer patients undergoing chemotherapy in the department of Surgical Oncology, KGMU, Lucknow"*** submitted by Mr. Aryan Kumar, Mr. Ashutosh Kumar, Ms. Ayasha Bano, Ms. Ayushi Verma, Ms. Bavita Verma, Ms. Deepali Dubey, Mr. Dhananjay Singh, Mr. Dharmendra Yadav, Ms. Divya Maurya, Ms. Eshita Singh through their guide Mr. G. Srinivasan, Clinical Instructor, & Miss. Amanjeet Kaur, Nursing Tutor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.1636/2023 dated 21st October, 2023.

Previous PGTSC Comments	PI response
Kindly provide Patient Information Sheet as per EC SOP and plan of analysis.	Patient Information sheet (English & Hindi) and plan for analysis enclosed.
A Co-Investigator from Department of Surgical Oncology & Psychiatry may better facilitate the project.	Prof. (Dr.) Amit, Department of Psychiatry and Prof. (Dr.) Sameer Gupta, Department of Surgical Oncology has been added as Co-Investigators.

	The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer. ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XX-PGTSC-IIC/P8***
10-	Clarification of research proposal entitled ***"A study to assess the knowledge regarding risk factors and warning signs of stroke among hypertensive patients attending OPD in KGMU Lucknow"*** submitted by Miss. Ruchi Kumari, Mr. Rudra Pratap Singh, Miss.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Sandhya Kumari, Mr. Sangam Verma, Miss. Sangeeta Yadav, Miss. Sarita Verma, Miss. Sarjahan, Mr. Satya Prakash Nishad, Miss. Saumya Upadhyay, Miss. Shalinee Medhankar through their guide Mrs. Urvashi Sharma, Clinical Instructor, Department of KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.nil dated 28th November, 2023. **Previous PGTSC Comments:-** • Kindly provide Patient Information Sheet as per EC SOP. • The ICF English version describes oral cancer instead of hypertensive Patient Information Sheet. Kindly rectify. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XX-PGTSC-IIC/P10***
11-	Clarification of research proposal entitled ***"A study of screen use profile, internet addiction, and cyberchondria in patients with unipolar depression"*** submitted by Dr. Isha Prakash, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. nil dated 28th November, 2023. **Previous PGTSC Comments:-** • Kindly provide a properly filled Patient Information Sheet. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XX-PGTSC-IIA/P22***
12-	Clarification of research proposal entitled ***"Prevalence of dental anxiety and effect of School oral health education programe on anxiety level among 10 to 15 years old School Children in Lucknow. U.P."*** submitted by Dr. Deepak. S, JRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 771/PHD/23 dated 7th December, 2023. **Previous PGTSC Comments:-** • Hindi Title of Annexure 7 needs to be translated appropriately. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XX-PGTSC-IIA/P38***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

13-	Clarification of research proposal entitled ***"A comparative evaluation of biological marker and prosthodontic compliocation in splinted and nonsplinted implant supported prostheses: A split mouth study"*** submitted by Dr. Divya Dharshini M, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 666/23 dated 22nd December, 2023. **Previous PGTSC Comments:-** • Patient Information sheet: Kindly fill it properly. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P12***
14-	Clarification of research proposal entitled ***"A prospective study to compare perioperative and quality of life outcomes of hernioplasty versus herniorrhaphy for complicated primary ventral hernia"*** submitted by Dr. Amit Pandey, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1955/SY/2023 dated 18th December, 2023. **Previous PGTSC Comments:-** • Patient information sheet is incomplete. • Patient information sheet in Hindi is not attached. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P17***
15-	Clarification of research proposal entitled ***"Assessment of osteoprotegerin (OPG) and implant stability through the topical application of UV irradiated "Vitamin D" on implant surface during placement: A randomized controlled clinical trial"*** submitted by Dr. Ruby Singh, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 579/23 dated 1st December, 2023. **Previous PGTSC Comments:-** • Spelling of ELISA needs to be corrected. • Vitamin D estimation technique not mentioned. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Provisionally approved

Decision: Kindly modify the title to ***"randomized controlled study"*** instead of ***"randomized controlled clinical trial".***

Ref. code: XXI-PGTSC-IIA/P21

16- Clarification of research proposal entitled ***"Morphological and morphometric analysis of coronary vessels in relation to atrioventricular annuli: A cadaveric study"*** submitted by Dr. Keerthy. L. K, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 516/ANAT/23 dated 29th November, 2023.

Previous PGTSC Comments	PI response
Kindly provide Patient Information Sheet as per EC SOP and plan of analysis.	Ticked and mentioned basic science.
Pont no. -5- Subject selection –PI should mention cadaveric autopsied hearts	Ticked and mentioned cadaveric autopsied hearts
Point no. -8- ICF- mentioned as written oral consent ,but as the study is on Cadaveric autopsied heart – PI – should tick and mention it accordingly	Ticked and mentioned
Study design- mentioned-Cross sectional study but as this is a Cadaveric study on autopsied Hearts, Study Design may be changed to Prospective cross -sectional analytical cadaveric study / or PI to justify.	Changed to prospective cross-sectional analytical cadaveric study.
ICF-H/E –Attached- but as the study is on Cadaveric autopsied heart specimens and no living subject is involved therefore PI to submit Human Subject Review Waiver Form (HSRWF) instead of regular ICF).	Changed to human subject review waiver form.

The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.

Second opinion of reviewer:-

PI did not attach the human subject review waiver form.

The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.

Recommendation of reviewer:-

Provisionally approved

Decision: Approved

Ref. code: XXI-PGTSC-IIA/P28

17- Clarification of research proposal entitled ***"An observational prospective cohort study to evaluate different drugs used in viral hepatitis and adverse drug reactions associated with those drugs in patient coming to Gastroenterology and Medicine OPD KGMU"*** submitted by Dr. Shilpi Rani Biswas, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 906/Pharm/23 dated 20th November, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous PGTSC Comments	PI response
Study design in protocol is mentioned as Prospective observational study, But in title the study design is mentioned as prospective observational cohort study- PI to clarify or correct.	The **word cohort has been removed** from the title. It was mentioned by mistake.
In Inclusion/ Exclusion criteria- Pregnant & lactating women criteria not mentioned.	If a pregnant and lactating woman suffering from viral hepatitis taking antiviral drugs and develops ADR will be included.
Methodology section is missing, only flow chart of the study is given. PI should include detailed methodology.	Detailed Methodology section is mentioned below.

The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.

Recommendation of reviewer:-
Provisionally approved

Decision: Approved

Ref. code: XXI-PGTSC-IIA/P30

18- Clarification of research proposal entitled ***"Iron profile of very low birth weight preterm neonates in an NICU before and after iron supplementation"*** submitted by Dr. Anu Shree Chaudhary, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2041/Ped/23 dated 8th August, 2023.

Previous PGTSC Comments	PI response
This seems to be a pretest-posttest study design. The same set of subjects is being used before and after supplementation.	Yes
Everything should be planned for this design, including primary objective and corresponding research hypothesis.	Yes, Now as per suggestion, we have done all changes.
There are too many secondary objectives. Actually, these are the data which will be collected during the study.	We have removed some objectives.
Sample size calculation is missing. Only a number (88) is given without any justification.	Sorry for this mistake. Now we have incorporate the calculation.
The statistical analysis section is very general. It should be specific to the research hypothesis.	The statistical analysis has been modified.

The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer:- Provisionally approved **Decision:** Approved *Ref. code: XXI-PGTSC-IIA/P31*
19-	Clarification of research proposal entitled *"Effect of customized oral health awareness program on knowledge and practice of oral hygiene maintenance among institutionalized visually impaired people of Lucknow city: A prospective interventional study"* submitted by Dr. Mohit Kumar Kanoujia, JRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 762/PHD/23 dated 5th December, 2023. **Previous PGTSC Comments:-** • This seems to be a cluster randomized study. There are three intervention groups. • Everything should be planned and stated for the above study including the primary objective and corresponding research hypothesis. • The sample size calculation is missing. • After identifying the unit of analysis, how will the cluster-level analysis be done. • How the individual-level analysis will be done? *The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.* *Recommendation of reviewer:-* Provisionally approved **Decision:** Approved *Ref. code: XXI-PGTSC-IIA/P32*
20-	Clarification of research proposal entitled *"A study to identify potential vitamin a responsive OPMDs patients via prame immunohistochemical expression"* submitted by Dr. Sakshi Deorah, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1943/OP/23 dated 17th November, 2023.

Previous PGTSC Comments	PI response
Project is sketchy.	The proforma is modified now for easy comprehension.
Protocol for Vitamin A prescription not given.	Protocol for vitamin A prescription is mentioned and copy attached.
Inclusion and Exclusion of controls not defined.	The inclusion and exclusion criteria for control group is added and highlighted in the project proposal.
Hindi consent form needs to be re-	Hindi consent form after modification is attached below as Annexure 8.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	formatted as one is unable to read it. |
	The above comment forwarded to the Principal-Investigator was reviewed by the reviewer. ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P40***
21-	Clarification of research proposal entitled ***"Analysis of intellectual property rights reforms in India among health-care professionals in Lucknow Uttar Pradesh: A cross-sectional study"*** submitted by Dr. Atrey J. Pai Khot, SRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 777/PHD dated 7th December, 2023. **Previous PGTSC Comments:** • There are some misprints before point no 5 of the IEC. • Patient information sheet will not required for this protocol. And, if it is needed it may be participants information sheet. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P43***
22-	Clarification of research proposal entitled ***"Lesion characterstics using IVUS imaging in diabetic individuals undergoing PCI and its impact on plaque modifying strategies"*** submitted by Dr. Rajesh Prasad Sharma, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 2035/Cardio/23 dated 18th November, 2023. **Previous PGTSC Comments:** • The study has eight investigators from the same department with overlapping roles. Please reduce the number of Co-PIs or define their unique roles. • Sample size has not been calculated. Number of participants has not been mentioned. • Kindly modify the title ***"Randomized control study" in place of "Randomized control trial"*** ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P52***
23-	Clarification of research proposal entitled ***"A study on evaluating the role of cfDNA (Cell Free DNA) in prognosis of different histopathological grades of oral cancer"*** submitted by Dr. Akanchha Singh, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1944/OP/23 dated 17th November, 2023. **Previous PGTSC Comments:** • Study protocol is not clear as after cfDNA amplification without further processing by other techniques how grading will be carried out. It is not mentioned. • Hindi consent form needs to be re-formatted as one is unable to read it. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P54***
24-	Clarification of research proposal entitled ***"Patient perceptions regarding treatment following an adverse drug event"*** submitted by Dr. Avanish Kumar, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 937/Pharm/2023 dated 11th December, 2023. **Previous PGTSC Comments:** • In Title of the study Adverse drug event is mentioned but in Inclusion criteria /Flow chart –Adverse drug response/ Adverse drug reaction is mentioned –PI to clarify or correct. • In Inclusion/ Exclusion criteria-Age, sex specificity and Pregnant & lactating women criteria not mentioned. • Questionnaires are self prepared–please give proof (or reference) for authentication of Questionnaires. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P55***
25-	Clarification of research proposal entitled ***"Study to evaluate role of serum β-hCG and cystatin C as a predictive biochemical marker for preeclampsia"*** submitted by Dr.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Manvi Tyagi, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1758/23 dated 16th November, 2023. **Previous PGTSC Comments:** • Methodology incomplete Biochemical estimations (hormones) protocol not provided. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P58***
26-	Clarification of research proposal entitled ***"Memory T cell targeted immune response in patients of liver cirrhosis and immunocompetent recipient of ChAdOx1nCov-19 vaccine (Covishield): A cohort study"*** submitted by Dr. Mohd Faizan, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1501/Med/23 dated 2nd December, 2023. **Previous PGTSC Comments:** • Identify one primary objective. Identify the study variables and study parameters. • Convert the primary objective into proper research hypothesis in terms of study parameters identified in step 1. • Is there one cohort (group) only? • Sample size calculation is missing. The number 55 is given without any justification. • The statistical analysis section is very general. It should be specific to the research hypothesis. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P68***
27-	Clarification of research proposal entitled ***"A critical analysis of maternal mortality using three-delay model at tertiary care centre in the Northern India"*** submitted by Dr. Manvi Garg, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1760/23 dated 22nd November, 2023. **Previous PGTSC Comments:** • Case record form–not attached ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer:- Provisionally approved **Decision:** Approved *Ref. code: XXI-PGTSC-IIA/P69*
28-	Clarification of research proposal entitled *"Effect of prophylactic selective serotonin reuptake inhibitors on incidence of acute delirium in intensive care unit and neuropsychiatric illness in intensive care unit survivors"* submitted by Dr. Apoorva Jaiswal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1150/23 dated 20th November, 2023. **Previous PGTSC Comments:** • In Inclusion/ Exclusion criteria- Pregnant & lactating women criteria not mentioned. • As this is RCT study PI should include in methodology section-the method of randomization and Flow chart of the study. • CRF, Richmond Agitation Sedation Score and Sequential organ failure assessment score –not attached. • Clinical trial registry document is also missing. *The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.* *Recommendation of reviewer:-* Provisionally approved **Decision:** Approved *Ref. code: XXI-PGTSC-IIA/P74*
29-	Clarification of research proposal entitled *"Evaluation of differential expression of MUC20 and SPRR1B in oral squamous cell carcinoma and oral potentially malignant disorder"* submitted by Dr. Payal Panwar, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1972/OP/23 dated 2nd December, 2023. **Previous PGTSC Comments:** • The primer to be used for qRT-PCR has not been mentioned. It may be provided. Otherwise it is fine. *The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.* *Recommendation of reviewer:-* Provisionally approved **Decision:** Approved *Ref. code: XXI-PGTSC-IIA/P75*
30-	Clarification of research proposal entitled *"Prospective randomized controlled single centre study to assess efficacy and safety of over the wire mammoth ballon*

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	percutaneous mitral balloon valvotomy in patients with mitral stenosis" submitted by Dr. Rahul Sahu, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 2260/Cardio/23 dated 23rd November 2023. **Previous PGTSC Comments:** • If it is really, RCT, all the fundamentals are missing. • The two groups to be compared for efficacy should be defined exclusively. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary in the absence of proper research hypothesis. The different quantities used in the formula are not clear. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P77***
31-	Clarification of research proposal entitled ***"Clinical, demographic, psychological and molecular profile in patients of pre-extensively drug resistant pulmonary tuberculosis"*** submitted by Dr. Anjali, JRI, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1208/Res/Med/23 dated 9th November, 2023. **Previous PGTSC Comments:** • Sample size calculation has to be done. There can be no 'Pilot Study' in a dempgraphic cross-sectional study. • Inclusion criteria seem to be incorrect. Please check ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P87***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

32- Clarification of research proposal entitled ***"A study on level of compliance with disabled friendly Hospital guidelines in urology, Pharmacology Department and CFAR in a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Rajnish MP Singh, under the guidance Dr. Nitin Dutt Bharadwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/605/23 dated 20th November, 2023.

Previous PGTSC Comments:

- IEC needs to be filled properly.
- Topic of the study is written as the aim.
- How objective 3 of the will be addressed.

The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.

Recommendation of reviewer:-

Provisionally approved

Decision: Approved

Ref. code: XXI-PGTSC-II B-MHA/P1

33- Clarification of research proposal entitled ***"Evaluation of aloe vera loaded nanofibrous scaffold in vital pulp therapy: A randomized controlled trial"*** submitted by Dr. Anjali Mall, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 830/Coms&Endo/2023 dated 20th December, 2023.

Previous PGTSC Comments	PI response
The title mentions that the study is an RCT. If it is a Trial, it will need a CTRI registration, a CONSORT statement and submission for a full Committee meeting. Otherwise please change the title to Randomization Control study.	Evaluation of Aloe vera loaded nanofibrous scaffold in vital pulp therapy: A randomized controlled study.
Sample size mentions 20 patients in each group but the total sample size is also 20. Please correct this.	Sample size=20 (in each group) Number of groups=2 Total sample size=40
Section on Consent is incomplete.	Section on consent is completed and attached.
Age group in Material and Methods is 18-40 years and that in the inclusion criteria is 17-57 years.	Age group 17-57 years

The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.

Recommendation of reviewer:-

Provisionally approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Decision: Kindly modify the title to ***"randomized controlled study"*** instead of ***"randomized controlled trial".*** ***Ref. code: XXII-PGTSC-IIA/P1***
34-	Clarification of research proposal entitled ***"Study of adverse cardiac events and interventions in pregnant women with heart disease"*** submitted by Dr. Shashi, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/2314/2023 dated 22nd December, 2023. ***Previous PGTSC Comments:*** • Identify one primary objective and the rest should be marked as secondary objective. • Identify the study variables and study parameters. • Convert the primary objective, into proper research hypothesis in terms of study variables and parameters. • Sample size is mentioned as approximately 186 patients. Then at another place it is calculated as 120 patients. What are the different quantities in sample size calculation? Clarify it. • The statistical analysis section is general. It should be specific to the primary and secondary objectives of the study. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P5***
35-	Clarification of research proposal entitled ***"A study of 24 hr ambulatory blood pressure, salivary cortisol and urinary melatonin in subjects with acute stroke"*** submitted by Dr. Isha Atam, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3590/PHY/23 dated 19th December, 2023. ***Previous PGTSC Comments:*** • Methodology for biochemical estimations (Salivary cortisol/urinary melatonin) not provided. • Consent form in Hindi is written in first person (Stroke patients may not be able to give consent) • Consent form in English is incomplete. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P7***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

36-	Clarification of research proposal entitled ***"An observational study on comparison of efficacy, safety, cost effectiveness and Impact on quality of life of montelukast levocetirizine combination vs montelukast-bilastine combination therapy in patients of allergic rhinitis"*** submitted by Dr. Debendra Suman, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 1003/Pharm/23 dated 29th December, 2023. ***Previous PGTSC Comments:*** • Identify one primary objective, and the rest should be marked as a secondary objective. • Identify the study variables and study parameters. • Convert the primary objective into proper research hypotheses in terms of study variables and parameters. • This is a prospective cohort comparative study. Everything should be planned accordingly. • The Sample size calculation is arbitrary. It should be specific to the research hypothesis formulated in step 3. • The statistical analysis section is general. It should be specific to the primary and secondary objectives of the study. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P11***
37-	Clarification of research proposal entitled ***"Clinical audit of maternal and fetal outcome in pregnancies following artificial reproductive Technology"*** submitted by Dr. Shweta Priya, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/ 2013/23 dated 16th December, 2023. **Previous PGTSC Comments:** • Study involves pregnant women and their fetuses. The section on vulnerable participants does not mention this. • Patients Information Sheet is incomplete/improperly filled. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P12***
38-	Clarification of research proposal entitled ***"Efficacy of epidural transforaminal injection of ozone in comparison with transforaminal PRP (Platelet Rich Plasma) injection in***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	the management of chronic low back radicular pain: one year prospective randomized control study" submitted by Dr. Karthickraja, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 2213/Anaes/2023 dated 18th December, 2023. **Previous PGTSC Comments:** • Methodology for preparation of PRP not given. ***The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P14***
39-	Clarification of research proposal entitled ***"To study the prognostic indicators for mortality in cases of acute exacerbation of COPD"*** submitted by Dr. Abhishek Shukla, JRI, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1050/ResMed/2023 dated 18th December, 2023.

Previous PGTSC Comment	PI response
Number of subjects is given as 100 in IEC form and 60 in the sample size calculation. Please specify.	60 Cases included in the study attached separately.
Methodology mentions that the study is prospective but the data being collected is retrospective.	This study is Prospective cohort study methodology attached separately.
Patient Information Sheet is incomplete.	Attached separately.

The above comment forwarded to the Principal-Investigator was reviewed by the reviewer.
Recommendation of reviewer:-
Provisionally approved
Decision: Approved
Ref. code: XXII-PGTSC-IIA/P20

40-	Clarification of research proposal entitled ***"Study of P 100 wave latency of visual evoked potential test in persons with recently diagnosed type 11 diabetes mellitus as early diagnostic tool for diabetic retinopathy"*** submitted by Dr. Riya Raj, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3597/PHY/23 dated 31st December, 2023. ***Previous PGTSC Comments:*** • In Inclusion criteria the Age group of the patients not mentioned • Why not Co-PI from Ophthalmic department is included for better clinical interpretation - PI to justify. ***The above comment forwarded to the Principal-Investigator was reviewed by the***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	reviewer. *Recommendation of reviewer:-* Provisionally approved **Decision:** Approved *Ref. code: XXII-PGTSC-IIA/P31*
41-	Clarification of research proposal entitled *"Efficacy of time restricted eating in patients of non-alcoholic fatty liver disease-A chronophysiological interventional study"* submitted by Dr. Shaiphali Sharma, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 1239/Psy/2023 dated 18th December, 2023. *Previous PGTSC Comments:* • This is a prospective cohort comparative study. Everything should be planned accordingly. • Identify the study variables and study parameters. • Convert the primary objective into proper research hypotheses in terms of study variables and parameters. • The Sample size calculation is arbitrary. It should be specific to the research hypothesis formulated in step 3. • The statistical analysis section is missing. It should be specific to the primary and secondary objectives of the study. *The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.* *Recommendation of reviewer:-* Provisionally approved **Decision:** Approved *Ref. code: XXII-PGTSC-IIA/P33*
42-	Clarification of research proposal entitled *"Application of molecular methods to detect common pathogens in patients presenting with sore throat"* submitted by Dr. Prerna Singh, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1170/23 dated 18th December, 2023. *Previous PGTSC Comments:* • In Scientific review committee (SRC) the name and signature of three Co-PIs (Prof. Amita Jain, Prof. Vimala Venkatesht and Dr. Sheetal Verma) is also there. PI should submit the revise SRC report. • In Inclusion/ Exclusion criteria –Pregnant & lactating women criteria not mentioned. • As the all age group patients to be recruited in the study therefore , Child Assent Form, Guardian consent form apart from regular ICF (in both E/H versions) to be submitted (Presently only regular ICF with mention of guardian consent only in English version has been submitted).Case record

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	form –not attached ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P36***
43-	Clarification of research proposal entitled ***"Correlation of hand and foot dimensions with stature for their identification in age group between 19-30 years"*** submitted by Dr. Harshita, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 404/FMT/23 dated 20th December, 2023. ***Previous PGTSC Comments:*** • As this study is on living subjects (ICFs are included) then why PI in exclusion criteria mentioned about decomposed bodies/unknown, unclaimed bodies. • Informed consent forms in English and Hindi versions are not similar. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P39***
44-	Clarification of research proposal entitled ***"Sulfiredoxin levels in chronic periodontitis and healthy patients: A case control study"*** sponsored by Office of Dean, Research & Development, KGMU, Lucknow U.P submitted by Dr. Disha Dixit, JRI through her Mentor Prof. Shalini Kaushal, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 4045/P/23 dated 26th December, 2023. ***Previous PGTSC Comments:*** • Sample size discrepancy in SOP-Checklist (30 Pts in each group) and in Protocol (20 Pts in each group)-PI to correct or clarify • How Plaque and Gingival index will be assessed–PI to clarify. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIB-IMR-R/P1***
45-	Clarification of research proposal entitled ***"Safety and efficacy of azathioprine in the treatment of paradoxical reaction in patients with tuberculous meningitis: A randomized clinical trial"*** submitted by Dr. Saritesh Kumar Thakur, SRI, Department of

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Neurology, King George's Medical University, U.P., Lucknow vide letter no. 390/Neuro/23 dated 20th December, 2023. ***Previous PGTSC Comment:-*** • In SOP-Checklist -Point-6 -confidentiality statement- ticked as No, Point-7 -use of body organ /fluids not ticked for taking CSF -Please revise • Detailed sample size calculation -not done (written that calculation will be done by sample size calculator along with reference)-please give calculated sample size • CTRI document after registration should be send to office of Ethics Committee as soon as it will get registered (as it is RCT study) • Please attach diagnostic criteria for TBM according to Marais et al ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Pending ***Ref. code: XX-PGTSC-IIA/P17***
46.	Clarification of research proposal entitled ***"An analysis of factors affecting intracranial pressure during laparoscopic cholecystectomy using ultrasonography measurement of optic nerve sheath diameter: An observational study"*** submitted by Dr. Asma Fatima Rizvi, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1940/23 dated 8th November, 2023. ***Previous PGTSC Comment:-*** • Please inform, who among the investigators will perform ultrasonic evaluation for ONSD? • Sample size calculated is 108, whereas in IEC proforma it is mentioned as 80. Kindly explain the discrepancy. • ICF: Kindly explain the procedure in simple and understandable language, addressing the patient. • Kindly improve Patient Information Sheet. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P9***
47.	Clarification of research proposal entitled ***"Observational study of acceptability compliance and side effects of contraceptives antara (Depot Medroxyprogesterone Acetate) and chhaya (Centchroman) at a tertiary care centre"*** submitted by Dr. Namita, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P.,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Lucknow vide letter no. OG/2376/23 dated 2nd January, 2024. ***Previous PGTSC Comment:-*** • Sample size calculation not done (only total sample size-356 is given) • In Inclusion criteria –Age group of the patients not mentioned. • Case record form not included. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P6***
48.	Clarification of research proposal entitled ***"Analysis of gait in type-2 diabetes milletus with sarcopenia and without sarcopenia"*** submitted by Dr. Seema Tewari, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3609/PHY/23 dated 26th December, 2023. ***Previous PGTSC Comment:-*** • The name of the Department of Physical Medicine and Rehabilation needs to be corrected in the methodology as it is mentioned as Rehabilitation centre at two places. ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P29***
49.	Clarification of research proposal entitled ***"A study to estimate the level of total serum bile acids and delta bilirubin in intrahepatic cholestasis of pregnancy"*** sponsored by ICMR STS submitted by Ms. Apoorva Sharma, MBBS through her Mentor Dr. Kalpana Singh, Additional Professor & Head, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/970/23 dated 22nd December, 2023. ***Previous PGTSC Comment:-*** • In Inclusion criteria age group of pregnant women to be recruited is not mentioned • Sample size calculation not given (Only 40 cases & 40 control is given) ***The above comments forwarded to the Principal-Investigator were reviewed by the Primary reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XXII -PGTSC-IIB-STS/P1
IB	**Expedited review**
1-	Expedited review of research proposal entitled ***"Efficacy and safety of IV tranexamic acid in prevention of post partum haemorrhage-A randomized controlled study"*** submitted by Dr. Aradhya Garg, JRI, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1966/23 dated 11th December, 2023. ***The above research proposal was forwarded to two reviewers.*** ***Recommendation of Primary reviewer:-*** • In the proposal the references cited in the text are not properly done. In-text citations shall include the last name of the author followed by a comma and the publication year enclosed in parentheses: (Singh, 2024) or they shall be numbered in parenthesis at the end of the sentence or as superscript. Kindly correct. ***Recommendation of Secondary reviewer:-*** • It is better if the Investigators themselves do not participate in scientific review committee or be Chairman of the same. Also as per the comments it is mandatory that Investigating team is competent to carry out the research. Kindly resolve. • No indication of use of body fluid is indicated in Annexure 1. How will the hematocrit be estimated? • What is the role of healthy volunteers (Annexure 1 point 8)? Kindly indicate. • Is the risk not reasonable compared to benefits? Kindly resolve. • If there is a plan for reporting adverse events to IEC (Annexure 1 point 11) then such anticipated adverse events need to be indicated in consent form & patient information sheet. Who will bear the cost of its management? • While everywhere it is mentioned as randomized control study, the methodology section indicates it as randomized control trial. Kindly resolve. • The section of statistical analysis is missing. **Decision:** Revise & re-submit with response to queries in tabular format. *Ref. code: XXII-PGTSC-IB/P1*
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"Surgical outcomes in cases of locally advanced Carcinoma Gall Bladder treated with Neo-adjuvant chemotherapy plus surgery vs surgery alone: A randomized controlled study"*** submitted by Dr. Gargi Chaudhary, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1404/SY/23 dated 25th September, 2023. ***Recommendation of reviewer:*** • Annexure 1 is incomplete. • If patients of both sexes will not be selected (Annexure 1 point 5) then the

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	gender of inclusion criteria be mentioned in text. • Complete the left out items of annexure 1. • Is the risk not reasonable compared to benefits? (See annexure 1 point 10) • Kindly detail the various out come variables as per the objectives in methodology section. • In ICF, kindly correct randomized control trial to randomized control study. • Kindly revise ICF section "Benefits from the study" in a more understandable way particularly for the patient. • The patient information sheet in Hindi is of some other project- Kindly rewrite and resubmits. • If no biological material will be collected (Annexure 1) then how will blood cell counts be analysed (as per text)? • What are the anticipated adverse events & SAE that will be reported as indicated in text. Kindly incorporate them in ICF & patient information sheet as well. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P1***
2.	Research proposal entitled ***"The role of T-Cell TH 17 levels in patients undergoing Laparoscopic/open cholecystectomy and its effect on Gastro-intestinal immunity- A prospective cross-sectional study"*** submitted by Dr. Akash Nikhil Srivastav, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1416/SY/23 dated 28th September, 2023. ***Recommendation of reviewer:*** • Several sections of the IEC form are incomplete. • Title of the study does not adequately reflect the aim of the study. • Sample size calculated has been split between cases and controls. • Kindly clarify the study design; is it a "cross-sectional study" or a "prospective case-control" or a "prospective cohort design". **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Assessment of quality of life after reduction of limb volume by compression Therapy in lower limb Lymphedema patients: A prospective observational study"*** submitted by Dr. Mithlesh Kumar, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1414/SY/23 dated 28th September, 2023. ***Recommendation of reviewer:*** • Kindly complete the left out blanks in Annexure 1.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Seal of Chairperson in scientific review committee is missing. • Is the risk not reasonable compared to benefits?(See annexure 1 point 10) • If there is a plan to report adverse events (Annexure 1 point 11) then incorporate them in ICF & patient information sheet. • Kindly incorporate statistical analysis mentioning the various anticipated outcome measures. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Early onset Neonatal Sepsis in Neonates born through preterm prelabor rupture of Membrane: A Prospective cohort study"*** submitted by Dr. Anita Gautam, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2955/Ped/23 dated 30th August, 2023. ***Recommendation of reviewer:*** • The objective of the study should be mentioned in the title. • There are too many objectives. Identify one primary objective and the rest should be clubbed into secondary objectives. • Make a list of the study variables and population parameter. • Convert the primary objective into research hypothesis using the population parameters. • Sample size is not given. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P4***
5.	Research proposal entitled ***"Prevalence of ionized hypocalcaemia in trauma patients and its role in predicting mortality at level I trauma center- A prospective observational study"*** submitted by Dr. Mohd Tahir, JRI, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. TS/610/23 dated 18th September, 2023. ***Recommendation of reviewer:*** • In SOP-Checklist point no.-7 (use of biological samples) -ticked as NO. but samples will be taken, Point no.-10 (Risk & benefit)-ticked as not reasonable-PI to correct or revise SOP-Checklist. • Informed consent form /Guardian consent form -English/Hindi versions not similar -please resend and as all age group patients will be recruited therefore Child Assent form should also be submitted , • Case record form not included **Comment:** As above **Decision:** Approval subject to appropriate modification of proposal.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XXIII-PGTSC-IIA/P5
6.	Research proposal entitled ***"Perioperative and quality of life outcomes in Laparoscopic repair of hiatal Hernia in a tertiary care center- A prospective study"*** submitted by Dr. Konni Hemanth, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1405/SY/23 dated 25th September, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved *Ref. code: XXIII-PGTSC-IIA/P6*
7.	Research proposal entitled ***"To study empathy scores amongst undergraduate medical students and its correlation with their academic performance"*** submitted by Dr. Danish Rastogi, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3402/PHY/23 dated 4th October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved *Ref. code: XXIII-PGTSC-IIA/P7*
8.	Research proposal entitled ***"Study of Pulmonary function test in young adults engaged in green outdoor versus indoor exercise: A comparative study"*** submitted by Dr. Amit Kumar Balmiki, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3401/PHY/23 dated 4th October, 2023. ***Recommendation of reviewer:*** • Name & Seal of chairperson from SRC is missing. • IEC to be filled properly e.g. point no 5 indicates both sexes subjects are to be recruited whereas, the protocol state male will be the participants. Options of point no 10.i, ii should also be filled appropriately. **Comment:** As above **Decision:** Approval subject to appropriate modification of proposal. *Ref. code: XXIII-PGTSC-IIA/P8*
9.	Research proposal entitled ***"To compare efficacy and safety of imeglimin vs Metformin in patients of type 2 Diabetes mellitus in a tertiary care hospital"*** submitted by Dr. Saurabh Kumar Maurya, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 769/Pharm/23 dated 4th October, 2023. ***Recommendation of reviewer:*** • In SOP-Checklist point no. 3 (Clinical trial)-not attended and point no.—7 • (use of biological samples)-ticked as NO but samples will be taken -PI to correct the SOP-Checklist. **Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	As above **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Fungal infection in burn patients: A prospective study in a University Hospital"*** submitted by Dr. Prashant Kumar Pandey, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 925/23 dated 23rd October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Prevalence of scrub typhus in Pediatric patients with acute Febrile illness in a tertiary care Hospital"*** submitted by Dr. Rajasree Majumdar, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 931/23 dated 25th October, 2023. ***Recommendation of reviewer:*** • The role of supervisor/co-supervisors is not given. • There are too many objectives. Identify one primary objective and the rest should be clubbed into secondary objectives. • Make a list of the study variables and population parameter. • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is not clear. What is the formula used? It should be specific to the research hypothesis. • Statistical Analysis section is missing. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P11***
12.	Research proposal entitled ***"Assessment of drug prescribing pattern in Geriatric type 2Diabetes mellitus patients in a tertiary care teaching hospital"*** submitted by Dr. Deeksha Gupta, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 629A/Pharm/23 dated 29th August, 2023. ***Recommendation of reviewer:*** • In SOP-Checklist, Point no.-10 (Risk & benefit) -ticked as not reasonable -PI to correct. • In Inclusion criteria, sex specification of the patients is not mentioned. • Sample size calculation not given (only total no. of patients-600 is mentioned). • In Tools, WHO-ATC Classification -not attached

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Comment: As above **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-IIA/P12***
13.	Research proposal entitled ***"Comparing the efficacy and safety of Sitagliptin and Glimepiride incombination with Metformin in Geriatric type 2 Diabetes mellitus patients"*** submitted by Dr. Keerthi Rajan M, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 816/Pharm/23 dated 11th October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P13***
14.	Research proposal entitled ***"An observational prospective study to evaluate different drugs used in Hepatitis and adverse Drug reaction associated with those drugs in Paediatric patients coming to Paediatric and Medicine OPD and IPD of KGMU"*** submitted by Dr. Rahul Kumar Soni, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 765/Pharm/23 dated 3rd October, 2023. ***Recommendation of reviewer:*** • Assent form for children not present. **Comment:** As above **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-IIA/P14***
15.	Research proposal entitled ***"A comparison of treatment decision for adhesive restorations using different clinical diagnostic criteria in high caries risk children"*** submitted by Dr. Simran Shivhare, JRI, Department of Paediatrics & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/355/23 dated 21st October, 2023. ***Recommendation of reviewer:*** • What is the meaning of treatment decision? • Make a list of the study variables and population parameter • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is arbitrary. It should be specific to the research hypothesis. • Statistical analysis section is very general. It should be specific to the research hypothesis. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XXIII-PGTSC-IIA/P15
16.	Research proposal entitled ***"Comparison of clinical outcome in Doppler guided hemorrhoidal artery ligation versus laser hemorrhoidoplasty in symptomatic hemorrhoids: A randomized control study"*** submitted by Dr. Lalit Pandey, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1403/SY/23 dated 25th September, 2023. ***Recommendation of reviewer:*** • Is the risk not reasonable compared to benefits? (See annexure 1 point 10)- Kindly clarify. • What are the anticipated adverse events that are planned to be reported to IEC. Kindly state then in ICF/Patient information sheet. • It is expected that sample size consideration are finalized with the help of a statistician. • Kindly incorporate the questionnaire used in study as stated in check list of annexure 1 **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P16***
17.	Research proposal entitled ***"A prospective, observational and comparative study correlating two serum Biomarkers HbA1c and netrin-1 in type-II Diabetes Mellitus patients before and after treatment with oral hypoglycemic agents at a tertiary care hospital"*** submitted by Dr. Anurag Sharma, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 715/Pharm/23 dated 13th September, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Dr. Rajendra Nath did not take part in the discussion and making decision.*** ***Ref. code: XXIII-PGTSC-IIA/P17***
18.	Research proposal entitled ***"A follow up study to asses adherence, Therapeutic outcome & quality of life in patients receiving disulfiram for Alcohol use disorder"*** submitted by Dr. Zoya Khan, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 783/Pharm/23 dated 9th October, 2023. ***Recommendation of reviewer:*** • There are too many objectives. Identify one primary objective and the rest should be clubbed into secondary objectives. • Make a list of the study variables and population parameters required for adherence, therapeutic outcomes, quality of life etc. • Convert the primary objective into research hypothesis using the population parameters.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Sample size calculation is arbitrary. It should be specific to the research hypothesis. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Dr. Rajendra Nath did not take part in the discussion and making decision.*** ***Ref. code: XXIII-PGTSC-IIA/P18***
19.	Research proposal entitled ***"Nerve conduction study in asymptomatic type-II Diabetes mellitus patients and its comparison with healthy controls"*** submitted by Dr. Tipu Sultan, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3415/PHY/23 dated 9th October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P19***
20.	Research proposal entitled ***"Morphological and morphometric analysis of internal ilicc artery and its Variations; CT angiography study"*** submitted by Dr. Saiyadah Kaneez Mehdi, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 233/ANAT/23 dated 31st July, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P20***
21.	Research proposal entitled ***"Comparative evaluation of clinical and Radiographic success of lesion sterilization tissue repair (LSTR), modified LSTR with triple Anibiotic paste and Metapex Pulpectomy in primary molars: A randomized controlled clinical study"*** submitted by Dr. Ayisha Beevi T P, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/354/23 dated 21st October, 2023. ***Recommendation of reviewer:*** • The numbers of objective are 6 in number (synopses) at one place & only 2 at other. Kindly consolidate 6 to 2. • The 'Study procedures" in ICF needs to be in a patient friendly language. • Annexure 1 point 8 indicate that healthy volunteers will be recruited. This is not indicated in the text. Kindly clarify. • Kindly complete left over blanks in annexure 1. • It is expected that sample size allocation in each group has been finalized by a statistician. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XXIII-PGTSC-IIA/P21
22.	Research proposal entitled ***"A comparative study on efficacy, adherence, adverse drug events and quality of life between single fixed dose combination inhaler versus multiple inhalers in triple therapy of COPD"*** submitted by Dr. Vyaktika Shree, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 587/Pharma/23 dated 9th August, 2023. ***Recommendation of reviewer:*** • Chairperson of the SRC is one of the co-investigators of the projects. • Study procedure is not written on the ICF. • Patient information sheet and ICF need to be written in understandable language. • Contact details of the Member Secretary need not be a part of patient information sheet; kindly remove the details. List only the details of the Mentee and the Mentor. **Comment:** • Kindly delete the name of the Member-Secretary, IEC **Decision:** Revise & re-submit with response to queries in tabular format.
	Ref. code: XXIII-PGTSC-IIA/P22
23.	Research proposal entitled ***"Clinical and radiographic evaluation of three different indirect pulpcapping materials in primary molars : A randomized clinical study"*** submitted by Dr. Bhawana Kumari, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/350/23 dated 16th October, 2023. ***Recommendation of reviewer:*** • In Title the study design mentioned as Randomized Controlled Clinical Study, but in Protocol it is mentioned as Randomized Controlled Clinical Trial -PI to clarify. • If this is RCT study then outcome measures should also be included in Protocol apart from method of randomization, blinding and flow chart of the study. • In Inclusion criteria heading -Age and sex of the patients not mentioned (age and sex mentioned in Participants heading)-PI to include it in Inclusion criteria as well. • As 4-9 yrs. age group patients to be recruited in the study therefore, Guardian consent form should also be submitted. • If this is RCT study then Clinical trial registry document should be submitted (after ethical approval)-PI to clarify about study design. • In Tools- FRANKL rating criteria should be attached. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XXIII-PGTSC-IIA/P23
24.	Research proposal entitled ***"Impact of yogic breathing exercises on mental wellbeing in adults"*** submitted by Dr. Divyanshu Arora, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3435/23 dated 18th October, 2023. ***Recommendation of reviewer:*** • Sample size calculation not mentioned. • Review of literature not written properly. • References are written not as per format. Kindly modify them as per Vancouver format. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format.
	Ref. code: XXIII-PGTSC-IIA/P24
25.	Research proposal entitled ***"Factors associated with acute kidney injury in Children with diphtheria and its impact on outcome: An observational study"*** submitted by Dr. Vanshika, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 1311/Ped/23 dated 4th September, 2023. ***Recommendation of reviewer:*** • The consent is to be taken from the parent or the guardian and that need to be written accordingly. Patient information sheet also needs modification accordingly. • In both languages consent and assent forms for children to be written with similar content. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format.
	Ref. code: XXIII-PGTSC-IIA/P25
26.	Research proposal entitled ***"Knowledge, attitudes and practices of oral health care providers and radiation oncologists regarding oral health care needs in head and neck cancer patients undergoing radiotherapy: A multinational questionnaire survey"*** submitted by Dr. Jagruti Mutalikdesai, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 400/Coms&Endo/23 dated 20th October, 2023. ***Recommendation of reviewer:*** • The title of the study mentions 'A multi-national questionnaire survey'. • Kindly clarify is it Multi-national or Multi-centric? • Kindly elaborate the names of Principal Investigators from all collaborating centers with their consent. The consent may either be digital (supported by a mentor verified email) or in a conventional hard copy format. **Comment:** As above

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Decision: Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P26***
27.	Research proposal entitled ***"To study adverse drug reactions of anti tubercular therapy in patient of tuberculosis"*** submitted by Dr. Ankit Sharma, JRI, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 745/ResMed/23 dated 11th October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P27***
28.	Research proposal entitled ***"A multi-centric survey based study of dentists on evidence based dentistry"*** submitted by Dr. Saloni Verma, JRI, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1928/OP/23 dated 6th November, 2023. ***Recommendation of reviewer:*** • There are too many objectives. Identify one primary objective and the rest should be clubbed into secondary objectives. • Make a list of the study variables and population parameters required for adherence, therapeutic outcomes, quality of life etc. • Convert the primary objective into research hypothesis using the population parameters. • The questionnaire for assessment of the knowledge, attitude and practice of Evidence Based Dentistry is required. • Its reliability, validity and utility etc. have to assessed. • There are certain guidelines for multicenter studies. These must be followed. The name of participating centres is required. • What will be the common protocol? • Which will be a coordinating center to collect, process and analyze the data? • The number of field sites varies greatly across studies according to their size, complexity and purpose. How will this be handled? • Sample size calculation is arbitrary. • Sample size calculation will be based on the research hypothesis. • Statistical analysis section is very general. It should be specific to the research hypothesis. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P28***
29.	Research proposal entitled ***"Evaluation of use of fresh frozen plasma and***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	cryoprecipitate in surgical patients" submitted by Dr. Rajeev Kumar, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 428/23 dated 6th November, 2023. ***Recommendation of reviewer:*** • The scientific committee report should be in a proper prescribed format with specific decision and countersigned by Chairman with proper seal. • If anticipated adverse events are planned to be reported to IEC then kindly state those adverse events in IEC & patient information sheet. • Kindly include age in inclusion criteria. • Enumerate the anticipated outcome measures used in statistical analysis. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P29***
30.	Research proposal entitled ***"Viral etiology of fever with rash in Children-A descriptive study"*** submitted by Dr. JBTS Sri Harsha, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 927/23 dated 23rd October, 2023. ***Recommendation of reviewer:*** • Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P30***
31.	Research proposal entitled ***"Assessment of bedside blood transfusion practices in hematological disorder patients"*** submitted by Dr. Manigandan S, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 433/23 dated 1st November, 2023. ***Recommendation of reviewer:*** • Signature, name of the chairperson is not there on the SRC. • As the topoc of the study is to assess bedside blood transfusion practices in hematological disorder patients which is to be followed at each step. However, details are not provided accordingly. The protocol need to be reviewed thoroughly for aim, objectives and methodology. Also, the pt information sheet and ICF to be written accordingly. • IEC needs to be filled properly. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P31***
32.	Research proposal entitled ***"Therapeutic drug monitoring of anti-fungal drug voriconazole in cases of invasive aspergillosis among adult Hemato-Oncological***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	patients" submitted by Dr. Saurabh Kumar Nande, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 428/23 dated 23rd October, 2023. ***Recommendation of reviewer:*** • In SOP-Checklist, Point no.-10 (Risk & benefit) -ticked as not reasonable -PI to correct. • Study design should be elaborated as Prospective observational study • In inclusion /Exclusion criteria Sex specification and pregnant & lactating women criteria not mentioned • In Tools- EORTC/MSG revised guidelines should be included • Where TDM for Voriconazole concentrations will be performed-PI to clarify. • In addition, details of TDM have not been appropriately provided in the proposal. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P32***
33.	Research proposal entitled ***"Urinary lipoarabiomannan detection by lateral flow assay in recently diagnosed HIV-TB patients at a tertiary care centre: An Observational study"*** submitted by Dr. Nanndaputhra Das S, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 426/23 dated 23rd October, 2023. ***Recommendation of reviewer:*** • Vulnerable subjects have been marked as 'Any other' but no details have been given. • Use of biological material has been ticked as 'No' but urine sample is being collected. • Section on consent is incomplete. **Comment:** As above **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-IIA/P33***
34.	Research proposal entitled ***"The least incompatible crossmatched PRBC transfusion by biological in vivo compatibility test"*** submitted by Dr. Manoj Kumar, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 430/2023 dated 3rd November, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P34***
35.	Research proposal entitled ***"Low dose emicizumab prophylaxis in patients with hemophilia a with or without inhibitors-A single center, prospective observational study"*** submitted by Dr. Gaurav Datta, SRI, Department of Clinical Hematology, King

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. 676/CH/2023 dated 9th November, 2023. ***Recommendation of reviewer:*** • Scientific review committee should be revised as the name and signature of three Co-investigators (Dr. S P Verma, Dr. A K Tripathi and Dr. Swasti Sinha) are present. • In SOP-Checklist-Point no. 6 (confidential handling of data) ticked as No and Point no.-10 (Risk & benefit) -ticked as not reasonable -PI to correct. • Sample size calculation not done (only total no. of patients-36 is given) • In Inclusion /Exclusion criteria Sex specification and pregnant & lactating women criteria not mentioned • As the age of recruited subjects are from 2 years onwards, the Child Assent form (in English /Hindi versions) should also be submitted. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P35***
36.	Research proposal entitled ***"To assess correlation of logitudinal strain analysis with timi frame count in patients with non obstructive coronary artery disease with preserved ejection fraction"*** submitted by Dr. Rajendra Kumar Singh, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 2158/Cardio/2023 dated 26th September, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P36***
37.	Research proposal entitled ***"Comparative evaluation of effectiveness of green tea Polyphenoles, triphala, Morinda citrifolia and 5% sodium Hypochorite as intracanals irrigants against isolated Microorganisms from infected root canal-An interventional study"*** submitted by Dr. Daulat Kumar, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/376/2023 dated 31st October, 2023. ***Recommendation of reviewer:*** • In scientific committee report the seal of chairperson is missing. • Since this study includes testing of an ayurvedic product i.e. Triphala, an ayurvedic Co-Investigator may be added. • Regarding preparation of test solutions the references concerning recommended concentration for endodontic irrigation need to be added. • If samples for bacterial load assessment from root canal is to be collected then it should be indicated in annexure 1 (point 7) • Annexure 1 indicates that healthy volunteers will be recruited but this is not indicated in the plan.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Is the risk not reasonable compared to benefits (annexure 1 point 10) • In ICF the 'Study procedure' & 'Benefits from study' sections need to be in a more patient-friendly language. **Comment:** • Kindly provide AYUSH permission letter • Kindly provide the Assent form **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P37***
38.	Research proposal entitled ***"Bacterial and fungal colonization trends in critically ill patients admitted to intensive care unit of a tertiary care center"*** submitted by Dr. Deen Bandhu Prasad, SRI, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1829/2023 dated 14th September, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P38***
39.	Research proposal entitled ***"Prognostic utility of ratio of central venous-to-arterial carbon-dioxide tension difference to arterial-to-venous oxygen content difference combined with arterial lactate clearance rate in early resuscitation of septic shock"*** submitted by Dr. Rahul Kanjilal, SRI, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1888/2023 dated 3rd October, 2023. ***Recommendation of reviewer:*** • The protocol is incomplete. • Actually, the title itself is not clear. • The primary objectives and secondary objectives give a list of study variables. • Make a list of the study variables and population parameters required for adherence, therapeutic outcomes, quality of life etc. • Convert the primary objective into research hypothesis using the population parameters. • There is no methodology section. • There is no study design. • Sample size calculation has no meaning in the absence of properly defined objectives. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P39***
40.	Research proposal entitled ***"Diagnostic utility of contrast enhanced ultrasonography along with grey scale ultrasound and real time elastography in predicting the***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	malignancy risk in Bethesda 3,4,5 lesions-An interventional study" submitted by Dr. Meghana V. Shetty, SR, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. EndoSurg/447/2023 dated 23rd November, 2023. ***Recommendation of reviewer:*** • Section on Biological materials has been answered as 'No' but cytopathology and excision biopsy of the lesion is being done. This needs to be corrected. **Comment:** • Kindly defend the title of the study "an interventional study" vis-à-vis "an exploratory analysis" as the type of study. Actually, the denotation "Diagnostic utility" is sufficient to define the type of study. • Title does not include the site of evaluation; kindly correct. • Should be in ICF corrections. **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-IIA/P40***
41.	Research proposal entitled ***"Reliability of on-site surgeon performed fine needle aspiration cytology with toluidine blue staining in thyroid and breast diseases-An interventional study"*** submitted by Dr. Asiya Zehra, SR, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. EndoSurg/446/2023 dated 23rd November, 2023. ***Recommendation of reviewer:*** • In Inclusion /Exclusion criteria pregnant & lactating women criteria not mentioned. • How PI will assess the learning curve of surgeon performing FNAC across the study. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P41***
42.	Research proposal entitled ***"A study of acute kidney injury in Neurocritical patients and its relationship to short-term outcome"*** submitted by Dr. Amit Kumar Singh, JR, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2021/Med/2023 dated 5th October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P42***
43.	Research proposal entitled ***"Outcome assessment after surgical intervention (Angioplasty with catheter guided thrombolysis and stenting)in infra-inguinal peripheral arterial vascular disease-prospective observational study"*** submitted by Dr.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Kumar Kaushik, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1418/SY/2023 dated 28th September, 2023. ***Recommendation of reviewer:*** • In scientific committee report the seal of chairperson is missing. • In annexure 1 point 8. What will be the role of healthy volunteers as stated? • In the risk not reasonable compared to benefits (see annexure 1 point 10) • If there is a plan of reporting adverse events to the IEC, kindly include them in ICF & patient information sheet. • Kindly eneumerate the outcome variables as per the objectives & the methodology to assess them. • In ICF, kindly detail the 'Study procedure' section in a patient friendly language. Make similar correction in Hindi version. • Point 7 of patient information sheet seems out of context indicating 'Students'. Kindly clarify. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P43***
44.	Research proposal entitled ***"A study of sleep difficulties in children with autism spectrum disorder"*** submitted by Dr. Sonu Maddheshiya, JR, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 1151/Psy/2023 dated 24th July, 2023. ***Recommendation of reviewer:*** • Vulnerable subjects section is ticked as 'No' but children are being used as subjects. • ICF is not signed by the Investigator. **Comment:** As above **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-IIA/P44***
45.	Research proposal entitled ***"Follow up study of drug resistant TB patient enrolled under NTEP on all Oral bedaquiline based regimen at nodal DR-TB center KGMU"*** submitted by Dr. Vineet Kumar Yadav, JR, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 755/RM/2023 dated 18th November, 2023. ***Recommendation of reviewer:*** • Make a list of the study variables and population parameters required for follow up study of drug resistant TB patients enrolled under NTEP on all oral bedaquiline based regimen. • Convert the primary objective into research hypothesis using the population parameters. • Study design says "prospective study". What kind of prospective study?

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Sample size calculation is not given. It just says 100 cases approximately. • Statistical analysis section is very general. It should be specific to the research hypothesis. **Comment:** As above **Decision:** Revise & re submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P45***
46.	Research proposal entitled ***"Study of SLR (Sentinel LN Identification Rate) in patients undergoing sentinel lymphnode biopsy in post NACT breast cancer patients using dual dye technique -A pilot study"*** submitted by Dr. Vivek Rav Prashantkar, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1856/SY/2023 dated 26th November, 2023. ***Recommendation of reviewer:*** • In scientific review committee report the seal of chairperson is missing. • While one document indicates 4 Co-Investigators, the other shows 6 Co-Investigators including 2 additional, Dr. Patwa & Dr. Mala Sagar. Kindly resolve. • In annexure 1 kindly fill up the empty responses and state the sample size. • Is the risk not reasonable compared to benefits (annexure 1 point 10)? • If there is a plan of reporting adverse events to IEC then kindly include the adverse events in ICF & patient information sheet as indicated in annexure 1 point 11. • In under taking by PI the date is missing. • Regarding primary objectives, kindly eneumerate the anticipated short term outcomes that will be analysed. • How will the quality of life be assessed. Kindly include the questionnaire. • In the inclusion criteria state whether all or any specific stage of breast cancer will be included. • Whether pregnant females be also included. If not then show them in exclusion criteria (Since the safety of SLNB in pregnant ladies is not fully established) • How will drug safety be analysed in enrolled patients as indicated in statistical analysis section. • In ICF the study procedure section need to be detailed and as per patient-understandable language. • Kindly revise patient information sheet especially points 6 & 7 as they are totally irrelevant. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P46***
47.	Research proposal entitled ***"Comparative study of sentinel lymph node biopsy and***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	marked axillary lymph node biopsy in assessing axillary lymph node status in patients of locally advanced breast cancer" submitted by Dr. Akansha, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2020/SY/2023 dated 4th November, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P47***
48.	Research proposal entitled ***"Comparative evaluation of different priming solutions in prevention of hypotension in critically ill patients undergoing sustained low efficiency dialysis (SLED) a randomized controlled trial"*** submitted by Dr. Ujjwal Yadav, SR, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1904/2023 dated 11th October, 2023. ***Recommendation of reviewer:*** • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary in the absence of proper research hypothesis. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. • Statistical analysis section is very general. It should be specific to the research hypothesis. **Comment:** • Kindly modify the title to ***"A randomized controlled study"*** in place of ***"Randomized control trial"*** **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P48***
49.	Research proposal entitled ***"Macular thickness and vascular density changes with treatment in unilateral amblyopia - optical coherence tomography angiography based study"*** submitted by Dr. Mariam Saad, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 686/OPH/2023 dated 18th November, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer: Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P49***
50.	Research proposal entitled ***"Matrix metalloproteinase-9 (MMP-9) levels in bronchoalveolar lavage (BAL) samples: implications for diagnosis and prognosis in early-onset and late-onset ventilator-associated pneumonia (VAP): An observational study"*** submitted by Dr. Vikram Singh, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1070/2023 dated 28th November, 2023. ***Recommendation of reviewer:*** • In SOP-Checklist-Point no-10 (Risk & benefit)-ticked as not reasonable -PI to correct.In Inclusion /Exclusion criteria Sex specification and pregnant & lactating women criteria not mentioned. Tools-APACHE score & SOFA score document not attached. **Comment:** As above **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-IIA/P50***
51.	Research proposal entitled ***"Evaluation of perioperative outcomes of pulmonary hydatid cyst special emphasis on bronchopleural fistula: A retrospective observational study"*** submitted by Dr. Chinmoy Chakraborty, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1855/SY/2023 dated 26th November, 2023. ***Recommendation of reviewer:*** • The title and aim/objective do not match. • The "quality of life" instrument is required. • Its reliability, validity, utility have to be assessed. • The title says: retrospective observational study. The study type says: Prospective observational study. • Sample size calculation is arbitrary in the absence of proper research hypothesis. • Statistical analysis section is missing. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P51***
52.	Research proposal entitled ***"Role of cartridge based nucleic acid amplification test in cerebrospinal fluid and gastric aspirate and urinary lipoarabinomannan antigen in the diagnosis of tubercular meningitis in children"*** submitted by Dr. Meghna Singh, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3507/Ped/2023 dated 14th November, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer: Approved **Decision:** Approved *Ref. code: XXIII-PGTSC-IIA/P52*
53.	Research proposal entitled ***"Autologous platelet rich fibrin versus normal saline dressings in chronic venous leg ulcer patients in ulcer size reduction and quality of life: A randomized control study"*** submitted by Dr. Pallaprolu Jyothirmai, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2976/2023 dated 7th November, 2023. *Recommendation of reviewer:* • Section on PIS incomplete **Comment:** As above **Decision:** Approval subject to appropriate modification of proposal. *Ref. code: XXIII-PGTSC-IIA/P53*
54.	Research proposal entitled ***"Role of diagnostic laparoscopy in abdominal penetrating trauma in stable patients: A prospective analytical study"*** submitted by Dr. Arpita Shukla, JRI, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. 608/2023 dated 3rd November, 2023. *Recommendation of reviewer:* • There are too many objectives. Identify one primary objective and the rest should be clubbed into secondary objectives. • Make a list of the study variables and population parameters to define the role of Diagnostic laparoscopy in treatment of stable penetrating abdominal trauma. • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is arbitrary in the absence of proper research hypothesis. • Statistical analysis section is missing. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. *Ref. code: XXIII-PGTSC-IIA/P54*
55.	Research proposal entitled ***"To investigate the prevalence of various single nucleotide polymorphism on COL11A1 gene coding for collagen XI α1 Chain in primary angle closure glaucoma (PACG): A neuro degenerative disease, at a tertiary healthcare center in North India"*** submitted by Dr. Farheen Parveen, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 404/2023 dated 21st November, 2023. *Recommendation of reviewer:*

(Hardeep Singh) Malhotra
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Primer sequence of PCR has not been mention **Comment:** As above **Decision:** Revise & re-submit ***Ref. code: XXIII-PGTSC-IIA/P55***
56.	Research proposal entitled ***"Quality of life of dacryocystitis patients: An observational study"*** submitted by Dr. Anji Jain, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 687/2023 dated 18th September, 2023. ***Recommendation of reviewer:*** • Only the sign of the chairperson is given on the SRC; the seal and name is missing. Also, 2 of the members are Co-Investigators in the project. • IEC needs to be filled properly **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P56***
57.	Research proposal entitled ***"Incidence of development of lymphedema in carcinoma breast patients undergoing modified radical mastectomy using axillary reverse mapping (ARM)"*** submitted by Dr. Akshay, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2018/2023 dated 21st November, 2023. ***Recommendation of reviewer:*** • Make a list of the study variables and population parameters to measure and study the incidence of development of lymphedema in carcinoma breast patients. • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is not given. • Statistical analysis section is very general. It should be specific to the research hypothesis. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P57***
58.	Research proposal entitled ***"A pharmacovigilance study of profile of adverse drug reactions to antihypertensive medications in a tertiary care hospital in Northern India"*** submitted by Dr. Ranjan Awana, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 876/Pharma/2023 dated 3rd November, 2023. ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P58***
59.	Research proposal entitled ***"The expression of prevotella ORIS, neissera flava, neisseria flavescens/subflava, fusobacterium nucleatum, aggregatibacter segnis, streptococcus mitis, porphyromonas and candida albicans in oral potential malignant disorder and oral cancer-A histopathological correlation"*** submitted by Dr. Hrithik Kaushal Jain, JRI, Department of Oral Medicine & Radiology, FODS, King George's Medical University, U.P., Lucknow vide letter no. 519.OMSR/23 dated 27th October, 2023. ***Recommendation of reviewer:*** • The PI is investigating correlation of eight pathogens with oral potentially malignant disorder. This may be scientifically unsound since the minimum sample size will be distributed amongst all these sub-types of patients and correlation of result will be difficult. It is suggested that the PI choose one pathogen and observe its association with OPM lesions for the study to be scientifically relevant. • Project is REJECTED till it is suitably modified. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIA/P59***
II-B	**IMR-Resident**
1-	Research proposal entitled ***"Adjunctive photodynamic therapy in management of periodontal intrabony defects"*** submitted by Dr. Sheetal Sharma, JRI through her Mentor Prof. Rameshwari Singhal, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow funded by Office of Dean, Research & Development, KGMU vide letter no. 1330/P/23 dated 2nd August, 2023. ***Recommendation of reviewer:*** • In SOP-Checklist-Point no-10 (Risk & benefit)-ticked as not reasonable-PI to correct. • In Inclusion criteria Sex specification not mentioned. • Study design mentioned is RCT, but CONSORT guidelines are not followed. • (Randomization method, blinding and Outcome measures are not given in Protocol), therefore PI is requested to change the study design as Randomized Controlled study and mention the randomization method. • The sample size per group given is 20 and total patients no. given as 40, but PI made three groups in methodology (Gp-1, Gp-2 and Gp-3 as control group)-PI to clarify **Comment:** • Study type to be included in the title. **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-II B IMR-R/P1***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

2.	Research proposal entitled ***"A study to estimate circulating level of serum Osteoprotegerin (OPG)and analysis of its gene expression in Prediabetes"*** submitted by Dr. Kriti Kathuria, JRI through her Mentor Dr. Kalpana Singh, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow funded by Office of Dean, Research & Development, KGMU vide letter no. Bio/740/23 dated 17th October, 2023. ***Recommendation of reviewer:*** • Section on biological material/organs/body fluids is ticked as 'No' • Section on DSMB is ticked as 'Yes'. There is no DSMB in the University. • Section on Compensation for injury is ticked as 'Yes'- What injuries are expected? **Comment:** As above **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-II B IMR-R/P2***
II-B	**MHA**
1.	Research proposal entitled ***"To study the cost incurred in inguinal Hernia repair at a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Paayas Raj Verma under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/561/23 dated 31st October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-II B-MHA/P1***
2.	Research proposal entitled ***"To study the expense on Medical and Surgical consumables in Trauma Centre at a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Paayas Raj Verma under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/563/23 dated 31st October, 2023. ***Recommendation of reviewer:*** • Why PI has attached Informed Consent form English & Hindi when this study does not need the living subjects and Human Subject Review Waiver (HSRW) form is already attached. PI to justify. **Comment:** • Permission granted for waiver **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-II B-MHA/P2***
3.	Research proposal entitled ***"A study on level of compliance for laQshya in a tertiary care***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Government Teaching Hospital, Lucknow" submitted by Dr. Diksha Dwivedi under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/574/23 dated 31st October, 2023. ***Recommendation of reviewer:*** • Only the sign of the chairperson is given on the SRC; the seal and name is missing. Tick or comments on none of the decisions are given. • IEC needs to be filled properly. • As the study is to be done on the basis of records. The study aims to analyze the level of compliance for LaQshya in a tertiary care Government hospital where the ICF and patient information sheet will be used? Methodology part needs to be written accordingly. And, for this study waiver may be applied. • As records of Queen Merry hospital are to be extracted a PI from there would be helpful. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-II B-MHA/P3***
4.	Research proposal entitled ***"A time motion study on nurses working in a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Rajnish MP Singh under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/567/23 dated 31st October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-II B-MHA/P4***
5.	Research proposal entitled ***"To study the utilization of x-ray machine in the out patients Department in a tertiary care Government Teaching Hospital, Lucknow"*** submitted by Dr. Paayas Raj Verma under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/562/23 dated 31st October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-II B-MHA/P5***
6.	Research proposal entitled ***"A study on BED mapping in a tertiary care Government Teaching Hospital, Lucknow India"*** submitted by Dr. Deepu Sharma under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	HA/578/23 dated 31st October, 2023. ***Recommendation of reviewer:*** • Only the sign of the chairperson is given on the SRC; the seal and name is missing. • The topic needs to be modified as per the purpose of the study aim. • No need for ICF, waiver may be given. **Comment:** As above **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-II B-MHA/P6***
7.	Research proposal entitled ***"A study on cost incurred in liver Transplant Surgery in a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Deepu Sharma under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/577/23 dated 31st October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-II B-MHA/P7***
8.	Research proposal entitled ***"To study the cost incurred of laproscopic and open cholecystectomy done in the Department of General Surgery in a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Vishika Singh under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/573/23 dated 31st October, 2023. ***Recommendation of reviewer:*** • The seal of chairperson of scientific review committee is missing. • This project deals with cost calculation from financial archival records with no patient participation and PI has applied for consent waiver. **Comment:** As above **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-II B-MHA/P8***
9.	Research proposal entitled ***"A study on the compliance of out-patients Department (OPD) in a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Junaid Ali under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/564/23 dated 31st October, 2023. ***Recommendation of reviewer:*** • Only the sign of the chairperson is given on the SRC; the seal and name is

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	missing. • IEC to be filled properly. • As pattern of prescriptions of the OPD are to be assessed to ensure the quality, will the researcher directly interview the patient or only NQAS checklist for OPDs are to be matched with prescriptions. Clarity is needed. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-II B-MHA/P9***
10.	Research proposal entitled ***"A study of prescriptions in the Rheumatology Department of a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Junaid Ali under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/565/23 dated 31st October, 2023. ***Recommendation of reviewer:*** • Kindly clarify the sample size calculation in more detail. • On One hand it is indicated that the patients will be selected randomly (in patient-information sheet) while on the other hand it is mentioned that sampling will be according to PPS (Population proportion to size) model. In case of latter kindly clarify further, (Methodology). **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-II B-MHA/P10***
11.	Research proposal entitled ***"To study knowledge and attitude of fire safety precautions in tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Meenu Pal under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/566/23 dated 31st October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-II B-MHA/P11***
12.	Research proposal entitled ***"A study of Ayushman Bharat Health Account (ABHA) in tertiary care Government Teaching Hospital in Lucknow, India"*** submitted by Dr. Seema Khan under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/569/23 dated 31st October, 2023. ***Recommendation of reviewer:*** • Seal and name of Chairperson is missing from SRC.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Waiver may be given. **Comment:** As above **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-II B-MHA/P12***
13.	Research proposal entitled ***"A study on safe injection practices among the Nursing staff in a tertiary care Government Teaching Hospital Lucknow, India"*** submitted by Dr. Seema Khan under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/568/23 dated 31st October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-II B-MHA/P13***
14.	Research proposal entitled ***"To study the funds utilized under the chief minister discretionary fund (CMDF) schema in a tertiary care Government Teaching Hospital Lucknow, Uttar Pradesh"*** submitted by Dr. Sakshi Pathak under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/572/23 dated 31st October, 2023. ***Recommendation of reviewer:*** • Seal and name of Chairperson from the SRC is missing. Consent form is not needed. Waiver may be given. **Comment:** As above **Decision:** Approval subject to appropriate modification of proposal. ***Ref. code: XXIII-PGTSC-II B-MHA/P14***
15.	Research proposal entitled ***"To study the level of compliance for kayakalp in a tertiary care Government Teaching Hospital, Lucknow, Uttar Pradesh"*** submitted by Dr. Sakshi Pathak under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/571/23 dated 31st October, 2023. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-II B-MHA/P15***
16.	Research proposal entitled ***"To study claims under Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY) in a tertiary care Government Teaching Hospital Lucknow, India"*** submitted by Dr. Mahwish Suhaib under the guidance Dr. Nitin Dutt

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/570/23 dated 31st October, 2023. ***Recommendation of reviewer:*** • Seal and name of the chairperson is missing from SRC. • Study needs waiver which may be given. However, the protocol needs modification as some of the sentences in methodology section are in past or present tense. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-II B-MHA/P16***
II-B	**STS grant, ICMR, New Delhi**
1.	Research proposal entitled "***The psychological well being of mothers of newborns admitted to a north Indian tertiary care Hospital's neonatal intensive care unit: A cross sectional study***" submitted by Ms. Pragati Jha-MBBS II-Year through her Mentor Dr. Shalini Tripathi, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3255/Ped/23 dated 4th October, 2023. ***Recommendation of reviewer:*** • Correction needs to be done in annexure 1(point 10), that the anticipated risk is not reasonable compared to benefits. • The patient information sheet should be submitted both in English & Hindi (Not just guidelines) **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIII-PGTSC-IIB-STS/P1***
2.	Research proposal entitled "***To determine the appropriateanthropometric tool to analyse body fat***" submitted by Mr. Devansh Mishra, MBBS through her Mentor Prof. NarsinghVerma, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3436/PHY/23 dated 19th October, 2023. ***Recommendation of reviewer:*** • In SOP-Checklist-it is mentioned that MBBS students are to be recruited, but in Inclusion criteria in Protocol the detail about recruited subjects is missing-Please include the specific details of recruited subjects. **Comment:** As above

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Decision: Approval subject to appropriate modification of proposal. *Ref. code: XXIII-PGTSC-IIB- STS /P2*

* Please note that a policy decision is required on the conduct of randomized controlled trial/ academic trial/ investigator-initiated trial or their counterparts as "study", when there is no provision for the insurance of subjects involved. It may be reiterated that residents/students are NOT allowed to conduct such a trial/study at most Institutes in India, including SGPGIMS and RMLIMS from Uttar Pradesh.

** The declaration sought from the investigators is being attached for your reference.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 130th IEC Meeting held on 9th March, 2024

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the 130th Institutional Ethics Committee Meeting held on **9th March, 2024 from 02:15 P.M. till 5:00 P.M.** in the Board-Room, Administrative Block, King George's Medical University, U.P., Lucknow **in hybrid mode.**

The following Members were present in the Meeting:

1. Dr. Alok Dhawan -Chairman
2. Dr. G.G. Agarwal -Member
3. Mrs. Akansha Dubey -Member
4. Mrs. Vasundhara Kumari -Member
5. Mr.Ujjawal Krishna -Member
6. Dr. G.G. Agarwal -Member
7. Dr. Rajendra Nath -Member
8. Dr. Anita Rani -Member
9. Dr. Anupam Mishra -Member
10. Dr. Nisha Mani Pandey -Member
11. Dr. D.N. Upadhyaya -Additional Member-Secretary, IEC
12. Dr. Hardeep Singh Malhotra -Member-Secretary, IEC, ex-officio

The following Members were not present in the Meeting:

1. Dr. Shubha R Phadke
2. Dr. Akaksh Agarwal
3. Dr. K.K. Yadav

	Action Taken
1.	Clarification of research proposal entitled "***Effect of dopamine as VEGF antagonist on progression of sepsis to septic shock, ALI (acute lung injury) and AKI (acute kidney injury)***" submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 46/CCU/2024 dated 6th February, 2024. **Previous EC Comment:-** • The submitted methodology is acceptable now.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The left blanks in annexure 1 need to be completed such as number of subjects etc. • The patient information sheet is incorrect; it should be as per the guidelines already attached with this revised submission. • The consent form should detail 'study procedure' according to the patients understanding and relevant layman language. • Kindly refer to the SOP of IEC (KGMU website). ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** • Kindly fill in the left blank spaces in annexure 1 pt 5 (i), such as number of subjects etc. • The 'Study procedure' section of ICF should explain the patient regarding the procedure that he will undergo and that too in patient friendly language. Moreover the corresponding part in Hindi version communicate similar information. • The initial part of patient information sheet mentioning the guidelines should be deleted. In addition the word 'Randomized trial' needs to be avoided altogether. • If there are any anticipated adverse events as per annexure 1 point 11, then they need to be included in ICF & patient information sheet. ***The aforementioned comments were sent to the Principal-Investigator.*** ***Awaiting reply from the PI.*** **Decision:** Reminder to be sent to the PI ***Ref. code: 119th ECM IIA/P3***
2-	Clarification of research proposal entitled "***Evaluation of lignocaine HCl as a therapeutic and diagnostic tool in myofascial pain dysfunction syndrome (MPDS0 and internal derangement***" submitted by Prof. U.S Pal, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. nil dated 17th February, 2024. **Previous Comment:-** • There are 4 groups of patients: Patients who will not have effect of Lignocaine, MPDS, ID, ID+MPDS. • Measurements are made at 4 time points. • A difference to detect a difference of 1.3% (of what?) will be detected in 20 patients. • I don't think this is feasible. • Outcome measure will be what type of measurements: N/O/I/R? • Why will direct identifiers be used? ***Studied by another investigator at the request of the Principal Investigator after Chairman's permission.*** ***Recommendation of Secondary reviewer.*** PI has already made corrections according to the comments, which are valid and made by Primary Reviewer as- • PI cleared that Indirect Identifiers will be taken • Efficacy measures are added • Sample size calculation is revised • Case Record form is attached

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• PI has given satisfactory answer to quarries of Primary Reviewer for ADR and Compensation • Grouping has also been explained by PI • But PI has not corrected the SOP-Checklist accordingly and did not highlighted the change in protocol–PI should send the corrected SOP-Check list and protocol (Highlighted) with incorporating additional comments, which are as follows: 1. As this is not a Clinical Trial and the Drug Lignocaine is already approved in India, therefore SOP-Checklist must be corrected (SECTION-3 and subsections I, ii, iii). Section 6 – Privacy and Confidentiality–section–I-Indirect Identifier not ticked according to the corrections made by PI in answer to quarries made by Primary Reviewer. Secondly-in section ii- Confidential handling of data by staff is not ticked as YES (Therefore PI is required to send corrected and revised SOP-Check list) 2. In Inclusion /Exclusion criteria–Age/ Sex criteria not mentioned 3. Study design–PI mentioned it as prospective study, which is to be corrected/clarified, as the study design seems to be prospective Interventional and comparative prospective/post operative study. 4. For clarity in methodology PI should add Flow chart of the study. ***The above Comment forwarded to PI vide letter no.2539/Ethics/2023 dated 15th December, 2023 but reply has not been received.*** Reply pending from PI. **Decision:** Reminder to be sent to the PI ***Ref. code: 119th ECM IIA/P18***
3-	Clarification of amended research protocol no. RVP-30-001 RECOVER entitled ***"Brilaroxazine (RP5063), phase 3, randomized, 28 days, double-blind, placebo-controlled, multicenter study to assess the safety and efficacy of brillaroxzine (RP5063) in subjects with an acute exacerbation of schizophrenia, followed by a 52-week open-label extension"*** sponsored by M/s Revive Pharmaceuticals Holdings. Inc. submitted by Prof. Adarsh Tripathi, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter nos. 2020/Psy dated 15th December, 2023, 2229/Psy/2023 dated 25th January, 2024. **Previous EC Comment:** • Latest documents pertaining to insurance which has been asked by EC is not given please clarify. ***Insurance received & valid till 26th July, 2026.*** ***The following documents were reviewed in Its Meeting:-*** DCGI Approval letters:- 1) DCGI Approval letter dated 17 Jul2023 2) DCGI Approval Letter dated 25 Sep23-Increase in sample size for India Study Part 2 open label_ Protocol Amendment 4 Version No. 5.0 dated 17-Jul-2022 Amendment PA04:- 1. Protocol RVP-30-001 v5.0, Amendment 4 dated 17-Jul-2022 i. RVP-30-001_PA4_17Jul2022_Final_Blinded_Tracked_Changes ii. Summary of Changes in Protocol 2. RVP-30-001 Protocol Clarification Memo for PA4_03Oct2022 3. RVP-30-001_Protocol Clarification Letter Addition of Optional Microbiome Samples in India_04Jan2023 4. RVP 30-001_PCL dated 31-Jan-23_Table 5 Inclusion and Exclusion Clarification 5. Informed Consent Forms:-

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

1. Main ICF:-
a. RVP-30-001_India_Site 205_Main ICF_V3.0_12Jan2023_English
b. RVP-30-001_India_Site 205_Main ICF_V3.0_12Jan2023_Hindi including Back translation & Translation Certificate
2. Caregiver ICF:-
a. RVP-30-001_India_Site 205_Caregiver ICF_V3.0_12Jan2023_English
b. RVP-30-001_India_Site 205_Caregiver ICF_V3.0_12Jan2023_Hindi including Back translation & Translation Certificate
Updated V5 ICFs and Justification letter for Sample Size Increase:-
1.1 RVP-30-001_5906-0001_India_Site 205_Main ICF_V4.0_05 Jul 2023_English
1.2 RVP-30-001_5906-0001_India_Site 205_Main ICF_V4.0_05 Jul 2023_Hindi
1.3 RVP-30-001_5906-0001_India_Site 205_Main ICF_V4.0_05 Jul 2023_BT of Hindi
1.4 RVP-30-001_5906-0001_India_Site 205_Caregiver ICF_V4.0_05 Jul 2023_English
1.5 RVP-30-001_5906-0001_India_Site 205_Caregiver ICF_V4.0_05 Jul 2023_Hindi
1.6 RVP-30-001_5906-0001_India_Site 205_Caregiver ICF_V4.0_05 Jul 2023_BT of Hindi
1.7 RVP-30-001_Translation Certificate_Site_205_Hind+BT_25JUL2023
2.0 DCGI submission Sample size increase Justification letter_07 July 2023
V5 ICFs
1. RVP-30-001 Main Master SIS-ICF V5.0 India_ V5.0_Site 205_ V5.0_01Dec2023_ English
2. RVP-30-001_Main Master SIS-ICF_V5.0_India_V5.0_Site 205_V5.0_01Dec2023_Hindi
3. RVP-30-001 Main Master SIS-ICF_V5.0_India_ V5.0Site 205_V5.0_01Dec2023_Hindi_BT
4. RVP-30-001 5906-0001_IND_Site 205_Caregiver_V5.0_01 Dec 2023_English
5. RVP-30-001_Caregiver Master SIS-ICF_V4.0_India_V5.0_Site 205_V5.0_01Dec2023_Hindi
6. RVP-30-001_Caregiver Master SIS-ICF_V4.0_India_V5.0_Site 205_V5.0_01Dec2023_Hindi
7. RVP-30-001 5906 0001_India_205_PP ICF_V3.0_01 Dec 2023_English
8. RVP-30-001 Pregnant Partner SIS-ICF_V2.0_India_v2.0_ Site 205_V3.0_01Dec2023_Hindi
9. RVP-30-001 Pregnant Partner SIS-ICF_V2.0_India_v2.0_ Site 205_ V3.0_01Dec2023_Hindi BT
10. 0295-TR-243917 GNS Translation Certificate_11DEC2023_1343GMT
Updated V5 ICFs and Justification letter for Sample Size Increase:-
1.1 RVP-30-001_5906-0001_India_Site 205_Main ICF_V4.0_05 Jul 2023_English
1.2 RVP-30-001_5906-0001_India_Site 205_Main ICF_V4.0_05 Jul 2023_Hindi
1.3 RVP-30-001_5906-0001_India_Site 205_Main ICF_V4.0_05 Jul 2023_BT of Hindi
1.4 RVP-30-001_5906-0001_India_Site 205_Caregiver ICF_V4.0_05 Jul 2023_English
1.5 RVP-30-001_5906-0001_India_Site 205_Caregiver ICF_V4.0_05 Jul 2023_Hindi
1.6 RVP-30-001_5906-0001_India_Site 205_Caregiver ICF_V4.0_05 Jul 2023_BT of Hindi
1.7 RVP-30-001_Translation Certificate_Site_205_Hind+BT_25JUL2023
2.0 DCGI submission Sample size increase Justification letter_07 July 2023
V5 ICFs
1. RVP-30-001 Main Master SIS-ICF V5.0 India_ V5.0_Site 205_ V5.0_01Dec2023_ English
2. RVP-30-001_Main Master SIS-ICF_V5.0_India_V5.0_Site 205_V5.0_01Dec2023_Hindi
3. RVP-30-001 Main Master SIS-ICF_V5.0_India_ V5.0Site 205_V5.0_01Dec2023_Hindi_BT
4. RVP-30-001 5906-0001_IND_Site 205_Caregiver_V5.0_01 Dec 2023_English
5. RVP-30-001_Caregiver Master SIS-ICF_V4.0_India_V5.0_Site 205_V5.0_01Dec2023_Hindi
6. RVP-30-001_Caregiver Master SIS-ICF_V4.0_India_V5.0_Site 205_V5.0_01Dec2023_Hindi
7. RVP-30-001 5906 0001_India_205_PP ICF_V3.0_01 Dec 2023_English
8. RVP-30-001 Pregnant Partner SIS-ICF_V2.0_India_v2.0_ Site 205_V3.0_01Dec2023_Hindi
9. RVP-30-001 Pregnant Partner SIS-ICF_V2.0_India_v2.0_ Site 205_ V3.0_01Dec2023_Hindi BT
10. 0295-TR-243917 GNS Translation Certificate_11DEC2023_1343GMT

Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 121st ECMIIC/P1

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

4-	Clarification of research proposal entitled ***"Elucidate the regulatory role of miRNAs in epithelial to mesenchymal transition in cervical cancer patients"*** submitted by Mr. Praveen Kumar, Ph.D. Scholar under the guidance Dr. Nitu Nigam, Associate Professor, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 297/CFAR/23 dated 10th January, 2024. **Previous EC Comment:-** • Are there enough funds to be revised before re-submission? • No charge should be levied to subjects. • It is understood that no intervention is involved. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** Provisionally Approved **Decision:** Approved ***Ref. code: 124th ECMIIB-Ph.D/P3***
5-	Clarification of research proposal entitled ***"Elucidate the role of miRNA mediating epithelial to mesenchymal transition in chronic myeloid leukemia"*** sponsored by DST Inspire Fellowship submitted by Ms. Surbhi Gupta, under the guidance Dr. Nitu Nigam, Associate Professor, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 296/CFAR/23 dated 10th January, 2024. **Previous Comment:** • The existing short-coming were informed in person and asked for rectification. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** Approved **Decision:** Approved ***Ref. code: 124th ECM II B-FS/P1***
6-	Clarification of research proposal entitled ***"Impact of awareness of menstrual hygiene and identification of premenstrual dysphoric disorder on quality of life among adolescent Girls in Rural and Urban Area, Lucknow"*** sponsored by Office of Dean, Research & Development, KGMU Lucknow submitted by Dr. Rashmi P. John, Assistant Professor, Department of College of Nursing, King George's Medical University, U.P., Lucknow vide letter no. 94/PF/24 dated 20th January, 2024. **Previous Comment:** • Objectives are not well defined. Objectives should be specific. The reviewer is unable to decide whether you will try to find out level or something else in the awareness of menstrual hygiene. Similarly in the second objective what will be your objective like diagnosis, burden of symptoms for PMS and PMDD is not clear. • Statistical Analysis of various scores/answers/scales are not given. • Since the study population is adolescent girls from the school question number 20 and 21 (How satisfied are you with your personal life and how satisfied are you with your sex life) are not permissible school environments. Moreover, we need a child's Assent

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	form and parents ICF prior to recruitment in the study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** Approved **Decision:** Approved ***Ref. code: 125th ECM II B-IMR-F/P3***
7-	Clarification of research proposal entitled "***Study on clinical outcomes and drug resistance profile (both phenotypic and genotypic) in MDR tuberculosis patients treated with bedaquiline containing regimen***" submitted by Mrs. Rashmi Ratnam, Ph.D. 2021 Scholar through her guide Prof. R.A.S. Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 253/24 dated 26th February, 2024. ***Previous Comment:-*** • Formalities related to vulnerable subjects within the proposal as well as in the annexure (such as assent form; patient information sheet; etc) to be completed. ***The aforementioned comments were reviewed by the Chairperson and the Member-Secretary, IEC.*** Provisionally approved **Decision:** PI to kindly inform if any charges would be levied on the participants/subjects involved? If yes, kindly substantiate the same. ***Ref. code: 126th ECMIIB-Ph.D/P1***
8-	Clarification of research proposal entitled "***To explore the relationship between periodontitis and preterm delivery with fcγ receptor polymorphisms as genetic susceptibility factor***" submitted by Dr. Iman Baig, Ph.D 2019 Scholar through her guide Prof. Pavitra Kumar Rastogi, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 4141/P/24 dated 20th February, 2024. ***Previous Comment:-*** • The PI tried to modify the proposal as per observation; still, there are some font errors in the Hindi consent form and information sheet and some sentences with difficult words. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** • Provisionally approved **Decision:** Approved ***Ref. code: 126th ECMIIB-Ph.D/P2***
9-	Clarification of research protocol no. EX6018-4915 entitled ***"Effects of ziltivekimab versus placebo on morbidity and mortality in patients with heart failure with mildly reduced or preserved ejection fraction and systemic inflammation"*** sponsored by M/s Nova Nordisk India Pvt. Ltd. submitted by Dr. Monika Bhandari, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no. 677/Cardio/Res/2024 dated 3rd February, 2024. **Previous Comment:** • Permission to send sample abroad –Not attached

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- No other Ethical Issue

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of reviewer.

Provisionally approved

The following documents were reviewed in Its Meeting:-

S. No.	Study documents
1-	**Clinical Trial Protocol**
	a) Protocol Version 1.0, Dated 11 Oct 2022 b) Protocol attachment 1: Global list of key staff and relevant departments and suppliers of clinical relevance Version 1.0_Dated 7 Oct 2022 c) Protocol attachment 2: Country list of key staff and relevant departments Version 1.0_Dated 11 Oct 2022 d) HERMES_EX6018-4915_PSP Protocol V1.0_Final_Site#1207_Dr. Monika Bhandari signed on 20 Dec 2022
2-	**Investigator's Brochure**
	a) Investigator's Brochure Ziltivekimab (EX6018-4915), edition 5, Version 1.0 dated 27 Jun 2022 b) Investigator's Brochure receipt form Ziltivekimab (EX6018-4915), edition 5, Version 1.0 dated 27 Jun 2022 signed by Dr. Monika Bhandari on 05 Dec 2022
3-	**Case Record Form**
	a) Sample eCRF Version 1.0, dated 18 Oct 2022 b) Sample CRF 18 Oct 2022 Additional pages Version 1.0 containing Adverse Event form standard version 1.0, Technical Complaint forms for Clinical Study version 1.0 dated 18-Oct-2022 Safety Information forms and Pregnancy (Maternal & Paternal) forms standard version 1.0, and their instruction pages
4-	**Subject Information and Informed Consent Form**
	a) EX6018-4915, Subject Information/Informed Consent Form – Main Version 3.7_IN_EN Dated 22 March 2023, Status: Final b) EX6018-4915, Subject Information/Informed Consent Form – Main Version 3.7_IN_HI Dated 30 March 2023, Status: Final c) EX6018-4915, Subject Information/Informed Consent Form– Main Version 3.7_IN_HI_BT, Dated 30 March 2023, Status: Final d) Translation certificate 3.7_IN_HI Dated

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		e) Translation certificate 3.7_IN_HI_BT Dated
	4.1	f) EX6018-4915, Subject Information/Informed Consent Form – Main Version 3.7_IN_EN Dated 22 March 2023, Status: Final g) EX6018-4915, Subject Information/Informed Consent Form – Main Version 3.7_IN_HI Dated 30 March 2023, Status: Final h) EX6018-4915, Subject Information/Informed Consent Form– Main Version 3.7_IN_HI_BT, Dated 30 March 2023, Status: Final i) Translation certificate 3.7_IN_HI Dated j) Translation certificate 3.7_IN_HI_BT Dated
	4.2	a) EX6018-4915, Subject Information/Informed Consent Form_DTP_Version 2.7_IN_EN Dated 22 March 2023, Status: Final b) EX6018-4915, Subject Information/Informed Consent Form_DTP Version 2.7_IN_HI Dated 30 March 2023, Status: Final c) EX6018-4915, Subject Information/Informed Consent Form_DTP Version 2.7_IN_HI_BT, Dated 30 March 2023, Status: Final d) Translation certificate 2.7_IN_HI Dated e) Translation certificate 2.7_IN_HI_BT Dated
	4.3	a) EX6018-4915, Subject Information/Informed Consent Form_Future Research_Version 3.7_IN_EN Dated 22 March 2023, Status: Final b) EX6018-4915, Subject Information/Informed Consent Form_Future Research_Version 3.7_IN_HI Dated 30 March 2023, Status: Final c) EX6018-4915, Subject Information/Informed Consent Form_Future Research_Version 3.7_IN_HI_BT Dated 30 March 2023, Status: Final d) Translation certificate 3.7_IN_HI Dated e) Translation certificate 3.7_IN_HI_BT Dated
	4.4	a) EX6018-4915, Subject Information/Informed Consent Form_Male Partner_Version 2.7_IN_EN Dated 22 March 2023, Status: Final b) EX6018-4915, Subject Information/Informed Consent Form_Male Partner_ Version 2.7_IN_HI Dated 30 March 2023, Status: Final c) EX6018-4915, Subject Information/Informed Consent Form_Male Partner_ Version 2.7_IN_HI_BT Dated 30 March 2023, Status: Final d) Translation certificate 2.7_IN_HI Dated e) Translation certificate 2.7_IN_HI_BT Dated

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

4.5	a) EX6018-4915, Subject Information/Informed Consent Form_Cardiosignal_Version 2.7_IN_EN Dated 22 March 2023, Status: Final b) EX6018-4915, Subject Information/Informed Consent Form_Cardiosignal_Version 2.7_IN_HI Dated 30 March 2023, Status: Final c) EX6018-4915, Subject Information/Informed Consent Form_Cardiosignal_Version 2.7_IN_HI_BT Dated 30 March 2023, Status: Final d) Translation certificate 2.7_IN_HI Dated e) Translation certificate 2.7_IN_HI_BT Dated
5	**Other information to subjects**
5.1	HERMES PIIC study visits
	a) HERMES PIIC study visits table_English (India)_Dated 14 Dec 2022 b) HERMES PIIC study visits table_Hindi (India)_Dated 19 Dec 2022 c) HERMES PIIC study visits table_English (India)_TCert_Dated 14 Dec 2022 d) HERMES PIIC study visits table_Hindi (India)_TCert_Dated 19 Dec 2022
5.2	4915_ Other Info to Subjects CardioSignal Home Measurement (RoW)
	a) 4915_ Other Info to Subjects CardioSignal Home Measurement (RoW)_English_Updated 10.11.2022. – Precordior Ltd. 2017–2022 b) 4915_ Other Info to Subjects CardioSignal Home Measurement (RoW)_HI_ Updated on 03.04.2023 from English Updated 10.11.2022 – Precordior Ltd. 2017–2022 c) 4915_ Other Info to Subjects CardioSignal Home Measurement (RoW)_HI_BT_ Back translated on 04.04.2023 from Hindi Updated 03.04.2023 – Precordior Ltd. 2017–2022. d) Translation Certificate _SIIC _CardioSignal App_ HI_ Dated 03 April 2023 e) Translation Certificate _SIIC _CardioSignal App_ HI_BT_ Dated 04 April 2023
5.3	4915_CardioSignal India Registration
	a) 4915_CardioSignal India Registration_English_File No. Precor – FIN/I/MD/006237
5.4	4915_CardioSignal-Manual
	a) 4915_CardioSignal-Manual_English_Updated on13 April 2022 – ©Precordior Ltd. 2017–2022
6	**Patient Reported Outcome_English and Translations**
6.1	EQ5D5L_eCOA Handheld

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	a) EQ5D5L_eCOA Handheld_English (India)_v1.00_Dated 16 Nov 2022 b) EQ5D5L_eCOA Handheld_Hindi (India)_v1.00_Dated 17 Nov 2022 c) EQ5D5L_eCOA Handheld_English (India)_v1.00_TCert_Dated 16 Nov 2022 a) EQ5D5L_eCOA Handheld_Hindi (India)_v1.00_TCert_Dated 17 Nov 2022
6.2	KCCQ_eCOA Handheld_v2.00
	a) KCCQ_eCOA Handheld_English (India)_v2.00_Dated 07 Dec 2022 b) KCCQ_eCOA Handheld_Hindi (India)_v2.00_Dated 09 Dec 2022 c) KCCQ_eCOA Handheld_English (India)_v2.00_TCert_Dated 07 Dec 2022 a) KCCQ_eCOA Handheld_Hindi (India)_v2.00_TCert_Dated 09 Dec 2022
6.3	NOVONOR_EX6018-4915_eCOA Handheld_Alarms
	a) NOVONOR_EX6018-4915_eCOA Handheld_Alarms_English (India)_v1.00_Dated 25 Nov 2022 b) NOVONOR_EX6018-4915_eCOA Handheld_Alarms_Hindi (India)_v1.00_Dated 21 Dec 2022 c) NOVONOR_EX6018-4915_eCOA Handheld_Alarms_English (India)_v1.00_TCert_Dated 25 Nov 2022 a) NOVONOR_EX6018-4915_eCOA Handheld_Alarms_Hindi (India)_v1.00_TCert_Dated 21 Dec 2022
6.4	NOVONOR_EX6018-4915_eCOA Handheld_Dialog_Push_Notification
	a) NOVONOR_EX6018-4915_eCOA Handheld_Dialog_Push_Notification_English (India)_v1.00_Dated 25 Nov 2022 b) NOVONOR_EX6018-4915_eCOA Handheld_Dialog_Push_Notification_Hindi (India)_v1.0_Dated 21 Dec 2022 c) NOVONOR_EX6018-4915_eCOA Handheld_Dialog_Push_Notification_English (India)_v1.00_Tcert_Dated 25 Nov 2022 a) NOVONOR_EX6018-4915_eCOA Handheld_Dialog_Push_Notification_Hindi (India)_v1.00_Tcert_Dated 21 Dec 2022
6.5	NOVONOR_EX6018-4915_eCOA Handheld_Dosing Diary
	a) NOVONOR_EX6018-4915_eCOA Handheld_Dosing Diary_English (India)_v1.00_Dated 25 Nov 2022 b) NOVONOR_EX6018-4915_eCOA Handheld_Dosing Diary_Hindi (India)_v1.00_Dated 21 Dec 2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	c) NOVONOR_EX6018-4915_eCOA Handheld_Dosing Diary_English (India)_v1.00_TCert_Dated 25 Nov 2022 a) NOVONOR_EX6018-4915_eCOA Handheld_Dosing Diary_Hindi (India)_v1.00_TCert_Dated 21 Dec 2022
6.6	NOVONOR_EX6018-4915_eCOA Handheld_HH Training Module
	a) NOVONOR_EX6018-4915_eCOA Handheld_HH Training Module_English (India)_v1.00_Dated 25 Nov 2022 b) NOVONOR_EX6018-4915_eCOA Handheld_HH Training Module_Hindi (India)_v1.00_Dated 21 Dec 2022 c) NOVONOR_EX6018-4915_eCOA Handheld_HH Training Module_English (India)_v1.00_Tcert_Dated 25 Nov 2022 a) NOVONOR_EX6018-4915_eCOA Handheld_HH Training Module_Hindi (India)_v1.00_Tcert_Dated 21 Dec 2022
6.7	NOVONOR_EX6018-4915_eCOA Handheld_Patient Connect
	a) NOVONOR_EX6018-4915_eCOA Handheld_Patient Connect_English (India)_v1.00_Dated 25 Nov 2022 b) NOVONOR_EX6018-4915_eCOA Handheld_Patient Connect_Hindi (India)_v1.00_Dated 21 Dec 2022 c) NOVONOR_EX6018-4915_eCOA Handheld_Patient Connect_English (India)_v1.00_TCert_Dated 25 Nov 2022 a) NOVONOR_EX6018-4915_eCOA Handheld_Patient Connect_Hindi (India)_v1.00_TCert_Dated 21 Dec 2022
6.8	NOVONOR_EX6018-4915_eCOA Handheld_PGIC
	a) NOVONOR_EX6018-4915_eCOA Handheld_PGIC_English (India)_v1.00_Dated 25 Nov 2022 b) NOVONOR_EX6018-4915_eCOA Handheld_PGIC_Hindi (India)_v1.00_Dated 21 Dec 2022 c) NOVONOR_EX6018-4915_eCOAHandheld_PGIC_English (India)_v1.00_Tcer_Dated 25 Nov 2022 a) NOVONOR_EX6018-4915_eCOAHandheld_PGIC_Hindi (India)_v1.00_Tcert_Dated 21 Dec 2022
6.9	NOVONOR_EX6018-4915_eCOA Handheld_PGIS
	a) NOVONOR_EX6018-4915_eCOA Handheld_PGIS_English (India)_v1.00_Dated 25 Nov 2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		b) NOVONOR_EX6018-4915_eCOA Handheld_PGIS_Hindi (India)_v1.00_Dated 21 Dec 2022 c) NOVONOR_EX6018-4915_eCOAHandheld_PGIS_English (India)_v1.00_Tcert_Dated 25 Nov 2022 a) NOVONOR_EX6018-4915_eCOAHandheld_PGIS_Hindi (India)_v1.00_Tcert_Dated 21 Dec 2022
	6.10	NOVONOR_EX6018-4915_eCOA Handheld_Reminder Icon
		a) NOVONOR_EX6018-4915_eCOA Handheld_Reminder Icon_English (India)_v1.00_Dated 25 Nov 2022 b) NOVONOR_EX6018-4915_eCOA Handheld_Reminder Icon_Hindi (India)_v1.00_Dated 21 Dec 2022 c) NOVONOR_EX6018-4915_eCOA Handheld_Reminder Icon_English (India)_v1.00_Tcert_Dated 25 Nov 2022 a) NOVONOR_EX6018-4915_eCOA Handheld_Reminder Icon_Hindi (India)_v1.00_Tcert_Dated 21 Dec 2022
	6.11	NOVONOR_EX6018-4915_eCOA Handheld_SPFQ
		a) NOVONOR_EX6018-4915_eCOA Handheld_SPFQ_English (India)_v1.00_Dated 25 Nov 2022 b) NOVONOR_EX6018-4915_eCOA Handheld_SPFQ_Hindi (India)_v1.00_Dated 21 Dec 2022 c) NOVONOR_EX6018-4915_eCOAHandheld_SPFQ_English (India)_v1.00_Tcert_Dated 25 Nov 2022 a) NOVONOR_EX6018-4915_eCOAHandheld_SPFQ_Hindi (India)_v1.00_Tcert_Dated 21 Dec 2022
	6.12	NOVONOR_EX6018-4915_eCOA Handheld_Study CheckIn
	6.13	NOVONOR_EX6018-4915_eCOA Handheld_Study Introduction Video
		a) NOVONOR_EX6018-4915_eCOA Handheld_Study Introduction Video_English (India)_v1.00_Dated 25 Nov 2022 b) NOVONOR_EX6018-4915_eCOA Handheld_Study Introduction Video_Hindi (India)_v1.00_Dated 21 Dec 2022 c) NOVONOR_EX6018-4915_eCOA Handheld_Study Introduction Video_English (India)_v1.00 TCert_Dated 25 Nov 2022 a) NOVONOR_EX6018-4915_eCOA Handheld_Study Introduction Video_Hindi

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	(India)_v1.00 TCert_Dated 21 Dec 2022
6.14	NOVONOR_EX6018-4915_eCOA Handheld_Visit Questionnaires
	a) NOVONOR_EX6018-4915_eCOA Handheld_Visit Questionnaires_English (India)_v1.00_Dated 25 Nov 2022 b) NOVONOR_EX6018-4915_eCOA Handheld_Visit Questionnaires_Hindi (India)_v1.00_Dated 21 Dec 2022 c) NOVONOR_EX6018-4915_eCOA Handheld_Visit Questionnaires_English (India)_v1.00_Tcert_Dated 25 Nov 2022 a) NOVONOR_EX6018-4915_eCOA Handheld_Visit Questionnaires_Hindi (India)_v1.00_Tcert_Dated 21 Dec 2022
8	DCGI Submission Letter for the study dated 12 Jan 2023 along with SUGAM screenshot
9	Global Clinical Trial Insurance 390-08654942-30078 certificate, Issue date 01 May 2022
10	Local Clinical Trial Insurance P0023200001/9999/100060 certificate, Issue date 1 Sep 2022
11	Principal Investigator's Undertaking signed by Dr.Monika Bhandari and dated on 21 Dec 2022
12	CV of the Dr.Monika Bhandari, signed and dated on 22 Nov 2022 and copy of Medical Registration Certificate 12-11803 and GCP 7 Jan 2025
13	Subject Recruitment and Retention Materials
13.1	4915-hq-srr-HERMES-Patient ID-visit reminder card_version 1.0
	a) 4915-hq-srr-HERMES-Patient ID-visit reminder card_English_version 1.0 a) 4915-hq-srr-HERMES-Patient ID-visit reminder card_Hindi_version 1.0(IN)
13.2	4915-hq-srr-HERMES-Patient study booklet version 1.0
	a) 4915-hq-srr-HERMES-Patient study booklet_English_version 1.0 a) 4915-hq-srr-HERMES-Patient study booklet_Hindi_version 1.0(IN)
13.3	4915-hq-srr-HERMES-Contact persons checklist version 1.0
	a) 4915-hq-srr-HERMES-Contact persons checklist_English_version 1.0 a) 4915-hq-srr-HERMES-Contact persons checklist_Hindi_version 1.0(IN)
13.4	4915-hq-srr-HERMES-Patient newsletter 1 version 1.0
	a) 4915-hq-srr-HERMES-Patient newsletter 1_English_version 1.0 a) 4915-hq-srr-HERMES-Patient newsletter 1_Hindi_version 1.0(IN)

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

13.5	4915-hq-srr-HERMES-Patient newsletter 2 version 1.0
13.6	4915-hq-srr-HERMES-Patient newsletter 3_version 1.0
	a) 4915-hq-srr-HERMES-Patient newsletter 3_English_version 1.0 a) 4915-hq-srr-HERMES-Patient newsletter 3_Hindi_version 1.0(IN)
13.7	4915-hq-srr-HERMES-Patient newsletter 4_version 1.0
	a) 4915-hq-srr-HERMES-Patient newsletter 4_English_version 1.0 a) 4915-hq-srr-HERMES-Patient newsletter 4_Hindi_version 1.0(IN)
13.8	4915-hq-srr-HERMES-Patient recruitment advertisement_version-digital 1.0
	a) 4915-hq-srr-HERMES-Patient recruitment advertisement_English_version-digital 1.0 a) 4915-hq-srr-HERMES-Patient recruitment advertisement_Hindi_version-digital 1.0(IN)
13.9	4915-hq-srr-HERMES-Patient recruitment advertisement_version-poster 1.0
	a) 4915-hq-srr-HERMES-Patient recruitment advertisement_English_version-poster 1.0 a) 4915-hq-srr-HERMES-Patient recruitment advertisement_Hindi_version-poster 1.0(IN)
13.10	4915-hq-srr-HERMES-Patient recruitment advertisement_version-trifold 1.0
	a) 4915-hq-srr-HERMES-Patient recruitment advertisement_English_version-trifold 1.0 a) 4915-hq-srr-HERMES-Patient recruitment advertisement_Hindi_version-trifold 1.0(IN)
13.11	4915-hq-srr-HERMES-Patient thank you letter_version 1.0
	a) 4915-hq-srr-HERMES-Patient thank you letter_English_version 1.0 a) 4915-hq-srr-HERMES-Patient thank you letter_Hindi_version 1.0(IN)
13.12	4915-hq-srr-HERMES-Patient welcome letter_version 1.0
	a) 4915-hq-srr-HERMES-Patient welcome letter_English_version 1.0 a) 4915-hq-srr-HERMES-Patient welcome letter_Hindi_version 1.0(IN)
13.13	HERMES Study Intro movie script 1.0
13.15	Translation Certificate
	a) HERMES_Hindi (IN)_TCert for Subject Recruitment and Retention Materials dated 21 Oct 2022
14	**CTRI Registration_REF/2023/02/063131**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

15	**Central lab manual along with FC and Lab certificate**
	a) Lab Certificate HERMES Central lab letter (India)_Dated 14 Oct 222 b) Q2 Solutions Lab Manual_4915- DRAFT ASIA 16 NOV 22_English Q2 Solutions Lab Flowchart V01 c Dated 16 Dec 2022
16	**Draft Clinical Trial Agreement**
17	Investigator's Brochure Ziltivekimab (EX6018-4915), edition 6, Version 1.0 dated 01Jun 2023
18	CRF Completion Requirements 04 Apr 2023 v.1.0
19	Filenote HERMES Lab Flow Chart additional clarifications 22-may-23
20	IP Instructions TMM V1.0_23 Feb 2023
21	IRT User Manual User Guide Site and Investigator v 2.0_09 March 2023
22	Lab Manual Flowchart V01 01-mar-2023, India (English)
23	Lab Manual Q2_final_India V1.0_10 Feb 2023
24	Operational Oversight Guidance on tuberculosis for sites V1.0
25	Operational Oversight Ziltivekimab & infections guidance for site V1.0
26	Operational procedure Manual Clario_How to activate the Site Tablet V1.0
27	Operational procedure Manual Clario_How to create a participants V1.0
28	Operational procedure Manual Clario_How to support your participants V1.0
29	Operational procedure Manual Clario_Key report V1.0
30	Operational procedure Manual Clario_Site Manual V1.0_07 Feb 2023
31	Operational procedure Manual Cardio Signal HERMES Site manual V3.0_13 April 2023
32	Operational Procedure Manual Event Adjudication Site Manual v1.0_29 March 2023
33	Protocal Standard of Care guidance V1.0
34	Techincal Design Sample eCRF Specs v.1.0_05 April 2023
35	Local Insurance_P0124200001/9999/100060_Expiry:30 April 2024
36	Global Insurance_390-08654942-30078_Wxpiry:30 April 2024

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	37	National Strategic Plan for Tuberculosis 2017-25 Elimination by 2025
	38	CT-06 NOC Letter – Ct/23/000009
	39	CTRI Registration

Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 126th ECMIIC/P1

10- Clarification of research proposal entitled "***An analysis of the anomalous fissure of ligamentum teres hepatis: A morphological perspective in North Indian population***" submitted by Dr. Heena Singh, Assistant Professor, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 650/ANAT/23 dated 21st February, 2024.

Previous Comment:

- Data management cannot be NA
- Part of methodology has been written in past tense.

The aforementioned comments were reviewed by the Member-Secretary, IEC. Recommendation of reviewer.

Provisionally approved

Decision: Approved

Ref. code: 127th ECM IIA/P4

11- Clarification of research proposal entitled ***"Differential profiling and assessment of early phase non-coding RNAs and adipokines in healthy controls, pre-diabetic, and diabetic patients- A pilot study"*** submitted by Prof. Wahid Ali, Department of Pathology, King George's Medical University, U.P., Lucknw vide letter no. 30/24 dated 11th January, 2024.

Previous Comment:

- It is CDRI sponsored project, to be conducted by KGMU, SMS Jaipur and CDRI. It is clear that the patients will be enrolled from Medicine Department but the role of SMS Jaipur and CDRI is unclear. Will the samples be transferred to Jaipur/ CDRI for some part of the study? What will be the contributions of KGMU pathology department? Kindly explain the workflow clearly.
- Who will collect informed consent from patients and when?
- Kindly, define criteria to Label study subjects as healthy, pre-diabetic or diabetic.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

Decision: Approved

Ref. code: 127th ECM IIA/P5

12- Clarification of research proposal entitled "***Role of heavy metal toxicity in progression of bladder cancer and their effect on quality of life***" sponsored by CST-UP, Lucknow submitted by Prof. Vishwajeet Singh, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 117/URO/24 dated 21st February, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Previous Comment:

- ICF for patients & healthy volunteers is same.

The aforementioned comments were sent to the Principal-Investigator.

The response received was reviewed and found to be reasonable.

Decision: Approved

Ref. code: 127th ECM IIA/P10

13- Clarification of research proposal entitled ***"A quality improvement study to assess patient satisfaction in surgical out patient Department at a tertiary care Hospital in North India: A cross sectional study"*** submitted by ICMR under supervision of Dr. Saumya Singh, Associate Professor, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 73/24 dated 9th January, 2024.

Previous EC Comment	PI response
Section 5: Duration of Subjects participation: not mentioned	Duration of Subjects participation is 3 months.(It has been corrected in the proposal)
What is the role of volunteers in this study?	Volunteers will be excluded from the study.
Why take Vulnerable Subjects in this study?	Vulnerable Subjects will be excluded from the study.
Why take Special group: "Staff" in this study?	Special group: "Staff" has been removed from the study.
Section 6: Why use direct identifiers?	No direct identifiers word will be included in the study.
Section 8ii: Volunteer consent is not checked.	Not Applicable (As volunteers will not be included)
Section 10: If risk are not reasonable compared to anticipated benefits: Unethical to do the study. In view of this, there is no point doing this research. The rest of the proposal has thus not been reviewed.	There is no risk to participants because this is only a questionnaire based study.
Section 10iii: What is the expected direct benefit to the subject?	These are expected direct benefits to the subject: • This study will help to increase general awareness in patients and attendants regarding the services and facilities available. • Patients can avail the facilities provided by hospital eg. Vippana, Ayushman card etc.(Financial benefits) • This study will give subjects a

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		chance to discuss the problems and challenges

The aforementioned comments were sent to the Principal-Investigator.
Awaiting response from PI.

Decision: Reminder to be sent to the PI

Ref. code: 127th ECM IIA/P14

14- Clarification of research entitled ***"An analysis of risk factors associated with delayed presentation, neglected presentation and relapse in cases of clubfoot treated with ponseti technique at the clubfoot clinic of KGMU: A record review"*** submitted by Dr. Vikas Verma, Associate Professor, Department of Paediatric Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 2810/PaedOrtho/24 dated 18th January, 2024.

Previous EC Comment	PI response
Kindly submit the list of anticipated outcome variables and summarise the statistical analysis as per the respective variables	The outcome variables are 1. Delayed presentation 2. Neglected presentation 3. Relapse SECTION ON STATISTICAL ANALYSIS HAS BEEN REWRITTEN AS FOLLOW:- "The data will be entered in MS EXCEL spreadsheet using a password protected computer. Statistical analysis will be done using Statistical Package for Social Sciences (SPSS) version 23.0.Categorical variables will be presented in number and percentage (%) and continuous variables will be presented as mean ± SD and median. Normality of data will be tested by Kolmogorov-Smirnov test. Quantitative variables will be compared using Unpaired t-test (for normally distributed data) or Mann-Whitney Test (when the data sets are not normally distributed) between two groups. For three groups, Anova (for normally distributed data) and Kruskalwallis test (for non parametric data) would be used. Qualitative variables will be compared using Chi-Square test /Fisher's exact test. Bivariable analysis would be done to identify factors associated with delayed presentation, neglected presentation and relapse. Factors associated with < 0.25

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		significance on bivariate analysis will be used to design separate logistic regression models to predict delayed presentation, neglect and relapse. A p value of <0.05 will be considered as significant."

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

Decision: Approved

Ref. code: 127th ECM IIA/P15

15- Clarification of research entitled ***"Radiation induced damage in head and neck and its management by hyperbaric oxygen therapy-randomized control trial"*** submitted by Prof. Vijay Kumar, Head, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 31/24 dated 10th January, 2024.

Previous EC Comment	PI response
Fundamentals of RCT are missing Research hypothesis is missing Study variables Primary and secondary outcome Measures Method used to generate random allocation How double blinding is done	Research hypothesis and study variables, primary and secondary outcomes, method to use random allocation, method of blinding, etc added in methodology.
The two comparative groups should be explicitly identified	Modified and added in the study
The sample size calculation is not given	Sample size calculation is added in the study
Method for statistician analysis.	Method for statistician analysis added in the study.
How the result will be presented Participants flow, Baseline data Outcomes and estimation, Adverse events	Added in the methodology

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

Comment:

- Kindly modify the title *"A randomized control study"* in place of *"Randomized control trial"*

Decision: Approval subject to modification of the title

Dr. Anupam Mishra did not take part in the discussion and making decision.

Ref. code: 127th ECM IIA/P19

16- Clarification of research proposal entitled ***"To investigate the potential source of DNA and its STR-DNA profiling for human identification from the most challenging body fluids in a medico-legal setting"*** submitted by Office of the Dean, Research & Development, KGMU

	Lucknow under supervision of Dr. Anshu Priya, Assistant Professor, Department of Forensic Finger Printing Lab (CFAR) King George's Medical University, U.P., Lucknow vide letter no. 39/FMT/24 dated 1st February, 2024. **Previous Comment:** • Approval subject to modification of ICF (English & Hindi) into simple language. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** Provisionally Approved **Decision:** Approved ***Ref. code: 127th ECM II B-IMR-F/P1***
17-	Clarification of research protocol no. CTIN816A12201 entitled "***A randomized, multi-centric, placebo-controlled, participant, and investigator blinded study to evaluate the safety, tolerability and efficacy of TIN816 in adult patients at risk for acute kidney injury following cardiac surgery***" submitted by M/s Novartis Healthcare Private Limited under supervision of Dr. Sarvesh Kumar, Professor Junior Grade, Department of Cardiovascular & Thoracic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 172/CVTS/24 dated 23rd February, 2024. **Previous Comment:** • IEC form section 7 (I-VIII) are still mentioned as 'NO' which means no samples are being collected. • Study may be after some minor changes in the IEC form and subject to acknowledgement/approval from DCGI once it is obtained. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** Provisionally Approved ***The following documents were reviewed in its Meeting:-***

S.no	Name of documents	Version/reference no.	Date
1.	Clinical Trail Protocol	Version Number: 01	18-Apr-2023
2.	Investigator's brochure TIN816	Edition 03	13-Mar-2023
3.	eCRF2.0_CTIN816A12201_15MAR2023(PROD)		
4.	Patient Information and Informed Consent Form	Version 4.0	15 May 2023
5.	Patient Information and Informed Consent Form translated from English to Hindi on 05 Jun 2023	Version 4.0	15 May 2023
6.	Patient Information and Informed Consent Form back translated from	Version 4.0	15 May 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Hindi to English on 09 Jun 2023		
7.	Translation and back translation certificate for Patient Information and Informed Consent Form • Hindi	Version 4.0	15 May 2023
8.	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants	Version 1.0	20 Sep 2022
9.	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants translated from English to Hindi on 29 Sep 2022	Version 1.0	20 Sep 2022
10.	Informed Consent Form: Pregnancy Follow-up for Pregnant Participants back translated from Hindi to English on 11 Oct 2022	Version 1.0	20 Sep 2022
11.	Translation and back translation certificates for Informed Consent Form: Pregnancy Follow-up for Pregnant Participants • Hindi	Version 1.0	20 Sep 2022
12.	Informed Consent for Exploratory Genetic Research	Version 1.0	20 Sep 2022
13.	Informed Consent for Exploratory Genetic Research translated from English to Hindi on 29 Sep 2022	Version 1.0	20 Sep 2022
14.	Informed Consent for Exploratory Genetic Research back translated from Hindi to English on 11 Oct 2022	Version 1.0	20 Sep 2022
15.	Translation and back translation certificates for Informed Consent for Exploratory Genetic Research • Hindi	Version 1.0	20 Sep 2022
16.	Audio-Video Informed Consent Form	Version 1.0	1 Apr 2021
17.	Audio-Video Informed Consent Form translated from English to	Version 1.0	1 Apr 2021

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Hindi on 23 Jun 2021		
18.	Audio-Video Informed Consent Form back translated from Hindi to English on 25 Jun 2021	Version 1.0	1 Apr 2021
19.	Translation and back translation certificates for Audio-Video Informed Consent Form • Hindi	Version 1.0	1 Apr 2021
20.	Patient card_English	--------	--------
21.	Patient card translated to Hindi	--------	--------
22.	Patient card back translated from hindi to english	--------	--------
23.	Certificate of translation for Patient Card • Hindi	--------	--------
24.	Trial Participant Treatment Info Shell-Hindi	Version 00	23.08.2022
25.	Translation certifcate for Trial Participant Treatment Info Shell-Hindi	--------	--------
26.	Participant Thank you Letter Study start_English	--------	--------
27.	Participant Thank you Letter Study start_Hindi	--------	--------
28.	Participant Thank you Letter Study start_Hindi to English	--------	--------
29.	Trial Participant Treatment Info Shell-Hindi	Version 00	23.08.2022
30.	Translation and back translations for Thank you letter study start-Hindi	--------	--------
31.	Participant Thank you Letter Study end_English	--------	--------

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

32.	Participant Thank you Letter Study end_Hindi	--------	--------
33.	Participant Thank you Letter Study start_Hindi to English	--------	--------
34.	Ineligible Participant Thank you card_Hindi	--------	--------
35.	Translation certifcate for Ineligible Participant Thank you card • Hindi	--------	--------
36.	The Complete Training Manual CAM ICU_English	--------	--------
37.	Translation certificate for the Complete Training Manual CAM ICU_English	--------	--------
38.	Insurance certificate	--------	1st January 2024 to 31st December 2024
39.	Draft CTA	--------	--------
40.	PI – CV, GCP and MRC	--------	--------
41.	IU	--------	--------
42.	HA Acknowledgement copy_CTIN816A12201 iCTA_1 Nov 2022	--------	1 Nov 2022
43.	HLM review CTIN816A12201 - Patient Flyer _ HLM_final in English	--------	--------
44.	HLM review CTIN816A12201 - Patient Flyer_February 2023_ HLM_final in Hindi	--------	--------
45.	Draft CTA	--------	--------
46.	PI – CV, GCP and MRC	--------	--------
47.	Translation certificate: HLM review CTIN816A12201 -	--------	--------

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Patient Flyer_ February 2023_ HLM_final in Hindi		
48.	HLM review CTIN816A12201_Infographic_v1_ FE_HLM_final in English	--------	--------
49.	HLM review CTIN816A12201_Infographic_v1_ FE_HLM_final in Hindi	--------	--------
50.	Translation Certificate: HLM review CTIN816A12201_Infographic_v1_ FE_HLM_final in Hindi	--------	--------
51.	DCGI Acknowledge letter		04-Dec-2023

Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 127th ECM II C/P1

18- Clarification of research protocol no. BIO-PERTUZ-301 entitled "***A multicenter, double-blind, randomized, parallel-group, phase 3 study to compare the efficacy and safety of the proposed biosimilar PERT-IJS and EU-Perjeta® along with trastuzumab and chemotherapy (Carboplatin and Docetaxel) as neo adjuvant treatment in patients with hormone receptor negative (HR-ve) human epidermal growth factor receptor2 (HER2) positive early stage or locally advanced breast cancer***" submitted by M/s Biocon Biologics UK Limited under supervision of Dr. Sameer Gupta, Additional Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow, vide letter no. SONC/385/2024 dated 21st February, 2024.

Previous comment:-

- Permission to conduct clinical trial-Awaited (Submission acknowledgement-attached)
- Permission to import the biosimilar drugs from abroad-Awaited (Submission acknowledgement-attached)
- Permission letter to send sample abroad-missing (But mentioned in SOP-Checklist-point 7-ix)

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

The following documents were reviewed in its Meeting:-

1.1 BIO-PERTUZ-301_Protocol, V1.0_09Jun2023
1.2 BIO-PERTUZ-301_Protocol Administrative changes and Clarifications, V1.0_19Jul2023
2.0 BIO-PERTUZ-301_Site 539_Dr. Sameer Gupta_Protocol Signature Page_20-Jul-2023
3.1 BIO-PERTUZ-301_Investigator's Brochure, V4.0_09Jun2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	3.2 BIO-PERTUZ-301_Investigator Brochure_Addendum_V1.0_30Jun23 4.1 BIO_PERTUZ-301_Subject Case Report Form_Unique_Annotated eCRF_V0.11_07Jul2023 5. Main_V1.1IND(en)1.0(18Jul2023) 5.1 Main_V1.1IND(hi)1.0(18Jul2023) 5.2 Main_V1.1IND(hi)1.0(18Jul2023)_Translation certificate 29-Jul-2023 5.3 Back translation of Main_V1.1IND(hi)1.0(18Jul2023) 5.4 Back translation of Main_V1.1IND(hi)1.0(18Jul2023)_Back Translation Certificate 29-Jul-2023 6. BIO-PERTUZ-301_Patient ID Card_V01Global(en)_19-Jun-2023 6.1 BIO-PERTUZ-301_Patient ID Card_V01 IND(hi)_19-Jun-2023 6.2 BIO-PERTUZ-301_Patient ID Card_V01 IND(hi)_19-Jun-2023_Translation certificate_30-Jun-2023 7. BIO-PERTUZ-301_Patient Brochure_V01Global(en)_21Jun2023 7.1 BIO-PERTUZ-301_Patient Brochure_V01 IND(hi)_21-Jun-2023 7.2 BIO-PERTUZ-301_Patient Brochure_V01 IND(hi)_21-Jun-2023_Translation certificate_30-Jun- 2023 8. BIO-PERTUZ-301_Patient Poster_V01Global(en)_15-Jun-2023 8.1 BIO-PERTUZ-301_Patient Poster_V01 IND(hi)_15-Jun-2023 8.2 BIO-PERTUZ-301_Patient Poster_V01 IND(hi)_15-Jun-2023_Translation certificate_30-Jun-2023 9. BIO-PERTUZ-301_Patient Study Guide_V01Global(en)_21Jun2023 9.1 BIO-PERTUZ-301_Patient Study Guide_V01 IND(hi)_21-Jun-2023 9.2 BIO-PERTUZ-301_Patient Study Guide_V01 IND(hi)_21-Jun-2023_Translation certificate_30-Jun-2023 10. BIO-PERTUZ-301_Dr-to-Patient Letter_V01Global(en)_21Jun2023 10.1 BIO-PERTUZ-301_Dr-to-Patient Letter_V01 IND(hi)01_22-Jun-2023 10.2 BIO-PERTUZ-301_Dr-to-Patient Letter_V01 IND(hi)01_22-Jun-2023_Translation certificate_30-Jun-2023 11. BIO-PERTUZ-301_Insurance Certificate_4066A24798487401000_Valid till 29Feb2024 12. BIO-PERTUZ-301_India CTA Template_28Jul2023 13. BIO-PERTUZ-301_511_Dr. Sameer Gupta_CV_20JUL2023 14. BIO-PERTUZ-301_511_Dr. Sameer Gupta_GCP_12Jun2021 15. BIO-PERTUZ-301_511_Dr. Sameer Gupta_MRC 16. BIO-PERTUZ-301_511_Dr. Sameer Gupta_Investigator Undertaking_20Jul2023 17. BIO-PERTUZ-301_RA Submission Cover Letter_24Jul2023 18. BIO-PERTUZ-301_RA Submission acknowledgment_27Jul2023 **Decision:** Approval subject to fulfillment & Administrative formalities ***Ref. code: 127th ECMIIC/P2***
19-	Clarification of research entitled ***"A cytogenetic study of suspected cases of chromosomal aberration in the Uttar Pradesh region of northern India"*** under supervision of Prof. Rakesh Kumar Verma, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 549/ANAT/23 dated 3rd January, 2024.

Previous EC Comment	PI response
Regarding ICF	I sincerely apologies for the same. By mistake I forget to enclose ICF previously Please find the ICF attached here. (Enclosure-1)
Regarding clinical investigators	As per your suggestion, I have added following clinical investigators: (Enclosure-2) 1. Dr. Kamlesh Kumar Gupta Professor department of Medicine

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		2. Dr. Rekha Sachan Professor department of Obst & Gynae 3. Dr Nishant Verma Additional Professor department of Paediatrics
	Regarding the risks outweigh the benefits	Clarification already given. Kindly find attached the same document. (Enclosure-3)
	Regarding the budget	I have received the details of budget allocated to me. (Enclosure-4)

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

Decision: Approved

Ref. code: 128th ECM IB/P5

20- Clarification of research proposal entitled "***Association of bedtime procrastination with sleep behavior and subjective well-being in the Indian population- A cross-sectional study***" under supervision of Dr. Sujit K. Kar, Additional Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 2419/Psy/24 dated 22nd February, 2024.

Comments of the reviewers	Response
1. The reliability and validity of the instruments to be assessed.	It has been added to the description of the tools.
2. Can the scale be completed in a reasonable amount of time?	The scales can be completed in 20 minutes time.
3. How will it be scored/evaluated?	The tools used are likert scales. The responses are coded and added to get the total score.
4. Give the exclusive list of social media platforms to be used in the study.	It has already been provided. …….. circulating the questionnaire link on social media networking sites like Watsap, Twitter, Facebook, Instagram, Telegram.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	5. Why do you want to choose convenient sampling? It is a non-probability sampling method. The non-probability sample cannot depend upon the rationale of probability theory. At least with a probabilistic sample, we know the odds or probability that we have represented the population well. We are able to estimate confidence intervals for the static or do the testing of hypotheses. With non-probability samples, we may or may not represent the population well, and it will often be hard for us to know how well we have done so.	We have revised it. We will be using a convenient and purposive sampling method. For online surveys it is the most commonly used sampling technique. We agree the limitation of this method: *a study conducted on a convenience and purposive sample was methodologically sound, the internal validity would be good; but because the sample was both a convenience and purposive sample, the external validity would be limited by the restrictions defined by the convenience and purposive nature of the sample.* However, considering the feasibility this method is the appropriate method for survey.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

Decision: Approved

Ref. code: 128th ECM IIA/P3

21- Clarification of research entitled ***"Effectiveness of continuing nursing education on knowledge regarding intellectual property right among nursing professionals working in various states of India"*** under supervision of Mrs. Sudha Mishra, Assistant Professor, KGMU College of Nursing, King George's Medical University, U.P., Lucknow vide letter no. 86/PF/24 dated 18th January, 2024.

Previous Comment:

- Kindly modified the proposal title edited the previous version: ICF and the inform consent form have the previous title.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

Decision: Approved

Ref. code: 128th ECM IIA/P12

22- Clarification of research proposal entitled ***"Implementation of LASER based cost effective motion monitoring system for left breast cancer radiotherapy: Application of python programming for automation"*** under supervision of Mr. Shriram A. Rajurkar, Ph.D. Scholar under the guidance Prof. Teerthraj Verma, Department of Radiotherapy, King George's

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Medical University, U.P., Lucknow vide letter no. 170/RT/23 dated 5th February, 2024.

Previous EC Comment	PI response
Project Incomplete	The incomplete section of the project has been added in Annexure-01. This includes the introduction, hypothesis, review of literature, and references.
Review of literature not provided	A review of the literature is added in Annexure-01
No references	References are added inAnnexure-01

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

Decision: Approved

Ref. code: 128th ECMIIB-Ph.D/P1

23- Clarification of research proposal entitled ***"Dietary profile, cognitive status and Vitamin B12 level in aging individuals with type2 diabetes mellitus: A cross sectional Hospital comparative study"*** under supervision of Ms. Vidya Priya, Ph.D. Scholar under the guidance Dr. Nisha Mani Pandey, Professor Jr. Grade, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 44/DGMH/24 dated 5th February, 2024.

Previous EC Comment	PI response
Although in the title it is mentioned that the B12 level will be assessed but neither its methodology is given nor it is mentioned where it will de estimated	Vitamin B12assay will be done by using ARCHITECT i1000 which uses the CMIA (Chemiluminescent Microparticle Immunoassay) method. The test will be performed in the ICU stat lab (Gandhi ward) running under the Department of Biochemistry.
It is mentioned in the materials and method section that no biochemical estimations will be carried out.	Patients are to be recruited from the OPDs of Medicine and Geriatric Mental Health. The biochemical investigation will be advised by the consultant as per the usual treatment protocol the researcher will note down the B12 level from their report. However to clarify the statement. Please check pg no 6 subheading D.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

Decision: Approved

Dr. Nisha Mani Pandey did not take part in the discussion & making decision.

Ref. code: 128th ECMIIB-Ph.D/P3

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

24- Clarification of research entitled ***"Comparison of self collected cervicovaginal smears with clinician collected cervical smears for human papillomavirus testing to detect high grade cervical intraepithelial lesions: A North Indian cross sectional study"*** submitted by Office of Dean, Research & Development, KGMU Lucknow under supervision of Dr. Shilpa Singh, Associate Professor, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/129/24 dated 12th January, 2024.

Previous EC Comment	PI response
The researcher has mentioned in point 10, that the risks outweigh the benefits. Kindly clarify.	Attached Separately

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

Decision: Approved

Ref. code: 128th ECM II B-IMR-F/P1

25- Clarification of protocol no. #: R3918-PNH-2021 entitled ***"A randomized, open-label, C5 inhibitor-controlled study to evaluate the efficacy and safety of pozelimab and cemdisiran combination therapy in patients with paroxysmal nocturnal hemoglobinuria who are complement inhibitor treatment-naïve or have not recently received complement inhibitor therapy"*** submitted by M/s Regeneron Pharmaceuticals Inc under supervision of Prof. Shailendra Prasad Verma, Principal Investigator, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow, vide letter no. CH/CT/01/2024 dated 13th January, 2024.

Previous EC Comment	PI response
In SOP-Checklist -Point no.-3 vaccine is ticked ? And subdivision (ii) & (iii)-not ticked.	Point 3.1 should be drugs not vaccine it was inadvertently ticked on vaccine (we are doing trial for drug IMP – cemdiseran and Pzelimab and vaccine Comparator – Raviluzumab and Eculuzimab is supporting therapy recommended by protocol) Attached document from protocol explains about the Vaccine. Point 3.2 IMP cemdiseran and Pzelimab is not approved globally, but comparator Raviluzumab and Eculuzimab is approved in USA.
Point no.-7-(ix) -necessary clearance for sending Samples abroad - ticked as yes, but clearance letter is missing-PI to clarify.	Point 7 Necessary clearances for sending Samples to abroad is not applicable for this study as per the regulatory.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

The following documents were reviewed in its Meeting:-

Sr. No	Name of the document	Version No.	Version date
1.	Protocol including Protocol synopsis	Amendment no. 2	30 March 2023
1.1	Dr. _Protocol Signature page signed on 08 June 2023	Amendment no. 2	24 Jan 2024
2.0	R3918-PNH-2050_Protocol_Amendment 3_AAA_Source_ 24AUG2023	Amendment no. 3	24 Aug 2023
2.1	Dr. Upendra Sharma_ 356504_Protocol Signature page signed on	Amendment no. 3	23 Jan 2024
3.0	Investigator Brochure Edition 8_Cemdisiran	Edition 8	22 November 2022
3.1	REGN3918_IB_6_Original_Source_Pozelimab	Edition 6	25 Apr 2023
4.0	ALN-CC5 Investigator Brochure Edition 8_Cemdisiran Receipt	Edition 8	20 Jan 2024
4.1	REGN3918_IB_6_Original_Source_Pozelimab Receipt	Edition 6	20 Jan 2024
5.0	R3918-PNH-2050 India Site 356507 Dr.Shailendra Prasad Verma Main ICF English V1.0 dated 19 Dec 2023 based on _India Main ICF English V2.1 Dated 19 Dec 2023	V.1	19 DEC 2023
6.0	R3918-PNH-2050 India Site 356507 Dr.Shailendra Prasad Verma Main ICF English V1.0 dated 19 Dec 2023 based on India Main ICF English V2.1 Dated 19 Dec 2023	V1.0	19 Dec 2023
7.0	R3918-PNH-2050 India Site 356507 Dr.Shailendra Prasad Verma Main ICF English V1.0 dated 19 Dec 2023 based on_India Main ICF English V2.1 Dated 19 Dec 2023Translated from Hindi to English on 10Jan2024	V1.0	19 Dec 2023
8.0	356507 Main ICF V1 _HI-IN_TCert	NA	10 Jan 2024

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

5.0	R3918-PNH-2050 India Site 356507 Dr.Shailendra Prasad Verma Main ICF English V1.0 dated 19 Dec 2023 based on _India Main ICF English V2.1 Dated 19 Dec 2023	V.1	19 DEC 2023	
6.0	R3918-PNH-2050 India Site 356507 Dr.Shailendra Prasad Verma Main ICF English V1.0 dated 19 Dec 2023 based on India Main ICF English V2.1 Dated 19 Dec 2023	V1.0	19 Dec 2023	
7.0	R3918-PNH-2050 India Site 356507 Dr.Shailendra Prasad Verma Main ICF English V1.0 dated 19 Dec 2023 based on_India Main ICF English V2.1 Dated 19 Dec 2023Translated from Hindi to English on 10Jan2024	V1.0	19 Dec 2023	
8.0	356507 Main ICF V1 _HI-IN_TCert	NA	10 Jan 2024	
9.	R3918-PNH-2050 _India 356507 Dr.Shailendra Prasad Verma FBR ICF English_V1.0_dated 12 Dec 2023_based on India FBR_ICF English _V1.0_Dated 17 Jul 2023	V1.0	12 Dec 2023	
10.	R3918-PNH-2050_India 356507 Dr. Shailendra Prasad Verma FBR ICF English_ V1.0_dated 12 Dec 2023_based on India FBR_ICF English _V1.0_Dated 17 Jul 2023Translated from Hindi to English on 10Jan2024	V1.0	12 Dec 2023	
11.	R3918-PNH-2050 _India 356507 Dr. Shailendra Prasad Verma FBR ICF English_V1.0_dated 12 Dec 2023_based on India FBR_ICF_English_V1.0_Dated 17 Jul 2023 Translated from English to Hindi on 10Jan2024	V1.0	12 Dec 2023	
12.	356507 FBR Dated 12 Dec 2023_HI-IN_TCert	NA	10 Jan 2024	
13.	R3918-PNH-2050 India_Site 356504 Dr.Shailendra Prasad Verma Pharmacogenomics ICF English V1.0 dated 12 DEC 2023_ based on India Pharmacogenomics ICF V1.0_Dated 17 Jul 2023	V1.0	12 Dec 2023	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

14.	R3918-PNH-2050 India_Site 356507 Dr.Shailendra Prasad Verma Pharmacogenomics ICF English V1.0 dated 12 DEC 2023_based on India Pharmacogenomics ICF V1.0_Dated 17 Jul 2023 Translated from English to Hindi on 10Jan2024	V1.0	12 Dec 2023
15.	R3918-PNH-2050 India_Site 356507 Dr.Shailendra Prasad Verma Pharmacogenomics ICF_ English V1.0 dated 12 DEC 2023_based on India Pharmacogenomics ICF V1.0_Dated 17 Jul 2023 Translated from Hindi to English on 10Jan2024	V1.0	12 Dec 2023
16.	15.356507 PGX Dated 12 Dec 2023_HI-IN_TCert	NA	10 Jan 2024
17.	R3918-PNH-2050 India Site _ 356507 Dr.Shailendra Prasad Verma Pregnant Partner ICF English V1.0 dated 12 DEC 2023 based on India Pregnant Partner ICF English v1.0 dated 17 Jul 2023 Translated from English to Hindi on 10Jan2024	V1.0	12 Dec 2023
18.	R3918-PNH-2050 India Site _ 356507 Dr.Shailendra Prasad Verma Pregnant Partner ICF English V1.0 dated 12 DEC 2023 based on India Pregnant Partner ICF English v1.0 dated 17 Jul 2023 Translated from Hindi to English on 10Jan2024	V1.0	12 Dec 2023
19.	R3918-PNH-2050_PP ICF_356507_HI-IN_TCert	NA	10 Jan 2024
20.	R3918-PNH-2050_eCOA Subject Facing Screen Report_India (English)_v1.0_2MAR2023	V1.0	2 march 2023
21.	Certification_R3918-PNH-2050_eCOA Subject Facing Screen Report_India (English)_v1.0_20MAR2023	NA	20 March 2023
22.	.R3918-PNH-2050_eCOA Subject Facing Screen Report_India (Hindi)_v1.0_20MAR2023	V1.0	20 March 2023
23.	Certification_R3918-PNH-2050_eCOA Subject Facing Screen Report_India	NA	20 March 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	(Hindi)_v1.0_20MAR2023		
24.	R3918-PNH-2050_IN_Patient Emergency Card_Master_V1.0_Final	V1.0	3 JAN 202
25.	R3918-PNH-2050_IN_Patient Emergency Card_Master_V1.0_Final_3Jan2024_HI-IN	V1.0	3 JAN 2024
26.	R3918-PNH-2050_IN_Patient Emergency Card_Master_V1.0_Final_3Jan2024_HI-IN_TCert	NA	
27.	R3918-PNH-2050_Subject Safety_Participation Card Pozelimab-Cemdisiran - 26dec2023_IN FINAL	V1.0	26 DEC 2023
28.	.R3918-PNH-2050_Subject Safety_Participation Card Pozelimab-Cemdisiran - 26dec2023_IN FINAL_3Jan2024_HI-IN	V1.0	26 DEC 2023
29.	31.R3918-PNH-2050_Subject Safety_Participation Card Pozelimab-Cemdisiran - 26dec2023_IN FINAL_3Jan2024_HI-IN_TCert	NA	
30.	Annotated Case Report Form (aCRF) - V03 - 11 Jul 2023	V3.0	11 July 2023
31.	R3918-PNH-2050 Insurance		
32.	276439 IND 20231123 RA Approval-CDSCO Import License for Study Drugs	NA	23 Nov 2023
33.	276439 IND 20231123 RA Approval-CDSCO Initial Clinical Trial Application	NA	23 Nov 2023
34.	36.PI CV Dr. S.P Verma	NA	08 Jan 2024
35.	GCP Dr. S.P Verma	NA	06 june 2023
36.	MRC Dr.shailendra Parasad Verma	NA	
37.	39.276439 R3918-PNH-2050 IND 356007 CSA 20230731 1	NA	
38.	40..276439 R3918-PNH-2050 IND 356007 Budget 20230731 1	NA	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

39	Investigator Undertaking	NA	
40.	R3918-PNH-2050 Insurance		

Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 128th ECMIIC/P2

26- Clarification of protocol no. D7830C00004/Site-3520 entitled ***"A randomized, double-blind, placebo-controlled, multi-centre phase 2b study to evaluate the efficacy, safety and tolerability of AZD2693 in participants with non-coirrhotic non-alcoholic steatohepatitis (NASH) with fibrosis who are carriers of the PNPLA3 rs 738409 148M risk allele"*** submitted by M/s The Executive Centre Lavel 7, M-Far Greenheart, Manyate Embassy Tech Park under supervision of Prof. Ajay Kumar Patwa, Principal Investigator, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/08/2024 dated 29th January, 2024.

Previous EC Comment	PI response
Sponsor Address mention two sponsor one in Sweden One in Japan.	Both the address will be applicable and correct as per the confirmation with sponsor
Consolidated Budget approved as per the CTA must be mentioned in the CTA.	Budget was mentioned in the study as per the IEC requirements.
Please mention type of study Clinically/epidemiological.	Special Group Subject ***non-alcoholic steatohepatitis (NASH) patient with fibrosis.***
Collection for banking/future research **has** been ticked No, but consent for baking and future research is being taken. Please explain/correct.	There is a future research consent form present There is a future research consent form present for the patient, if the patient agrees to participate in the future research and gives consent the same will be collected and kept for any future research. for the patient, if the patient agrees to participate in the future research and gives consent the same will be collected and kept for any future research.
Samples are being sent outside the country for tests. Please specify which tests are being conducted inside the country and which are being sent outside. **Has** necessary clearance been obtained?	Local ALT, AST, and liver function test would be conducted locally. Rest all the samples will be sent out to the central lab. We don't require clearance for sending the samples to central lab for processing.
DCGI approval does not list KGMU sites and **the** approval is subject to submission of Phase-I results to the Central Licensing Authority.	KGMU is an additional site for the study, once we get the EC approval is when we will go ahead and submit for DCGI approval to the site to be added in the

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	study.
Certificate of Insurance coverage is not present **in** the proposal.	Certificate of Insurance coverage is present **in** the dossier and Copy of Insurance is attached for the reference.

- Permission for tissue banking for future research and sending samples outside the country for tests has to be obtained from DCGI
- Insurance documents have not been attached to the reply document
- DCGI approval has to be submitted once it is obtained.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

The following documents were reviewed in its Meeting:-

S.No	Documents
1	Regulatory Authority Submission letter DCG(I) Submission Letter for Grant of permission to participate in Global Clinical" Trial (File No:REG/2023/CT/DGHS/RK/038) dated 17 Feb 2023
2	Regulatory Authority Approval letter dated 12 June 2023
3	Clinical Study Protocol Version 2.0, dated 14 February 2023
4	Adult Study Subject Master Information and Consent Form Master Version Number 2.0 Master Version Date 16 Feb 2023 India Version Number 1.1 India Version Date 07 June 2023: English. **Translation:** ➢ English to Hindi, (Adult Study Subject Master Information and Consent Form Master Version Number 2.0 Master Version Date 16 Feb 2023 India Version Number 1.1 India Version Date 07 June 2023) Translated on 12 June 2023. **Back Translation:** ➢ Hindi to English: (Adult Study Subject Master Information and Consent Form Master Version Number 2.0 Master Version Date 16 Feb 2023 India Version Number 1.1 India Version Date 07 June 2023) Back translated on 12 June 2023. **Translation & Back Translation Certificates dated 12 June 2023.** ➢ English to Hindi, Hindi to English
5	Withdrawal of Consent Checklist Master Version Number 2.0 Master Version Date 20 Feb 2023 India Version Number 1.1 India Version Date 07 June 2023: English
6	Future Research Information and Consent Form, India Version Number 1.1 India Version Date 07 Jun 2023 Derived from Master Version Number 2.0 Master Version Date 16 Feb 2023 (Adult Study Subject Master Information and Consent Form) - English **Translation:** ➢ English to Hindi: Future Research Information and Consent Form, India Version Number 1.1 India Version Date 07 Jun 2023 Derived from Master Version Number 2.0 Master Version Date 16 Feb 2023 (Adult Study Subject Master Information and Consent Form), Translated on 12 June 2023. **Back Translation:** Hindi to English: Future Research Information and Consent Form, India Version Number 1.1 India Version Date 07 Jun 2023 Derived from Master Version Number 2.0 Master Version Date 16 Feb 2023 (Adult Study Subject Master Information and Consent Form), Back translated on 12 June 2023. **Translation & Back Translation Certificates dated 12 June 2023.**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	> English to Hindi, Hindi to English
7	Study Information and Consent Form for Adults Genotyping visit Master Version Number 2.0 Master Version Date 20 Feb 2023. India Version Number 1.1 India Version Date 07 June 2023. English **Translation:** English to Hindi (Study Information and Consent Form for Adults Genotyping visit Master Version Number 2.0 Master Version Date 20 Feb 2023 India Version Number 1.1 India Version Date 07 June 2023), Translated on 12 June 2023 **Back Translation:** Hindi to English (Study Information and Consent Form for Adults_Genotyping visit Master Version Number 2.0 Master Version Date 20 Feb 2023 India Version Number 1.1 India Version Date 07 June 2023), Back Translated on 12 June 2023 **Translation & Back Translation Certificates dated 12 June 2023.** English to Hindi, Hindi to English
8	Optional Genetic Research Information Master Version Number 1.0 Master Version Date 07 Sep 2022, India Version Number 1.1 India Version Date 07 June 2023: English Translation: Date 2007_202.3 > English to Hindi: (Master Version Number 1.0 Master Version Date 07 Sep 2022, India Version Number 1.1 India Version Date 07 June 2023, Translated on 12 June 2023. **Back Translation:** > Hindi to English: (Master Version Number 1.0 Master Version Date 07 Sep 2022, India Version Number 1.1 India Version Date 07 June 2023, Translated on 12 June 2023. **Translation & Back Translation Certificates dated 12 June 2023** > English to Hindi, Hindi to English
9	Adult Informed Consent Form for Audio-Visual Recording of Subject's Consent Process in India, IN India India Master Version Number 1.1 India Master Version Date 07 June 2023 **Translation:** > English to Hindi: (Adult Informed Consent Form for Audio-Visual Recording of Subject's Consent Process in India, IN India Master Version Number 1.1 India Master Version Date 07 June 2023), Back translated on 12 June 2023 **Back Translation:** ➢ Hindi to English: (Adult Informed Consent Form for Audio-Visual Recording of Subject's Consent Process in India, IN India Master Version Number 1.1 India Master Version Date 07 June 2023), Back translated on 12 June 2023. **Translation & Back Translation Certificates dated 12 June 2023** ➢ English to Hindi, Hindi to English
10	Investigator's Brochure Edition 2.0, dated 31 Aug 2022
11	Curriculum Vitae, GCP and MRC of Principal Investigators (PI)
12	Investigator Undertaking by the Principal Investigator dated 20 June 2023
13	Declaration to HA regarding site facility for conduct of the study
14	Declaration for participation in number of clinical trials
15	Protocol Signature Page – 16 May 2023
16	Certificate of Insurance- From 1-March-2023 to 29-February-2024 Policy no P0823200001/9999/106914.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

17	Case Report Form Sample/ annotated e-CRF sample. a. D7830C00004: Annotated PDF version V2.0 03MAY2023 b. D7830C00004: Non-Annotated PDF V1.0 21FEB2023
18	Patient Report Outcome Assessment of symptoms and health-related quality of life in non-alcoholic steatohepatitis (Nash-Check) - NASH eCOA Tablet Screenshots version 1.00, dated 08-Mar-23- English. Translation Certificate: Assessment of symptoms and health-related quality of life in non-alcoholic steatohepatitis (Nash-Check)- NASH-CHECK_eCOA Tablet_v1.00_English- IN_08Mar2023. Assessment of symptoms and health-related quality of life in non-alcoholic steatohepatitis (Nash-Check)- NASH eCOA Tablet Screenshots version 1.00, dated 07-Mar-23- Hindi Translation Certificate: > Assessment of symptoms and health-related quality of life in non-alcoholic steatohepatitis (Nash-Check)- NASH-CHECK_eCOA Tablet_v1.00_Hindi- IN 07Mar2023:
19	AZ_D7830C00004 Patient Instructions eCOA Tablet Screenshots- Version 1.00, dated 08-Mar-23- English Translation Certificate: ➢ AZ D7830C00004 eCOA Tablet Patient Instructions__ eCOA Tablet_v1.00_English- IN_08Mar2023. AZ D7830C00004 Patient Instructions eCOA Tablet Screenshots- Version 1.00, dated 07- Mar-23- Hindi. Translation Certificate: ➢ AZ_D7830C00004_eCOA Tablet Patient Instructions_ eCOA Tablet_v1.00_Hindi-IN 07Mar2023.
20	AZ_D7830C00004 PGIS eCOA Tablet Screenshots-Version 1.00 dated 08 -Mar-23-English. Translation Certificate: ➢ Patient Global Impression of Severity-NASH (PGIS-NASH)- eCOA Tablet_v1.00_English-IN_08Mar2023 AZ D7830C00004 PGIS eCOA Tablet Screenshots-Version 1.00 dated 07 -Mar-23-Hindi. Translation Certificate: ➢ Patient Global Impression of Severity-NASH (PGIS-NASH)- eCOA Tablet_v1.00_Hindi-IN_07Mar2023.
21	SF36v2AT eCOA Tablet Screenshots- Version 1.00 dated 08-Mar-23-English. Translation Certificate: SF36v2AT_eCOA Tablet_v1.00_English-IN_08Mar2023. SF36v2AT eCOA Tablet Screenshots- Version 1.00 dated 07-Mar-23-Hindi. Translation Certificate: ➢ SF36v2 Acute eCOA Tablet v1.00 Hindi-IN_07Mar2023.
22	Draft/Final Clinical Study Agreement
23	Study specific item: Thank you, card, English _IN_ Version 1.0, date 27-Oct-2022. Translation Certificate: ➢ AZ D7830C00004_TY-EN-IN-v1.0__ date 27-Oct-2022 Thank you, card, Hindi _IN_ Version 1.0, date 20-Jan-2023. Translation Certificate: ➢ AZ D7830C00004_TY-HI-IN-V1.0_20-Jan-2023.
24	Patient Participation Card Master Version Number & Date: version 1.0; 05Sep2022 India Version Number & Date: 1.0, 03 Nov 2022: English

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Translation: English to Hindi, Translated on 09 November 2022 **Back Translation:** > Hindi to English, back translated on 09 November 2022 **Translation & Back Translation Certificates (dated): 09 Nov 2022** English to Hindi. > Hindi to English.
	25	Pamphlet_India_UK English_V2.0 **Translation:** ➢ Pamphlet_India_Hindi_V2.0 **Certificate of Translation:** ➢ Pamphlet_India_V2.0_COT Hindi
	26	Summary Guide_India_UK English_V2.0 **Translation:** Summary Guide_India_Hindi_V2.0 **Certificate of Translation:** > Summary Guide India COT Hindi V2.0
	27	Visit Guide_India_UK English_V2.0 **Translation:** ➢ Visit Guide_India_Hindi_V2.0 **Certificate of Translation:** ➢ Visit Guide India COT Hindi V2.0
	28	Patient Accrual Methods

Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 128th ECMIIC/P3

27- Clarification of protocol no. DRL-IND-NDA08-TEG/2022 entitled ***"Multi-national, multi-centric, prospective, randomized, double-blind, active-controlled, parallel-group study to evaluate the efficacy and safety of tegoprazan in patients with erosive gastroesophageal reflux disease"*** submitted by M/s Dr. Reddy's Laboratories Ltd. under supervision of Dr. Ajay Kumar Patwa, Principal Investigator, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/09/2024 dated 29th January, 2024.

Previous EC Comment	PI response
The SRC of the department has not confirmed the content of the proposal, but merely written ' Attached in Dossier'. The SRC has to affirm the scientific validity of the study.	The SRC reviews the Study dossier and confirm all the mentioned documents are attached in the dossier so they mention **attached in the dossier.**
Specific budget is not mentioned either in the IEC form or the CTA.	Budget was mentioned in the study as per the IEC requirements.
The DCGI Approval letter attached to the application is protocol amendment approval letter. Please attach the original letter.	Attached the DCGI approval letter for protocol version 3.0.
No approval letter mentioned KGMU as a	The DCGI notification for site addition of

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

site.	KGMU is attached for reference. KGMU is an additional site for the study, once we get the EC approval then we will go ahead and submit for DCGI approval to the site to be added in the study.
Insurance is Valid only up to March 2024 which will lapse soon	The sponsor has already initiated the process of extending the insurance of the current policy for next year. As soon as the insurance renewal certificate is received, it will be shared with the site well in advance of the expiry. But the Insurance is Valid till March 2024, before the expiry we will notify the EC as well.

- SRC document of the department has to be submitted again attesting the validity of the study

PI mentions that budget has been mentioned in the study but the same doesn't find mention in the IEC form, and has not been submitted to the reviewer.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Provisionally Approved

The following documents were reviewed in its Meeting:-

Sr. No.	Study Document	Version	Date
1.	Study Protocol	Ver 4.0	26 Jun 2023
2.	Protocol Signature Page	Ver 4.0	26 Jun 2023
3.	Investigator Brochure	Ver 01	03 Oct 2022
4.	CV of Principal Investigator	NA	16 May 2023
5.	MRC of Principal Investigator	NA	16 May 2023
6.	GCP Certificate of Principal Investigator	NA	16 May 2023
7.	Investigator's Undertaking	Ver 4.0	28 Jul 2023
8.	Patient Information Sheet and Informed Consent Form- English	Ver 3.0	27 Jul 2023
9.	Patient Information Sheet and Informed Consent Form – Final Hindi	Ver 3.0	28 Jul 2023
10.	Patient Information Sheet and Informed Consent Form - Back translated from Hindi to English	Ver 3.0	28 Jul 2023
11.	Translation and Back translation Certificates - Patient Information Sheet and Informed Consent Form - Hindi	NA	28 Jul 2023
12.	MRC of Principal Investigator	NA	16 May 2023
13.	GCP Certificate of Principal Investigator	NA	16 May 2023
14.	Site Specific-Patient Information Sheet and Informed Consent Form - Back	Ver 3.0	28 Jul 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	translated from Hindi to English		
15.	Site Specific-Translation and Back translation C ertificates - Patient Information Sheet and Informed Consent Form - Hindi	NA	28 Jul 2023
16.	Subject Diary – English	Ver 2.0	31 Jul 2023
17.	Subject Diary – Final Hindi	Ver 2.0	03 Aug 2023
18.	Subject Diary - Back translated from Hindi to English	Ver 2.0	03 Aug 2023
19.	Translation and Back translation Certificates - Subject Diary - Hindi	NA	03 Aug 2023
20.	GERD Questionnaire English	Ver 1.0	NA
21.	GERD Questionnaire Final Hindi	Ver 1.0	27 Sep 2023
22.	GERD Questionnaire Translated Hindi to English	Ver 1.0	27 Sep 2023
23.	Certificate of GERD Questionnaire Final Hindi and Back translated Hindi to English	NA	27 Sep 2023
24.	Draft CRF	Ver 2.0	12 Jun 2023
25.	Draft CTA	Ver 0.1	05 Oct 2023
26.	DCGI Submission Acknowledgement	NA	28 Jul 2023
27.	DCGI Approval letter	NA	14 Nov 2023
28.	Certificate of Insurance	NA	15 Mar 2023

Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 128th ECMIIC/P4

28- Clarification of research proposal entitled ***"Uncovering the gene expression profile of programmed cell death ligand 1 (PD-L1) gene and its polymorphism and its association in regulation to platinum drug resistance in head and neck squamous cell carcinoma"*** submitted by Prof. Navin Singh, Department of Radiotherapy, K.G's Medical University, U.P., Lucknow vide letter no. 131/RT/2023 dated 31st January, 2024.

Dr. Anupam Mishra, Primary reviewer:-

- Annexure 1 point 10 still needs to be rectified.
- Annexure 1 point 8 (ii) needs to be mentioned as YES or No.
- The information sheet mentions inclusion criteria for healthy subjects as having cancer while inclusion criteria of cases as having no cancer. Kindly correct

Dr. Nisha Mani Pandey, Secondary reviewer:-

- Statement 10.i you did specify that there will be no risk to both the case and the control; kindly correct it.
- Please Hindi ICF should be in layman language.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the PI.

Awaiting response from PI:-

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Decision: Reminder to be sent to the PI

Ref. code: 129th IEC IB/P5

29- Clarification of research proposal entitled" ***Partial penectomy under local anaesthesia: A retrospective review of our experience"*** submitted by Dr. Madhur Anand, Assistant Professor, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 112/URO/URO/23 dated 17th February, 2024.

Previous EC Comment	PI response
Primary objective elaboration	We have performed partial penectomy under local anesthesia for the past several years, however, there is only one published abstract in the available literature on the feasibility of this surgery under local anesthesia. Therefore, we wish to assess our outcomes in performing this surgery under local anesthesia to make a recommendation for others to try or not to try. To express it better, we have modified our primary objective as "to assess the feasibility of performing partial penectomy under local anesthesia or nerve block".
Express the objective in terms of study variables	The feasibility will be assessed by the following variables: Intraoperative: patient reported pain scores intraoperatively, operative time and blood loss, requirement of additional analgesia or conversion of the procedure to general anaesthesia. Postoperative: pain scores at 1, 6 and 24 hours after surgery, postoperative stay at the hospital, analgesia requirement and completeness of tumor resection (margins) at the final histopathological evaluation
Study design is not clear	We reviewed our data and found that we have data of 45 patients undergoing partial penectomy under local anaesthesia. Since this is the first study, the clear outcomes are not yet available for a proper sample size calculation. We therefore intend to include all these patients in the case group. For control group we intend to include 45 age matched controls.
Statistical analysis specific to the research hypothesis	Statistical analysis will be done with t-test for independent variables with SPSS software.Additionally descriptive statistics with mean, standard deviation and range will be done for appropriate variables (age, pain scores, hospital stay, blood loss, number of analgesic doses etc.)

The aforementioned comments were sent to the Principal-Investigator, the response to which

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	was forwarded to the reviewer. Provisionally Approved **Decision:** Approved ***Ref. code: 129th IEC IIIA/P4***
30-	Clarification of research proposal entitled "***Nutrigenomic insights into thalassemia: resveratrol's influence on HIF-1α and clock/BMAL1 genes expression, oxidative stress and bone mineral density (BMD) of North Indian thalassemia patients***" submitted by Ms. Neha Rawat, Ph.D. Scholar under the guidance Dr. Nitu Nigam, Additional Professor, Department of Centre for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 382/CFAR/24 dated 22nd February, 2024. **Previous Comment:** • Sample size calculation not mentioned. • The type of study to be conducted is not clear. • It has been mentioned that the subjects will be recruited from the Department of Paediatrics but the age group mentioned is 15-65 years. • The consent form needs to be corrected as for minors the consent has to be taken from the parents or the legal guardian. • Where the BMD will be carried out and the make of the instrument shall also be mentioned. • The dosage of Resveratrol is also not mentioned. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** Provisionally Approved **Decision:** Approved ***Ref. code: 129th ECMIIB-Ph.D/P1***
31.	Clarification of research proposal entitled "***Relationship between implementation of evidence-based and supportive ICU care and outcomes of patients with acute respiratory distress syndrome (The ICU Liberation Study)***" submitted by Dr. Saumitra Misra, Assistant Professor, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/073/24 dated 3rd February, 2024. **Previous comment:** • Sample size calculations are not clear. There are too many numbers. Where are they coming from? Sample size formula is required. • There are too many objectives. • One primary objective should be sorted out and the rest should be put into secondary objectives. • The primary objective should be converted into a proper research hypothesis in terms of study variables and population parameters. Sample size should be done for this hypothesis. • Statistical analysis section is missing ***The aforementioned comments were sent to the Principal-Investigator, the response to which***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	was forwarded to the reviewer. Provisionally approved **Decision:** Approved ***Ref. code: 124th ECM IIA/P9***
32.	Clarification of expedited review of research proposal entitled **"*Improved data on dengue covering differences in epidemiological surveillance, patient demographics, the health seeking behavior of patients and standards of care*"** under supervision of Prof. Avinash Agrawal, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/147/24 dated 4th March, 2024. ***The above research proposal was forwarded to two reviewers, for review.*** ***Recommendation of Dr. G.G. Agarwal:-*** • This is a multi-centre study. • There are certain guidelines for multi-centre studies. These must be followed. Only a list of potential sites is given. The name of participating centres is required. • What will be the common protocol? • Which will be a coordinating centre to collect, process and analyze the data? • The number of field sites varies greatly across studies according to their size, complexity and purpose. How will this be handled? • Sample size calculation is arbitrary. This is due to the fact that there are too many objectives. • Identify one primary objective and put the rest into secondary objectives. The primary objective should be converted into a proper research hypothesis in terms of the study variables and parameters. • Sample size calculation will be based on the research hypothesis defined in step 7. • Data analysis plan is very general. It should be specific to the research hypothesis. • The reliability and validity of instruments have to be assessed. • Can the scale be completed in a reasonable amount of time? • How will it be scored/evaluated? ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the primary reviewer.*** ***Recommendation of Secondary reviewer:-*** • Provisionally approved ***Recommendation of Secondary reviewer:-*** • Provisionally approved **Decision:** Approved ***Ref. code: 128th ECM IB/P4***
33.	**Minutes of ADR Subcommitte**
	Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 9th March, 2024 from 01:00 P.M. till 1:30 p.m. ***in hybrid mode***, Administrative Block, K.G's Medical University, U.P., Lucknow.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	The following Members were present in the Meeting: 1. Dr. Alok Dhawan -Chairman 2. Mrs. Akansha Dubey -Member 3. Mrs. Vasundhara Kumari -Member 4. Mr. Ujjawal Krishna -Member 5. Dr. Rajendra Nath -Member 6. Dr. D.N. Upadhyaya -Additional Member-Secretary, IEC 7. Dr. Nisha Mani Pandey -Member 8. Dr. Hardeep Singh Malhotra -Member-Secretary, IEC, ex officio
1	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial"*** submitted by Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 611/Cardio/Res/2024 dated 12th January, 2023 & preliminary email dated 1st January, 2024 at 3:50 PM. **Death** **Site no.: 109** **Patient ID & age and gender:** P-C-045/ 29 years/Male **Patient Diagnosis:** RHD/Sev-MS/MVA 1.0 cm. **Patient enrollment date:** 19-10-2022 **Patient enrollment arm-**Digoxin **Patient follow up under study-**6th Month ,12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed-**Enrolment & Baseline Follow-up & 6-months follow-up **Planning on visit-** 12th Month **SAE detected on date:** 31-12-2023 **Follow up visit remaining:** 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor-**01-01-2024 **14 days analysis report submitted to EC-**12th January, 2024 **Subject History:** A letter was received in the office of the Ethics Committee on 12th January, 2024 by PI, The subject had to visit the site on 27th May, 2023 for 06-months actual on site visit. The subject was last contacted telephonically on 27th August, 2023 for a 9th month telephonic follow-up call, but, the subject didn't answer the call. The subject was again contacted on 27th November, 2023 for 12 month on site actual visit reminder call. The contact numbers provided by the subject were not reachable. Despite repeated reminder calls the subject did not answer the calls. The subject was again contacted on 27th December, 2023 for a reminder call; this time again the call was not answered. But, the subject's LAR informed on 31st December, 2023 that the subject had complaints of loss of appetite, breathlessness

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	since 17th July, 2023 and he passed away on 18th July, 2023 around 1:00 P.M. at home. A local practitioner came and confirmed the patient's death and no autopsy was done. As per the information given by the patient's LAR, it seems to be a case of worsening of heart failure. Despite multiple reminders the subject's LAR was unable to provide the death certificate of the subject. The SAE is not related to the investigational drug. *Recommendation of reviewer:* a- **Enrolment date-**19-10-2022 **b-The SAE (Death) occurred on:** 18-07-2023. **c- SAE detected on:** 31-12-2023 **d- Details of Event:** SAE (Death) is likely due to disease outcome (RHD/Sev.-MS/MVA 1.0 cm) and not due to intervention (Tab Digoxin) as patient was randomized in enrolment arm of Digoxin -on 19-10-2022 and SAE occurred on 24-07-2023, i.e. nearly 9 months have elapsed after intervention. Patient died at home after developing breathlessness and loss of appetite which was likely due to progression of disease leading to heart failure. No autopsy was done. **e- 24 hrs notification by email:** 01-01-2024. **f- 14 day analysis submitted on:** 12th January, 2024. **g- Causal relationship and Compensation:** Causal relationship of SAE (Death) with intervention cannot be established; therefore, no compensation is warranted. **Comment: Besides aforementioned, nothing further** **Decision: Approved** ***Ref. code: 102nd ECM IIA/P24***
2	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial"*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 628/Cardio/Res/2024 dated 19th January, 2024 & preliminary email dated 1st January, 2024 at 3:50 PM. **Death** **Site no. 109** **Patient ID & age and gender:** G-D/121,69 years, DOB 01-01-1975/Female **Patient Diagnosis:** RHD/Sev-MS/MVA 0.8 cm. **Patient enrollment date:** 26-05-2023 **Patient enrollment arm-**Digoxin **Patient follow up under study-**6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed-**Enrolment & Baseline **Planning on visit-** 06th Month **SAE detected on date:** 08-01-2024 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor-**08-01-2024

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

14 days analysis report submitted to EC-19th January, 2024
Subject History:

A letter of PI was received in the Office of the Ethics Committee on 19th January, 2024 from PI. The subject 121 was randomized on 26th May, 2023 in the Digoxin study. The subject was called telephonically on 26th August, 2023 for a 3 months. The subject's number was switched off. The subject was contacted telephonically on 25th November, 2023 for 6 month follow-up visit on site. But, the provided numbers were not reachable. The subject was contacted again on 25th December, 2023 for a 6 months visit reminder calls. This time the patient didn't answer the calls.Despite repeated reminder calls the subject did not answer any of the calls, the subject was again contacted on 8th January 2024 for the 6 month actual on site due visit. The subject's LAR picked the call and informed that the subject had complains of breathlessness and urine retention on 13th July, 2023. As per the LAR, she was not able to reach the hospital and she passed away at home on 13th July, 2023 around 1.00 PM. As per the information given by the patient's LAR, it seems to be a case of heart failure. A local practitioner came and confirmed the patient's death and no autopsy was done. Despite multiple reminders the subject's LAR was unable to provide the death certificate of the subject. The SAE is not related to the investigational drug.

Recommendation of reviewer:

a- **Enrolment date-**26-05-2023
b- The SAE (Death) occurred on: 13-07-2023.
c- SAE detected on : 08-01-2024
d- Details of Event: SAE (Death) is likely due to disease outcome (RHD/Sev.-MS/MVA 0.8 cm) and not due to intervention (Tab Digoxin) as patient was randomized in enrolment arm of Digoxin -on 26-05-2023 and SAE occurred on 13-07-2023 ,i.e. more than 1½ months have elapsed after intervention . Patient died at home after developing breathlessness and urine retention. The SAE according to PI is most likely due to progression of disease leading to heart failure. No autopsy was done.
e- 24 hrs notification by email: 08-01-2024.
f- 14 day analysis submitted on : 19th January , 2024.
g- Causal relationship and Compensation: Causal relationship of SAE (Death) with intervention cannot be established; therefore, no compensation is warranted.

Comment: Besides aforementioned, nothing further

Decision: Approved

Ref. code: 102nd ECM IIA/P24

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

3-	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 22/Neuro/24 dated 19th January, 2024 & 32/ Neuro/24 dated 29th January, 2024 ***preliminary email dated 24th January, 2023 at 1:41 PM.*** **Patient ID & age and gender:** S-45-3-2718(MML)/58 years/Male **Subject Initial:** R-K **Patient Diagnosis:** Left intracranial (Basal ganglia) bleed **Patient enrollment date:** 14-01-2024 **Patient enrollment Arm:** Intervention **Patient follow up under study-**No. **Follow up visit completed-**No **SAE (Death) occurred on date:** Expired on 27-01-2024 **(UGIB):** 17-01-2024 **Follow up visit remaining:** No **24 hours, notified to EC, Sponsor-**Yes **14 days analysis report submitted to EC-**No **Subject History:-** The ***Two*** letters was received in the Office of the Ethics Committee on 20th January, 2024 & 30th January, 2024 from PI. The above mentioned patient was recruited in this clinical trial after fulfilling due checklist and informed consent. His clinical details are as follows. Patient with subject Id- S-45-3-2718, 58 years/Male, admitted on 14.01.2024 in the Emergency medical ward with c/o sudden weakness of right side of the body diagnosed to have Left intracerebral (basal ganglia) bleed, volume approximately 32.45 ml. He was transferred to Neurology emergency on the same day (14.01.2024), and there he was randomized to the intervention arm and was given Tranexamic acid and other standard treatment. The patient had h/o chronic alcoholism. On 17.01.2024 after a few episodes of coffee colored vomit us & coffee-colored gastric contents in RT. Gastro medicine opinion was taken. Patient's GCS fell from E2V1M5 TO E1V1M5 and the patient developed respiratory distress, for which the patient was shifted to ICU under critical care medicine and was intubated there on the same day around 5pm (17.01.2024).Post intubation Patient was not maintaining saturation at 100% FiO2 for which chest X Ray was done and it showed right sided pneumothorax. ICD was inserted for the same. Repeat routine investigations were suggestive of sepsis with multiple organ dysfunction in view of raised TLC; deranged blood urea and creatinine. Blood cultures and urine cultures were sent and accordingly antibiotics were upgraded. Patient was managed with inotropes for hypovolemic shock. Patient condition gradually deteriorated, GCS fell to E1VTM1, vasopressor support increased are not maintain vitals on 24/1/2024, in view of persistent encephalopathy and deranged serum urea, CRRT was done for 48 hrs. post CRRT patient had persistent hyperkalemia and metabolic acidosis and was planned for the 2nd cycle of CRRT. Dose of vasopressors was increased in view of refractory shock. Patient landed into sudden cardiac arrest on 27/1/2024 at 7:00 am, CPR was given according to ACLS protocol. Despite all methods of CPR, the patient couldn't revive. The patient was dead and death was declared at 08:25 am on 27.01.2024. *Recommendation of reviewer:*

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	a. Enrolment date – 14.01.2024 b. SAE detected on 17.01.2024 (GI bleed) which was managed but patient kept deteriorating. Further SAE (death) occurred on 27.01.2024. c. Notification to IEC on 19.01.2024 (for first SAE), and 27.01.2024 by email (for death on 27.01.2024) d. Total patients in the study – 48. SAE – 11. Deaths – 6. e. The SAE (death) doesn't appear to be related to the study and seems to be an outcome of the disease process. Patient deteriorated and died during the same admission in the hospital. No compensation, therefore, is warranted. **Comment: Besides aforementioned, nothing further** **Decision: Approved**
4	***Ref.code: 115th ECMIIA/P5*** ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial"*** submitted by Dr. Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 752/Cardio/Res/24 dated 26th February, 2024 & preliminary email dated 13th February, 2024 at 3:49 PM. **Death** **Site no.: 109** **Patient ID & age and gender:** R-099/21 Year/Male **Patient Diagnosis:** RHD/Sev-MS/MVA 0.7 **Patient enrollment date:** 11-03-2023 **Patient enrollment arm-**Digoxin **Patient follow up under study-**6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed-**Enrolment & Baseline **Planning on visit-** 6th Month **SAE detected on date:** 12-02-2024 **Follow up visit remaining:** 6th Month, 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor-**13-02-2024 **14 days analysis report submitted to EC-**26th February, 2024 **Subject History:** A letter was received in the office of the Ethics Committee on 26th February, 2024 by PI. The subject contacted telephonically on 11th Jun, 2023 for a 3-month telephonic follow-up call. The subject's number was switched off. Despite further multiple reminder calls made to the subject, the calls were not answered from any of the number provided by the subject. The subject's 6 month visit was overdue so again repeated calls were made to the subjects for 6 month visit completion. These calls were

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	also not answered. The subject's LAR informed on 12th February, 2024 that the subject had complained of breathlessness on 21st July, 2023. He passed away on 21st July, 2023 at home around 6:00 P.M. As per the information given by the patient's LAR, it seems to be a case of worsening of Heart failure. A local practitioner came and confirmed the patient's death and no autopsy was done. *Recommendation of reviewer:* a. **Enrolment date – 11.03.2023.** b. **Follow-up completed – None. First FU was 6 month which the patient skipped and was lost to follow up till 12.02.2024 when LAR informed site of the SAE.** c. **SAE date – 21.07.2023. SAE detected on – 12.02.2024** d. **24-hr notification to IEC by email on 13.02.2024.** *e.* **14-day notification to IEC on 26.02.2024** *f.* **Number of patients in study – 151. SAE – 22. Deaths – 18.** g. The SAE (death) doesn't appear to be related to the study. The patient had worsening heart failure and did not seek medical attention and died at home. No autopsy was done. No compensation, therefore, is warranted. **Comment: Besides aforementioned, nothing further** **Decision: Approved** ***Ref. code: 102nd ECM IIA/P24***
5-	ADR of research protocol *ISCHEMIA* entitled ***"International study of comparative health effectiveness with Medical and invasive approaches"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no.728/Cardio/Res/24 dated 23rd February, 2024. **Death** **Site no. 091019** **Patient ID & age and gender:** D-D-G/045,55 years, DOB-01-04-1961/Male **Patient Diagnosis:** Coronary Artery Disease/Chronic Stable Angina **Patient enrollment date:** 09-05-2016 **Patient follow up under study**-Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic Follow up till 5 year. **Follow up visit completed**-Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18 **Planning on visit-** Telephonic Follow-up Visit of month of February, 2024. **SAE detected on date:** 13-Feb-2024 **Follow up visit remaining:** Telephonic Visits (Every Month) till 2025 **24 hours, notified to EC, Sponsor-**13-Feb-2024 **14 days analysis report submitted to EC-** 27-Feb-2024

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Subject History: A letter was received in the office of the Ethics Committee on 26th February, 2024 by PI. Study Coordinator made a scheduled monthly follow up call to the subject on 13th February, 2024 at 13:30 PM. Subject's son picked the call and informed to PI that subject passed away on 28th January, 2024 at 11:30 PM. LAR informed that subject had sudden weakness in right upper limb on 7th January, 2024 for which he was taken to the hospital, where he was hospitalized for 03 days and discharged on 10th January, 2024. After few days on 28th January, 2024, at around 09:00 AM in morning, subject became unconscious & his LAR took him to Trauma Centre, where he expired at night on 28th January, 2024 around 11:30 PM. Family members destroyed all documents of hospitalization after cremation and death certificate was also not provided. No autopsy was done. *Recommendation of reviewer:* **a. Enrolment date – 09.05.2016** **b. Follow-up completed – All (till five years). Study on extension now.** **c. SAE date – 28.01.2024. SAE detected on – 13.02.2024.** **d. Patient became unwell on 07.01.2024. Admitted to hospital (which?) and discharged after 3 days on 10.01.2024. Again, became unwell on 28.01.2024, brought to Trauma Centre, died in the night of 28.01.2024.** **e. 24-hr notification to IEC by email on 13.02.2024.** *f.* **14-day notification to IEC on 27.02.2024** *g.* **Number of patients in study – 102. SAE – 18. Deaths – 18.** h. Patient was on extended follow-up. No details regarding the extension of study present in the IEC letter attached to the file. i. The patient had worsening heart failure and was admitted to the hospital twice. The SAE (death) doesn't appear to be related to the study intervention; therefore, no compensation is warranted. **Comment: Besides aforementioned, nothing further** **Decision: Approved** ***Ref. code: 60th ECM II-A/P13***
6-	ADR of research protocol ***ISCHEMIA*** entitled ***"International study of comparative health effectiveness with Medical and invasive approaches"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no.761/Cardio/Res/24 dated 28th February, 2024. **Death** **Site no. 091019** **Patient ID & age and gender:** J-G/110.82 years/Male **Patient Diagnosis:** Coronary Artery Disease/Chronic Stable Angina **Patient enrollment date:** 03-08-2017

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Patient follow up under study-Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic Follow up till 5 year. **Follow up visit completed**-Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18 **Planning on visit-** Telephonic Follow-up Visit of month of February, 2024. **SAE detected on date:** 15-Feb-2024 **Death:** 24-01-2024 **Follow up visit remaining:** Telephonic Visits (Every Month) till 2025 **24 hours, notified to EC, Sponsor-**15-Feb-2024 **14 days analysis report submitted to EC-** 29-Feb-2024 **Subject History:** A letter was received in the office of the Ethics Committee on 28th February, 2024 by PI. Study Coordinator made a scheduled monthly follow up call to the subject on 15th February, 2024 at 14:00 PM. Subject's son picked the call and informed to PI that subject passed away on 24th January, 2024 at 12:12 PM. LAR informed that subject had complained of whole body pain on 23rd January, 2024 at night and next day subject's son was taking him to the hospital but patient died on the way and did not reach the hospital. Since there was no hospital visit or medical care given, no documents were available to PI, related to his death. *Recommendation of reviewer:* a- **Enrolment date-**03-08-2017 **b- The SAE (Death) occurred on:** 24-01-2024. **c- SAE detected on :** 15-02-2024 **d- Details of Event:** SAE (Death) is likely due to disease outcome (Coronary Artery Disease/Chronic Stable Angina) and not due to intervention as patient was randomized in Conservative arm-on 04-08-2017 and SAE occurred on 24-01-2024 i.e. more than 6 yrs. and 5 months have elapsed after intervention . Patient developed whole body pain on 23-01-2024 in night and next day subject's son has taken him to the hospital but he died on the way on 24-01-2024. No autopsy was done and no documents were available to the PI for review. **e- 24 hrs notification by email:** 15-02-2024. **f- 14 day analysis submitted on:** 29-02-2024. **g- Causal relationship and Compensation:** Causal relationship of SAE (Death) with intervention cannot be established and therefore, no compensation is warranted. **Comment: Besides aforementioned, nothing further** **Decision: Approved** ***Ref. code: 60th ECM II-A/P13***
IB	**Expedited review**
1-	Expedited review of research proposal entitled ***"To validate the efficacy of an artificial intelligence (AI)-based developed mobile application for cataract detection in selected districts of Uttar Pradesh"*** sponsored by TSU, Lucknow submitted by Prof. Apjit Kaur, Head,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Department of Ophthalmology, K.G's Medical University, U.P., Lucknow vide letter no.7994/OPH dated 18th December, 2023 & letter no.8301/OPH dated 1st February, 2024.

The above research proposal was forwarded to two reviewers.

Recommendation of Primary reviewer	**PI response**
The sponsor mentioned in the covering letter is UP Technical Support Unit (TSU) and the sponsor mentioned in the project synopsis is India Health Action Trust (IHAT), however none of these are mentioned in the IEC proforma where Sponsor detail is marked as NA	Uttar Pradesh Technical Support Unit (UPTSU) has been established by GoUP to provide techno-managerial support to medical, health, family welfare and nutrition departments. India Health Action Trust (IHAT) is a non-government organization which operates the UPTSU. This study is a joint learning work by KGMU and IHAT. Further, it is mentioned that the study partner IHAT will bear all the cost related to this study. Hence, there are no other separate sponsors to this study. That's why the sponsor details are marked as NA. The relevant details are added in the study protocol as well **(refer page.no: 8 of the study protocol)**
Sponsor details along with budgetary allocation must be submitted	There is no sponsor to this study.
Recommendation of Secondary reviewer	**PI response**
Inclusion/Exclusion criteria for subjects- not defined clearly- PI to clarify	Inclusion & exclusion criteria have been revised and added to the study protocol and IEC form **(Refer (i) page.no: 5 of the study protocol (ii) in IEC form under section-5 subject selection)** *Inclusion:* The population above 50 years of age with normal looking eyes on torchlight. *Exclusion:* a) Diffuse macular to leucomatous corneal opacity covering central part of the cornea b) chronic anterior uveitis resulting in seclusion pupilae where Crystalline lens/ intra ocular lens cannot be discerned well
Two types of ICFs are enclosed- PI to justify	The content in both consent forms is the same.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		In KGMU format, there are 2 separate versions of consent forms have been prepared: one in English and another in Hindi. Further, a consent form, which has both Hindi and English in a single version, has been prepared for the ease of use in the field. The content of this consent form is as same as the one in KGMU format. This consent form will be used in the field during data collection.
	Budget requirement for the KGMU Center has not been given.	The cost required for the study will be borne by IHAT, the study partner. KGMU will provide the overall guidance to this study. Hence, the budget requirement for KGMU was not included.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the both reviewers.
Recommendation of Primary reviewer:-
Provisionally approved
Recommendation of Secondary reviewer:-
Provisionally approved
Decision: Approved

Ref. code:130th IEC IB/P1

2- Expedited review of the research proposal entitled ***"AI-based burn percentage and fluid estimation: Enhancing burn care efficacy"*** sponsored by UPCST, Lucknow submitted by Prof. Brijesh Mishra, Department of Plastic Surgery, K.G's Medical University, U.P., Lucknow vide letter no.56 dated 17th January, 2024.

The above research proposal was forwarded to two reviewers.
Recommendation of Primary reviewer:-
Provisionally approved
Recommendation of Secondary reviewer:-

- Protocol summary including study design, Inclusion/Exclusion criteria, sample size calculation is missing-PI to attach the same in IEC format.
- In methodology-flow chart is given but is not readable-PI to five revised flow chart of the study.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the secondary reviewer.
Provisionally approved
Decision: Approved

Ref. code:130th IEC IB/P2

3- Expedited review of the research proposal entitled ***"Role of immune regulatory cells in the development of inhibitors in Hemophilia A patients with special reference to T regulatory***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	cells (T regs), B regulatory cells (B regs) and myeloid derived suppressor cells (MDSC's)" submitted by Prof. Rashmi Kushwaha, Department of Pathology, K.G's Medical University, U.P., Lucknow vide letter no.46 dated 18th January, 2024. ***The above research proposal was forwarded to two reviewers.*** ***Recommendation of both reviewers:-*** Provisionally approved **Decision:** Approved ***Ref. code:130th IEC IB/P3***
4-	Expedited review of the research proposal entitled ***"Hospital-based surveillance of acute encephalitis syndrome (AES) in India"*** submitted by Prof. Amita Jain, Head, Department of Microbiology, K.G's Medical University, U.P., Lucknow vide letter no.1313/24 dated 9th January, 2024. ***The above research proposal was forwarded to two reviewers.*** **Decision:** Approved ***Ref. code:130th IEC IB/P4***
5-	Expedited review of the research proposal entitled ***"Non-alcoholic fatty liver disease as a potential risk factor for the development of cardio-vascular disease with or without metabolic syndrome"*** submitted by Dr. Shweta Kumari, Assistant Professor, Department of Biochemistry, K.G's Medical University, U.P., Lucknow vide letter no.2023/958 dated 20th December, 2023. ***The above research proposal was forwarded to two reviewers.*** ***Recommendation of Primary reviewer:-*** Provisionally approved ***Recommendation of Secondary reviewer:-*** No reply was received from the **Secondary reviewer**. The proposal, therefore, was put up for discussion in the committee. After deliberations, the proposal for recommended for approval. **Decision:** Approved ***Ref. code:130th IEC IB/P5***
6-	Expedited review of the research proposal entitled ***"Enhancing infectious disease diagnosis quality: External quality assurance program"*** submitted by Dr. Shruti Radera, Assistant Professor, Department of Microbiology, K.G's Medical University, U.P., Lucknow vide letter no.1426/2024 dated 2nd February, 2024. ***The above research proposal was forwarded to two reviewers.*** ***Recommendation of Primary reviewer:-*** Approved for waiver ***Recommendation of Secondary reviewer:-*** Approved for waiver **Decision:** Grant of "Waiver of consent" approved ***Ref. code:130th IEC IB/P6***
7-	Expedited review of the research proposal entitled ***"Pan India surveillance for respiratory viruses through DHR-ICMR VRDL Network"*** submitted by Prof. Amita Jain, Head, Department of Microbiology, K.G's Medical University, U.P., Lucknow vide letter no.1447/2024 dated 2nd

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	February, 2024. *The above research proposal was forwarded to two reviewers.* ***Recommendation of both reviewers:-*** Provisionally Approved ***Recommendation of Secondary reviewer:-*** Provisionally Approved **Decision:** Approved ***Ref. code:130th IEC IB/P7***
8-	Expedited review of the research proposal entitled ***"National Mental Health Survey-2"*** submitted by Prof. S.K. Singh, Department of **Community Medicine and Public Mental Health,** K.G's Medical University, U.P., Lucknow vide letter no.1356/CM/NMHS-2(Ethics) dated 23rd February, 2024. *The above research proposal was forwarded to two reviewers.* ***Recommendation of Primary reviewer:-*** Provisionally approved ***Recommendation of Secondary reviewer:-*** • In SOP-Checklist-Point no.-5-Subject selection section-partly mentioned and vulnerability ticked as–No, but in survey mentally challenged subjects will be taken-PI to clarify or revise. • Informed consent form-regular (E/H versions)-attached but as in this survey children and adolescents subjects are also to be taken, therefore Guardian consent and Child Assent form should also be submitted. • PI is requested to submit the protocol summary along with the given Project of NIMHANS. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Secondary reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code:130th IEC IB/P8***
II-A	**New Proposal**
1.	Research proposal entitled **"*Development implementation and evaluation of protocolized cardio-obstetric care in improving maternal cardiac, obstetric and fetal outcomes of pregnant women with heart diseases in India*"** funded by ICMR, New Delhi submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 618/Cardio/Res/24 dated 17th January, 2024. ***Recommendation of reviewer:-*** • This is a comprehensive study consisting of many objectives. • The study must be split into different parts. • Each part requires formulation of research hypotheses, identification of outcome measure, calculation of sample size etc. • The research hypothesis will be in terms of study parameters (Such as mean, standard

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	deviation, prevalence etc.). • This is a multi-centric study. • There are certain guidelines for multi-center studies. These must be followed. Only a list of potential sites is given. The name of participating centres is required. • What will be the common protocol? • Which will be a coordinating center to collect, process and analyze the data? • The number of field sites varies greatly across studies according to their size, complexity and purpose. How will this be handled? • Sample size calculation is arbitrary. Only tentative numbers are mentioned. This is due to the fact that the aim/objective is not clearly defined. The outcome event should be clearly defined. The primary objective should be converted into a proper research hypothesis in terms of the study variables and parameters. • Sample size calculation (using appropriate formula) will be required. • Data analysis plan is very general. It should be specific to the research hypothesis. **Comment:** As above **Decision:** Revise and resubmit with response to comments in a tabular format.
	Ref. code: 130th ECM IIA/P1
2.	Research proposal entitled "***Incidence, clinical characteristics and factors associated with development of heterotopic ossification in patients with spinal cord injury- A retrospective single institution study in Northern part of India***" submitted by Dr. Sandeep Kumar Gupt, Assistant Professor, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 5304/23 dated 2st December, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** Approved
	Ref. code: 130th ECM IIA/P2
3.	Research proposal entitled "***Clinico-demographic characteristics of pressure ulcers in patients with spinal cord injury-retrospective single centre study in Northern part of India***" submitted by Prof. Anil Kumar Gupta, Head, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 5305/23 dated 2st December, 2023. ***Recommendation of reviewer:-*** • In this retrospective study of 6 month duration, the investigator plans to analyse the old records and obtain only telephonic (audiovisual) consent & not written consent from the patient. Then what is the role of submitted ICF that is supposed to be signed by the patient and also the role of patient information sheet. Kindly clarify. • Is the risk not reasonable compared to benefits? (Annexure point 10) • Kindly mention the anticipated sample size. **Comment:** As above **Decision:** Approval subject to clarification

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 130th ECM IIA/P3
4.	Research proposal entitled "***Influenza vaccine to reduce cardiovascular events in patients with recent myocardial infarction: a multicentric randomized, double-blind, placebo-controlled trial***" submitted by Prof. Sharad Chandra, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 601/Cardio/Res/23 dated 30th December, 2023. ***Recommendation of reviewer:-*** • This is a multi-center randomized controlled trial (RCT). • This is a multi-centric study. • There are certain guidelines for multi-center studies. These must be followed. Only a list of potential sites is given. The name of participating centres is required. • What will be the common protocol? • Which will be a coordinating center to collect, process and analyze the data? • The number of field sites varies greatly across studies according to their size, complexity and purpose. How will this be handled? • Sample size calculation is arbitrary. Only tentative numbers are mentioned. This is due to the fact that the aim/objective is not clearly defined. The outcome event should be clearly defined. The primary objective should be converted into a proper research hypothesis in terms of the study variables and parameters. • Sample size calculation (using appropriate formula) will be required. • Data analysis plan is very general. It should be specific to the research hypothesis. • The method of randomization is not given. • A mere statement that so many patients with such and such diagnosis were randomized is unsatisfactory. • The method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.) is required. • Was there any blinding procedures used? • Was there any randomization blinding? • Was there any blinding of patients? • How is the handling of withdrawal done? **Comment:** As above **Decision:** Revise and resubmit with response to comments in a tabular format.
	Ref. code: 130th ECM IIA/P4
5.	Research proposal entitled "***Effect of stress management and resilience training through meditation (SMART-Me) (Soft Skill Development) programme on psychological resilience and well-being of paramedical students: A case control experimental study***" submitted by Dr. Bhupendra Singh, Additional Professor, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 426/DGMH/23 dated 23rd December, 2023. ***Recommendation of reviewer:-*** • The design of the study needs clarification; it can either be a "case-control" or an

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	"experimental" study. • Has this SMART-Me technique been implemented before? • Kindly mention the reference for SMART-ME technique of medication and it will be better to include a Co-Investigator qualified for implementing yoga technique. • Has this SMART-Me technique been implemented before? • Is the risk not reasonable compared to benefit? (Annexure 1 point 10) • Information sheet & ICF need to be customized for controls & cases separately. **Comment:** As above **Decision:** Revise and resubmit with response to comments in a tabular format.
	Ref. code: 130th ECM IIA/P5
6.	Research proposal entitled "***Developing capacity to strengthen district system for PHC performance***" submitted by Prof. Monika Agarwal, Head, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1150/CM/2024 dated 2nd January, 2024. ***Recommendation of reviewer:-*** • IEC to be filled properly. If no patients are to be studied, on whom patient information sheet and ICF will be applied? • The study is to be carried out to strengthen the PHC performance system and secondary data are to be extracted and analyzed by performing various activities-discussion with various district, PHC and community level stakeholders. Thus, to obtain consent developing a customized form related to the same along with the questionnaire/ discussion points may be suitable. **Comment:** As above **Decision:** Approval subject to clarification
	Ref. code: 130th ECM IIA/P6
7.	Research proposal entitled "***Prevalence of oral premalignant and malignant lesions amongst tobacco users: A community-based study***" submitted by Prof. Vinay Kumar Gupta, Head, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 4/2024 dated 8th January, 2024. ***Recommendation of reviewer:-*** • Approved **Decision:** Approved
	Ref. code: 130th ECM IIA/P7
8.	Research proposal entitled "***Multidimensional analysis of pain in burning mouth syndrome: A questionnaire based study***" submitted by Dr. Akhilanand Chaurasia, Additional Professor, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 15/OM&R/24 dated 9th January, 2024. ***Recommendation of reviewer:-*** • The design of the study lacks clarity. The proposal should clearly define the study

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	design and whether the evaluation would be prospective or not. • IEC to be filled properly. • Sample size is to be checked and written as per the study requirement. The protocol-related details are to be given in a sequence. • Methods to be written properly and tense of sentences to be checked. • ICF to be prepared in an understandable language. **Comment:** As above **Decision:** Revise and resubmit with response to comments in a tabular format. ***Ref. code: 130th ECM IIA/P8***
9.	Research proposal entitled "***Awareness of orofacial pain among general population and dental health care professionals***" submitted by Dr. Akhilanand Chaurasia, Additional Professor, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 23/OM&R/24 dated 10th January, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P9***
10.	Research proposal entitled "***Antenatal myomectomy: A surgical challenge***" submitted by Prof. S. P. Jaiswar, Head, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/08/24 dated 2nd January, 2024. ***Recommendation of reviewer:-*** • The PI has presented a case series comprising of five patients, based on which conclusions have been drawn. **Decision:** Retrospective approval for a completed study/analysis cannot be granted. ***Ref. code: 130th ECM IIA/P10***
11.	Research proposal entitled "***Medical and psychiatric comorbidities among patients with alcohol dependence: A multi-center study from India***" submitted by Dr. Amit Singh, Assistant Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 2190/Psy/24 dated 16th January, 2024. ***Recommendation of reviewer:-*** • Content written under-sampling and sample size sub-heading to be re-checked and modified. **Comment:** As above **Decision:** Revise and resubmit with response to comments in a tabular format. ***Ref. code: 130th ECM IIA/P11***
12.	Research proposal entitled "***Thought, language and communication in schizophrenia and related disorders: A cross-sectional study using speech data***" submitted by Dr. Sujita Karm Kar, Additional Professor, Department of Psychiatry, King George's Medical University, U.P.,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Lucknow vide letter no. 2189/Psy/24 dated 16th January, 2024. ***Recommendation of reviewer:-*** • To analyze the qualitative data one needs to choose a distinct style. All the approaches stated in the proposal are different from each other in a qualitative framework. Thus, a specific method needs to be applied giving an be-fitting reason. **Comment:** As above **Decision:** Approval subject to clarification ***Ref. code: 130th ECM IIA/P12***
13.	Research proposal entitled "***Efficacy and Safety of Platelet Rich Plasma as an adjunct therapy to split thickness skin graft in burn patients with granulating raw wounds***" submitted by Prof. Vijay Kumar, Head, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 36/24 dated 10th January, 2024. ***Recommendation of reviewer:-*** • In the consent form it is mentioned that there will be no any complication associated with the study. However, there may be transfusion related adverse reactions or events associated with immune-mediated reactions which may be mentioned. **Comment:** As above **Decision:** Approval subject to clarification ***Ref. code: 130th ECM IIA/P13***
14.	Research proposal entitled "***Relation of resilience and coping orientation with perceived burden of care of carers of neurodegenerative disorder (NDD) patients : A cross-sectional study***" submitted by Dr. Bhupendra Singh, Additional Professor, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 41/DGMH/24 dated 31st January, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Dr. Nisha Mani Pandey did not participate in discussion and decision making.*** ***Ref. code: 130th ECM IIA/P14***
15.	Research proposal entitled "***MAGPIES-mapping global surgery***" submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/448/24 dated 10th February, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P15***
16.	Research proposal entitled "***Study of stigma and discrimination among people living with HIV AIDS (PLHIV) and key population in Uttar Pradesh***" submitted by Dr. Rajeev Misra, Assistant Professor, Department of Community Medicine & Public Health, King George's

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Medical University, U.P., Lucknow vide letter no. 1263/CM/24 dated 3rd February, 2024. ***Recommendation of reviewer:-*** • The title should be more explicit defining the target population exclusively. • The present study looks like to be multi-stage stratified random sampling. • It should be accordingly planned. • The sample size calculation will use stratified sampling methods, may be proportional allocation. • Nothing is said about the reliability of the instrument. • Nothing is said about the face validity and content validity of the instrument. • What is the construct validity of the instrument? • Research hypothesis should be defined in term of the population parameters involved in the study. • The population parameters will be derived from the quantitative evaluation of the instrument being used. **Comment:** As above **Decision:** Revise and resubmit with response to comments in a tabular format. ***Ref. code: 130th ECM IIA/P16***
17.	Research proposal entitled "***2023 ESCP collaborating group audit and cohort study: wound closure and SSI prevention in abdominal surgery with long term follow-up (WOLVERINE)***" submitted by Dr. Shiv Rajan, Associate Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/449/24 dated 10th February, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P17***
18-	Research proposal entitled "***Identifying host-protein biomarkers for predicting infectious disease in low resource health care settings; and experimental study to enhance infectious disease surveillance***" submitted by Prof. Avinash Agarwal, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter nos. DCCM/2024/0032 dated 22nd January, 2024 & DCCM/2024/0069 dated 2nd February, 2024. ***Recommendation of reviewer:-*** • This is a retrospective case-control study. It should be accordingly planned. • Identify the study variables (variables associated with acute febrile illness). • Identify the study parameters (such as mean, proportion, standard deviation etc.). These will be derived from the study variables. • Define the research hypothesis using the study parameters. • Calculate the sample size using the research hypothesis. There is no sample size given. • The statistical analysis will be specific to the research hypothesis. **Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	As above **Decision:** Approval subject to clarification with response to comments in a tabular format. ***Ref. code: 130th ECM IIA/P18***
19-	Research proposal entitled "***Feasibility, acceptability & students' perception about MiniCEX for WPBA in Obstetrics & Gynaecology postgraduate education***" submitted by Prof. Amita Pandey, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/481/24 dated 20th February, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P19***
20-	Research proposal entitled "***Can kangaroo mother care (KMC) during the first 72 hours lead to improved breastfeeding and growth among normal birth weight newborns? A randomized controlled trial***" submitted by Prof. Mala Kumar, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 239/Ped/2024 dated 20th February, 2024. ***Recommendation of reviewer:-*** • The Chief Investigator is the chairperson of the SRC. • In the patient information sheet, both of the names of the person to whom contact is to be made are not from KGMU • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** **Comment:** As above **Decision:** Approval subject to clarification ***Ref. code: 130th ECM IIA/P20***
21-	Research proposal entitled "***Acceptability of value added courses in Pathology for phase 2 MBBS students***" submitted by Prof. Riddhi Jaiswal, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 135 dated 19th February, 2024. ***Recommendation of reviewer:-*** • Nothing is said about the reliability and validity of the instrument. • How be the instrument converted into quantitative score? • Research hypothesis will be in terms of the study parameters (mean, proportion etc.) derived from the quantitative scores. • Sample size calculation is not given. • Statistical analysis (quantitative as well as qualitative) has to be more specific. At present, it is unclear. **Comment:** As above **Decision:** Revise and resubmit with response to comments in a tabular format. ***Ref. code: 130th ECM IIA/P21***
22-	Research proposal entitled "***Piloting & refinement of an in-facility supportive care package***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	for optimal feeding and preventive-promotive care of low birthweight and preterm infants admitted to level-2 neonatal intensive care units" submitted by Prof. Mala Kumar, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 240/Ped/2024 dated 20th February, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P22***
II-B	**New Ph. D Proposal**
1.	Research proposal entitled "***Identification of novel metabolic biomarkers in drug resistant pulmonary tuberculosis patients using metabolomics***" submitted by Ms. Sushma Yadav, Ph.D Scholar, under the guidance Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1427/Res/23 dated 20th December, 2023. ***Recommendation of reviewer:-*** • Unrelated project information is mentioned in the IEC under the sponsor information. • Role of investigators to be redefined? • IEC to be filled properly. There is a mismatch in no. of subjects in the proposal and IEC. • Inclusion criteria should mention subjects/ patient age groups. • Who will be the control? Inclusion and exclusion criteria of control to be mentioned. • Who will be responsible for investigations of the control group? • Who will take the responsibility for extracting blood sample, storage etc. • Methodology to be checked thoroughly and written properly. • ICF and patient information sheet to be written properly. **Comment:** • As mentioned in the form, this study has already been conducted; hence, retrospectively ethical approval cannot be granted. • Kindly provide evidence of funding for metabolomics study. • Prospective nature? • Check the ICMR project/proposal. • Source of funding/Medicine-Metabolomics **Decision:** Revise and resubmit with response to comments in a tabular format. ***Ref. code: 130th ECMIIB-Ph.D/P1***
2.	Research proposal entitled "***Evaluation of ctDNA/cfDNA ratio as a biomarker of oral squamous cell carcinoma progression through high throughput sequencing data analysis and real-time PCR***" submitted by Ms. Ekta Anthony, Ph.D. Scholar, under the guidance Prof. Shalini Gupta, Head, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2018/OP/23 dated 21st December, 2023. ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• There are too many objectives. • Methodology to be written sequentially. • Who will be responsible for extracting blood and tissue samples as well as their storage and analysis? • Who is going to bear the cost of investigation(s). • The consent form is to be written in simple language. **Comment:** • Prospective nature? • Check the ICMR project/proposal. • Source of funding: Patients/PI **Decision:** Revise and resubmit with response to comments in a tabular format. ***Ref. code: 130th ECMIIB-Ph.D/P2***
3.	Research proposal entitled "***Elucidation of the interactions of inflammasome and cytokines in oral cancer***" submitted by Ms. Shatakshi Naang, Ph.D. Scholar under the guidance Dr. Sayali Mukherjee, Assistant Professor, Amity Institute of Biotechnology, Amity University Lucknow through her Co-guide, Dr. Fahad Mansoor Samadi, Additional Professor, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 2058/OP/24 dated 12th January, 2024. ***Recommendation of reviewer:-*** • Neither aim nor hypothesis of the study is given. • Amount of blood to be taken is also not mentioned. • How DNA will be extracted is not mentioned. **Comment:** Where is it registered? Funding **Decision:** Revise and resubmit with response to comments in a tabular format. ***Ref. code: 130th ECMIIB-Ph.D/P3***
4.	Research proposal entitled "***Dead body handing practices and exposure to blood borne infections among mortuary workers in Uttar Pradesh***" submitted by Ms. Geetika Bajpai, Ph.D Scholar under the guidance Dr. Mousami Singh, Additional Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 29/FMT/24 dated 30th January, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Dr. Nisha Mani Pandey did not take part in the discussion and decision making.*** ***Ref. code: 130th ECMIIB-Ph.D/P4***
5.	Research proposal entitled "***Estimation of polychlorinated bi-phenyl (PCB) & brominated flame retardants (BFRs) in the blood of workers at E-waste recycling sites***" submitted by Ms. Rakhi Rajput, Ph.D. Scholar under the guidance Dr. Shiuli, Associate Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	letter no. 49/FMT/24 dated 7th February, 2024. ***Recommendation of reviewer:-*** • It is not clearly mentioned how much blood will be collected. (Just mentioned that 4-10 ml of the blood will be taken) • It is unclear who would fund the project and how expenses would be managed. **Decision:** Revise and resubmit with response to comments in a tabular format. ***Ref. code: 130th ECMIIB-Ph.D/P5***
6.	Research proposal entitled "***The effect of brief psychological nursing intervention on quality of life and coping among burn patients undergoing plastic and reconstructive surgery in a tertiary care centre, of North India: A randomized control study***" submitted by Ms. Deblina Roy, Ph.D. Scholar under the guidance Dr. Pradeep Maderana, Associate Professor, Community Health Nursing, NIMS Nursing College, NIMS University, Rajasthan through Dr. Sujita Kumar Kar, Co-guide & Additional Professor, Department of Psychiatry, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 2224/Psy/24 dated 23rd January, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 130th ECMIIB-Ph.D/P6***
II-C	**Review of New Drug Trial**
1.	Research protocol no. GB44332 entitled "***A phase III, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of astegolimab in patients with chronic obstructive pulmonary disease***" sponsored by M/s F. Hoffmann-La Roche Ltd. submitted by Dr. Ajay Kumar Verma, Additional Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. CT/RM/22/2023 dated 19th December, 2023. ***Recommendation of reviewer:-*** • Insurance policy is valid up to 01-01-2024- to be renewed. **Comment:** The renewal of insurance was furnished by the PI on communication. ***The following documents were reviewed in its Meeting:-***

Sr. No.	Document/Language	Document Details/Versions
1.	Protocol	Protocol Version 2 dated 09Nov2022
2.	Investigators Brochures	Investigator Brochure Version 8 dated April 2023
3.	Insurance Policy and Certificate	Insurance Policy and Certificate date 03 Apr 2023
4.	Draft CTA & Budget	Draft CTA and Budget

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

5.	eCRF	GB44332_eCRF R2.0 dated 13Jun2023
6.	Main Informed Consent Document_English	GB44332_Main ICF_v2.0_India_English_Dr. Ajay Kumar Verma_26Sep2023
6.1	Main Informed Consent Document_Hindi	GB44332_Main ICF_v2.0_India_Hindi_Dr. Ajay Kumar Verma_26Sep2023
6.2	Main Informed Consent Document_Hindi_Translation Certificate	GB44332_Main ICF_v2.0_India_Hindi_Dr. Ajay Kumar Verma_26Sep2023 Translation Certificate
6.3	Main Informed Consent Document_Hindi Back Translation	GB44332_Main ICF_v2.0_India_English back translated from Hindi_Dr. Ajay Kumar Verma_26Sep2023
6.4	Main Informed Consent Document_Hindi Back Translation Certificate	GB44332_Main ICF_v2.0_India_English back translated from Hindi_Dr. Ajay Kumar Verma_26Sep2023_Translation Certificate
7.	Infant Authorization Form_English	GB44332_Infant Authorization Form_v1.0_India_English_Dr. Ajay Kumar Verma_26Sep2023
7.1	Infant Authorization Form_Hindi	GB44332_Infant Authorization Form_v1.0_India_Hindi_Dr. Ajay Kumar Verma_26Sep2023
7.2	Infant Authorization Form_Hindi_Translation Certificate	GB44332_Infant Authorization Form_v1.0_India_Hindi_ Dr. Ajay Kumar Verma_26Sep2023_Translation Certificate
7.3	Infant Authorization Form_Hindi Back Translation	GB44332_Infant Authorization Form_v1.0_India_English back translated from Hindi_Dr. Ajay Kumar Verma_26Sep2023
7.4	Infant Authorization Form_Hindi Back Translation Certificate	GB44332_Infant Authorization Form_v1.0_India_English back translated from Hindi_Dr. Ajay Kumar Verma_26Sep2023 Translation Certificate
8.	Pregnant Partner ICF_English	GB44332_Pregnant Partner Authorization Form_v1.0_India_English_ Dr. Ajay Kumar Verma_26Sep2023
8.1	Pregnant Partner ICF_Hindi	GB44332_Pregnant Partner Authorization Form_v1.0_India_Hindi_ Dr. Ajay Kumar Verma_26Sep2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

8.2	Pregnant Partner ICF_Hindi_Translation Certificate	GB44332_Pregnant Partner Authorization Form_v1.0_India_Hindi_ Dr. Ajay Kumar Verma_26Sep2023_Translation Certificate
8.3	Pregnant Partner ICF_Hindi Back Translation	GB44332_Pregnant Partner Authorization Form_v1.0_India_English back translated from Hindi_Dr. Ajay Kumar Verma_26Sep2023
8.4	Pregnant Partner ICF_Hindi Back Translation Certificate	GB44332_Pregnant Partner Authorization Form_v1.0_India_English back translated from Hindi_Dr. Ajay Kumar Verma_26Sep2023
9.	Pregnant Partner ICF_English	GB44332_Pregnant Partner Authorization Form_v1.0_India_English_ Dr. Ajay Kumar Verma_26Sep2023
9.1	Audio Video ICF_Hindi	GB44332_AV_ICF_V1.0_India_Hindi_Dr. Ajay Kumar Verma_26Sep2023
9.2	Audio Video ICF_Hindi_Translation Certificate	GB44332_AV_ICF_V1.0_India_Hindi_ Dr. Ajay Kumar Verma_26Sep2023_Translation Certificate
9.3	Audio Video ICF_Hindi Back Translation	GB44332_AV ICF_V1.0_India_English back translated from Hindi_Dr. Ajay Kumar Verma_26Sep2023
9.4	Audio Video ICF_Hindi Back Translation Certificate	GB44332_AV ICF_V1.0_India_English back translated from Hindi_Dr. Ajay Kumar Verma_26Sep2023
10.	Patient Card	Patient Card INDIA English v2.0.06 Apr 2023
10.1	Patient Card_Hindi	Patient Card INDIA Hindi v2.0 06 Apr 2023
10.2	Patient Card_Hindi Back Translation	Patient Card INDIA Hindi v2.0 06 Apr 2023 Back Translation
10.3	Patient Card_Hindi FT and BT Translation Certificate	Patient Card_Hindi FT and BT Translation Certificate dated 06 Apr 2023
11.	GP Letter	GB44332_General Practitioner letter_Master_English_version 2_12Dec2022
12	A-1489-0101-5151QRG_enIN	A-1489-0101-5151QRG v1_enIN_21Mar2023
12.	A-1489-0101-5151QRG v1_enIN_TCert	A-1489-0101-5151QRG v1_enIN_TCert_21Mar2023
12.	Guide to using your Study eDiary/your own	GB44332_ A-1489-0101-5151_QRG_v1_Hindi (India)_20 Jan 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Device_Hindi	
12.	Guide to using your Study eDiary/your own Device_Hindi_Translation Certificate	GB44332_ A-1489-0101-5151_QRG_v1_Hindi (India)_ Translation Certificate dated _20 Jan 2023
13.	A-1489-0101/GB44332 Subject Facing Screen report_Eng	A-1489-0101-5270SR-Web-Subject-enIN_v1_20Mar2023
13.	A-1489-0101/GB44332 Subject Facing Screen report_Eng_Tcert	A-1489-0101-5270SR-Web-Subject-enIN_v1_TCert_20Mar2023
13.3	GB44332 Subject Facing Screen Report_Hindi	GB44332_A-1489-0101_Subject_Master_Hindi India(hiIN)_v1_18Jan2023
13.4	GB44332 Subject Facing Screen Report_Hindi_Translation Certificate	Subject_Master_Hindi India(hiIN)_v1_Translation Certificate dated 20-Jan-23
14	A-1489-0101-5350DL_Device Label_Eng	A-1489-0101-5350DL-enIN_v1_21Mar2023
14.1	CRF Certificate of translation English DL	CRF Certificate of translation English DL_22Feb2018
14.2	GB44332_Device Label_Hindi	GB44332_Device Label_Hindi_India_V1_17Jan2023
14.3	GB44332_Device Label_Hindi_Translation Certificate	GB44332_Device Label_Hindi_ Translation Certificate dated Mar2017
15.	ARNASA_Appointment_ Reminder_Card_English	ARNASA_Appointment_Reminder_Card_V1_02May23_English_(India)
15.1	ARNASA_Appointment_ Reminder_Card_Hindi	ARNASA_Appointment Reminder Card_V1_13Mar23_Hindi (India)

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

16	ARNASA_Posters_English	ARNASA_Posters_V1_02May23_English_(India)
16.1	ARNASA_Posters_Hindi	ARNASA_Posters_V1_13Mar23_Hindi (India)
17.	ARNASA_Print_Adverts_Eng	ARNASA_Print_Adverts_V1_02May23_English_(India)
17.1	ARNASA_Print_Adverts_Hindi	ARNASA_Print Adverts_V1_13Mar23_Hindi (India)
18.	ARNASA_Study_Flyers_Eng	ARNASA_Study_Flyers_V1_02May23_English_(India)
18.1	ARNASA_Study_Flyers_Hin	ARNASA_Study_Flyers_V1_02May23_Hindi_(India)
19	ARNASA_Study_Visit_Guide	ARNASA_Study_Visit_Guide_V1_02May23_English_(India)
19.1	ARNASA_Study_Visit_Guide	ARNASA_Study_Visit_Guide_V1_02May23_Hindi_(India)
20.	ARNASA_Thank You Letter_Eng	ARNASA_Thank_You_Letter_V1_02May23_English_(India)
20.1	ARNASA_Thank You Letter_Hindi	ARNASA_Thank You Letter_V1_13Mar23_Hindi (India)
21	ARNASA_Welcome Letter_Eng	ARNASA_Welcome Letter_V1_02May23_ Eng (India)
21.1	ARNASA_Welcome Letter_Hindi	ARNASA_Welcome Letter_V1_13Mar23_Marathi (India)
21.2	ARNASA_Hindi_Tcert	ARNASA_Translation Certificate_Hindi (India)_ 13Mar23
22	DCGI Approval letter	DCGI Approval letter dated 18Oct2023
23	Undertaking of PI	Signed and Dated 19Sep2023
24.	CV for PI	Signed and Dated 19Sep2023
25.	Medical Registration Certificate for PI	Signed and Dated 19Sep2023
26.	GCP of PI	Completion Dated 13Jun2022

Decision: Approval subject to fulfilment & Administrative formalities.

Ref. code: 130th ECMIIC/P1

2. Research protocol no. OPX-PR-03 entitled "***Randomized, double-blinded, placebo-controlled study to evaluate the safety, tolerability, and efficacy of intravenous varespladib followed by oral varespladib in addition to standard of care in subjects bitten by venomous snakes***"

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	sponsored by M/s Ophirex, Inc submitted by Dr. Medhavi Gautam, Assistant Professor, Department of Medicine, King George's Medical University, U.P., Lucknow, vide letter no. MED/CT/28/2023 dated 27th December, 2023. ***Recommendation of reviewer:-*** • Sponsor is Ophirex Inc. Contract research organization is Syneos Health. CDSCO approval has been sought by M/S InVentiv International Pharma Services Pvt. Ltd. CTA is with Syneos? • CDSCO letter does not mention KGMU site. • Insurance policy is lapsing in June 2024. **Comment:** As above **Decision:** Approval subject to clarification; if needed, legal vetting will be opted. ***Ref. code: 130th ECMIIC/P2***
3.	Research protocol no.23-03 entitled "***A prospective, randomized, parallel, active controlled, multicentre, phase III clinical trial to assess the efficacy and safety of vilanterol, glycopyrronium and fluticasone furoate inhalation as compared to indacaterol, glycopyrronium and mometasone furoate inhalation in patients with persistent Asthma***" sponsored by M/s Zydus Healthcare Limited submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow, vide letter no. CT/RM/23/2023 dated 29th December, 2023. ***Recommendation of reviewer:-*** • The Scientific review committee report should specifically comment upon acceptability of the points rather than "Attached in Dossier" • Kindly mention the anticipated budget in Annexure 1 rather than referring to the draft. • Being multicentric study, kindly name the collaborating centers. • What is the role of healthy volunteers in this study? (as per Annexure 1 point 8 ii) Kindly mention their inclusion criteria, numbers and more so separate ICF/ information sheet for them. • Kindly note that insurance policy is valid till 19th March, 2024. • Please furnish the document showing KGMU as a centre as well as the IEC/IRB approval from the nodal centre. **Comment:** As above **Decision:** Revise and resubmit with response to comments in a tabular format. ***Ref. code: 130th ECMIIC/P3***
4.	Research protocol no. 2301 entitled "***A prospective, randomized, parallel, three-arm, open-label, multicenter, phase IV clinical trial to evaluate the immunological non-interference of typhoid vi conjugate vaccine with yellow fever vaccine administered to healthy subjects***" sponsored by M/s Regeneron Pharmaceuticals Inc submitted by Dr. Ambuj Yadav, Assistant Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/01/2024 dated 01st January, 2024. ***Recommendation of reviewer:-*** • In SOP-Checklist -Point no.-5 – Subject selection –Vulnerability-ticked-No, but

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Children /Elderly subjects are to be recruited –PI to clarify. • Insurance policy is valid up to 19th March, 2024–to be renewed. • CTRI document-number allotment pending –to be submitted to EC after allotment. **Comment:** As above **Decision:** Revise and resubmit with response to comments in a tabular format. ***Ref. code: 130th ECMIIC/P4***
5.	Research protocol no. PB016-03-01 entitled "***A randomized, double-blind, multicenter phase 3 study in patients with moderately to severely active ulcerative colitis (UC) to compare the efficacy, safety and immunogenicity of PB016 and entyvio® for the induction and maintenance of clinical response and remission (UCESIVE)***" sponsored by M/s Polpharma Biologics S.A. Trzy Lipy submitted by Prof. Abhijit Chandra, HOD, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow, vide letter no. SGE/CT/24/24 dated 2nd January, 2024. ***Recommendation of reviewer:-*** • IEC form Section 3 (iii) not completed. • Section 7 of IEC form mentions no biological materials being used, but section 7(ix) mentions that samples will be sent abroad. • Section 8 on consent is incompletely filled. • Section 5(v) of IEC form mentions subject as those with constipation, however the study is being done on subjects with ulcerative colitis. **Comment:** As above **Decision:** Approval subject to clarification ***Ref. code: 130th ECMIIC/P5***
6.	Research protocol no. D7984C00002 entitled "***A phase III, randomized, double-blind, placebo-controlled, multi-centre, global study of volrustomig in women with high risk locally advanced cervical cancer who have not progressed following platinum-based, concurrent chemoradiation therapy (eVOLVE-Cervical***" sponsored by M/s Astra Zeneca AB, 151 85 Sodertalje submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/158/24 dated 19th January, 2024. ***Recommendation of reviewer:-*** • The name of other 3 Co-Investigators along with their designations need to include in Annexure 1-RV-1/2019 (SOP IEC KGMU). Add missing. • Kindly included anticipated budget in annexure 1 (Sponsor information) • Of the number of subject as mentioned in Annexure 1 point 5 will all the cases be done in KGMU? It not then what be the anticipated numbers. • A signed CTRI certification be submitted before initiation of trial. • DCGI & insurance ending in 2029 are acceptable. • The scientific review committee should not include the Co-Investigators in this study.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

The above response was furnished by the PI on communication.

The following documents were reviewed in its Meeting:-

Sl.no.	Documents
1.	Clinical Study Protocol Version 2.0, Date: 07 Aug 2023
2.	Clinical Study Protocol Addendum - Version 1.0, Date: 21 Aug 2023
3.	Investigator's Brochure – MEDI5752, Volrustomig, Edition No. 6.0, Edition date: 27 Jun 2023
4.	Case Report Form Version 2.0 28 Aug 2023
5.	Insurance certificate for the period of 01 Mar 2023 to 29 Feb 2024 (Policy No. P0823200001/9999/106914)
6.	DCG(I) Submission Letter dated 04 Sep 2023 (File No: **GCT/CT04/FF/2023/39490**, Submission date: 04 Sep 2023)
7.	DCGI NOC dated 26th Dec 2023
8.	DCG(I) Import License Application Submission Letter dated 01 Sep 2023 (File No: **GCT/CT16/TL/2023/137727**, Submission date: 04 Sep 2023)
9.	Screening Part I Adult Study Subject Master Information and Consent Form Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023 **Translation:** • English to Hindi (Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023) Translated on 01 Sep 2023 **Back Translation:** • Hindi to English (Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023) Back translated on 01 Sep 2023 **Translation & Back Translation Certificates:** • English to Hindi • Hindi to English
10.	Screening Part II Adult Study Subject Master Information and Consent Form Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023 **Translation:** • English to Hindi (Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023) Translated on 01 Sep 2023 **Back Translation:** • Hindi to English (Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023) Back translated on 01 Sep 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Translation & Back Translation Certificates: • English to Hindi • Hindi to English
	11.	Future Research Information and Consent Form (Screening Part I Adult Study Subject Master Information and Consent Form) Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023 **Translation:** • English to Hindi (Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023) Translated on 01 Sep 2023 **Back Translation:** • Hindi to English (Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023) Back translated on 01 Sep 2023 **Translation & Back Translation Certificates:** • English to Hindi, • Hindi to English
	12.	Future Research Information and Consent Form (Screening Part II Adult Study Subject Master Information and Consent Form) Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023 **Translation:** • English to Hindi (Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023) Translated on 01 Sep 2023 **Back Translation:** • Hindi to English (Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023) Back translated on 01 Sep 2023 **Translation & Back Translation Certificates:** • English to Hindi • Hindi to English
	13.	Optional Genetic Research Information Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023 **Translation:** • English to Hindi (Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023) Translated on 01 Sep 2023 **Back Translation:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		• Hindi to English (Master Version Number 2.0 Master Version Date 9 Aug 2023 India Version Number 1.0 India Version Date 16 Aug 2023) Back translated on 01 Sep 2023 **Translation & Back Translation Certificates:** • English to Hindi • Hindi to English
	14.	Adult Informed Consent Form for Audio-Visual Recording of Subject's Consent Process in India India Master Version Number 1.0 India Master Version Date 12 Jun 2023 **Translation:** • English to Hindi (India Master Version Number 1.0 India Master Version Date 12 Jun 2023) Translated on 06 Jul 2023 **Back Translation:** • Hindi to English (India Master Version Number 1.0 India Master Version Date 12 Jun 2023) Back translated on 06 Jul 2023 **Translation & Back Translation Certificates:** • English to Hindi Hindi to English
	15.	Study Participation Card Version 1.0 27 Arp 2023, India version 1.0 05 Sep 2023 – English **Translation:** • English to Hindi (India Version 1.0 dated 05 Sep 2023) Translated on 08 Sep 2023 **Back Translation:** • Hindi to English (India Version 1.0 dated 05 Sep 2023) Translated on 08 Sep 2023 **Translation & Back Translation Certificates** • English to Hindi • Hindi to English
	16.	Subject Facing Screen Report - App Version 1.0 Date 29 Jun 2023
	17.	Subject Facing Screen Report - Web Version 1.0 Date 29 Jun 2023
	18.	Thank you card English Version: 1.0 31 Mar 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Translation: • English to Hindi (Version 1.0 dated 02 Aug 2023) **Certificate of Accuracy –** • Hindi dated 02 Aug 2023
19.	**Patient-Reported Outcomes (ePRO)- Effective_REPR_India EQ-5D-5L Digital Self-Complete v1.0** • English (US) to English (India), Screenshot Document Version 1.0 dated February 2012 • English (US) to Hindi (India), Screenshot Document Version 1.0 dated 19 Jan 2023 **Certificate of Translation and Proofreading:** • English (US) to English (India) dated February 2012 • English (US) to Hindi (India) dated 19 Jan 2023
20.	**Patient-Reported Outcomes (ePRO)- IL172** • English (US) to English (India), dated 27 Mar 2023 • English (US) to Hindi (India), dated 27 Mar 2023 **Certificate of Translation and Proofreading:** • English (US) to Hindi (India) dated 27 Mar 2023
21.	**Patient - Reported Outcomes (ePRO) - IL304** • English (US) to English (India), dated 27 Mar 2023 • English (US) to Hindi (India), dated 27 Mar 2023 **Certificate of Translation and Proofreading:** • English (US) to Hindi (India) dated 27 Mar 2023
22.	**Patient - Reported Outcomes (ePRO) –** IL317 • English (US) to English (India), dated 27 Mar 2023 • English (US) to Hindi (India), dated 27 Mar 2023 **Certificate of Translation and Proofreading:** • English (US) to Hindi (India) dated 27 Mar 2023
23.	**Patient - Reported Outcomes (ePRO) –** IL318 • English (US) to English (India), dated 27 Mar 2023 • English (US) to Hindi (India), dated 27 Mar 2023 **Certificate of Translation and Proofreading:** • English (US) to Hindi (India) dated 27 Mar 2023
24.	**Patient - Reported Outcomes (ePRO) – PGIC-GENERIC** • English (US) to English (India), dated 15 Apr 2020

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		• English (US) to Hindi (India), dated 15 Apr 2020 **Certificate of Translation and Proofreading:** • English (US) to English (India) dated 15 Apr 2020 • English (US) to Hindi (India) dated 15 Apr 2020
	25.	**Patient - Reported Outcomes (ePRO) – PGIS-Cancer** • English (US) to English (India), dated 22 Jul 2021 • English (US) to Hindi (India), dated 22 Jul 2021 **Certificate of Translation and Proofreading:** • English (US) to English (India) dated 22 Jul 2021 • English (US) to Hindi (India) dated 22 Jul 2021
	26.	**Patient - Reported Outcomes (ePRO) - PGI-TT** • English (US) to English (India), dated 31 Jan 2019 • English (US) to Hindi (India), dated 25 Jan 2019 **Certificate of Translation and Proofreading:** • English (US) to English (India) dated 31 Jan 2019 • English (US) to Hindi (India) dated 25 Jan 2019
	27.	**Patient - Reported Outcomes (ePRO) - pro-ctcae** • English (US) to English (India), Version 1.0 dated 06 Jun 2023 • English (US) to Hindi (India), Version 1.0 dated 05 May 2023 **Certificate of Translation and Proofreading:** • English (US) to Hindi (India) dated 11 Oct 2022
	28.	**Patient - Reported Outcomes (ePRO) - PROMIS SF** • English (US) to English (India), Version 2.0 dated 05 May 2020 • English (US) to Hindi (India), Version 2.0 dated 03 Aug 2021 **Certificate of Translation and Proofreading:** • English (US) to Hindi (India) dated 30 Nov 2020
	29.	App-Subject-Screen-Report English India Version 1.0 Date 04 Oct 2023 **Translation:** • English to Hindi (Version 1.0 Dated 17 Oct 2023) **Certification:** • English to English Dated 05 Oct 2023 • English to Hindi Dated 17 Oct 2023
	30.	Web-Subject-Screen-Report_English India Version 1.0 Date 06 Oct 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		Translation: • English to Hindi (Version 1.0 Dated 19 Oct 2023) **Certification:** • English to English Dated 06 Oct 2023 • English to Hindi Dated 19 Oct 2023
	31.	Dosing Modification and TMGs for MEDI5752 Monotherapy or Combination Therapy Version 4 Dated 31 Jan 2023
	32.	Quick Reference Guide_ English India Version 1, Dated 09 Nov 2023 **Translation:** • English to Hindi (Version 1.0 Dated 08 Nov 2023) **Certification:** • English to English Dated 13 Nov 2023 • English to Hindi Dated 08 Nov 2023
	33.	UnBlinded Cards_English Version 1.0, Dated 28 Jul 2023 **Translation:** • English to Hindi (Version 1.0 Dated 02 Aug 2023) **Certification:** • English to English Dated 28 Jul 2023 English to Hindi Dated 02 Aug 2023
	34.	Undertaking letter by Principal Investigator
	35.	Curriculum Vitae, MRC and CGP of PI
	36.	Draft Clinical Study Agreement (CSA)
	37.	Declaration to HA regarding site facility for the conduct of the study
	38.	Declaration for participation in number of clinical trials
	39.	**Curriculum Vitae of Sub-Investigators**
	40.	**Patient accrual methods**
	Decision: Approval subject to fulfillment & Administrative formalities. ***Ref. code: 130th ECMIIC/P6***	
7.	Research protocol no. nil entitled "***Evaluation of efficacy and safety of aceclofenac+ paracetamol+serratiopeptidase combination after impacted lower third molar surgery: A randomized, double-blind comparison with aceclofenac+paracetamol combination***" sponsored by M/s IPCA Laboratories Limited submitted by Dr. Arunesh Kumar Tiwari, Additional Professor, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences,	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	King George's Medical University, U.P., Lucknow vide letter no. 48/OMSD/24 dated 25th January, 2024. ***Recommendation of reviewer:-*** • Insurance policy is valid up to 30-06-2024; to be renewed before the due date to ensure the continued validity of the IEC clearance. • SOP-Checklist-Point no.-10 (risk & benefit)-ticked as 'No': Kindly check. **Comment:** As above **Decision:** Approval subject to clarification ***Ref. code: 130th ECMIIC/P7***
8.	Research protocol no. 2567901 entitled ***"Prospective, non-interventional, multi-centre, post marketing surveillance study to evaluate the safety and tolerability of gaviscon double action oral suspension and gaviscon double action tablets for the management of symptoms of gastroesophageal reflux disease"*** sponsored by M/s Danson Lane Hull HU89DS United Kingdom submitted by Prof. Ajay Kumar Patwa, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/18/24 dated 31st January, 2024. ***Recommendation of reviewer:-*** • CTRI document is missing; kindly provide the approval. **Comment:** • The CTRI document was furnished by the PI on communication. ***The following documents were reviewed in Its Meeting:-***

S. No.	Table of Contents
1.	Investigational Study Protocol Version 2.0, dated 04-Apr-2022.
2.	Protocol Signature Page signed on 21-Sep-2023.
3.	Core Study ICD Version No. and date: 2.0, 17-Aug-2023.
4.	**Subject Information Sheet (Translations)** Core Study ICD Version No. and date: 2.0, 17-Aug-2023, Translated from English to Hindi Version No. 1.0 dated 21-Sep-2023.
5.	**Subject Information Sheet (Back Translations)** Core Study ICD Version No. and date: 2.0, 17-Aug-2023, Back translated from Hindi to English Version No. 1.0 dated 21-Sep-2023.
6.	ICD – Translation and Back-Translation Certificates for Hindi dated 22-Sep-2023.
7.	7.1 Prescribing Information sheet Gaviscon Double Action Tablet (Summary of Product Characteristics V1.0 dated 28-11-2019).

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	7.2 Prescribing Information sheet_ Gaviscon Double Action Oral Suspension (Summary of Product Characteristics V 1.0 dated 08-02-2021).
8.	Case Report Form Version 4.0 dated 12-Dec-2023.
9.	**Patient Diary** 9.1 2567901, Patient Diary in English Version No. 3.0, 06-Sep-2023. 9.2 2567901, Patient Diary in English Version No. 3.0, 06-Sep-2023, Translated from English to Hindi Version No. 1.0 dated 21-Sep-2023. 9.3 2567901, Patient Diary in English Version No. 3.0, 06-Sep-2023, Back Translated from Hindi to English Version No. 1.0 dated 21-Sep-2023
10.	Patient Diary – Translation and Back-Translation Certificates for Hindi dated 22-Sep-2023.
11.	11.1 Curriculum Vitae of Investigator Signed on 21-Sep-2023 11.2 MRC No. – 49103 11.3 GCP certificate – Valid till 13-Jun-2025 11.4 Undertaking by the Investigator signed on 21-Sep-2023
12.	12.1 Regulatory Submission letter dated 01-Nov-2021 12.2 No Objection certificate from DCGI / DCGI approval letter (27-May-2022) 12.3 DCGI notification and acknowledgment (Protocol amendment 01) dated 06-May-2022
13.	Insurance complete Policy and certificate dated 14-Sep-2023 (Policy No. 4067/298208522/00/ 000 and Policy Period from 30-Jun-2023 to 31-Dec-2024)
14.	Draft Clinical Study Agreement

Decision: Approval subject to fulfillment & Administrative formalities

Ref. code: 130th ECMIIC/P8

9. Research protocol no. HCR/IV/TRUMAB/05/2022 entitled ***"A phase IV multi-centric, post-marketing study evaluating the safety, immunogenicity and efficacy of the marketed formulation of hetero-trastuzumab in female patients with HER2+ breast cancer"*** sponsored by M/s Hetero Biopharma Limited submitted by Dr. Naseem Akhtar, Additional Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/390/24 dated 12th January, 2024.

Recommendation of reviewer:-

- Justification of sample size of 200 not provided.
- KGMU site not mentioned in DCGI letter.

Comment:

As above

Decision: Revise and resubmit with response to comments in a tabular format.

Ref. code: 130th ECMIIC/P9

10. Research protocol no. #: R3918-PNH-2050 entitled ***"An open-label extension study to evaluate the long-term safety, tolerability, and efficacy of pozelimab and cemdisiran***

(Hardeep Singh) Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	combination therapy in patients with paroxysmal nocturnal hemoglobinuria" sponsored by M/s Regeneron Pharmaceuticals, Inc submitted by Dr. S.P. Verma, Additional Professor & Head, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. CH/CT/02/24 dated 14th February, 2024. ***Recommendation of reviewer:-*** • Under Sponsor information in IEC form, section 3 (Industry) is incomplete. • Section on Clinical trial (3(i)) mentions that the study is for device/vaccines. • DCGI approval mentions the name of Dr A K Tripathi as the PI. Insurance certificate has the name of Dr S P Verma. Kindly submit an amendment and ensure that the Insurance is valid. • This study is a continuation of a study under Dr A K Tripathi, ex-HOD, Department of Clinical Hematology. Kindly get the same amended. **Comment:** As above **Decision:** Revise and resubmit with response to comments in a tabular format. ***Ref. code: 130th ECMIIC/P10***
11.	Research protocol no. ZUV/EFNOCAR-T/2022 entitled ***"A multicentric, open label study to evaluate the safety and efficacy of fixed-dose combination of efonidipine 40 mg and telmisartan 40 mg tablets in the management of stage II hypertension"*** sponsored by M/s Zuventus Healthcare Limited submitted by Dr. Amit Kumar, Assistant Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/19/24 dated 14th February, 2024. ***Recommendation of reviewer:-*** • CTRI document is missing. • No other ethical issues. **Comment:** The CTRI document was furnished by the PI on communication. ***The following documents were reviewed in its Meeting:-***

Sr. No.	Document/Language	Document Details/Versions
1.	CV & MRC of Dr. Amit Kumar	25-Nov-2023
2.	Protocol	Version No. 1.0 dated 24 May, 2022
3.	Investigator's Brochure	Version No. 1.0 dated 24 May, 2022
4.	Screening & Case Report Form (CRF)	Version No. 1.0 dated 24 May, 2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	5.	Informed Consent Document (ICD)-English	Version No. 1.0 dated 24 May, 2022
	6.	Informed Consent Document (ICD Hindi Translation, Back Translation &Translation Certificate)	Version No. 1.0 dated 24 May, 2022
	7.	Patient Diary (English)	Version No. 1.0 dated 24 May, 2022
	8.	Patient Diary (Hindi Translation, Back Translation &Translation Certificate)	Version No. 1.0 dated 24 May, 2022
	9.	Investigator Undertaking	25 Nov 2023
	10.	Declaration	25 Nov 2023
	11.	CDA	09 Jan 2023
	12.	Insurance	24 Jan 2024
	13.	DCGI Approval Letter	18 Jan 2023
	14.	Serious Adverse Reporting Form	NA
	Decision: Approval subject to fulfilment & Administrative formalities ***Ref. code: 130th ECMIIC/P11***		
12.	Research protocol no. EX601/-4979 entitled ***"ARTEMIS Effects of ziltivekimab versus placebo on cardiovascular outcomes in patients with acute myocardial infarction"*** sponsored by M/s Novo Nordisk submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no. 706/Cardio/Res/24 dated 15th February, 2024. ***Recommendation of reviewer:-*** • In sponsor information on IEC form, UN Agencies has been ticked. • Contact address of sponsor is missing from IEC form. • Details of 'organs and body fluids' mentioned under section on Biological materials not given. • Adverse events reporting are being done to DSMB as per the IEC form. This needs to be corrected. • DCGI application has been attached, not approval. • Insurance cover is expiring in April, 2024. • Sample size is mentioned as 10,000 in protocol and as 20 in the IEC form. • Has the study been approved at any other site? If yes, kindly submit the same. **Comment:** As above **Decision:** Revise and resubmit with response to comments in a tabular format. ***Ref. code: 130th ECMIIC/P12***		
III	**Additional Document**		

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

A-	
1.	Additional of research protocol no. CTQJ230A12301 entitled "***A randomized double-blind, placebo-controlled, multicentre trial assessing the impact of lipoprotein (a) lowering withTQJ230 on major cardiovascular events in patients with established cardiovascular disease*" *(LPA Horizon Study)*** submitted by Prof. S. K. Dwivedi, Head, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 614/Cardio/Res/24 dated 15th January, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: 101stECMIIC/P18***
III-B	**Modification**
1.	Modification of research protocol no. EX6018-4758 **ZEUS** entitled "***Effects of ziltivekimab versus placebo on cardiovascular outcomes in participants with established atherosclerotic cardiovascular disease, chronic kidney disease and systemic inflammation***" submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 686/Cardio/Res/24 dated 8th February, 2024. ***Recommendation of reviewer:-*** • Being a modification, it is understood that the prior version had a valid IEC approval and that all related documents were in place. • It is noted that the insurance is expiring in April, 2024. • CTRI documents & DCGI documents is expected to be appropriate. • The modification documents need to be filed. **Comment:** • As above **Decision:** Approval subject to clarification. ***Ref. code: 116thECMIIC/P1***
2.	Modification of research protocol no. Vedolizumab-4020 entitled "***A multicentre, single-arm, open-label, phase 4 study to evaluate the safety and efficacy of vedolizumab in Indian patients with ulcerative colitis and Crohn's disease***" sponsored by M/s Takeda Pharmaceutical India Pvt. Ltd. submitted by Dr. Ajay Kumar Patwa, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/06/24 dated 31st January, 2024. ***Recommendation of reviewer:-*** • Being a modification, it is understood that the prior version had a valid IEC approval and that the scientific review committee report has been affirmative. • The investigator has submitted 2 sets of ICF. • The insurance has expired on 15-09-2023. • CTRI documents & DCGI documents is expected to be appropriate. • The modification documents need to be filed.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Comment: • As above **Decision:** Approval subject to clarification. *Ref. code: 114th ECMIIC/P1*
IV	**Indian Association of Public Health Dentistry**
1.	Research proposal entitled ***"Effectiveness of Customised Animated video-based oral health education and Conventional method on the oral health status and practices among pregnant women's visiting tertiary care hospital, Lucknow -A Double-blind randomized controlled trial"*** submitted by Mr. Pushpendra Singh, BDS III-Year Student through her Mentor Prof. Vinay Kumar Gupta, Head, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 749/PHD/23 dated 29th November, 2023 funded by Indian Association of Public Health Dentistry, Registered under the Registrar of Societies, Bangalore. ***Recommendation of reviewer:-*** • Kindly modify the title to ***"A randomized control study"*** in place of ***"Randomized control trial"*** **Comment:** As above **Decision:** Approval subject to modification *Ref. code: 130th ECM-IV/P1*
V	**Corrigendum**
1-	The title of research proposal should be read as ***"Impact of environmental endocrine disruptors, diet and lifestyle on sex hormone levels and consequences thereof in human breast tissues of Indian and German women"*** instead of ***"An Indo-German approach to identify universal and specific molecular targets in breast cancer prevention: Impact of environmental endocrine disruptors, diet and lifestyle on sex hormone levels and cellular consequences thereof in human breast tissues (ICMR-DFG project)"*** submitted by Prof. Vijay Kumar, Head, Department of Surgical Oncology, KGMU, UP, Lucknow. **Decision:** Noted
VI	**Other Matter with the permission of Chair**
1-	As per updated Investigator Undertaking the PI has changed Prof. Sharad Chandra in place of Prof. S.K. Dwivedi. Department of Cardiology, King George's Medical University, U.P., Lucknow under the research protocol no. CKJX839D12302 entitled ***"A randomized, double-blind, placebo-controlled multicenter study to evaluate the effect of inclisiran on preventing major adverse cardiovascular events in high-risk primary prevention patients (VICTORION-1 PREVENT)"*** sponsored by M/s Novartis Healthcare Private Limited vide letter no.656/Cardio/Res/24 dated 29th January, 2024 & 668/Cardio/Res/24 dated 31st January, 2024. **Comment:** Kindly get your insurance renewed. **Decision:** Noted with condition to please renew your insurance and submit it to the office of the Ethics Committee.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: 123rd ECMIIC/P3
2-	As per updated Investigator Undertaking the PI has changed Prof. Pravesh Vishwakarma in place of Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow under the protocol no.CKJX839D12303 entitled "***A multi-center, randomized, double-blind, placebo-controlled, parallel-group IIIb study evaluating the effect of inclisiran on atherosclerotic plaque progression assessed by coronary computed tomography angiography (CCTA) in participants with a diagnosis of non-obstructive coronary artery disease without previous cardiovascular events (VICTORION-PLAQUE)***" sponsored by M/s Novartis Healthcare Private Limited vide letter no. 658/Cardio/Res/24 dated 29th January, 2024. **Comment:** Insurance valid till December, 2024 **Decision:** Noted ***Ref. code: 124th ECMIIC/P1***
3-	After superannuation of Prof. R.N. Srivastava, Dr. Shah Waliullah is the current PI under the research protocol no. CLNA043A12202 entitled "***A 5-year, randomized, double-blind, placebo-controlled, multi-center study assessing the efficacy, safety, and tolerability of intra-articular regimens of LNA043 versus placebo in patients with symptomatic knee osteoarthritis (ONWARDS)***" sponsored by M/s Novartis Healthcare Pvt. Ltd. vide letter no.256/P/OS/24 dated 24th February, 2024. **Decision:** Noted ***Ref. code: 114th ECMIIC/P3***
4-	Reg. Addendum Clinical trial agreement (CTA) for Levolin drug an expense flat charge of INR 235 (Two Hundred Thirty-Five Rupees Only) per drug per visit of the research protocol no. CP/03/22; NV-05-1387-2022 entitled "***A randomized, double blind, placebo-controlled, prospective, multicentre, phase2, dose-finding study of itraconazole administered as a dry powder for inhalation (PUR 1900) in adult subjects with asthma and allergic bronchopulmonary aspergillosis (ABPA)***" sponsored by M/s Cipla Ltd. submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow, vide letter no. RM/06/CT/24 dated 22nd February, 2024. **Comment:** Protocol amendment submit to Drug Controller of India **Decision:** Noted as above ***Ref. code: 120th ECMIIC/P2***
VII	**Other Matter with the permission of Chairman**
	Other matters discussed in the meeting are as under: 1. The matter whether a faculty member who has left KGMU can continue to guide a post-graduate/ PhD thesis or not, was discussed at length. It was agreed that faculty members who have superannuated should not continue to be the 'Chief Guide' and should transfer the responsibility to an eligible (should be a P.G Teacher) and appropriate (related to the subject) faculty member. However, the overall matter of superannuated faculty members and those who were otherwise not

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	available (lien, deputation, etc.) was noted to be beyond the purview of IEC; it was decided to refer the matter to relevant authorities for an amicable resolution. 2. The unprecedented load of post-graduate theses (>400) was discussed in the meeting. It was agreed that a post-graduate thesis screening and advisory group (PGT-SAG) be formed to speed up screening and to serve as an advisor to the thesis candidates. The group shall function under the PGT-SC and shall not have any decision-making power whatsoever. As per discussions with the Hon. Vice Chancellor, a token amount of Rs. 1000=00 (One thousand only) for a minimum batch of 10 (up to 15) may be given after obtaining a formal approval from her office. 3. With an increasing number of proposals, the human resource needs an increase to support the working of Ethics Cell. To manage the same and to reduce the use of paper, a push towards a software-based process of submission, review, presentation, finalisation and archival of proposals is urgently needed. 4. It was unanimously agreed that any proposal that goes beyond the ambit of the practice of modern medicine, viz. involving AYUSH or any other alternative system, shall mandatorily require inclusion of an investigator formally trained and well-versed in the subject under-consideration; inclusion of private partners should be best avoided and is strongly discouraged. In line with aforementioned, the SRC must have an expert related to the subject for a meaningful evaluation and review of the proposal. 5. It has been noted that certain proposals mandate inclusion of a subject-specific expert for critical inputs that otherwise cannot be obtained from the formal IEC. In consonance with ICMR/AIIMS-New Delhi documents, it was approved that such subject-experts can be invited from within or outside KGMU for their expertise; these experts, however, shall not have any decision-making powers in the proposal-under-consideration or any other proposal listed in the IEC agenda on that date. 6. To address the deficiency in reporting of SAE for non-DCGI/ Phase IV trials on SUGAM portal, it was decided to hold a meeting with the Pharmacovigilance Committee of KGMU and involve them to formalize the same for smooth functioning. 7. Regarding 'Academic Trials/Study', it was discussed that there is an urgent need to earmark a corpus dedicated to issues related to insurance/compensation etc., if any, in the conduct of such studies. 8. The letter of approval from the IEC needs to be restructured to mention the validity of approval, conditional modifications leading to invalidation of approval, and other issues pertinent to the given proposal. 9. The last SOP-KGMU was created in 2019 and was completing 5 years since its inception. It was discussed that this necessitates that a newer version of SOP be created in view of several new notifications and regulatory guidelines with an increased ambit of application.
V	**Brought to Ethics Committee after XXIV-PGTSC held on 29th February, 2024**
	Minutes of the XXIV-PGTSC of IEC Meeting ***in hybrid mode*** held on **29th February, 2024 02:00 P.M. till 5:00 P.M.** on III-floor, Central Library, King George's Medical University, Lucknow. ***The following Members were present in its Meeting:-*** 1- Dr. G.G. Agarwal -Member 2- Dr. A.A. Mahdi -Member 3- Dr. Anupam Mishra -Member 4- Dr. Rajendra Nath -Member

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	5- Dr. Nisha Mani Pandey -Member ***The following Members were not present in its Meeting:-*** 1. Dr. D.N. Upadhyaya -He has sent his in written comment 2. Dr. Anita Rani -She has sent her written comment
IA	**Action Taken**
1-	Clarification of research proposal entitled ***"Prevalence of overweight and obesity amongst adolescents along with their multidimensional factors in rural and urban school settings of Lucknow"*** submitted by Dr. Ajit Kumar Singh, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1266/CM/23 dated 5th February, 2024. ***Previous PGTSC Comment:-*** • The questionnaire is required to study the association between obesity/overweight/underweight and the multidimensional factors. • The study can be planned only after the construction of the questionnaire. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XVI-PGTSC-IIA/P9***
2-	Clarification of research proposal entitled ***"Efficacy of tissue engineered scaffold in recession coverage: A randomized clinical trial"*** submitted by Dr. M. Priyadarshini, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1038/P/23 dated 21st December, 2023.

PGTSC Comments	PI response
Even with remote possibility of allergic reaction, the investigator has to be prepared with its management protocol and more importantly mention it in patient information sheet .in the rarest of such event that will bear the cost of management?	The material used in the study holds no possibility of any potent allergic reaction but in the rarest of such event the material will be removed and the patient will be managed medically. The cost of management will be beared by the primary investigator. The following is mentioned in the Patient information sheet and is attached below.
Regarding point 4, the investigator states that "PCONSORT guidelines are attached." since this is RCT , kindly refer to the checklist of CONSORT statement to refine the submission.	The study design is refined according to the checklist of CONSORT and attached below.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Recommendation of reviewer:-
Reply awaited from reviewer side.

Comment:

- Kindly modify the title to "Randomized controlled study"
- Kindly provide PGT declaration form

Decision:

- **Pending, subject to submission of PGT Declaration form and response to comments in a tabular format.**

Ref. code: XIX-PGTSC-IIA/P3

3- Clarification of research proposal entitled ***"A comparative study of ozone therapy and photodynamic therapy as an adjunct to scaling and root planning in chronic periodontitis"*** submitted by Dr. Shilpi Mangal, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 4108/P/24 dated 12th January, 2024.

Previous comment	PI response
CTRI Registration	After getting approval from IEC (Institutional Ethics Committee). Registration for CTRI will be done.
Consort guidelines	Checklist attached
Aged matched randomization	Each group is further divided into different age groups i.e. 18-34, 35-54, 55-75. Here randomization is through stratified randomization, so that each group has an equal chance of participation and that is how age matching is achieved.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.
Provisionally approved

Decision:

- **Pending, subject to submission of PGT Declaration form.**

Ref. code: XIX-PGTSC-IIA/P4

4. Clarification of research proposal entitled ***"The impact of low pressure negative pleural suction versus underwater seal drainage in patient of thoracic trauma: A randomized controlled trial"*** submitted by Dr. Shahnawaz Ahmad, JRI, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. 839/TS/23 dated 21st December, 2023.

Previous Comment:-

- Please provide sample size and its calculation
- Please rectify the ICF, as per standard guidelines.
- Please provide a properly filled Patient Information Sheet.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.
Recommendation of Primary reviewer:-

- Provisionally approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Comment: • Kindly modify the title to *"randomized controlled study"* instead of *"randomized control trial"* **Decision:** • **Pending, subject to submission of PGT Declaration form and response to comments in a tabular format.** *Ref. code: XIX-PGTSC-IIA/P28*
5-	Clarification of research proposal entitled ***"Role of parasternal intercostals plane block using ropivacaine in attenuating hemodynamic fluctuations at the time of sternotomy in patients undergoing elective cardiac surgery"*** submitted by Dr. Mohd Akhtar Ansari, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1635/24 dated 5th February, 2024. ***Previous comments:*** Revised Patient Information Sheet not related to study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XX-PGTSC-IIA/P11*
6-	Clarification of research proposal entitled ***"A study on episodic memory impairments and functional connectivity networks using resting state functional MRI in patients of intractable mesial temporal lobe epilepsy- A prospective observational study"*** submitted by Dr. Om Prakash, SRI, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 391/Neuro/23 dated 20th December, 2023. **Previous comment:-** • Child Assent Form is not in correct format and English/Hindi versions are not the same (PI to re-submit correct Child Assent Form in both versions). Guardian consent form not needed. • Questioners are not given. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XX-PGTSC-IIA/P18*
7-	Clarification of research proposal entitled ***"To study the effect of curcumin on inflammatory markers and microbial flora in hemimaxillectomy patients with obturator prosthesis: A randomized controlled study"*** submitted by Dr. Yangchin Drema, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 722/24 dated 9th January, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Previous PGTSC Comments: • As stated in Annexure 1 this study involves a (herbal) medicine of Indian system of medicine. So it would be better to include an Ayurvedic Co-Investigator. • This is stated to be double blind RCT. Kindly mention the technique of allocation, randomization & double blinding. Is placebo not indicated here? • Who will bear the cost of curcumin & tests. Do you plan to register this RCT.? • Summarize the anticipated outcome variables and anticipated statistical analysis of the same. • Kindly mention the dose, duration , brand and mode of administering curcumin. • No need to submit the SOP guidelines of Pt information sheet. Instead kindly submit the actual patient information sheet both in English & Hindi accordingly. • Kindly revise "purpose of study" & "Study procedure" in ICF in such a language that the patient may understand. • In annexure 1 regarding use of biological specimen it is indicated as "NA" while lower down 'Yes' in indicated for the use of infectious & biohazardous specimen. This is contrasting statement. Also no indication of blood collection is mentioned for IL &TNF? • Kindly refer to CONSORT guidelines for RCT before resubmitting ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Comment:** • Kindly modify the title to ***"randomized controlled study"*** instead of ***"randomized control trial"***; correct the same within the proposal as well as in annexures. **Decision:** • **Pending, subject to submission of PGT Declaration form and response to comments in a tabular format.** ***Ref. code: XXI-PGTSC-IIA/P3***
8-	Clarification of research proposal entitled ***"A comparative evaluation of the clinical & biological outcome of different provisional crowns on immediate loaded implant in maxillary esthetic zone-A randomized controlled trial"*** submitted by Dr. Deepak Verma, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 712/24 dated 4th January, 2024. **Previous comment:-** • Kindly provide the cost of two types of implants. • The cost of the Implant, if borne by the patient, may be a concern for its blind selection. Patient Information sheet: Kindly fill it properly. • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** ***The aforementioned comments were sent to the Principal-Investigator, the response to which***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	was forwarded to the reviewer. *Recommendation of Primary reviewer:-* Provisionally approved **Decision:** • Approved *Ref. code: XXI-PGTSC-IIA/P11*
9-	Clarification of research proposal entitled ***"To determine prevalence of suboptimal levels of Vitamin D in preterm very low birth weight neonates in an NICU and to monitor response to treatment with Vitamin D"*** submitted by Dr. Abiya Nabi, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 125/Ped/24 dated 3rd February, 2024. **Previous comment:-** • The role of PI is not provided. • Annexure 1… the title of the proposal to be corrected as there is no space between words. • The patient information sheet needs to be revised as per the needs of the protocol. • The proposal aimed to enroll and assesse the newborn at age 4-10 days and at 38±2 wks after supplementation with 1000 IU/day Vit D levels or on discharge of the newborn. How the PI will approach for assessment after 38±2 wks, if the newborn will discharge much before 38±2 wks? Will she visit newborn place for final assessment? ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXI-PGTSC-IIA/P14*
10-	Clarification of research proposal entitled ***"Evaluation of ozone therapy in comparison with occlusal splint in treating internal derangement of temporomandibular joint: A randomized controlled trial"*** submitted by Dr. Satyendra Pratap Singh, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 713/24 dated 6th January, 2024. ***Previous comment:*** • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed. • The sample size calculation is arbitrary in the absence of proper research hypothesis. The different quantities used in the formula are not clear. There is no design effect for this study. It is for cluster-randomized trial. • The statistical methods used to compare groups for primary outcomes, methods for

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P15***
11-	Clarification of research proposal entitled ***"Comparative evaluation of amniotic membrane and platelet-rich fibrin membrane on osseous healing post direct maxillary sinus lift augmented with graft around dental implants: A randomized controlled trial"*** submitted by Dr. Sonali Kaundal, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 723/24 dated 9th January, 2024. **Previous comment:** • Patient Information sheet: Kindly fill it properly. • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Provisionally approved subject to submission of Declaration form, as attached. **Comment:** As above **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P20***
12.	Clarification of research proposal entitled ***"A comparative study of endoxifen and divalproex in patients with bipolar disorder (Manic Episode)"*** submitted by Dr. Alisha Raj, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 76/Pharm/24 dated 12th February, 2024. **Previous comment:** • In Inclusion criteria -Sex specificity has not been mentioned. • How evaluation of pharmacological actions and efficacy of the drug (with single dose) will be done as written in Aims and objective-PI to explain. • Study design–mentioned as Prospective, parallel groupcomparative study, but PI has mentioned in Methodology section that the grouping will be done by randomization–PI to clarify and correct it in the Title of the study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	was forwarded to the reviewer. ***Recommendation of Primary reviewer:-*** Provisionally approved **Comment:** • Kindly seek PGT declaration form **Decision:** • **Pending, subject to submission of PGT Declaration form**
	Ref. code: XXI-PGTSC-IIA/P29
13-	Clarification of research proposal entitled ***"Evaluation of postoperative outcomes of advanced electrosurgical devices v/s conventional clamp and tie technique for neck dissection- A randomized control trial"*** submitted by Dr. Aryan Dwivedi, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 85/SY/24 dated 2nd February, 2024. **PGTSC Comment:** • Kindly modify the title to ***"A randomized control study"*** in place of ***"Randomized control trial"*** • IEC form is incorrectly/incompletely filled. • Short forms should not be used in the consent form (English). • Section on sample size calculation is incomplete. Sample size calculation should be based on the prevalence of the disease rather than operative time taken. • Patient information sheet is incomplete. • PGT declaration form received. **Previous Decision:** Modify & re-submit with response to queries in tabular format. **Decision:** • Approved
	Ref. code: XXI-PGTSC-IIA/P41
14-	Clarification of research proposal entitled ***"Cyanoacrylatevs tacker for mesh fixation in laparoendoscopic inguinal hernia repair-double blinded, randomized control trial"*** submitted by Dr. Vivek Vishwakarma, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 86/SY/24 dated 2nd February, 2024. **Previous Comment:-** • Kindly modify the title to ***"A randomized control study"*** in place of ***"Randomized control trial"*** • There are ten investigators in the study from the same department with overlapping roles. Please decrease the number of Co-PI or define their unique roles. • PGT declaration form received. **Decision:** • Approved
	Ref. code: XXI-PGTSC-IIA/P46
15-	Clarification of research proposal entitled ***"Lesion characterstics using IVUS imaging in diabetic individuals undergoing PCI and its impact on plaque modifying strategies"***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	submitted by Dr. Rajesh Prasad Sharma, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 2769/Cardio/23 dated 6th February, 2024. **Previous Comment:-** • The study has eight investigators from the same department with overlapping roles. Please reduce the number of Co-PIs or define their unique roles. • Sample size has not been calculated. Number of participants has not been mentioned. • Kindly modify the title ***"Randomized control study" in place of "Randomized control trial"*** **Previous Decision:** Revise & re-submit with response to queries in tabular format. PGT declaration sheet received. **Decision:** • Approved ***Ref. code: XXI-PGTSC-IIA/P52***
16-	Clarification of research proposal entitled ***"Comparison of LMA proseal, ambu aurgagain, baska mask and LMA protector for airway management in laparoscopic surgeries: A randomized comparative, open label study"*** submitted by Dr. Ayur Verma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/1535/24 dated 3rd February, 2024. **Previous Comment:-** • The ICF should be modified specially with respect to study procedure that needs to be in a simple language for the patient to understand. • Pt information sheet should re-written specially for the pts 7,8,9,13,14,16,17. • Also mention the anticipated adverse events that need to be reported to IEC. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** • Provisionally approved • PGT declaration form received. **Decision:** • Approved ***Ref. code: XXI-PGTSC-IIA/P61***
17-	Clarification of research proposal entitled ***"To study oxidative stress and antioxidant status in adolescents and young women with primary dysmenorrhea"*** submitted by Dr. Monika Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/45/24 dated 12th January, 2024. **Previous Comment:-** • Methodology incomplete Biochemical estimations (oxidative stress parameters) protocol not provided. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Provisionally approved **Comment:** • Kindly provide the PGTS declaration sheet. **Decision:** • Approved
	Ref. code: XXI-PGTSC-IIA/P72
18-	Clarification of research proposal entitled ***"Effect of prophylactic selective serotonin reuptake inhibitors on incidence of acute delirium in intensive care unit and neuropsychiatric illness in intensive care unit survivors"*** submitted by Dr. Apoorva Jaiswal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/169/24 dated 12th February, 2024. **Previous Comment:** • In Inclusion/Exclusion criteria- Pregnant & lactating women criteria not mentioned. • As this is RCT study PI should include in methodology section-the method of randomization and Flow chart of the study. • CRF, Richmond Agitation Sedation Score and Sequential organ failure assessment score–not attached. • Clinical trial registry document is also missing. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** • Provisionally approved PGT declaration form received **Decision:** Approved
	Ref. code: XXI-PGTSC-IIA/P74
19-	Clarification of research proposal entitled ***"To evaluate the disinfectant hazard profile in a tertiary care Government Teaching Hospital, Lucknow"*** submitted by Dr. Sairaj Subhash Chodankar, JRII, under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/79/24 dated 14th February, 2024. **Previous Comment:** • Scientific review committee report and tools of the study are not enclosed. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Provisionally approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Decision: • Approved *Ref. code: XXI-PGTSC-II B-MHA/P2*
20-	Clarification of research proposal entitled ***"To study the cost of disinfectants being used in high-risk areas of a tertiary care Government Teaching Hospital, Lucknow"*** submitted by Dr. Sairaj Subhash Chodankar, JRII under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/78/24 dated 14th February, 2024. **Previous Comment:** Recommendations of Departmental Scientific Review Committee not attached. Human subjects consent waiver may be granted. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXI-PGTSC-II B-MHA/P3*
21-	Clarification of research proposal entitled ***"Study of perception of respectful maternity care amongst post natal women before and after training of healthcare workers"*** submitted by Dr. Monika Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/2377/24 dated 2nd January, 2024. **Previous comment:** • Identify one primary objective and the rest should be marked as secondary objective. • Convert the primary objective, which is based on pretest posttest design, into proper research hypothesis in terms of study variables and parameters. • The sample size calculation is incorrect. It is for prevalence study. • The statistical analysis section is incomplete. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Provisionally approved **Decision:** • Approved *Ref. code: XXII-PGTSC-IIA/P4*
22-	Clarification of research proposal entitled ***"An observational study on drugs causing liver injury, its clinical patterns and severity in a tertiary care Hospital in Northern India"*** submitted by Dr. Fatima Rani, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 43/Pharm/24 dated 15th January, 2024. **Previous comment:** • Identify one primary objective, and the rest should be marked as secondary objective.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Identify the study variables and study parameters. • Convert the primary objective into proper research hypothesis in terms of study variables and parameters. • The objectives mentioned do not pose a research question. These looks to be statements only. • The Sample size calculation is arbitrary. It should be specific to the research hypothesis formulated in step 3. • The statistical analysis section is general. It should be specific to the primary and secondary objectives of the study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Provisionally approved **Decision:** • Approved ***Ref. code: XXII-PGTSC-IIA/P9***
23-	Clarification of research proposal entitled ***"Mullerian anomalies diagnosis, management, with its impact on the quality of life-A retrospective study"*** submitted by Dr. Nivedita Prakash, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/ 2381/24 dated 3rd January, 2024. **Previous comment:** • Seal of Chairperson in Scientific review committee is absent. • The study period in annexure 1 patient 5 states is 1.5 years while elsewhere it is year. Kindly resolve the confusion. • Is the risk not reasonable compared to anticipated benefits? (Annexure 1 patient 10) • What are the anticipated adverse events that need to be reported to IEC? (Annexure 1 patient 11) • While study design is reported as "Retrospective", the inclusion criteria includes all new cases in the upcoming year. Why this confusion? • The outcomes are confusing. Kindly indicate all the primary & secondary out-comes point wise. • Kindly brief the statistical analyses in reference to out come variables. • Kindly eneumerate the anticipated common association with mulleran anomalies. Elaborate their assessment. • Kindly provide the details of the questionnaire used for detailed assessment including the quality of life. • The methodology should include all the steps of data collection needed to achieve the desired outcomes. • In ICF 'Study procedures' & 'Benefits from study' need to be re-written, elaborated and in the language which patient can better understand. • Patient information sheet is to be carefully re-written completely in a customized

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	fashion and excluding the pregnant women with heart disease. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Provisionally approved **Comment:** • Kindly provide the PGT declaration sheet **Decision:** • Approved ***Ref. code: XXII-PGTSC-IIA/P13***
24-	Clarification of research proposal entitled ***"Efficacy of epidural transforaminal injection of ozone in comparison with transforaminal PRP (Platelet Rich Plasma) injection in the management of chronic low back radicular pain: one year prospective randomized control study"*** submitted by Dr. Karthickraja, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/510/24 dated 12th February, 2024. **Previous Comment:-** • Methodology for preparation of PRP not given. • PGT declaration form received **Decision:** • Approved ***Ref. code: XXII-PGTSC-IIA/P14***
25-	Clarification of research proposal entitled ***"Preoperative factors predicting close/positive surgical margins in oral cancer-A retrospective cohort study"*** submitted by Dr. Akanksha Singh, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1240/SY/23 dated 29th December, 2023. ***Previous comment:*** • Sample size calculation has not been done. Patient Information Sheet is incomplete/incorrectly filled. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P16***
26-	Clarification of research proposal entitled ***"Evaluation of oral health care practice and awareness among health care Students in Lucknow"*** submitted by Dr. Mohit Kumar Kanoujia, JRI, Department of Public Health Dentistry, King George's Medical University, U.P., Lucknow vide letter no. 835/PHD/23 dated 29th December, 2023. ***Previous PGTSC Comments:*** • Both Co-guides has similar role. • No stamp on SRC.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

- Title of the study needs correction.
- There are many objectives; it should be restricted to 1-2 objectives.
- Sentences written in the inclusion/ exclusion criteria of the study are in present and past tense which needs to be recomposed.
- In the study procedure it is written that *a pilot study on 30 subjects has been done for the validation and reliability of the study tool…* is the questionnaire developed by the investigator; if yes, what tests of reliability and validity were applied?
- The flowchart written with procedure portrays selection of study population=Lko….and training and calibration of personnel …? Needs clarification.
- There is no mention about how the study participants will be identified and recruited for the study?
- As this study is to be done on students medical, dental and nursing students there will be no need to provide *guidelines for patient information sheet*, if PI wishes to provide any information to the participants it may be tailored as participant's information sheet.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of Primary reviewer:-

Provisionally approved

Decision: Approved

Ref. code: XXII-PGTSC-IIA/P17

27- Clarification of research proposal entitled ***"Role of fetal head circumference-to-maternal-height ratio in predicting cesarean section for labor dystocia"*** submitted by Dr. Garima Singh, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/316/24 dated 31st January, 2024.

Previous PGTSC Comment:

- In the informed consent form under the heading benefits of study language is not clear.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of Primary reviewer:-

- Provisionally approved

Decision: Approved

Ref. code: XXII-PGTSC-IIA/P21

28- Clarification of research proposal entitled ***"Comparative analysis of mouth self-examination awareness amongst tobacco consumers in urban and rural populations of Lucknow"*** submitted by Dr. Aman Rajput, JRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 836/PHD/23 dated 29th December, 2023.

Previous comment	PI response
No stamp on covering and SRC.	Stamped covering and SRC attached
Study aim should be re-framed as written in past tense.	The aim of the study to evaluate the knowledge and practice towards mouth-self-examination

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

		among tobacco users in urban and rural population.
	Patients are to be taken from OPD of KGMU too, where patients come from different places. A clear mention in the inclusion criteria regarding patient recruitment would be better.	**Inclusion Criteria:** 1. Patients attending the Outpatient Department (OPD) of King George's Medical University (KGMU) and Banthra Satellite Centre. 2. Patients will be selected based on convenience sampling, categorized into urban and rural populations based on their respective places of origin.
	The study duration is only 3 months and 300 rural/ urban patients are to be recruited, will it be feasible for the PI to complete the task in the said period.	Gantt Chart attached
	Consent form to be written in an understandable language.	Consent form attached in an understandable language.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of Primary reviewer:-

- Provisionally approved

Decision: Approved

Ref. code: XXII-PGTSC-IIA/P28

29- Clarification of research proposal entitled ***"Effect of long-term use of electroacoustic devices on hearing of healthy young adults"*** submitted by Dr. Sunil Kumar Paharia, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. nil dated 2nd January, 2024.

Previous Comment:

- Hypothesis and primary objective do not match. These are stating different statements.
- Identify the study variables and study parameters.
- Convert the primary objective into proper research hypothesis in terms of study variables and parameters.
- The Sample size calculation is arbitrary. It is for prevalence study. It should be specific to the research hypothesis formulated in step 3.
- The statistical analysis section is general. It should be specific to the primary and secondary objectives of the study.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of Primary reviewer:-

- Provisionally approved

Decision: Approved

Ref. code: XXII-PGTSC-IIA/P32

30- Clarification of research proposal entitled ***"Study of sexual dysfunction in clinically stable patients with bipolar affective disorder receiving valproate"*** submitted by Dr. Rishabh Tiwari, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	no. 2284/Psy/24 dated 10th February, 2024. ***Previous Comments:*** • Role of PI needs to be reconsidered, Chief supervisor and supervisor have similar role. • In IEC format no of participants to be written as provided in the proposal i.e. 110. • Hindi ICF needs to be written in a simple and understandable language. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** • Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P44***
31-	Clarification of research proposal entitled ***"Assessment of awareness and attitude regarding early Childhood caries among parents of Pre-School Children attending Pediatric OPD:A cross-sectional study"*** submitted by Dr. Deepak S, JRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 93/PHD/24 dated 12th February, 2024. **Previous PGTSC Comments:** • Both supervisors have similar role. • In the role of supervisors' sheet Dr. Sumit is given chief supervisor role but the Annexure: 1 RV confirms Dr. Gaurav Mishra as chief supervisor….needs clarification and correction. • There is no one from the pediatrics dept and participants are to be recruited from there. • Study procedure needs a re-check, as sentences are in past tense. • Study duration is 3 months, 500 participants are to be recruited; is it feasible? • Translation to Guidelines for Patient Information Sheet to be translated as मरीज की सूचना/ जानकारी हेतु दिशानिर्देश या मार्गदर्शिका not मार्गदर्शिका प्रिय प्रयोगशाला के .....Further, this study is neither a clinical trial nor to be done on patients so it can be removed. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** • Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P46***
32-	Clarification of research proposal entitled ***"Effect of pre-procedural behavior guidance using video based intervention for reducing anxiety during restorative dental care in Children: A randomized controlled study"*** submitted by Dr. Tanisha Gambhir, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/01/24 dated 4th January, 2024. ***Previous comment:*** • In Methodology, how Phase-I assessment will be done by Interview-If questionnaire is

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	required then please submit it-PI to clarify. • As the age group of the recruited patients will be 5-10 yrs., therefore, Guardian consent and Child Assent forms instead of regular ICF in both versions (E/H) should be submitted • Attach the following Tools – Frankel Behavior classification, Wong–Baker Faces pain rating scale, Modified YPAS anxiety scale. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** • Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P51***
33-	Clarification of research proposal entitled ***"Effect of duration of type 2 diabetes mellitus on impairment of lung functions: A cross sectional study"*** submitted by Dr. Abhishek Kumar Singh, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3688/PHY/24 dated 30th January, 2024. ***Previous comment:*** • Is the project already reviewed? There is a paper just after covering letter indicating PGTSC comment. • What method was applied to calculate the sample of the study? Sample size not provided in IEC. • Hindi consent to be written in an understandable language. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** • Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P52***
34-	Clarification of research proposal entitled ***"Study of Pulmonary function test in young adults engaged in green outdoor versus indoor exercise: A comparative study"*** submitted by Dr. Amit Kumar Balmiki, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3736/PHY/24 dated 9th February, 2024. ***Previous PGTSC Comment:*** • Name & Seal of chairperson from SRC is missing. • IEC to be filled properly e.g. point no 5 indicates both sexes subjects are to be recruited whereas, the protocol state male will be the participants. Options of point no 10.i, ii should also be filled appropriately. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Provisionally Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Decision: • Approved ***Ref. code: XXIII-PGTSC-IIA/P8***
35-	Clarification of research proposal entitled ***"To compare efficacy and safety of imeglimin vs Metformin in patients of type 2 Diabetes mellitus in a tertiary care hospital"*** submitted by Dr. Saurabh Kumar Maurya, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 58/Pharm/24 dated 2nd February, 2024. ***Previous PGTSC Comment:*** • In SOP-Checklist point no. 3 (Clinical trial)-not attended and point no.—7 (use of biological samples)-ticked as NO but samples will be taken -PI to correct the SOP-Checklist. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** • Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P9***
36-	Clarification of research proposal entitled ***"Assessment of drug prescribing pattern in Geriatric type 2 Diabetes mellitus patients in a tertiary care teaching hospital"*** submitted by Dr. Deeksha Gupta, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 57/Pharm/24 dated 2nd February, 2024.

Previous Comment	PI response
In SOP-Checklist, Point no.-10 (Risk & benefit) -ticked as not reasonable -PI to correct.	Corrected the tick box as reasonable.
In Inclusion criteria, sex specification of the patients is not mentioned.	In inclusion criteria, patients of both the sex will be included.
Sample size calculation not given (only total no. of patients-600 is mentioned).	Sample size calculation and reference have been provided.
In Tools, WHO-ATC Classification-not attached	WHO-ATC index is given in reference no.18. Also, the broad classification and the website is mentioned.

	The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer. ***Recommendation of Primary reviewer:-*** • Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P12***
37-	Clarification of research proposal entitled ***"An observational prospective study to evaluate different drugs used in Hepatitis and adverse Drug reaction associated with those drugs in Paediatric patients coming to Paediatric and Medicine OPD and IPD of KGMU"*** submitted

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	by Dr. Rahul Kumar Soni, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 70/Pharm/2024 dated 7th February, 2024. **Previous Comment:** • Assent form for children not present. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P14***
38-	Clarification of research proposal entitled ***"A follow up study to asses adherence, Therapeutic outcome & quality of life in patients receiving disulfiram for Alcohol use disorder"*** submitted by Dr. Zoya Khan, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 783/Pharm/23 dated 9th October, 2023. ***Previous comment:*** • There are too many objectives. Identify one primary objective and the rest should be clubbed into secondary objectives. • Make a list of the study variables and population parameters required for adherence, therapeutic outcomes, quality of life etc. • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is arbitrary. It should be specific to the research hypothesis. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** **Decision:** Approved ***Dr. Rajendra Nath did not take part in the discussion & making decision.*** ***Ref. code: XXIII-PGTSC-IIA/P18***
39-	Clarification of research proposal entitled ***"A comparative study on efficacy, adherence, adverse drug events and quality of life between single fixed dose combination inhaler versus multiple inhalers in triple therapy of COPD"*** submitted by Dr. Vyaktika Shree, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 60/Pharm/24 dated 2nd February, 2024.

Previous Comment	PI response
Chairperson of the SRC is one of the co-investigators of the projects.	Modified as per advice
Study procedure is not written on the ICF.	Study procedure written on the ICF copy attached separately
Patient information sheet and ICF need to be written in understandable language.	Patient information sheet and ICF modified in understandable language. Copy attached separately.
Need opinion of Hon'ble members of the committee regarding patient information sheet point 20 **contact for further information** mentions the name of PI and	Removed

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Member Secretary…. is that OK?	
Kindly delete the name of the Member-Secretary, IEC	Removed

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of Primary reviewer:-

Provisionally approved

Decision: Approved

Ref. code: XXIII-PGTSC-IIA/P22

40- Clarification of research proposal entitled ***"Impact of yogic breathing exercises on mental wellbeing in adults"*** submitted by Dr. Divyanshu Arora, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3400/PHY/24 dated 3rd February, 2024.

Previous Comment	PI response
Sample size calculation not mentioned.	Sample size have been calculated and mentioned. It is n≥59 (Updated and document attached separately)
Review of literature not written properly.	Review of literature has been corrected in the recent document attached.
References are written not as per format. Kindly modify them as per Vancouver format.	References are modified as per Vancouver format.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of Primary reviewer:-

Provisionally approved

Decision: Approved

Ref. code: XXIII-PGTSC-IIA/P24

41. Clarification of research proposal entitled ***"Knowledge, attitudes and practices of oral health care providers and radiation oncologists regarding oral health care needs in head and neck cancer patients undergoing radiotherapy: A multinational questionnaire survey"*** submitted by Dr. Jagruti Mutalikdesai, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 400/Coms&Endo/23 dated 20th October, 2023.

Previous Comment:

- The title of the study mentions 'A multi-national questionnaire survey'.
- Kindly clarify is it Multi-national or Multi-centric?
- Kindly elaborate the names of Principal Investigators from all collaborating centers with their consent. The consent may either be digital (supported by a mentor verified email) or in a conventional hard copy format.

The aforementioned comments were sent to the Principal-Investigator, the response to which

	was forwarded to the reviewer. *Recommendation of Primary reviewer:-* Provisionally approved **Decision:** • Approved ***Ref. code: XXIII-PGTSC-IIA/P26***
42-	Clarification of research proposal entitled ***"Autologous platelet rich fibrin versus normal saline dressings in chronic venous leg ulcer patients in ulcer size reduction and quality of life: A randomized control study"*** submitted by Dr. Pallaprolu Jyothirmai, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow. **Comment:** • In IEC form, the tick on the Patient Inform Sheet is marked 'No' but patient information sheet is attached. • Kindly Hindi patient information sheet should be 'Layman language' Google translation will not be allowed. • PGT declaration form received. **Decision:** Revise & re-submit ***Ref. code: XXIII-PGTSC-IIA/P53***
43-	Clarification of research proposal entitled ***"To study the expense on Medical and Surgical consumables in Trauma Centre at a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Paayas Raj Verma under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/2024/052 dated 7th February, 2024. **Previous Comment:** • Why PI has attached Informed Consent form English & Hindi when this study does not need the living subjects and Human Subject Review Waiver (HSRW) form is already attached. PI to justify. • Waiver of consent provisionally approved **Decision:** • Approved ***Ref. code: XXIII-PGTSC-II B-MHA/P2***
44.	Clarification of research proposal entitled ***"A study on level of compliance for LaQshya in a tertiary care Government Teaching Hospital, Lucknow"*** submitted by Dr. Diksha Dwivedi under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/67/24 dated 10th February, 2024. **Previous Comment:** • Only the sign of the chairperson is given on the SRC; the seal and name is missing. Tick or comments on none of the decisions are given. • IEC needs to be filled properly. • As the study is to be done on the basis of records. The study aims to analyze the

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	level of compliance for LaQshya in a tertiary care Government hospital where the ICF and patient information sheet will be used? Methodology part needs to be written accordingly. And, for this study waiver may be applied. • As records of Queen Merry hospital are to be extracted a PI from there would be helpful. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Waiver of consent provisionally approved **Decision:** • Waiver of consent approved ***Ref. code: XXIII-PGTSC-II B-MHA/P3***
45-	Clarification of research proposal entitled ***"A study on BED mapping in a tertiary care Government Teaching Hospital, Lucknow India"*** submitted by Dr. Deepu Sharma under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/60/24 dated 8th February, 2024. **Previous Comment:** • Only the sign of the chairperson is given on the SRC; the seal and name is missing. • The topic needs to be modified as per the purpose of the study aim. • No need for ICF, waiver may be given. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Waiver of consent provisionally approved **Decision:** • Waiver of consent approved ***Ref. code: XXIII-PGTSC-II B-MHA/P6***
46-	Clarification of research proposal entitled ***"To study the cost incurred of laproscopic and open cholecystectomy done in the Department of General Surgery in a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Vishika Singh under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/68/24 dated 10th February, 2024. **Previous Comment:** • The seal of chairperson of scientific review committee is missing. • This project deals with cost calculation from financial archival records with no patient participation and PI has applied for consent waiver. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** Provisionally approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

Decision:

- Approved

Ref. code: XXIII-PGTSC-II B-MHA/P8

47- Clarification of research proposal entitled ***"A study on the compliance of out-patients Department (OPD) in a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Junaid Ali under the guidance Dr. Pradeep Srivastava, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/61/24 dated 8th February, 2024.

Previous Comment:

- Only the sign of the chairperson is given on the SRC; the seal and name is missing.
- IEC to be filled properly.
- As pattern of prescriptions of the OPD are to be assessed to ensure the quality, will the researcher directly interview the patient or only NQAS checklist for OPDs are to be matched with prescriptions. Clarity is needed.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of Primary reviewer:-

Provisionally approved

Decision:

- Approved

Ref. code: XXIII-PGTSC-II B-MHA/P9

48- Clarification of research proposal entitled ***"A study of prescriptions in the Rheumatology Department of a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Junaid Ali under the guidance Dr. Pradeep Srivastava, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/62/24 dated 8th February, 2024.

Previous Comment	PI response
Kindly clarify the sample size calculation in more detail.	In methodology, the sample size calculation is mentioned in detail.
On One hand it is indicated that the patients will be selected randomly (in patient-information sheet) while on the other hand it is mentioned that sampling will be according to PPS (Population proportion to size) model. In case of latter kindly clarify further, (Methodology).	The researcher will select patients by random sampling method and the same is mentioned in methodology as well as in patient information sheet. The corrections are made and are enclosed.

The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of Primary reviewer:-

Provisionally approved

Decision:

- Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XXIII-PGTSC-II B-MHA/P10
49-	Clarification of research proposal entitled ***"A study of Ayushman Bharat Health Account (ABHA) in tertiary care Government Teaching Hospital in Lucknow, India"*** submitted by Dr. Seema Khan under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/54/24 dated 7th February, 2024. ***Previous comment:*** • Seal and name of Chairperson is missing from SRC. • Waiver may be given. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** waiver of consent provisionally approved **Decision:** • Waiver of consent approved
	Ref. code: XXIII-PGTSC-II B-MHA/P12
50-	Clarification of research proposal entitled ***"To study the funds utilized under the chief minister discretionary fund (CMDF) scheme in a tertiary care Government Teaching Hospital Lucknow, Uttar Pradesh"*** submitted by Dr. Sakshi Pathak under the guidance Dr. Pradeep Srivastava, Associate Professor, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/55/24 dated 8th February, 2024. **Previous Comment:** • Seal and name of Chairperson from the SRC is missing. Consent form is not needed. Waiver may be given. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of Primary reviewer:-*** waiver of consent provisionally approved **Decision:** • Waiver of consent approved
	Ref. code: XXIII-PGTSC-II B-MHA/P14
51-	Clarification of research proposal entitled ***"To study claims under Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY) in a tertiary care Government Teaching Hospital Lucknow, India"*** submitted by Dr. Mahwish Suhaib under the guidance Dr. Nitin Dutt Bhardwaj, Associate Professor, Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/53/24 dated 7th February, 2024. **Previous Decision:** waiver of consent provisionally approved **Decision:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Waiver of consent approved ***Ref. code: XXIII-PGTSC-II B-MHA/P16***
52.	Clarification of research proposal entitled ***"Matrix metalloproteinase-9 (MMP-9) levels in bronchoalveolar lavage (BAL) samples: implications for diagnosis and prognosis in early-onset and late-onset ventilator-associated pneumonia (VAP): An observational study"*** submitted by Dr. Vikram Singh, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1580/24 dated 23rd February, 2024. **Previous Comment:** • In SOP-Checklist-Point no-10 (Risk & benefit)-ticked as not reasonable -PI to correct. In Inclusion /Exclusion criteria Sex specification and pregnant & lactating women criteria not mentioned. Tools-APACHE score & SOFA score document not attached. **Decision:** • Approved ***Ref. code: XXIII-PGTSC-IIA/P50***
53-	Clarification of Expedited review of research proposal entitled ***"Efficacy and safety of IV tranexamic acid in prevention of post partum haemorrhage-A randomized controlled study"*** submitted by Dr. Aradhya Garg, JRI, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/357/24 dated 8th February, 2024. ***Previous Comments :-*** • In the proposal the references cited in the text are not properly done. In-text citations shall include the last name of the author followed by a comma and the publication year enclosed in parentheses: (Singh, 2024) or they shall be numbered in parenthesis at the end of the sentence or as superscript. Kindly correct. • It is better if the Investigators themselves do not participate in scientific review committee or be Chairman of the same. Also as per the comments it is mandatory that Investigating team is competent to carry out the research. Kindly resolve. • No indication of use of body fluid is indicated in Annexure 1. How will the hematocrit be estimated? • What is the role of healthy volunteers (Annexure 1 point 8)? Kindly indicate. • Is the risk not reasonable compared to benefits? Kindly resolve. • If there is a plan for reporting adverse events to IEC (Annexure 1 point 11) then such anticipated adverse events need to be indicated in consent form & patient information sheet. Who will bear the cost of its management? • While everywhere it is mentioned as randomized control study, the methodology section indicates it as randomized control trial. Kindly resolve. • The section of statistical analysis is missing. ***Recommendation of Primary:*** Provisionally approved ***Recommendation of Secondary reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Provisionally approved PGT declaration form received **Decision:** • Approved ***Ref. code: XXII-PGTSC-IB/P1***
54.	Clarification of research proposal entitled ***"Comparative evaluation of different priming solutions in prevention of hypotension in critically ill patients undergoing sustained low efficiency dialysis (SLED) a randomized controlled trial"*** submitted by Dr. Ujjwal Yadav, SR, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/2024/0127 dated 26th February, 2024. **Previous Comment:** • It is unclear whether the desired interventions are approved interventions/standard of care. • PGT declaration received **Decision:** • Approved ***Ref. code: XXIII-PGTSC-IIA/P48***
IB	**Expedited review-MHPE students**
1-	Research proposal entitled ***"Development and evaluation of Objective Structured Practical/Clinical examination (OSPE-OSCE) for clinical Microbiology residents in accordance with the new CBME curriculum: A pilot study"*** submitted by Dr. Parul Jain, Associate Professor under the guidance of Prof. Sandeep Bhattacharya, Department of Medical Education, King George's Medical University, U.P., Lucknow vide letter no. 455/DME/24 dated 24th February, 2024. ***The above document was forwarded to two reviewers:-*** ***Recommendation of Primary reviewer:-*** Provisionally approved ***Recommendation of Secondary reviewer:-*** • In SOP-Checklist –Point no.-5 (subject selection)–Special group subjects ticked as No- but students (PG) will be recruited for this study-PI to correct. • In Inclusion criteria & in the Title it is mentioned that the volunteers will be residents but in sample size –it is given that for convenient sample size-43 residents and 9 Faculty members will be taken for this Pilot study -PI to clarify. • The Background and rationale for the study is missing. • Please attaché-1)Guidelines for Competency-based New CBME Curriculum for Microbiology PG Students & 2) Sample of Questionnaires to be developed/ asked for OSPE/OSCE & how they will be authenticated? **Decision:** Approved ***Ref. code: XXIV-PGTSC-IB/P1***
2-	Research proposal entitled ***"Assessment of students' perspective on introduction of "Digital Dentistry" as self-directed learning module in undergraduate prosthodontics curriculum: A***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	prospective study" submitted by Prof. Shuchi Tripathi under the guidance of Prof. R.K. Dixit, Department of Medical Education, King George's Medical University, U.P., Lucknow vide letter no. 454/DME/23 dated 24th February, 2024. ***The above document was forwarded to two reviewers:-*** ***Recommendation of Primary reviewer:-*** Provisionally Approved & relevant information sheet may be added. ***Recommendation of Secondary reviewer:-*** Provisionally Approved **Decision:** Approved & relevant information sheet may be added. ***Ref. code: XXIV-PGTSC-IB/P2***
3-	Research proposal entitled ***"Assessment of emotional intelligence and empathy in Postgraduate Medical and Dental Students: A cross-sectional study"*** submitted by Dr. Nisha Mani Pandey under the guidance of Prof. Apul Goel, Department of Medical Education, King George's Medical University, U.P., Lucknow vide letter no. 453/DME/23 dated 24th February, 2024. ***The above document was forwarded to two reviewers:-*** ***Recommendation of Primary reviewer:-*** Provisionally Approved & relevant information sheet may be added. ***Recommendation of Secondary reviewer:-*** Provisionally Approved **Decision:** Approved & relevant information sheet may be added. ***Ref. code: XXIV-PGTSC-IB/P3***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"A prospective evaluation of outcomes of emergency Laparotomy using NELA Data Set"*** submitted by Dr. Swapnil Singh, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 3004/SY/23 dated 9th November, 2023. ***Recommendation of reviewer:-*** • The duration in point 5 annexure 1 is 2 yrs as well as 1.5 yrs. Kindly rectify. • Is the risk not reasonable compared to anticipated benefits? (Annexure 1 point 10) • In patient information sheet, point 6 relates to breast cancer while point 7 is totally unacceptable. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P1***
2.	Research proposal entitled ***"A prospective comparative cohort study of combined intravenous and intra-articular vs intravenous administration of tranexamic acid in patient of total knee arthroplasty"*** submitted by Dr. Deepak Chawda, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1105/Ortho/23 dated 6th December, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer:- • Following sections of IEC form are incomplete/incorrectly filled-type of subjects/special group subject, patient information sheet, risk and benefits. • Calculation of sample size has not been shown as per formula. • Patient information sheet is incorrectly filled. • Same information is repeated in different sections/headings. • Kindly submit the PGT Declaration form **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Functional outcome of fracture posterior wall acetabulum managed by spring plate using kocher- langenbeck approach"*** submitted by Dr. Ankur Maan, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1103/Ortho/23 dated 6th December, 2023. ***Recommendation of reviewer:-*** • In SOP-Checklist- point no.10 (Risk & benefit) -ticked as not reasonable -PI to correct or revise SOP-Checklist. • In Inclusion criteria sex specification not mentioned • Informed consent form-as the age group of patients to be recruited starts from 16 yrs., therefore Child Assent form should also be submitted. • PI should also clarify that how will he take consents of subjects taken retrospectively? Whether he will submit Human Subject Review Waiver Form (HSRWF) for retrospective part of the study. **Comment:** • The retrospective nature of the study may be included in the title. **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P3***
4.	Research proposal entitled ***"Prediction of hamstring graft thickness for anterior cruciate ligament reconstruction by anthropometric measurement: A prospective study"*** submitted by Dr. Amit Kumar, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1104/Ortho/23 dated 6th December, 2023. ***Recommendation of reviewer:-*** • There are 2 sets of annexure 1 where in sample sizes are indicated as 48 and 100 respectively. Kindly correct. • Is the risk not reasonable compared to benefits (Annexure 1 point 10). Kindly complete the left out blanks. • If there is a plan to report adverse events (annexure 1 pt 11) then what are those events? They need to be stated in ICF and patient information sheet as well. • What is the role of healthy volunteers as indicated in annexure 1 (pt 8). There needs to be separate ICF & information sheet for them.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Kindly enumerate the various outcome variables and summarize their statistical analysis in that context. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P4***
5.	Research proposal entitled ***"A comparative study of outcome of tympanoplasty with cortical mastoidectomy vs tympanoplasty alone for mucosal type of chronic otitis media"*** submitted by Dr. Abhilash Verma, JRI, Department of Oto-Rhino-Laryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1245/23 dated 8th December, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** As above ***Ref. code: XXIV-PGTSC-IIA/P5***
6.	Research proposal entitled ***"Assessment of 'probable surgical" traumatic Brain injury (TBI) patients"*** submitted by Dr. Samarthan SL, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 2304/NS/23 dated 8th December, 2023. ***Recommendation of reviewer:-*** Approved **Comment:** Kindly include the study design in the title. **Decision:** Revise & re-submit with response to the aforementioned comment. ***Ref. code: XXIV-PGTSC-IIA/P6***
7.	Research proposal entitled ***"To elucidate the role of serum nogo-a as predictor of Neurological recovery in spinal cord injury (SCI):A prospective study"*** submitted by Dr. Akash Singh, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1106/Ortho/23 dated 8th December, 2023. ***Recommendation of reviewer:-*** • In SOP-Checklist point no. 10 (Risk & benefit)-ticked as not reasonable and point no.7 (Use of biological samples) ticked as NO but samples will be taken-PI to correct the SOP-Checklist. • SCIM tool is not attached-please include. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Role of strain and shear wave ultrasound elastography in evaluating solid breast masses"*** submitted by Dr. Ananya Verma, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 1045/RD/23 dated 24th November, 2023. ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Provisionally approved **Comment:** • Kindly include in the title the design of the study **Decision:** Provisionally approved ***Ref. code: XXIV-PGTSC-IIA/P8***
9.	Research proposal entitled ***"Hirayama disease: role of magnetic resonance imaging and utility of MR neck angiography"*** submitted by Dr. Ishita Srivastava, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 1046/RD/23 dated 25th November, 2023. ***Recommendation of reviewer:-*** Provisionally approved **Comment:** • Kindly include in the title the design of the study **Decision:** Provisionally approved ***Ref. code: XXIV-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Association of serum periostin, IL 4 and IL 13 with severity of Asthma- an observational study"*** submitted by Dr. Swapnil Gupta, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3600/Ped/23 dated 9th December, 2023. ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Influence of comorbidites on functional outcome post total Knee replacement: A prospective cohort study"*** submitted by Dr. Juzer Jamil, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1102/Ortho/23 dated 6th December, 2023. ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P11***
12.	Research proposal entitled ***"Knee self efficacy and patient satisfaction post anterior cruciate ligament reconstruction: A prospective and retrospective study"*** submitted by Dr. Manjul Gupta, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1108/Ortho/23 dated 6th December, 2023. ***Recommendation of reviewer:-*** • The design of the study, as mentioned in the title, may be modified to "An ambispective study". • The sample size in annexure 1 point 5 is 95, while in methodology mention it is 105. Kindly correct. • Is the risk not reasonable compared to anticipated benefits? (Annexure 1 pt 10)

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• What is the role of healthy volunteers (Annexure 1 pt 8) Separate ICF & information sheet to be included for them? • What are the anticipated adverse events that need notification (Annexure 1 pt 11) • The latter part of methodology is in past tense. It needs correction. • Kindly enumerate all the anticipated outcome variables & summarize the statistical analysis based upon those variables. • Since this also has a retrospective component, how will the consent be obtained from them? Also kindly reformate 'Study procedure' section of ICF in a more patient friendly Language. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P12***
13.	Research proposal entitled ***"A prospective comparative study to evaluate the results of ACL reconstruction using hamstrings vs quadriceps tendon graft"*** submitted by Dr. Ayush Kumar, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1098/Ortho/23 dated 6th December, 2023. ***Recommendation of reviewer:-*** • In SOP-Checklist, point no.10 (Risk & benefit) ticked as not reasonable-PI to correct. **Comment:** As above **Decision:** Approval subject to modification ***Ref. code: XXIV-PGTSC-IIA/P13***
14.	Research proposal entitled ***"Functional outcome and health-related quality of life in younger patients with femoral Neck fracture treated with canulated cancellous screw: A prospective cohort study"*** submitted by Dr. Mahesh Kumar, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1099/Ortho/23 dated 6th December, 2023. ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P14***
15.	Research proposal entitled ***"A prospective study to evaluate the results of correction of angular deformities around the knee using computer assisted indigenous hexapod fixator system"*** submitted by Dr. Vivek Kumar, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1097/Ortho/23 dated 6th December, 2023. ***Recommendation of reviewer:-*** • IEC to be filled properly- specially point no. 5, 8, 10, 11. • As it is a follow up of OPD patients with angular deformity; title should reflect the same.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• In study population patients with angular deformity attending OPD to be written. • If patients 12 years and above age are to be taken there should be guardian consent and patient assent form. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P15***
16.	Research proposal entitled ***"Evaluation of effect of very low diet protein with ketoacid analogues supplementation in patients with chronic kidney disease"*** submitted by Dr. Anshuman Mishra, JRI, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/925/23 dated 14th December, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** • Approved ***Ref. code: XXIV-PGTSC-IIA/P16***
17.	Research proposal entitled ***"A study on effects of organo-chlorine pesticide exposure on progression of chronic myeloid leukemia"*** submitted by Dr. Syed Mohd Abuturab Rizvi, JRI, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/926/23 dated 14th December, 2023. ***Recommendation of reviewer:-*** • In SOP-checklist, point no.10 (Risk & benefit) ticked as not reasonable-PI to correct. • In inclusion criteria-Age and sex specifications of the patients not mentioned-PI to include. • Detailed sample size calculation is missing-Discrepancy in total sample size given (75) and in grouping (25/50) but in calculation n=31 is mentioned PI to clarify. • As this is a comparative cross-sectional study-flow chart of methodology is needed. • The title of the study mentions "progression of chronic myeloid leukemia" while the design of the study is cross-sectional; how will you achieve your objective/s? • Case record form is not attached. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P17***
18.	Research proposal entitled ***"Role of strain and shear wave ultrasound elastography in chronic kidney disease patients"*** submitted by Dr. Suryang Chaurasia, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. RD/848/23 dated 16th December, 2023. ***Recommendation of reviewer:-*** • This is a prospective comparative cohort study; kindly include this in the title too. • The two cohorts (Treatment and control) should be explicitly defined.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The sample size formula is inappropriate. It is for prevalence study. • After stating the research hypothesis (involving study variables and parameters) properly, right sample size formula should be used. • The statistical hypothesis section is very general. It should be specific to the research hypothesis. **Comment:** • Kindly include ***"Study design"*** in the title **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P18***
19.	Research proposal entitled ***"Epidemiology of acute febrile illness in a medical ward and ICU of a tertiary care centre of Northern India"*** submitted by Dr. Prince Kumar Singh, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 2011/Med/23 dated 4th December, 2023. ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P19***
20.	Research proposal entitled ***"Comparison of limb occlusion pressure and standard pneumatic tourniquet pressure in total knee arthroplasty -A prospective study"*** submitted by Dr. Ravi Kumar, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1107/Ortho/23 dated 6th December, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P20***
21.	Research proposal entitled ***"Validation of open injury scores in predicting salvageability of limb in type III B open tibial fractures"*** submitted by Dr. Utkarsh Bansal, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1197/Ortho/23 dated 6th December, 2023. ***Recommendation of reviewer:-*** • Informed consent mentions the study as Case control study. Please correct this. • Informed consent in Hindi not present. **Comment:** • Kindly clarify **"Study design"** • Title is different in the section on "Role of responsibilities" **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P21***
22.	Research proposal entitled ***"Evaluation of patient reported outcome in arthroscopically reconstructed anterior cruciate ligament tear using autologous tendon grafts"*** submitted by Dr. Sagar Meena, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1198/Ortho/23 dated 6th December, 2023.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Recommendation of reviewer:- • Role of supervisors are missing • IEC to be filled properly point no. 5.vi (elderly?), 8, 10, 11 • Tools to be applied should be mentioned in the proposal. • Both Hindi/ English ICF to be written properly. • If patients 16-50 years of age are to be taken there should be guardian consent and patient assent form. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P22***
23.	Research proposal entitled ***"Surgical management of spontaneous intracerebral haemorrhage-endoscopic versus open surgery- A prospective study"*** submitted by Dr. Sahil Garg, JRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. NS/1401/23 dated 16th December, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P23***
24.	Research proposal entitled ***"Study of morphometric and morphological variations and age associated changes in the vascular structures of middle mediastinum using contrast-enhanced computed tomography"*** submitted by Dr. Neha Hyanki, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 578/Anat/23 dated 19th December, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P24***
25.	Research proposal entitled ***"Development and validation of a regression model to predict human stature with the help of hand and feet measurements-An application to medicolegal investigations"*** submitted by Dr. Anshika Singh, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 579/Anat/23 dated 19th December, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** As above ***Ref. code: XXIV-PGTSC-IIA/P25***
26.	Research proposal entitled ***"Clinical profile of children with neuroregression and its association with Vitamin B12 deficiency"*** submitted by Dr. Himani Singh, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3163/Ped/23 dated 23rd December, 2023. ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• SRC should be revised as the name of Prof. Shally Awasthi who is superannuated is there. (Open house discussion needed) • In SOP-Checklist, point no.7 (use of biological samples) -ticked as NO .but samples will be taken -PI to correct. • In Inclusion criteria-Sex specifications of the patients not mentioned- PI to include. • Total sample size is given (105) and calculated, but no. of subjects in each group (healthy control and cases) has not been mentioned- PI to give details of grouping with sample size and include the Flow chart of the study. • Informed consent form for adults and Child Assent form is included but Guardian consent form is missing (as the age of recruited subjects will be 3 months to 12 yrs.)–PI to include Guardian consent form instead of regular ICF. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P26***
27.	Research proposal entitled ***"MRI imaging in patients of leprosy with neurological involvement"*** submitted by Dr. Anek Kumar, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 1284/RD/23 dated 6th December, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** As above ***Ref. code: XXIV-PGTSC-IIA/P27***
28.	Research proposal entitled ***"Computed tomographic evaluation of normal and variant Anatomy of craniovertebral junction in North Indian population at a tertiary health care center"*** submitted by Dr. Shiv Kumar Yadav, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 487/ANAT/23 dated 17th November, 2023. ***Recommendation of reviewer:-*** • If investigator wishes to analyse only the CT scan without patient contact and accordingly has submitted consent waiver from, then why has the PI submitted ICF 7 patient information sheet? Kindly clarify. Corresponding corrections need to be made in annexure 1. • Also clarify if this is a retrospective study or a prospective study and if any other clinical data will be collected or not? • Is the risk not reasonable compared to anticipated benefits? (Annexure 1 pt 10) • Kindly summarize statistical analysis in context of the anticipated outcome variables. • The patient information sheet should not mention the guidelines. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P28***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

29.	Research proposal entitled ***"Stress cytogenetic study of patients of aplastic anemia at a tertiary health care centre"*** submitted by Dr. Bedana Gautam, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 571/ANAT/23 dated 18th December, 2023. ***Recommendation of reviewer:-*** • The Seal of the chairperson on SRC is missing. • In the study inclusion criteria age groups to be written precisely. Inclusion criteria do not indicate age group; PI wishes to include up to the age of 40 years; please clarify and prepare the ICF accordingly. • Procedural details are to be written accordingly. • PI states another blood sample will be taken from the control subject. Needs clarification? Who will be the control subject? Should be written properly in the methodology section. • Who will bear the cost of the investigations? **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P29***
30.	Research proposal entitled ***"Endoscopic exploration of extracranial part of optic nerve in human cadavers"*** submitted by Dr. Vandana Kumari, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 581/ANAT/23 dated 21st December, 2023. ***Recommendation of reviewer:-*** • The aim says: "To describe endoscopic anatomy of extracranial part of optic nerve". This is just a description of study variables. • The objective should mention the use of these measurements. • Research hypothesis should be stated in terms of study parameters (such as proportion, mean, standard deviation etc.). • The sample size calculation is ad hoc in the absence of proper research hypothesis. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P30***
31.	Research proposal entitled ***"Role of biomarkers:- serum IL 8 and GM –CSF to predict short term outcomes in term neonates with perinatal asphyxia"*** submitted by Dr. Mukul Goel, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3269/Ped/23 dated 5th October, 2023. ***Recommendation of reviewer:-*** • The sample size calculation is not given • Statistical analysis section is very general. It should be specific to the study research hypothesis.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• The title of the proposal may be revised to include the design of the study **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P31***
32.	Research proposal entitled ***"Study of ct-coronary angiography in post COVID positive patients/vaccinated individuals: A single center study"*** submitted by Dr. Kajal Deepak, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 1221/RD/23 dated 18th November, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P32***
33.	Research proposal entitled ***"Correlations between DTI metrics and MRS metabolites in GLIOMA"*** submitted by Dr. Neeraj Meena, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 1222/RD/23 dated 18th November, 2023. ***Recommendation of reviewer:-*** • The title of the proposal may be revised to include the design of the study • The aim and objective paragraph should be corrected. • Firstly, it says: My aim & objectives..... • Secondly, there are too many statements included in one sentence. • It should be splatted. The primary objective should be specifically stated clearly. The rest should be identifies as secondary objectives. • In the absence of proper objectives, everything else (including sample size calculation) is not in line. • Methodology and statistical analysis section are missing. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P33***
34.	Research proposal entitled ***"Pediatric Dr TB: resistance pattern, treatment outcome and side effects profile"*** submitted by Dr. Palepu Sai Krishna Kaushik, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3567/Ped/23 dated 29th November, 2023. ***Recommendation of reviewer:-*** • Kindly enumerate the anticipated outcome variables. • The consent process in pediatric cases should include guardian/legal representative signature. Kindly modify the respective forms. **Comment:** As above

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Decision: Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P34***
35.	Research proposal entitled ***"Comparison of loading dose alone versus standard pritchard regimen in severe preeclampsia patients for prevention of eclampsia- A randomized control study"*** submitted by Dr. Divya, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1968/23 dated 11th December, 2023. ***Recommendation of reviewer:-*** • Seal of the chairperson on SRC is missing. • The Chairperson of the SRC is chief supervisor. • IEC to be filled properly. Same duration to be mentioned on the IEC and protocol. • ICF and Patient information sheet needs to be written with clarity so that a lay person (participants) can understand the purpose and procedure before giving the consent. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P35***
36.	Research proposal entitled ***"Role of strain and shear wave ultrasound elastography in evaluation of cervical lymphadenopathy"*** submitted by Dr. Himanshu Nirwal, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 1048/RD/23 dated 25th November, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** As above ***Ref. code: XXIV-PGTSC-IIA/P36***
37.	Research proposal entitled ***"Clinical presentation and outcome of post infectious broncholitis obliterans in children"*** submitted by Dr. Noopur Gupta, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3601/Ped/23 dated 9th December, 2023. ***Recommendation of reviewer:-*** • The aim says: "To determine the clinical features of PIBO in children. This is just a description of study variables. • The objective should mention the use of these clinical features. • Research hypothesis should be stated in terms of study parameters (such as proportion, mean, standard deviation etc.). • Sample size calculation is not given. • The statistical analysis section is very general. It should be specific to the research hypothesis. • Assent form from parents is required. • The title of the proposal may be revised to include the design of the study **Comment:** As above

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Decision: Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P37***
38.	Research proposal entitled ***"Clinical correlation of molecular behavior of CD117, CD31, CD34, Vimentin, SMA and synaptophysin in nasopharyngeal angiofibroma"*** submitted by Dr. Mohammad Akram, JRI, Department of Oto-Rhino-Laryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1274/ENT/23 dated 30th December, 2023. ***Recommendation of reviewer:-*** • The title of the proposal may be revised to include the design of the study such as an exploratory study, pilot study, etc. • In Inclusion criteria Age & Sex specification /Pregnant and lactating women criteria not mentioned. • Sample size calculation not done (total-40 patients will be recruited as a Pilot study)-PI to justify. • How PI will address (Consent) of the patients taken retrospectively –whether he will submit the HSRW Form–PI to clarify. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Dr. Anupam Mishra did not take part in the discussion & making decision.*** ***Ref. code: XXIV-PGTSC-IIA/P38***
39.	Research proposal entitled ***"Impact of nasal surgery on pulmonary function test in chronic nasal obstruction"*** submitted by Dr. Umang Baranwal, JRI, Department of Oto-Rhino-Laryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1273/ENT/23 dated 30th December, 2023. ***Recommendation of reviewer:-*** Approved **Decision:** As above ***Dr. Anupam Mishra did not take part in the discussion & making decision.*** ***Ref. code: XXIV-PGTSC-IIA/P39***
40.	Research proposal entitled ***"Role of FABP 1 and FABP 4 in detection of diabetic Nephropathy in Geriatric type 2 diabetes mellitus patients"*** submitted by Dr. Chitranshi Hyanki, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 879/Pharma/23 dated 3rd November, 2023. ***Recommendation of reviewer:-*** • Kindly fill up the blanks in annexure 1 (pt (i) & (ii). • On one hand investigator states that no body fluids will be collected (annexure 1 pt 7), while on the other hand he wishes to collect 5 ml blood. Kindly rectify. • Is the risk not reasonable compared to anticipated benefit? • Kindly enumerate the outcome variables & summarize the statistical analysis based on those anticipated variable.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• In ICF the PI is Chief Supervisor & this should be rectified. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P40***
41.	Research proposal entitled ***"Prevalence of psychological distress and it's risk factors in patients with primary bone tumors-A cross sectional single centre study"*** submitted by Dr. Sujeet Kumar Chaudhary, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1011/Ortho/23 dated 20th November, 2023. ***Recommendation of reviewer:-*** • This is basically observational study to find the prevalence of depressive and anxious symptomatology in cancer patients. • Since a cross-sectional study can only measure a distribution at a single time point, demographic, anthropometric, paraclinical, bioimpedance and genetic variables (not parameters) centered on dynamic or time-dependent quantities will introduce detection bias. • In view of the above comments, the title of the proposal may be revised suitably. • This cannot be used for making causal inference (risk factors). • Statisticians generally prefer to make causal inferences from randomized controlled experiments. • Data analysis section is incomplete. It just mentions the name of software to be used. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P41***
42.	Research proposal entitled ***"Analysis of autologous titanium-platelet rich fibrin and leukocyte-platelet rich fibrin in intra-bony periodontal defect patients: A randomized clinical trial"*** submitted by Dr. Prateek Yadav, JRI, Department of Periodontology, Faculty of Dental Sciences King George's Medical University, U.P., Lucknow vide letter no. 74107/P/24 dated 8th January, 2024. ***Recommendation of reviewer:-*** • Section on Clinical trial in IEC form is incomplete. • Answer to 'risk is reasonable' is mentioned 'No' • Data monitoring is mentioned as 'No' although PI is proposing to conduct a 'Trial' • Compensation of injury is 'No' • In a Trial there must be insurance cover for compensation. • No funding has been mentioned for the 'Trial'. • Declaration form regarding Randomised Controlled research is incomplete. • Trials must be accompanied by CTRI registration, CONSORT statement, statement regarding funding, insurance cover for compensation and legal advice.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Kindly provide the PGT declaration form. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P42***
43.	Research proposal entitled ***"Effectiveness of oral antibiotic therapy in children with low risk febrile neutropenia"*** submitted by Dr. Mohini Pal, JRII, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 68/Ped/2024 dated 15th January, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** As above ***Ref. code: XXIV-PGTSC-IIA/P43***
44.	Research proposal entitled ***"Role of simvastatin as an adjunct to non-surgical periodontal therapy in chronic peridontitis patients"*** submitted by Dr. Jayant Gupta, JRI, Department of Peridontology, Faculty of Dental Sciences King George's Medical University, U.P., Lucknow vide letter no. 4108/P/2024 dated 11th January, 2024. ***Recommendation of reviewer:-*** • Kindly fill in the blanks (Annexure-1 point 3 (iii) & point II) • Kindly eneumerate the specific objectives point wise & don't describe methodology in 'aims' section. • The title of the proposal may be revised to include the design of the study. • Regarding exclusion criteria how you will exclude the suspected allergy to simavastin. • In patient information sheet kindly exclude the initial guidelines. • Is the risk not reasonable compared to anticipated benefits? • Kindly provide PGT declaration form. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P44***
45.	Research proposal entitled ***"Assessment of nutritional status in childhood cancer patients and its impact on short term outcome"*** submitted by Dr. Meenkashi Kuntal, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 56/Ped/2024 dated 12th January, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** As above ***Ref. code: XXIV-PGTSC-IIA/P45***
46.	Research proposal entitled ***"Evaluation of anorectal manometry parameters in patients with active and quiescent inflammatory bowel diseases"*** submitted by Dr. Saurabh Kumar Mishra, SR, Department of Medical Gastroenterology, King George's Medical University, U.P.,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Lucknow vide letter no. 3227/MedGastro/2024 dated 17th January, 2024. ***Recommendation of reviewer:-*** • In Inclusion /Exclusion criteria–Sex specification not mentioned. **Comment:** • As above **Decision:** Approval subject to appropriate modification of the proposal. ***Ref. code: XXIV-PGTSC-IIA/P46***
47.	Research proposal entitled ***"Clinical profile and short term outcome of status epilepticus in children and risk factors for the development of refractory status epilepticus"*** submitted by Dr. Kirti Tripathi, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2360/Ped/2024 dated 13th January, 2024. ***Recommendation of reviewer:-*** • Sample size is given as 190 at one place, 200 at another and 236 where sample size calculation has been done. Please clarify. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P47***
48.	Research proposal entitled ***"A prospective follow up study on the development of new onset prediabetes and diabetes mellitus after an episode of acute pancreatitis"*** submitted by Dr. Gaya Prasad Shukla, SR, Department of Medical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. 3229/MedGastro/2024 dated 18th January, 2024. ***Recommendation of reviewer:-*** • ICF to be written in an understandable language. **Comment:** As above **Decision:** Approval subject to modification ***Ref. code: XXIV-PGTSC-IIA/P48***
49.	Research proposal entitled ***"Prevalence of multiorgan dysfunction in neonates with sepsis and its outcome"*** submitted by Dr. Aman Meena, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 2450/Ped/2023 dated 29th December, 2023. ***Recommendation of reviewer:-*** • In SOP-Checklist-point no-10 (Risk & benefit) -ticked as not reasonable and point no.--7 (use of biological samples)-ticked as NO but samples will be taken -PI to correct. • In Inclusion criteria Sex specification has not been mentioned. • ICF–English and Hindi versions are not similar–Hindi ICF should be revised accordingly. **Comment:** As above

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Decision: Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P49***
50.	Research proposal entitled ***"Profile of pulmonary infections in acute leukemia patients during induction phase"*** submitted by Dr. P Raghuveer, SRI, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. 640/CH/2023 dated 26th December, 2023. ***Recommendation of reviewer:-*** • IEC form incompletely/incorrectly filled. Difficult to read due to format issues. Please correct and submit complete form in legible print. • Tile of Co-PI, Prof A.K Tripathi is wrong since he has superannuated. This needs to be corrected. • Sample size calculation has not been done. • Summary is incomplete/poorly written. • PIS is in wrong format/incomplete/poorly written • ICF translation into Hindi is poor. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIA/P50***
51.	Research proposal entitled ***"Anatomical study of anterior tibial artery and its's perforators:"*** submitted by Dr. Arun Kumar, JRIII, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 590/ANAT/2024 dated 9th January, 2024. ***Recommendation of reviewer:-*** • The project can be approved but the left blank spaces be filled in annexure 1 (points 2,5,9,13) **Comment:** • As above **Decision:** Approval subject to appropriate modification of the proposal. ***Ref. code: XXIV-PGTSC-IIA/P51***
52.	Research proposal entitled ***"Prevalence of AKI in neonates with birth weight below 1800G receiving nephrotoxic drugs in NICU"*** submitted by Dr. Abhay Singla, JRII, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 180/Ped/2024 dated 8th February, 2024. ***Recommendation of reviewer:-*** • The proposal needs discussion during the meeting. • The title of the proposal may be revised to avoid the use of abbreviations and include the design of the study. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Ref. code: XXIV-PGTSC-IIA/P52
53.	Research proposal entitled ***"Study of laboratory and clinical profile of Vitamin B12 deficiency in tertiary health care centre"*** submitted by Dr. Alpika Shukla, SRI, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. 641/CH/2023 dated 26th October, 2023. ***Recommendation of reviewer:-*** • In SOP-Checklist-not ticked any option (submitted vacant)-PI to submit the ticked SOP-Checklist. • In Inclusion criteria Age & Sex specification not mentioned. • Sample size calculation not done (only total subjects-200-is mentioned)-PI to give calculated sample size. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format.
	Ref. code: XXIV-PGTSC-IIA/P53
II-B	**MHA**
1.	Research proposal entitled ***"A study on national quality assurance standard (NQAS) compliance in medical Gastroenterology ward in a tertiary care Government Teaching Hospital, Lucknow, India"*** submitted by Dr. Rajnish MP Singh under the guidance Dr. Nitin Dutt Bhardwaj, Professor Junior Grade & Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/20/24 dated 15th January, 2024. ***Recommendation of reviewer:-*** • It seems that information are to be extracted from the records of Gastroenterology ward; if so IEC to be filled accordingly and protocol need correction. • Further, if only records are to be extracted and analyzed there is no need of patient information sheet and for ICF; PI may apply for waiver of the study. • Also, if the PI has to interview staff and patients as written in the protocol; number of staff patients to be interviewed should be clearly mentioned. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format.
	Ref. code: XXIV-PGTSC-II B-MHA/P1
2.	Research proposal entitled ***"A study on the level of compliance with national quality assurance standard (NQAS): musqan in department of paediatric (WARD) in tertiary care government teaching Hospital, Lucknow"*** submitted by Dr. Vishika Singh under the guidance Dr. Nitin Dutt Bhardwaj, Professor Junior Grade, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/21/24 dated 18th January, 2024. ***Recommendation of reviewer:-*** • If information is to be taken from the records there is no need for patient information sheet and ICF. The IEC to be filled properly and proposal to be written accordingly. **Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-II B-MHA/P2***
IIC	**Nursing KGMU Institute**
1.	Research proposal entitled ***"Effectiveness of exercise based regimen on symptoms of chemotherapy induced peripheral neuropathy (CIPN), among patients undergoing chemotherapy, admitted in Medical Oncology ward, K.G.M.U, Lucknow"*** submitted by Mr. Malay Kumar Rai through his guide Dr. Suchana Roy Bhowmik, Assistant Professor, Department of College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4050/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** • In ICF study process to be written in simple and understandable language so that the participant could understand it. Hindi/ English both consent should have the same meaning. • CIPN scoring key needs revision; how a score of zero be treated as mild symptoms. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIC/P1***
2.	Research proposal entitled ***"Impact of maternal teaching regarding newborn danger signs on knowledge among mothers of newborn admitted in NICU and NNU at KGMU."*** submitted by Ms. Amrita Singh through her guide Dr. Suchana Roy Bhowmik, Assistant Professor, Department of College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4049/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** • Following sections of IEC form are incomplete/incorrectly filled-type of subjects/special group subject, patient information sheet, risk and benefits. • Calculation of sample size has not been shown as per formula. • Patient information sheet is incorrectly filled. • Same information is repeated in different sections/headings. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIC/P2***
3.	Research proposal entitled ***"Effectiveness of educational package on knowledge regarding respectful maternity care among staff nurse at Queen Mary Hospital Lucknow"*** submitted by Ms. Sushmita Yadav through her guide Mr. Subin S., Assistant Professor, Department of Obstetrics & Gynaecology, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4052/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	Approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIC/P3***
4.	Research proposal entitled ***"Effectiveness of educational bundle knowledge regarding antenatal care and family planning among antenatal Mothers"*** submitted by Ms. Smriti Singh through her guide Mr. Subin S., Assistant Professor, Department of Obstetrics & Gynaecology, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4054/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** • In SOP-Checklist-point no-6 (Confidential handling of data)-not ticked and point no.13–Conflict of interest not ticked –PI to correct. • In Inclusion criteria –Age range of subjects to be recruited- not mentioned • Tool–Questionnaire's validation has not been done-it is awaited **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIC/P4***
5.	Research proposal entitled ***"Effectiveness of nurse led education on knowledge and expressed practice regarding prevention of urinary tract infection among postnatal Mother in selected health centers"*** submitted by Ms. Kajal Mishra through her guide Mr. Rohitash Kumar, Assistant Professor, Department of Community Health Nursing, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4048/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** • Proposal cover letter not signed by the Guide. • Direct identifiers being used and confidential handling is ticked as 'No' • Section on consent all boxes is not ticked. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIC/P5***
6.	Research proposal entitled ***"Effectiveness of reverse pressure softening technique on the level of breast engorgement and breast feeding among postnatal Mothers at Queen Mary Hospital, KGMU, Lucknow"*** submitted by Ms. Nidhi Dwivedi through her guide Mr. Subin. S, Assistant Professor, Department of Obstetrics & Gynaecology, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4047/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** • As annexure 1, both patients & healthy volunteers are included in the study, accordingly separate ICF & information sheet need to be generated. • What will be the role of healthy volunteer and what will be their inclusion criteria. • Kindly define clearly the control & experimental groups.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Kindly submit a flow chart for methodology of this study starting from recruitment to final outcome. • Kindly enumerate the outcome variables & summarize the statistical analysis based upon those variables. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIC/P6***
7.	Research proposal entitled ***"Assess the quality of life of patients diagnosed with idiopathic generalized epilepsy at KGMU Hospital, Lucknow"*** submitted by Ms. Mansi Verma through her guide Dr. Suchana Ray Bhawmik, Assistant Professor, Department of Medical Surgical, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4059/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** • Kindly modify the title of the study to "Assessment of the quality…." • The sample size formula is inappropriate. It is for prevalence study. • The sample size formula shall be based on "reliability coefficient", since this is an assessment of an instrument on quality of life. • The statistical analysis section is missing. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Dr. Hardeep Singh Malhotra did not take part in the discussion & making decision.*** ***Ref. code: XXIV-PGTSC-IIC/P7***
8.	Research proposal entitled ***"A cross sectional study to assess the quality of life among patients with chronic liver disease in tertiary care Hospital"*** submitted by Ms. Divya Pal through her guide Dr. Rashmi P. John, Department of Medical Surgical, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4053/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIC/P8***
9.	Research proposal entitled ***"A study to assess the effectiveness of video assisted teaching programme on knowledge and practice regarding metered dose inhaler among patient diagnosed with bronchial asthma in tertiary care hospital Lucknow"*** submitted by Ms. Akanksha Yadav through her guide Dr. Rashmi P. John, Department of Medical & Surgical Nursing, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4060/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** • As per annexure 1, both patients & healthy volunteers are included in the study. Accordingly separate ICF & information sheet need to be generated.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• What will be the role of healthy volunteer and what will be their inclusion criteria. • The hypotheses H1 & H2 are same. Kindly explain or rectify. • Kindly enumerate the anticipated outcome variables that will be analyzed & summarize the statistical analysis based upon those variables. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIC/P9***
10.	Research proposal entitled ***"A study to assess the nutritional status of infants and effectiveness of educational package on knowledge and practice of mothers regarding feeding habit of infants in pediatric unit at tertiary care Hospital"*** submitted by Ms. Sandhya Singh through her guide Dr. Rashmi P. John, Department of Medical & Surgical Nursing, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4051/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIC/P10***
11.	Research proposal entitled ***"Effect of community based education program on knowledge regarding prevention of minor stroke among middle age adults in selected urban areas"*** submitted by Ms. Komal through her guide Mr. Rohitash Kumar, Department of Community Health Nursing, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4046/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** • In SRC–The Seal of Chairperson is missing • In SOP-Checklist-point no-6 (Confidential handling of data)-ticked as – • No-PI to correct • In Inclusion criteria sex specification not mentioned. Tool-Lesson Plan-Hindi version–not submitted. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIC/P11***
12.	Research proposal entitled ***"Assess the awareness and perceived barrier regarding vasectomy among male population residing in selected rural area of Lucknow"*** submitted by Mr. Mohammad Aquib Ansari through her guide Mr. Rohitash Kumar, Department of Community Health Nursing, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4045/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** • Kindly modify the title of the study to "Assessment of the awareness…." • The study uses direct identifiers and confidential handling is ticked as 'No'

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• Sections on consent-all boxes are not ticked. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIC/P12***
13.	Research proposal entitled ***"Effect of mode of delivery on maternal satisfaction, anxiety, stress depression in primiparous postnatal mothers"*** submitted by Ms. Renu Singh through her guide Miss. Sudha Mishra, Assistant Professor, Department of Obstetrics & Gynaecology, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4047/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** • Seems to be okay and approval may be given. **Comment:** As above **Decision:** Approval subject to modification ***Ref. code: XXIV-PGTSC-IIC/P13***
14.	Research proposal entitled ***"Assess the intimate partner violence, coping and psychological distress among spouses of patient with alcohol use disorder"*** submitted by Ms. Smriti through her guide Miss. Sudha Mishra, Assistant Professor, Department of Mental Health Nursing, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4058/X.51/24 dated 1st January, 2024. ***Recommendation of reviewer:-*** • The sample size formula is inappropriate. It is for prevalence study. • The sample size formula shall be based on "reliability coefficient", since this is an assessment of an instrument on violence, coping and psychological distress. • The statistical analysis section is very general. It should be specific to the objective of the study. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XXIV-PGTSC-IIC/P14***
III-A	**Modification**
1.	Modification of research proposal entitled ***"Assessment of midterm estimated GFR(EGFR) by different formula (24HRS CREATININE CLEARANCE, MDRD, CKD-EPI & NANRA) in patients of hypertensive disorders of pregnancy and its association with fetomaternal outcomes"*** submitted by Dr. Priya Agarwal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/224/2024 dated 27th January, 2024. ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

	• This is basically diagnostic test study. • The title should be : " Comparison of different diagnostic methods for midterm eGFR in pregnant women" • Association should be one of the secondary objectives. It should be deleted from the title. • Sample size calculation is inappropriate. It should use formula (involving sensitivity, specificity) for diagnostic test. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XIV-PGTSC-IIA/P6***
III-B	**Additional Document**
1.	Additional of research proposal entitled ***"A comparative study of ozone therapy and photodynamic therapy as an adjunct to scaling and root planning in chronic periodontitis"*** submitted by Dr. Shilpi Mangal, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 4105/P/24 dated 3rd January, 2024. ***Recommendation of reviewer:-*** • Seal of Chairperson in Scientific review committee report is missing. • Randomized control trial in study design should be replaced by Randomized control study. • On one hand the investigator states that no infective material will be collected (annexure 1 pt 7-vii) but on the other hand the microbiological out come is to be measured. Kindly rectify. • Is the risk not reasonable compared to anticipated benefits? (Annexure 1 pt 10) **Comment:** Kindly provide PGT declaration form. **Comment:** As above **Decision:** Revise & re-submit with response to queries in tabular format. ***Ref. code: XIX-PGTSC-IIA/P4***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(Alok Dhawan)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 131st IEC Meeting held on 13th May, 2024

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the 131st Institutional Ethics Committee Meeting held on **13th May, 2024 from 02:00 P.M. till 5:00 P.M.** in the Board-Room, Administrative Block, King George's Medical University, U.P., Lucknow in ***hybrid mode.***

The following Members were present in the Meeting:

- Dr. J.S. Srivastava -Chairman
- Dr. G.G. Agarwal -Member
- Dr. Amit Goel -Member
- Dr. Pradeep Maurya -Member
- Dr. Ritu Karoli -Member
- Dr. Meenakshi Pawha -Member
- Mr. Jayant Krishna -Member
- Dr. Rajeev Kumar Singh -Member
- Dr. D.N. Upadhyaya -Member & Additional Member-Secretary
- Dr. Mohammad Kaleem Ahmad -Member
- Dr. Riddhi Jaiswal -Member
- Dr. Rahul Kumar -Member
- Dr. Sujita Kumar Kar -Member & Vice Dean
- Dr. Hardeep Singh Malhotra -Member-Secretary, ex-officio

The following Member was not present in the Meeting:

- Hon'ble Justice Ritu Raj Awasthi

IA	Action Taken PGTSC Subcommittee held on 08-05-2024
1-	Clarification of research proposal entitled ***"Effect of mindful meditation an anxiety, haemodynamic parameters and inflammatory markers on patients undergoing surgery for varicose veins"*** submitted by Dr. Chaitanya Gahlot, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/627/24 dated 5th March, 2024. **Previous Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• The project is written in a sketchy way. To write a proposal a proper description of the problem statement along with a relevant review of literature, existing research gap, relevance of the study along with objectives to be there, which is missing? Further, there is a need for suitable methods to address the concerns. The introduction of the study barely talks about the research gap as per the topic chosen for the study. Methodology also not gives any clue about the strategy that is to be adopted for mindful meditation. • Who will guide modification techniques? ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** According to the clarification, the Sr. Chief PI will be responsible for the meditation procedure. Approval to the study may be provided in consensus with the learned committee members. **Decision:** Level 4: Not approved. ***Ref. code: XXI-PGTSC-IIA/P81***
2	Research proposal entitled ***"Laboratory markers of hematoma expansion in acute intra cerebral haemorrhage patients: A prospective observational study"*** submitted by Dr. Saritesh Kumar Thakur, SR, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 109/Neuro/24 dated 6th March, 2024. ***Recommendation of reviewer:*** • The plan of study is very clear • However, the entire Introduction under PROJECT SUMMARY is a mismatch to the proposal. To be re-written • In annexure 7, point no 20, name of Member secretary, IEC to be removed **PGTSC Comment:** As above **PGTSC Decision:** Level 1: Approved – with or without suggestions or comments ***The aforementioned comments were sent to the Principal-Investigator vide letter no.291/Ethics/2024 dated 09-05-2024 reply received from PI by email dated 09-05-2024.***

PGTSC COMMENT	CLARIFICATION WITH CHANGES ACCORDING TO COMMENT
However, the entire Introduction under Project Summary is a mismatch to the proposal. To be rewritten.	Intracerebral hemorrhage (ICH) is a devastating neurological event marked by the sudden rupture of blood vessels in the brain, leading to hematoma expansion and perilesional edema. These complications can cause increased intracranial pressure,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	secondary brain injury, and poor outcomes. Understanding the mechanisms underlying these processes is crucial for managing acute ICH effectively. Factors like low serum calcium, elevated RDW, altered leukocyte counts, low LDL and total cholesterol, and high serum ferritin levels are associated with hematoma expansion and edema formation. A prospective observational study aims to explore laboratory markers related to hematoma expansion and perilesional edema in acute ICH patients. By identifying specific biomarkers through serial measurements and comprehensive assessments, the research could enhance prognostication and guide therapeutic interventions, ultimately revolutionizing personalized medicine in ICH management. Rewritten Project Summary is attached.
In annexure 7, point no 20, Name of Member Secretary, IEC to be removed.	Name of Member Secretary, IEC removed as per comment. **20. Contact for further information** **Name of the PI - Dr Saritesh Kumar Thakur** **Address – Department of Neurology, KGMU, Lucknow** **Telephone Numbers – 7879079793** 20. अधिक जानकारी के लिए संपर्क करें पीआई का नाम - डॉ सरितेश कुमार ठाकुर पता - न्यूरोलॉजी विभाग, केजीएमयू, लखनऊ टेलीफोन नंबर – 7879079793 Corrected sheet attached.

Your name and address removed so that you cannot be recognized from it.

17. What will happen to the results of the research/trial study?

If the results get published you shall not be recognized in the document.

18. Who is organizing and funding the research/trial?

The research is being organized by Department of Neurology, King George Medical University, Lucknow and is not being funded by any private or government agency.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	19. Who has reviewed the study? Study has been reviewed and approved by Institutional Ethics Committee, KGMU, Lucknow. **20. Contact for further information** **Name of the PI - Dr Saritesh Kumar Thakur** **Address – Department of Neurology, KGMU, Lucknow** **Telephone Numbers – 7879079793** **21. Legally authorized representative** Legally authorized representative (LAR), under applicable law or judicial authority, can give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by the ethics committee. We Thank you of taking part in this study. **Decision:** Approved ***Ref. code: XXV-PGTSC-IIA/P27***
3-	Research proposal entitled ***"Burden of depression, anxiety, stress among School-going adolescents and factors affecting utilization of mental health services by School going adolescents of Lucknow disterict-A cross-sectional study"*** submitted by Dr. Abhinav Kumar, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1306/CM/24 dated 14th February, 2024. ***Recommendation of reviewer:*** • There are multiple objectives. It is suggested to identify one primary objective and the rest should be clubbed into secondary objectives. **Comment:** As above **PGTSC Decision:** Level 1: Approved – with or without suggestions or comments • Put-up will be IEC Meeting which will be held on 13-05-2024. **Decision:** Approved ***Ref. code: XXV-PGTSC-IIA/P18***
IB	**Action Taken of IEC**
1.	Clarification of research proposal entitled ***"Mechanisms of autophagy-mediated cell survival in breast cancers and its implication in therapeutics and diagnostics"*** submitted by Prof. M.L.B. Bhatt, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 1472/RT/2024 dated 21st February, 2024. **Previous comment:** • Clarification related AUTOPHAGE RELATED GENES IN BREAST CANCER • Looks ok. Autophagy related genes-can be simplified. • Just as studies related to genes which can be important modifies of effects of therapies.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Word [UTAK] FOR TISSUE SAMPLE CAN BE REPLACED BY ट्यूमर का नमूना या सर्जरी से निकले ट्यूमर का थोड़ा हिस्सा। ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 116th ECM IIA/P7***
2.	Clarification of research proposal entitled ***"Effect of dopamine as VEGF antagonist on progression of sepsis to septic shock, ALI (acute lung injury) and AKI (acute kidney injury)"*** submitted by Dr. Zia Arshad, Additional Professor, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 75/CCU/2024 dated 26th March, 2024. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** **Previous comment:** • Kindly fill in the left blank spaces in annexure 1 pt 5 (i), such as number of subjects etc. • The 'Study procedure' section of ICF should explain the patient regarding the procedure that he will undergo and that too in patient friendly language. Moreover the corresponding part in Hindi version communicate similar information. • The initial part of patient information sheet mentioning the guidelines should be deleted. In addition the word 'Randomized trial' needs to be avoided altogether. • If there are any anticipated adverse events as per annexure 1 point 11, then they need to be included in ICF & patient information sheet. ***Recommendation of reviewer:*** • The investigator has responded to all the queries of the reviewer. However, one of the co-investigators (Prof. GP Singh) has retired from KGMU. It needs to be corrected. **Decision:** Modified as above ***Ref. code: 116th ECM IIA/P7***
3.	Clarification of research proposal entitled ***"Evaluation of lignocaine HCI as a therapeutic and diagnostic tool in myofascial pain dysfunction syndrome (MPDS0 and internal derangement"*** submitted by Prof. U.S Pal, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences King George's Medical University, U.P., Lucknow vide letter no. OMSD/809/2024 dated 17th February, 2024. **Previous comment:** • As this is not a Clinical Trial and the Drug Lignocaine is already approved in India, therefore SOP-Checklist must be corrected (SECTION-3 and subsections I, ii, iii). • Section 6 – Privacy and Confidentiality–section–I-Indirect Identifier not ticked according to the corrections made by PI in answer to quarries made by Primary Reviewer.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Secondly-in section ii- Confidential handling of data by staff is not ticked as YES • (Therefore PI is required to send corrected and revised SOP-Check list) • In Inclusion /Exclusion criteria–Age/ Sex criteria not mentioned • Study design–PI mentioned it as prospective study, which is to be corrected/clarified, as the study design seems to be prospective Interventional and comparative prospective/post operative study. • For clarity in methodology PI should add Flow chart of the study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 119th ECM IIA/P18***
4.	Clarification of research proposal entitled "***Study on clinical outcomes and drug resistance profile (both phenotypic and genotypic) in MDR tuberculosis patients treated with bedaquiline containing regimen***" submitted by Ms. Rashmi Ratnam, Ph.D. 2021 Scholar through her guide Prof. R.A.S. Kushwaha, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 954/24 dated 22nd April, 2024. **Previous comment:** • Kindly inform if any charges would be levied on the participants/subjects involved. ***The aforementioned comments were reviewed by the Member-Secretary, IEC.*** Provisionally approved **Decision:** Approved ***Ref. code: 126th ECMIIB-Ph.D/P1***
5.	Clarification of research proposal entitled ***"Radiation induced damage in head and neck and its management by hyperbaric oxygen therapy-randomized control study"*** submitted by Prof. Vijay Kumar, Head, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 457/24 dated 9th April, 2024. **Previous comment:** • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 127th ECM IIA/P19***
6.	Clarification of research proposal entitled ***"Development of an efficient post mortem interval (PMI) estimation method using RNA degradation pattern and gene expression in human dental pulp tissue under varied temperature & time intervals"*** submitted by Ms. Amita Sangwan, Ph.D. Scholar under the guidance of Prof. Shalini Gupta, Head,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 3081/OP/24 dated 22nd March, 2024. **Previous comment:** • Hypothesis not provided. • In the consent form (both Hindi and English) it is mentioned that it is and in vitro study. • However, on going through the methodology it is not clear what in vitro studies are to be performed. • RNA isolation protocol not provided. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 127th ECMIIB-Ph.D/P1***
7.	Clarification of research proposal entitled ***"Usefulness of receiving prepared cytology smears over those prepared under direct vigilance of a Pathologist"*** under supervision of Prof. Riddhi Jaiswal, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 591/24 dated 1st May, 2024. **Previous comment:** • As title of the study suggests usefulness of a method over other but criteria or definition of usefulness is not defined. It should be clearly defined. • Study type and design is not clearly mentioned in the proposal under respective headings though it has been declared as retrospective study in the covering letter of EC review and clearance. • There is ICF form in the proposal. The PI should fill the form of consent waiver form. • After reading whole proposal it seems to be done already. The proposal should be revised in a manner that it reflect that the study will be done after getting ethical approval. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** • **The project may kindly be approved and waiver granted as requested since the study does not have any patient/subject identifying data.** **Decision:** Approved ***Ref. code: 128th ECM IIA/P5***
8.	Clarification of research proposal entitled ***"Centre of Excellence for adolescent Health and Development in KGMU, Lucknow"*** submitted to NHM (National Health Mission) under supervision of Prof. Sujata Deo, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1001/23 dated 12th April,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	2024. **Previous comment:** • Title should be "Justification for establishment of Centre of Excellence for adolescent Health and Development in KGMU, Lucknow." • Identify one primary objective and the rest should be clustered into secondary objectives. • Identify study variables and population parameters. • Convert the primary objective into "research hypothesis" using the study variables and parameters of step 3. • Sample size calculation is arbitrary. It should be specific to the research hypothesis of Step 4. • The statistical analysis section is very general. It should be in tune with the research hypothesis and other objectives of the study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 128th ECM IIA/P10***
9.	Clarification of research proposal (Expedited review) entitled ***"Uncovering the gene expression profile of programmed cell death ligand 1 (PD-L1) gene and its polymorphism and its association in regulation to platinum drug resistance in head and neck squamous cell carcinoma"*** submitted by Prof. Navin Singh, Department of Radiotherapy, K.G's Medical University, U.P., Lucknow vide letter no. 279/RT/2023 dated 7th March, 2024. **Previous comment:** • Annexure 1 point 10 still needs to be rectified. • Annexure 1 point 8 (ii) needs to be mentioned as YES or No. • The information sheet mentions inclusion criteria for healthy subjects as having cancer while inclusion criteria of cases as having no cancer. Kindly correct • Statement 10.i you did specify that there will be no risk to both the case and the control; kindly correct it. • Please Hindi ICF should be in layman language. ***The aforementioned comments were reviewed by the Member-Secretary, IEC.*** Provisionally Approved **Decision:** Approved ***Ref. code: 129th IEC IB/P5***
10.	Clarification of research proposal entitled ***"Development implementation and evaluation of protocolized cardio-obstetric care in improving maternal cardiac, obstetric and fetal outcomes of pregnant women with heart diseases in India"*** funded by ICMR, New Delhi submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 11/Cardio/Res/24 dated 12th April, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Previous comment: • This is a comprehensive study consisting of many objectives. • The study must be split into different parts. • Each part requires formulation of research hypotheses, identification of outcome measure, calculation of sample size etc. • The research hypothesis will be in terms of study parameters (Such as mean, standard deviation, prevalence etc.). • This is a multi-centric study. • There are certain guidelines for multi-center studies. These must be followed. Only a list of potential sites is given. The name of participating centres is required. • What will be the common protocol? • Which will be a coordinating center to collect, process and analyze the data? • The number of field sites varies greatly across studies according to their size, complexity and purpose. How will this be handled? • Sample size calculation is arbitrary. Only tentative numbers are mentioned. This is due to the fact that the aim/objective is not clearly defined. The outcome event should be clearly defined. The primary objective should be converted into a proper research hypothesis in terms of the study variables and parameters. • Sample size calculation (using appropriate formula) will be required. • Data analysis plan is very general. It should be specific to the research hypothesis. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P1***
11.	Clarification of research proposal entitled ***"Influenza vaccine to reduce cardiovascular events in patients with recent myocardial infarction: a multicentric randomized, double-blind, placebo-controlled trial"*** submitted by Prof. Sharad Chandra, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 60/Cardio/Res/24 dated 30th April, 2024. **Previous comment:** • This is a multi-center randomized controlled trial (RCT). • This is a multi-centric study. • There are certain guidelines for multi-center studies. These must be followed. Only a list of potential sites is given. The name of participating centres is required. • What will be the common protocol? • Which will be a coordinating center to collect, process and analyze the data? • The number of field sites varies greatly across studies according to their size, complexity and purpose. How will this be handled? • Sample size calculation is arbitrary. Only tentative numbers are mentioned. This is due to the fact that the aim/objective is not clearly defined. The outcome event

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	should be clearly defined. The primary objective should be converted into a proper research hypothesis in terms of the study variables and parameters. • Sample size calculation (using appropriate formula) will be required. • Data analysis plan is very general. It should be specific to the research hypothesis. • The method of randomization is not given. • A mere statement that so many patients with such and such diagnosis were randomized is unsatisfactory. • The method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.) is required. • Was there any blinding procedures used? • Was there any randomization blinding? • Was there any blinding of patients? • How is the handling of withdrawal done? ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P4***
12.	Clarification of research proposal entitled ***"Effect of stress management and resilience training through meditation (SMART-Me) (Soft Skill Development) programme on psychological resilience and well-being of paramedical students: A case control experimental study"*** submitted by Dr. Bhupendra Singh, Additional Professor, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 163/DGMH/24 dated 27th April, 2024. **Previous comment:** • The design of the study needs clarification; it can either be a "case-control" or an "experimental" study. • Has this SMART-Me technique been implemented before? • Kindly mention the reference for SMART-ME technique of medication and it will be better to include a Co-Investigator qualified for implementing yoga technique. • Has this SMART-Me technique been implemented before? • Is the risk not reasonable compared to benefit? (Annexure 1 point 10) • Information sheet & ICF need to be customized for controls & cases separately. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P5***
13.	Clarification of research proposal entitled ***"Antenatal myomectomy: A surgical challenge"*** submitted by Prof. S. P. Jaiswar, Head, Department of Obstetrics &

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1059/24 dated 19th April, 2024. **Previous comment:** • Retrospective approval for a completed study/analysis cannot be granted. ***The aforementioned comment was reviewed by the Member-Secretary, IEC.*** • Process for "Waiver of consent" **Decision:** Not approved ***Ref. code: 130th ECM IIA/P10***
14.	Clarification of research proposal entitled ***"Medical and psychiatric comorbidities among patients with alcohol dependence: A multi-center study from India"*** submitted by Dr. Amit Singh, Assistant Professor, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 2794/Psy/24 dated 26th April, 2024. **Previous comment:** • Content written under-sampling and sample size subheading to be rechecked and modified. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P11***
15.	Clarification of research proposal entitled ***"Thought, language and communication in schizophrenia and related disorders: A cross-sectional study using speech data"*** submitted by Dr. Sujit Kumar Kar, Additional Professor, Department of Psychiatry King George's Medical University, U.P., Lucknow vide letter no. 2793/Psy/24 dated 26th April, 2024. **Previous comment:** • To analyze the qualitative data one needs to choose a distinct style. All the approaches stated in the proposal are different from each other in a qualitative framework. Thus, a specific method needs to be applied giving can be-fitting reason. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P12***
16.	Clarification of research proposal entitled ***"Efficacy and Safety of Platelet Rich Plasma as an adjunct therapy to split thickness skin graft in burn patients with granulating raw wounds"*** submitted by Prof. Vijay Kumar, Head, Department of Plastic Surgery, King

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	George's Medical University, U.P., Lucknow vide letter no. 465/24 dated 9th April, 2024. **Previous comment:** • In the consent form it is mentioned that there will be no any complication associated with the study. However, there may be transfusion related adverse reactions or events associated with immune-mediated reactions which may be mentioned. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P13***
17	Clarification of research proposal entitled ***"Study of stigma and discrimination among people living with HIV AIDS (PLHIV) and key population in Uttar Pradesh"*** submitted by Dr. Rajeev Misra, Assistant Professor, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 72/CM/24 dated 13th April, 2024. **Previous comment:** • The title should be more explicit defining the target population exclusively. • The present study looks like to be multi-stage stratified random sampling. • It should be accordingly planned. • The sample size calculation will use stratified sampling methods, may be proportional allocation. • Nothing is said about the reliability of the instrument. • Nothing is said about the face validity and content validity of the instrument. • What is the construct validity of the instrument? • Research hypothesis should be defined in term of the population parameters involved in the study. • The population parameters will be derived from the quantitative evaluation of the instrument being used. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P16***
18.	Clarification of research proposal entitled ***"Identifying host-protein biomarkers for predicting infectious disease in low resource health care settings; and experimental study to enhance infectious disease surveillance"*** submitted by Prof. Avinash Agarwal, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1155/2024 dated 3rd April, 2024. **Previous comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Dated 13th May, 2024

	• Grant of waiver of consent is being approved with the understanding that all analyses shall be performed in house and none will be transported outside the campus. ***The aforementioned comments were reviewed by the Member-Secretary, IEC.*** **Decision:** Approved ***Ref. code: 130th ECMIIA/P18***
19.	Clarification of research proposal entitled ***"Acceptability of value added courses in Pathology for phase 2 MBBS students"*** submitted by Prof. Riddhi Jaiswal, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 529/24 dated 16th April, 2024. **Previous comment:** • Nothing is said about the reliability and validity of the instrument. • How be the instrument converted into quantitative score? • Research hypothesis will be in terms of the study parameters (mean, proportion etc.) derived from the quantitative scores. • Sample size calculation is not given. • Statistical analysis (quantitative as well as qualitative) has to be more specific. At present, it is unclear. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 130th ECMIIA/P21***
20.	Clarification of research proposal entitled ***"Identification of novel metabolic biomarkers in drug resistant pulmonary tuberculosis patients using metabolomics"*** submitted by Ms. Sushma Yadav, Ph.D. Scholar, under the guidance Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 986/Res/24 dated 2nd May, 2024. **Previous comment:** • Unrelated project information is mentioned in the IEC under the sponsor information. • Role of investigators to be redefined? • IEC proforma to be filled properly. There is a mismatch in no. of subjects in the proposal and IEC. proforma • Inclusion criteria should mention subjects/ patient age groups. • Who will be the control? Inclusion and exclusion criteria of control to be mentioned. • Who will be responsible for investigations of the control group? • Who will take the responsibility for extracting blood sample, storage etc. • Methodology to be checked thoroughly and written properly. • ICF and patient information sheet to be written properly.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• As mentioned in the form, this study has already been conducted; hence, retrospectively ethical approval cannot be granted. • Kindly provide evidence of funding for metabolomics study. • Prospective nature? • Check the ICMR project/proposal. • Source of funding/Medicine-Metabolomics ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 130th ECMIIB-Ph.D/P1***
21.	Clarification of research proposal entitled ***"Evaluation of ctDNA/cfDNA ratio as a biomarker of oral squamous cell carcinoma progression through high throughput sequencing data analysis and real-time PCR"*** submitted by Ms. Ekta Anthony, Ph.D Scholar, under the guidance Prof. Shalini Gupta, Head, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 3148/OP/24 dated 8th May, 2024. **Previous comment:** • There are too many objectives. • Methodology to be written sequentially. • Who will be responsible for extracting blood and tissue samples as well as their storage and analysis? • Who is going to bear the cost of investigation(s). • The consent form is to be written in simple language. • Prospective nature? • Check the ICMR project/proposal. • Source of funding: Patients/PI ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** • The investigator responded to all the queries. But, I don't understand why the waiver form is attached along with informed consent form. That too, the waiver form is of a different study with a sign of different investigator (Please check the attachment here). **Decision:** Approved ***Ref. code: 130th ECMIIB-Ph.D/P2***
22.	Clarification of research proposal entitled ***"Elucidation of the interactions of inflammasome and cytokines in oral cancer"*** submitted by Ms. Shatakshi Naang, Ph.D. Scholar, under the guidance Dr. Sayali Mukherjee, Assistant Professor, Amity Institute of Biotechnology, Amity University Lucknow, Co-Guide Dr. Fahad Mansoor Samadi,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Additional Professor, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 3110/OP/24 dated 16th April, 2024. **Previous comment:** • Neither aim nor hypothesis of the study is given. • Amount of blood to be taken is also not mentioned. • How DNA will be extracted is not mentioned. • Where is it registered? • Funding ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 130th ECMIIB-Ph.D/P3***
23.	Clarification of research proposal entitled "***Estimation of polychlorinated bi-phenyl (PCB) & brominated flame retardants (BFRs) in the blood of workers at E-waste recycling sites***" submitted by Ms. Rakhi Rajput, Ph.D Scholar under the guidance Dr. Shiuli, Associate Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 157/FMT/24 dated 24th April, 2024. **Previous comment:** • It is not clearly mentioned how much blood will be collected. (Just mentioned that 4-10 ml of the blood will be taken) • It is unclear who would fund the project and how expenses would be managed. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Approved ***Ref. code: 130th ECMIIB-Ph.D/P5***
24.	Clarification of research protocol no. OPX-PR-03 entitled "***Randomized, double-blinded, placebo-controlled study to evaluate the safety, tolerability, and efficacy of intravenous varespladib followed by oral varespladib in addition to standard of care in subjects bitten by venomous snakes***" sponsored by M/s Ophirex, Inc submitted by Dr. Medhavi Gautam, Assistant Professor, Department of Medicine, King George's Medical University, U.P., Lucknow, vide letter no. CT/RM/31/2024 dated 9th April, 2024. **Previous comment:** • Sponsor is Ophirex Inc. Contract research organization is Syneos Health. CDSCO approval has been sought by M/S InVentiv International Pharma Services Pvt. Ltd. CTA is with Syneos?

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• CDSCO letter does not mention KGMU site. • Insurance policy is lapsing in June 2024. • It is unclear who would fund the project and how expenses would be managed. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision: Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 130th ECM IIC/P2***
25.	Clarification of research protocol no. PB016-03-01 entitled ***"A randomized, double-blind, multicenter phase 3 study in patients with moderately to severely active ulcerative colitis (UC) to compare the efficacy, safety and immunogenicity of PB016 and entyvio® for the induction and maintenance of clinical response and remission (UCESIVE)"*** sponsored by M/s Polpharma Biologics S.A. Trzy Lipy submitted by Prof. Abhijit Chandra, HOD, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SGE/CT/28/24 dated 6th May, 2024. **Previous comment:** • IEC form Section 3 (iii) not completed. • Section 7 of IEC form mentions no biological materials being used, but section 7(ix) mentions that samples will be sent abroad. • Section 8 on consent is incompletely filled. • Section 5(v) of IEC form mentions subject as those with constipation, however the study is being done on subjects with ulcerative colitis. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 130th ECM IIC/P5***
26.	Clarification of research protocol no. HCR/IV/TRUMAB/05/2022 entitled ***"A phase IV multi-centric, post-marketing study evaluating the safety, immunogenicity and efficacy of the marketed formulation of hetero-trastuzumab in female patients with HER2+ breast cancer"*** sponsored by M/s Hetero Biopharma Limited submitted by Dr. Naseem Akhtar, Additional Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/954/24 dated 16th April, 2024. **Previous comment:** • Justification of sample size of 200 not provided. • KGMU site not mentioned in DCGI letter. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Provisionally Approved **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 130th ECM IIC/P9***
27	Clarification of research protocol no. #: R3918-PNH-2050 entitled ***"An open-label extension study to evaluate the long-term safety, tolerability, and efficacy of pozelimab and cemdisiran combination therapy in patients with paroxysmal nocturnal hemoglobinuria"*** sponsored by M/s Regeneron Pharmaceuticals, Inc submitted by Dr. S.P. Verma, Additional Professor & Head, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. CH/CT/04/24 dated 12th April, 2024. **Previous comment:** • Under Sponsor information in IEC form, section 3 (Industry) is incomplete. • Section on Clinical trial (3(i)) mentions that the study is for device/vaccines. • DCGI approval mentions the name of Dr A K Tripathi as the PI. Insurance certificate has the name of Dr S. P. Verma. Kindly submit an amendment and ensure that the Insurance is valid. • This study is a continuation of a study under Dr A K Tripathi, ex-Head, Department of Clinical Hematology. Kindly get the same amended. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 130th ECMIIC/P10***
28.	Clarification of research protocol no. EX601/-4979 entitled ***"ARTEMIS Effects of ziltivekimab versus placebo on cardiovascular outcomes in patients with acute myocardial infarction"*** sponsored by M/s Novo Nordisk submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no. 35/Cardio/Res/24 dated 22nd April, 2024. **Previous comment:** • In sponsor information on IEC form, UN Agencies has been ticked. • Contact address of sponsor is missing from IEC form. • Details of 'organs and body fluids' mentioned under section on Biological materials not given. • Adverse events reporting are being done to DSMB as per the IEC form. This needs to be corrected. • DCGI application has been attached, not approval. • Insurance cover is expiring in April, 2024. • Sample size is mentioned as 10,000 in protocol and as 20 in the IEC form. • Has the study been approved at any other site? If yes, kindly submit the same. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Provisionally Approved **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 130th ECMIIC/P12***
IC	**Expedited review**
	Expedited review of the research proposal entitled ***"Reducing C sections by Continuous education (ReSCuE) and implementation of strategic models for improvement-A quality improvement study"*** Prof. S.P. Jaiswar, Head, Department of Obst. & Gynaecology, K.G's Medical University, U.P., Lucknow vide letter no. OG/1060/24 dated 19th April, 2024. ***The above research proposal was forwarded to two reviewers.*** ***Recommendation of First reviewer:-*** • The PI/Co-PI of the project can not be part of the scientific review committee. Hence, it is recommended to identify a member outside the investigating to be member of scientific review committee and become the chairperson as well. • Kindly refer to the point number 10.i of IEC proforma. The response should be YES (as the risk is reasonable [i.e minimal in comparison to the benefits]). • Kindly refer to the undertaking of the PI form: Under the point number 3 (Other members of the research team) only the name of three Co-Investigators are mentioned however, there are six co-investigators as mentioned the proposal. Kindly clarify it. Similarly, the document mentioning the roles and responsibilities of the investigators also mentions the names of three Co-PIs. It is required to confirm whether there are three Co-PIs or six Co-PIs. • There is mismatch of the project title in multiple places. • In the IEC proforma point no. 10.iii, the investigators mentioned there is direct benefit to the patient. However, in the patient information sheet (point number 2), the investigators mentioned that there is no direct benefit to the patient. It is a contradicting statement and needs clarification. • The patient information sheet also mentions (point number 3), there is no involvement of patient directly in the study and information will be taken from the case sheets. If there is no direct involvement of the patients, what is the need of taking consent from the patient? The investigator may ask for waiver of consent by attaching appropriate forms with IEC proforma. • There is no information about sample size estimation in the protocol. Kindly mention it. ***Recommendation of secondary reviewer:-Pending*** ***Ref. code: 131st ECMIC/P1***
II-A	**New Proposal**
1.	Research proposal entitled ***"Post burn scars and contractures: A Hospital based study of the burden of disease, socioeconomic and clinical factors affecting the outcome, and steps to mitigate them"*** submitted by Prof. Vijay Kumar, HOD, Department of Plastic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 238/24 dated 17th February, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Recommendation of reviewer: • Control arm is lacking • Need Ascent from adolescent because all age group will be included • Consent from legal guardian of children will also be required **Comment:** • IEC form to be corrected as per study design • ICD & PID contact details to be added • Clarification required on 'Multicentric study' **Decision:** • Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P1***
2.	Research proposal entitled ***"Selective antibiotics when symptoms develop versus universal antibiotic therapy for neonates at-risk of early-onset sepsis: A multicentric, randomized, controlled, non-inferiority trial (The SAUNA Trial)"*** submitted by Prof. Mala Kumar, Head, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 263/Ped/24 dated 22nd February, 2024. ***Recommendation of reviewer:*** • Risk shall be explained more clearly, particularly for those who will not receive antibiotics at birth, in informed consent form. • Patient information sheet, Q20 shall not be written as "NO" because it is a drug trial • Sample size: 7% of non-inferiority margin for 20% of outcome is equal to almost 35% increased risk, which I feel is too much of a risk for newborns • How SNOSE technique will be used in a multicentric study??Whether random number sequence will separately be generated in each center? **Comment:** • ICMR sanction letter. • Vulnerable subjects to be marked specifically • Patient Information Document (PID) • Justification of increased risk • Clarify DSMB clearance • Clarification required on compensation and insurance details • Undertaking that they are a part of the proposal/project, is to be annexed. **Decision:** • Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P2***
3.	Research proposal entitled ***"Evaluation of clinic-pathological characteristics, prognostic factor and treatment outcomes in Children with osteosarcoma"*** submitted by Dr. Nishant Verma, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 320/Ped/24 dated 28th February, 2024. ***Recommendation of reviewer:*** It is a single center study or multicentric study as shown in Google form

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	It is a retrospective study as stated by the investigator. Considering the retrospective nature of the study, investigators shall clarify the following • How they will track the participants for consent • How they will collect blood sample and bone marrow sample from the participants? • How they will meet the expenses needed for genetic analysis? **Comment:** • Funding of the project is missing in the IEC form. **Decision:** • Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P3***
4.	Research proposal entitled ***"Effectiveness of self directed learning in Physiology for phase 1 undergraduate Medical Students"*** submitted by Prof. Archna Ghildiyal, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3792/PHY/24 dated 1st March, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: 131st ECM IIA/P4***
5.	Research proposal entitled ***"Lymph node yield in classical Glenn's versus extended lymph node dissection of cancer gall bladder: observation from an endemic area"*** submitted by Prof. Abhinav Arun Sonkar, Head, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 526/24 dated 29th February, 2024. ***Recommendation of reviewer:*** Though the investigators have submitted this study as a retrospective study and have asked for waiver of consent but actually it is a prospective study. In last paragraph of page 9, it is mentioned that the participants will be followed quarterly and repeated CT will be done every 6 monthly. In my opinion, this study has a few major ethical issues (consent, risk of radiation with repeated CT, cost of follow-up, and cost of repeated CT). Proposal is grossly incomplete and shall be resubmitted with more details for being considered in next meeting. **Comment:** • Clarification on whether the same patients would be followed or there would be another set of patients, is required. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P5***
6.	Research proposal entitled ***"Bile leak following surgery for hydatid cyst of liver: when to intervention?"*** submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	SG/173/24 dated 1st March, 2024. ***Recommendation of reviewer:*** Approved **Comment:** The design of the study needs clarification, along with how the data would be captured (prospective versus any other method) **Decision:** Level 2: Revision with minor modifications/amendments for resubmission. ***Ref. code: 131st ECM IIA/P6***
7.	Research proposal entitled ***"Progressive familial intrahepatic cholestasis in Indian Children-establishing an Indian PFIC Registry"*** submitted by Dr. Sanjeev Kumar Verma, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 280/Ped/24 dated 22nd February, 2024. ***Recommendation of reviewer:*** Investigators have written that no blood sample will be collected but the primary objectives include genetic analysis. How they will do genetic testing without blood sample, this need to be clarified. Further, they have also asked that no specimen will be stored for future research. **Comment:** As above **Decision:** • Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: 131st ECM IIA/P7***
8.	Research proposal entitled ***"Comparative outcomes of intramedullary nailing for diaphyseal forearm fracture in Paediatric and adolescent age group"*** submitted by Dr. Syed Faisal Afaque, Assistant Professor, Department of Paediatrics Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 2902/PaedOrtho/24 dated 7th March, 2024. ***Recommendation of reviewer:*** The proposal is full of major mistakes and shall be resubmitted after revision. • Page 4- it is written that it is not a trial but study design is written as RCT. • Sample size calculation is not given. • Arms proposed in this RCT are not acceptable because the participants are of different age groups but treatment are same. In my opinion, the investigator shall take help of someone who has experience in writing a protocol because major components of RCT are missing in the proposal. **Comment:** • Sponsor information and funding letter is required • MOU details are missing • Details of Insurance and compensation mechanism are not available • ICD and PID to be added/revised

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Assent forms to be added **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P8***
9.	Research proposal entitled ***"To decipher the immunomodulatory potential of the blue-green algae and algal nano-formulation"*** submitted by Prof. D. Himanshu, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 573/MED/24 dated 12th March, 2024. ***Recommendation of reviewer:*** Approved **Comment:** • Sponsor information and funding letter is required • MOU details are missing • Annexure 9: Add contact details • PID is required for all the groups included as participants in the study • It is unclear how the blood samples would be handled? • Role of Co-PIs is missing **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P9***
10.	Research proposal entitled ***"Elucidating the role of long non-coding RNSs (Inc RNAs) in HIV latency"*** submitted by Prof. D. Himanshu, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 572/MED/24 dated 12th March, 2024. ***Recommendation of reviewer:*** Approved **Comment:** • Sponsor information and funding letter is required • MOU details are missing • Annexure 9: Add contact details • PID is required for all the groups included as participants in the study • It is unclear how the blood samples would be handled? • IEC: Vulnerable groups/Elderly information is required • Kindly clarify on the median age-40. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P10***
11.	Research proposal entitled ***"Knowledge, attitude and perception of medical students regarding implementation of elective modules"*** submitted by Prof. Rakesh Kumar Dixit, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 185/Pharma/24 dated 6th March, 2024. ***Recommendation of reviewer:*** Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P14***
15.	Research proposal entitled ***"Long term outcome of esophageal replacement in Children"*** submitted by Prof. J. D Rawat, Head, Department of Paediatric Surgery, King George's Medical University, U.P., Lucknow vide letter no. 279/PedSy/24 dated 13th March, 2024. ***Recommendation of reviewer:*** **Comment:** • How the growth assessment will be performed. • 2.What questionnaire will be used to assess the "any problem" in these patients. • 3.Please define the age group of study participant. • 4.What will be the retrospective study duration. • Please include child assent form & guardian information sheet **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: 131st ECM IIA/P15***
16.	Research proposal entitled ***"Evaluation of lectin-like oxidized low-density lipoprotein receptor-1 (Lox-1) insulin resistance and lipoprotein a in the patients of obstructive sleep apnea"*** submitted by Dr. Jyoti Bajpai, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 774/24 dated 15th March, 2024. ***Recommendation of reviewer:*** • There is change of title at various places, please ensure uniformity. • 2.How insulin resistance will be measured. • In the budget estimate summary (page no.15) and prototype development section there is mention of (endoscopy/biopsy) are required. • Please clarify it. **Comment:** • Funding details are required • Define-Controls • Kindly provide UPCST-Letter. • The title should included the study design • Please review the authorship guidelines • Details of blood samples to be furnished **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P16***
17.	Research proposal entitled ***"Morphometric analysis of the lateral mass of atlas vertebrae and its clinical significance in craniovertebral junction surgeries"*** submitted by Dr. Noor Us Saba, Assistant Professor, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 04/ANAT/24 dated 1st April, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Comment: • IEC form 5 vii-Special groups. • Will this be a single Centre study? • Co-PI? • Please note that the consent is to be taken by an independent person where special groups are involved. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: 131st ECM IIA/P11***
12.	Research proposal entitled ***"Bowel-bladder dysfunction in adults: our initial experience with Biofeedback-based pelvic floor relaxation exercises"*** submitted by Dr. Madhur Anand, Assistant Professor, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 176/URO/24 dated 12th March, 2024. ***Recommendation of reviewer:*** Approved **Comment:** Clarification is required whether the PI wishes to process the proposal for 'waiver of consent' or otherwise. Exclusion criteria. Language-Data collection **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: 131st ECM IIA/P12***
13.	Research proposal entitled ***"To assess the knowledge, attitude and practices regarding disposal practices of unused and expired medicines among rural population of sarojininagar, Lucknow"*** submitted by Dr. Saurabh Kashyap, Assistant Professor, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1304/CM/24 dated 14th February, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: 131st ECM IIA/P13***
14.	Research proposal entitled ***"Laparascopic extraperitoneal ventral suture rectopexy (LEVR)"*** submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SG/175/24 dated 4th March, 2024. ***Recommendation of reviewer:*** • The proposal involved surgery with a novel technique which is not the standard of care. Hence, the proposal shall be resubmitted as a single center trial instead of observational study. • It shall meet all the requirements of a clinical trial. **Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Recommendation of reviewer: Approved **Comment:** • Kindly add the Co-PI from Neurosurgery. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: 131st ECM IIA/P17***
18.	Research proposal entitled ***"Cadaveric exploration of the adductor canal: mapping and clinical implications"*** submitted by Dr. Heena Singh, Assistant Professor, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 08/ANAT/24 dated 2nd April, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: 131st ECM IIA/P18***
19.	Research proposal entitled ***"Development and validation of screening tool to screen interstitial lung diseases (ILD)"*** submitted by Dr. Ankit Kumar, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 870/24 dated 2nd April, 2024. ***Recommendation of reviewer:*** • Funding letter to be attached • 2.In the subject selection (page 5-point no.5) it is written that all drug resistant TB cases registered under NTEP for DOTS. Please clarify? • What will be duration of study. • Publication policy and report writing (point no.10, page 19) there is mention of names of Dr. Deepak & Dr. Sandeep Salvi? there names are not mentioned as PI or co-pi at the beginning. • Publication policy there is mention of registry, please clarify. • Patient information sheet to be corrected regarding participants. • **Overall, the projects need major modification and needs to be resubmitted in clear form.** **Comment:** • Kindly provide funding details as well as the MoU • Is this a Multicentric evaluation? **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P19***
20.	Research proposal entitled ***"To study clinical outcomes and safety profile in dug resistant tuberculosis patients treated with bedaquiline containing regimen in Northern India"*** sponsored by UP State Operational Research NTEP, NHM submitted by Prof. Ajay Kumar Verma, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 892/24 dated 4th April, 2024. ***Recommendation of reviewer:*** • Please classify the objectives in to primary and secondary.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Attache the funding letter. • Ethical approval letter from other sites to be attached. • What are the outcome measures? Please define. **Comment:** • Kindly provide funding letter • It has been noted that a similar study is being conducted from the department with the same title; kindly clarify or submit a declaration in this regard. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P20***
21.	Research proposal entitled ***"Evaluating the oxygen preparedness & security: A mixed-method approach for oxygen survey"*** sponsored by Director of Edinburgh Research Office Charles Stewart House submitted by Prof. S. N. Singh, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. Respire/1145/24 dated 3rd April, 2024. ***Recommendation of reviewer:*** • Please mention the delegations of duties, responsibilities, and costing. • Funding letter needs to be attached. **Comment:** • Is there a functional MoU? • Kindly clarify on HMSC approval. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P21***
22.	Research proposal entitled ***"Circulating miRNA expression and its association with preeclampsia, its onset, and severity"*** sponsored by Council of Science & Technology U.P (UP-CST) submitted by Dr. Shuchi Agrawal, Additional Professor, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/956/24 dated 6th April, 2024. ***Recommendation of reviewer:*** • A similar study is being done by PI with **Ref. code: 131stECM IIA/P27.** • The budget mentioned is Rs. 1536000/-(page 5) while it is Rs. 1436000/- in the sanction letter? • Hindi PIS to be corrected like on page 15 it is written "किसी को उम्मीद नहीं थी" **Comment:** • Why should these projects be independent? • Kindly clarify on payment of MiRNA • Clarification is also required on Volunteers/subjects. **Decision:** Further processing of proposal halted due to duplicate submission. ***Ref. code: 131st ECM IIA/P22***
23.	Research proposal entitled ***"Effect of femoral chevron osteotomy fixed with K-Wire on mechanical axis deviation (MAD) and knee joint orientation (KJO) in children with***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	genu valgum- A retrospective study" submitted by Dr. Suresh Chand, Assistant Professor, Department of Paediatric Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 2958/Paed/Ortho/24 dated 9th April, 2024. ***Recommendation of reviewer:*** • It is a retrospective study, how the consent will be taken as per patient information sheet attached. • Can apply for waiver of consent. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P23***
24.	Research proposal entitled ***"A study assessing utility of left sided stellate ganglion block for management of refractory ventricular arrhythmia"*** submitted by Dr. Sudesh Prajapathi, Assistant Professor, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 3079/Cardio/24 dated 8th April, 2024. ***Recommendation of reviewer:*** • In the patient information sheet (PIS) the risk of study can't be none, please modify it and explain the possible risk to patient or relatives. • Guardian information sheet to be included. • Open label randomised term to be removed from the Hindi PIS. **Comment:** Is it an approved procedure? **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P24***
25.	Research proposal entitled ***"A pilot-cross-sectional study to assess knowledge & Attitude of Indian older adults towards advanced care planning"*** submitted by Dr. Akanksha Sonal, Assistant Professor, Department of Geriatric Mental Health, King George's Medical University, U.P., Lucknow vide letter no. 153/DGMH/24 dated 12th April, 2024. ***Recommendation of reviewer:*** • Please include Hindi version of validated scale if available. **Comment:** Validated version of Hindi questionnaire to be used. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P25***
26.	Research proposal entitled "***Comparative analysis of injury pattern caused by diverse animal species: insight for first responders (Prospective Title)***" submitted by Dr. Shiuli, Associate Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 150/FMT/24 dated 12th April, 2024. ***Recommendation of reviewer:*** • What is prospective title? please explain as it seems to be retrospective study. • Please mention the approximate number of subjects. • On page 12 the title includes case series please clarify it?

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Comment: • Source of information. • Outcome variables not defined clearly. • Format for date collection. • Study design. • Case series? • (Study is mentioned inside the protocol.) **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P26***
27.	Research proposal entitled "***Potential role of circulating miRNA and leptin expression as a predictor of preeclampsia, its onset and severity***" submitted by Dr. Shuchi Agrawal, Additional Professor, Department of Obst. & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1132/24 dated 30th April, 2024. ***Recommendation of reviewer:*** • A similar study is being done by PI with **Ref. code: 131stECM IIA/P22.** • On single budgetary approval two projects can't be done. • The budget mentioned is Rs. 1536000/-(page 5) while it is Rs. 1436000/- in the sanction letter? • Hindi PIS to be corrected like on page 15 it is written "किसी को उम्मीद नहीं थी" **Comment:** Why should then be combined justification? **Decision:** Further processing of proposal halted due to duplicate submission. ***Ref. code: 131st ECM IIA/P27***
28.	Research proposal entitled "***Design and development of a non-invasive, smart and portable device for real-time assessment of bone fracture healing progression***" submitted by Dr. Ravindra Mohan, Assistant Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 695/OS/2024 dated 5th April, 2024. ***Recommendation of reviewer:*** • On the cover letter, the proposal is stated as thesis. Please explain it. • The executive summary for the proposal is missing • Annexure 1 Q 5, In the subject selection point vi, you have marked vulnerable subjects as No and elderly subjects as Yes. Please explain. • Annexure 1 Q 8, how will you take consent in oral form? What are the set of questions you will ask them as per your study? • Annexure 1 Q 8, ii, it states that if healthy volunteers will be included in the study, the information sheet for them is to provided. Please attach the same. • Annexure 1 Q 10 ii, you have specified a minimal risk to study subjects. Please specify and explain in the informed consent (English and Hindi) for both case and healthy volunteers. • In the patient information sheet, please provide an appropriate answer to Q3 and Q

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	13 in both English and Hindi. • Sample size calculation is missing **Comment:** • Kindly provide approval letter of funding agency. • Not sure whether budget is approved or not (Supporting document missing) **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P28***
29.	Research proposal entitled "***Design and development of Biomechanical therapeutics to mitigate osteoporosis in Postmenopausal women with diabetes mellitus***" submitted by Dr. Ravindra Mohan, Assistant Professor, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 696/OS/2024 dated 5th April, 2024. ***Recommendation of reviewer:*** • On the cover letter, the proposal is stated as thesis. please explain it. • Annexure 1 Q5, In the subject selection point vi, you have marked vulnerable subjects as No and elderly subjects as Yes. Please explain. • Annexure 1 Q8, ii, it states that if healthy volunteers will be included in the study, the information sheet for them is to provided. Please attach the same. • Annexure 1 Q10 ii, you have specified a minimal risk to study subjects. Please specify and explain in the informed consent (English and Hindi) for both case and healthy volunteers. • Rewrite Patient information sheet in English & Hindi and submit • The executive summary for the proposal is missing • Mentioned the need for oral consent in the proposed project. • Sample size calculation is missing. • Study objectives are missing • Methodology ????? **Decision:** • Approval letter for funding-missing. • Annexure-7 (Patient information sheet-incorrect) • MoU **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P29***
30.	Research proposal entitled "***Knowledge, Attitude and practices regarding disposal of medicines among healthcare professionals, Medical students and patients: A cross-sectional observational study in a Medical University***" submitted by Dr. Suyog Sindhu, Associate Professor, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 320/Pharma/2024 dated 28th April, 2024. ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• The signs of Prof Sanjay Khattri and Dr. Sarvesh Singh are missing from the scientific review committee • Annexure 1 Q8, please mark all the appropriate boxes required in patient information sheet • Re-submit Hindi informed consent with appropriate answers. • The signature at the end of the patient information sheet (Hindi) is missing. Re-submit. • Please re-submit the participant information sheet (English) with all the 21 questions answered. • The executive summary for the proposal is missing. **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: 131st ECM IIA/P30***
31.	Research proposal entitled "***Assessing awareness, perception and attitudes of healthcare professionals and students towerds the environmental impact of pharmaceuticals in India and Malaysia-A mixed method collaborative study***" submitted by Dr. Suyog Sindhu, Associate Professor, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 321/Pharma/2024 dated 28th April, 2024. ***Recommendation of reviewer:*** • The sign of Prof Sanjay Khattri & Dr. Sarvesh Singh is missing from the scientific review committee. • The executive summary for the proposal is missing • The patient information sheet and informed consent, both in Hindi are missing • The signature at the end of the patient information sheet (English) is missing. Re-submit. • Annexure1 Q5vi, in the subject selection, please explain the need of patients in the study • Annexure1 Q8, please mark all the appropriate boxes required in patient information sheet • Co-Pi from Malaysia **Comment:** • Clarification regarding MoU • NOC & ethical approval from Malayasia University. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECM IIA/P31***
II-B	**New Ph. D Proposal**
1.	Research proposal entitled ***"Molecular Epidemiology of corynebacterium diphtheria in Uttar Pradesh"*** submitted by Mrs. Huma Jamal, Ph.D Scholar, under the guidance Prof.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Prashant Gupta, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1440/24 dated 2nd February, 2024. ***Recommendation of reviewer:*** • Budget has been mentioned as NA, so funding provision is not clear. • Direct identifier- yes has been marked • New born to age < 15 years of children will be included so Assent form along with consent forms from parents/ LAR will be needed. **Comment:** (Budget funding for doing molecular technique) patient information sheet (incorrect incomplete) **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: 131stECMIIB-Ph.D/P1***
2.	Research proposal entitled ***"Unraveling the epigenetic pathogenesis of gestational diabetes mellitus"*** submitted by Ms. Deeksha Chahar, Ph. D Scholar, under the guidance Dr. Gyanendra Kumar Sonkar, Additional Professor, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/1319/24 dated 19th March, 2024. ***Recommendation of reviewer:*** • Sample Size has been calculated on the basis of prevalence of GDM(total no.= 225), not seems to be based on objectives • Objectives can se divided into primary and secondary • Not group wise numbers have been given(GDM, Non diabetics or Type 2 DM) • Direct identifier has been ticked **Comment:** • Groups wise division of sample not done. • Sample size estimates erratic **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: 131stECMIIB-Ph.D/P2***
3.	Research proposal entitled ***"Breaking the silence: utilizing documentary media to understand, support, and prevent suicide attempts"*** submitted by Mr. Rohit Kumar Singh, Ph.D Scholar, under the guidance Prof. Anoop Kumar Verma, Head, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 104/FMT/24 dated 13th March, 2024. ***Recommendation of reviewer:*** • Direct identifier in the study can be of ethical concern. • Inclusion of a psychiatrist is suggested. • Statistical analysis can be mentioned appropriate to primary objective. **Comment:** • Role & responsibilities of investigators is missing. • Department/s of Co-PI need correction

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Co-PI from medicine should be added • Qualitative analysis plan is missing. • Clarification on suicide risk assessment scale is required. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131stECMIIB-Ph.D/P3***
4.	Research proposal entitled ***"To decipher the role of hepcidin through STAT and SMAD proteins in determining status of β-thalassemia"*** submitted by Ms. Kirti Upadhyay, Ph.D Scholar, under the guidance Dr. Nitu Nigam, Additional Professor, Department of Centre for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 1426/CFAR/24 dated 21st March, 2024. ***Recommendation of reviewer:*** • In the form sample size is 66, 22 in three subgroups to Thalassemia while in methodology described as case control study – 45 cases and 90 controls • No clarification/definition of controls • Separate PIS and ICF for controls will be needed • Since age less than 18 years so assent forms and LAR or ICF from parents should be enclosed **Comment:** • Sample size discrepancy (distribution) • Source of control (definition) • Information sheet for Assent form missing. • Patient information sheet to be added/modified.. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission. ***Ref. code: 131stECMIIB-Ph.D/P4***
5.	Research proposal entitled ***"To study the molecular mechanism of drug resistance in pneumocystis jirovecii from infected patients admitted in a tertiary care centre in North India"*** submitted by Mr. Vivek Kumar, Ph.D Scholar, under the guidance Prof. Prashant Gupta, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 56/24 dated 16th April, 2024. ***Recommendation of reviewer:*** • If patients age will be >5 years then assent form, parent information sheet and informed consent form for parent is required. **Comment:** • Assent form missing. • Parent information sheet missing. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission. ***Ref. code: 131stECMIIB-Ph.D/P5***
6.	Research proposal entitled ***"Effect of psychological intervention on traumatic stress, coping self-efficacy and quality of life in trauma patients"*** submitted by Ms. Sussana

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Yarusha John, Ph.D Scholar, under the guidance Prof. Samir Misra, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. TS/330/24 dated 19th April, 2024. ***Recommendation of reviewer:*** • Study looks a Qualitative study but Statistical analysis –quantitative analysis • Past tense has been used in statistical analysis. • Sample size calculation rationale/basis can be added. **Comment:** • Everything described in past tense. (It means study is already conducted) • Analysis plan qualitative component missing. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission. ***Ref. code: 131stECMIIB-Ph.D/P6***
7.	Research proposal entitled ***"Integrated transcriptomics and metabolomics analysis of rewired triple negative breast cancer"*** submitted by Mr. Ankit Pateriya, Ph.D Scholar, under the guidance Dr. Ashutosh Shrivastava, Additional Professor, Department of Centre for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. 311/CFAR/24 dated 18th April, 2024. ***Recommendation of reviewer:*** • Study deign has not been mentioned. • Definition of control patients and their number are missing. From where this control tissue/sample will be obtained needs clarification. • PIS and consent form for control is required. • Co-PI from pathology department/can be added. **Comment:** • Exclusive funding for project (Declaration by PI) • Details about control missing. • Consist form for control missing. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission. ***Ref. code: 131stECMIIB-Ph.D/P7***
8.	Research proposal entitled ***"Transcriptional dysregulation of homeobox gene family in oral potentially malignant disorders and oral cancer"*** submitted by Mrs. Jaya Singhal, Ph.D Scholar, under the guidance Prof. Amiya Agrawal, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. DHR/MRU/4769/24 dated 22nd April, 2024. ***Recommendation of reviewer:*** • PIS and consent form for control is required. • Whether tissue samples will be collected from the control is not clear. **Comment:** • Healthy control • tissue biopsy • How it will be done? • Source of healthy controls

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Selecting criteria of healthy controls. • Consent form & Information sheet for healthy controls. • Funding justification? **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECMIIB-Ph.D/P8***
9.	Research proposal entitled ***"Post traumatic stress disorder in patients with maxillofacial trauma and rehabilitation"*** submitted by Dr. Amiya Agrawal, Ph.D Scholar, under the guidance Prof. Anil Kumar Gupta, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 5859/DPMR/24 dated 29th April, 2024. ***Recommendation of reviewer:*** No scientific/ethical issue **Comment:** • Assessment sheet: Is it freely available? • If no, kindly declare the source and cite; it must be mentioned that no special permission is required for using the tool. • There is discrepancy in the assessment & work plan. • Cognitive assessment: Where will this be done? **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECMIIB-Ph.D/P9***
II-C	**Review of New Drug Trial**
1.	Research protocol no. CXXB750A12201 entitled ***"A multi-center, randomized, placebo-and active-controlled, parallel-group, 24 week proof of concept and dose-finding study to evaluate efficacy, safety, and tolerability of XXB750 in patients with heart failure"*** sponsored by M/s Novartis Healthcare Private Limited submitted by Prof. S. K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no. 753/Cardio/Res/2024 dated 27th February, 2024 & 17/Cardio/Res/24 dated 16th April, 2024. ***Recommendation of reviewer:*** DCGI Letter Received **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 131st ECMIIC/P1***
2.	Research protocol no. CT-CE-CREAVALVE-2023 entitled ***"A prospective, multi-centre, single arm, pivotal clinical study to determine the safety and effectiveness of crea aortic valve for use as a replacement aortic heart valve"*** sponsored by M/s Onecrea Medical India Pvt. Ltd submitted by Prof. S. K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 758/Cardio/Res/2024 dated 14th March, 2024. **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 131st ECMIIC/P2***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Dated 13th May, 2024

3.	Research protocol no. D798EC00001 entitled ***"A phase III, randomized, open-label, multi-centre, global study of volrustomig (MEDI5752) as sequential therapy versus observation in participants with unresected locally advanced Head and Neck squamous cell carcinoma, who have not progressed following definitive concurrent chemoradiotherapy (eVOLVE-HNSCC)"*** sponsored by M/s Astra Zeneca submitted by Prof. Vijay Kumar, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow, vide letter no. SONC/1066/2024 dated 24th April, 2024. **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 131st ECMIIC/P3***
III-A	**Modification**
1.	Modification of research protocol no. NN9838-4942 entitled ***"REDEFINE 3: The cardiovascular safety of cagrilintide 2.4 mg.s.c. in combination with semaglutide 2.4 mg s.c. (CagriSema 2.4 mg/2.4 mg.s.c.) once-weekly in participants with established cardiovascular disease called as "REDEFINE 3"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 725/Cardio/24 dated 22nd February, 2024. ***Recommendation of reviewer:*** • The insurance period ended on 30-04-2024. The investigator need to clarify whether the insurance has been renewed as the study period is extended. **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 123rd ECMIIC/P4***
2.	Modification of research protocol no. CKJX839B12302 entitled ***"A randomized, double-blind, placebo-controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT)"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 723/Cardio/24 dated 22nd February, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 114th ECMIIC/P4***
3.	Modification of research updated protocol version 3.1.1 entitled ***"Evaluate the effectiveness, safety and tolerability of various doses of linezolid in combination with bedaquiline and pretomanid in adults with Pre-extensively drug-resistant)PRE-XDR),or treatment intolerant/non-responsive multidrug-resistant (MDRTi/NR) pulmonary tuberculosis in India"*** Sponsored by ICMR-NIRT submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 735/24 dated 7th March, 2024. ***Recommendation of reviewer:*** Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Decision: Defer to the next meeting because quorum was incomplete. ***Ref. code: 109th ECM IB/P7***
4.	Modification of research updated protocol version 3.2 entitled ***"Evaluate the effectiveness, safety and tolerability of various doses of linezolid in combination with bedaquiline and pretomanid in adults with Pre-extensively drug-resistant)PRE-XDR),or treatment intolerant/non-responsive multidrug-resistant (MDRTi/NR) pulmonary tuberculosis in India"*** Sponsored by ICMR-NIRT submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 736/24 dated 7th March, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 109th ECM IB/P7***
5.	Modification of research protocol no. ITI-007-501 entitled ***"A randomized, double-blind, placebo-controlled, multicenter study to assess the efficacy and safety of lumateperone as adjunctive therapy in the treatment of patients with major depressive disorder"*** submitted by Prof. Adarsh Tripathi, Department of Psychiaty, King George's Medical University, U.P., Lucknow vide letter no. 2562/Psy/24 dated 22nd March, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 124th ECMIIC/P2***
6.	Modification of research protocol no. EX6018-4915 entitled ***"Effects of ziltivekimab versus placebo on morbidity and mortality in patients with heart failure with mildly reduced or preserved ejection fraction and systemic inflammation"*** sponsored by M/s Nova Nordisk India Pvt. Ltd submitted by Prof. Monika Bhandari, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 5/Cardio/Res/24 dated 9th April, 2024. ***Recommendation of reviewer:*** • The insurance period ended on 30-04-2024. The investigator need to clarify whether the insurance has been renewed as the study period is extended. • **Insurance 30-4-24** **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 126th ECMIIC/P1***
7.	Modification of research proposal entitled ***"Elucidation of novel prognostic markers and their role in progression of diabetes mellitus-associated neurocognitive disorder (DMAND)"*** submitted by Prof. Shailendra Kumar Saxena, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/16/24 dated 3rd April, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Defer to the next meeting because quorum was incomplete.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Ref. code: 122nd ECM IB/P1
IV	**Re-approval**
1-	Research proposal entitled ***"Electronic capture and machine learning analysis of data pertaining to childhood tuberculosis form tertiary hospitals in India"*** submitted by Prof. Chandra Kanta, Department of Pediatrics, K.G's Medical University, U.P., Lucknow vide letter no.731/Ped/24 dated 26th April, 2024. **Previous Decision:** Approved by 17th September, 2022 ***Recommendation of reviewer:*** Approved **Decision:** Approved *Ref. code: 118th ECMIB/P1*
V	**Missing document**
1.	Submission of study documents (missed in the initial dossier) to the Ethics Committee for review under the research protocol no. PB016-03-01 entitled ***"A randomized, double-blind, multicenter phase 3 study in patients with moderately to severely active ulcerative colitis (UC) to compare the efficacy, safety and immunogenicity of PB016 and entyvio® for the induction and maintenance of clinical response and remission (UCESIVE)"*** sponsored by M/s Polpharma Biologics S.A. Trzy Lipy submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow, vide letter no. SGE/CT/25/24 dated 22nd April, 2024. ***Previous Comment:-*** • IEC form Section 3 (iii) not completed. • Section 7 of IEC form mentions no biological materials being used, but section 7(ix) mentions that samples will be sent abroad. • Section 8 on consent is incompletely filled. • Section 5(v) of IEC form mentions subject as those with constipation, however the study is being done on subjects with ulcerative colitis. **Decision:** Defer to the next meeting because quorum was incomplete. *Ref. code: 130th ECMIIC/P5*
VI	**Other Matter with the permission of Chairman**
1-	Regarding a notification for Urine pregnancy test was performed at baseline (Visit-1) of patients with Subject ID:06-001,06-002 and 06-004, as per Investigator discretion after informing the patient and documenting the same to ensure the patient's safety-Product leaflet attached under the research protocol no.GPL/CT/2022/011/1V entitled ***"An open label single arm, multicentric, prospective, post marketing study to evaluate the safety and effectiveness of fluticasone Furoate/Vilanterol (FF/VI) DPI in the management of asthma patients (Promise OD)"*** submitted by M/s Glenmark Pharmaceuticals Ltd. submitted by Dr. Ankit Kumar, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. RM/12/CT/24 dated 12th April, 2024. **Decision:** Defer to the next meeting because quorum was incomplete. *Ref. code: 128th ECM IIC/P1*

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

2-	Regarding notification for not implementing Assent 7-11 years according to National Ethical Guidelines for Biomedical and Health Research involving Human participants 2017 (ICMR Ethical guidelines 2017), page no. 64, Box 6.6.under considerations for assents it is mentioned that- "For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded". In view of this ICMR ethical guidelines as referred above, all the below listed assent ICF's for the age group of 7-11 years is not required. Since the EC has approved the Assent 7-11 years within the initial approval letter dated 16th March, 2024 under the research protocol no. DEN302 entitled "***A randomized, double-blind, placebo-controlled, phase 3 trial to investigate the safety and immunogenicity of a dengue tetravalent vaccine (Live Attenuated) (TDV) administered subcutaneously to healthy subjects aged 4 to 60 years in India***" sponsored by M/s Takeda Vaccines, Inc. submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/35/2022 dated 28th December, 2022. **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 121st ECM IIC/P2***
3-	Regarding corrections in Patient information sheet and Informed consent form, Assent Form, Subject Diary visit-1, subject diary visit-2 under "***An open label single arm, multicentric, prospective, post marketing study to evaluate the safety and effectiveness of fluticasone Furoate/Vilanterol (FF/VI) DPI in the management of asthma patients (Promise OD)***" submitted by M/s Glenmark Pharmaceuticals Ltd. submitted by Dr. Ankit Kumar, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. RM/13/CT/24 dated 12th April, 2024. **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 128thECM IIC/P1***
4-	Regarding **ICF Erratum** " for subject information sheet and consent form in English, version 02 for India dated 24-01-2023 adapted from the master subject information sheet version 7.0 dated 17th November, 2022 protocol TILD-19-19 M/s Sun Pharmaceutical industries Limited" entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF naive subjects with active psoriatic arthritis II (INSPIRE 2)***" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/58/24 dated 4th April, 2024. **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 122nd ECM IIC/P6***
5-	Regarding declaration of Conflict of Interest under the research protocol no. BIO-PERTUZ-301 entitled "***A multicenter, double-blind, randomized, parallel-group, phase 3 study to compare the efficacy and safety of the proposed biosimilar PERT-IJS and EU-Perjeta® along with trastuzumab and chemotherapy (Carboplatin and Docetaxel) as neo adjuvant treatment in patients with hormone receptor negative (HR-ve) human epidermal growth factor receptor 2 (HER2) positive early stage or locally advanced breast cancer***" submitted by M/s Biocon Biologics UK Limited under supervision of Dr.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Dated 13th May, 2024

	Sameer Gupta, Additional Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow, vide letter no. SONC/576/2024 dated 20th February, 2024. **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 127th ECM IIC/P2***
6-	Regarding notification that KGMU Lucknow and Dr. P.K. Sharma names have been added as new site and as PI from KGMU Lucknow respectively in updated proposal in STENOSIS TRIAL under the research proposal entitled "***Longterm single versus dual antiplatelet therapy in patients with ischemic stroke due to intracranial atherosclerotic disease: A randomized trial***" submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 83/Neuro/24 dated 5th March, 2024. **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 125th ECM IIA/P11***
7-	Regarding translation certificate for Langland & visit cards extension under the research protocol no. CLNA043A12202 entitled "***A 5-year, randomized, double-blind, placebo-controlled, multi-center study assessing the efficacy, safety and tolerability of intra-articular regimens of LNA043 versus placebo in patients with symptomatic knee osteoarthritis (ONWARDS)***" sponsored by M/s Novartis Healthcare Pvt. Ltd. submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no.1076/OS/24 dated 30th April, 2024. **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 114th ECM IIC/P3***
8-	Regarding addendum budget included in CTA for DXA scans, travel reimbursement for unscheduled visit & equipment at site 20210025 Romosozumab (EVENITY®) entitled "***An open-label, single-arm, multicenter phase 4 study to evaluate safety and tolerability of romosozumab (EVENITY®) in postmenopausal women in India with osteoporosis and a high risk of fracture***" sponsored by M/s One Amgen Center Drive Thousand Oaks submitted by Prof. R.N. Srivastava, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no.1076/OS/24 dated 30th April, 2024. **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 121stECMIIC/P3***
9-	Regarding change in collection procedure for ADA and PK testing under the research protocol no. TILD-19-07 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF experienced subjects with active psoriatic arthritis I (INSPIRE 1)***" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow, vide letter no. Rh/CT/74/24 dated 4th May, 2024. **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 122ndECMIIC/P5***
10-	Regarding change in collection procedure for ADA and PK testing under the research

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	protocol no. TILD-19-19 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF naive subjects with active psoriatic arthritis II (INSPIRE 2)***" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow, vide letter no. Rh/CT/75/24 dated 4th May, 2024. **Decision:** Defer to the next meeting because quorum was incomplete. ***Ref. code: 122nd ECMIIC/P6***
VII	**Brought to Ethics Committee after XXV-PGTSC held on 8th May, 2024**
	Minutes of the XXV-PGTSC of IEC Meeting ***in hybrid mode*** held on 08th May, 202 02:00 P.M. till 05:00 P.M. in the Board Room, Administrative Block, King George's M University, U.P., Lucknow. ***The following Members were present in the Meeting:-*** 1-Dr. G.G. Agarwal -Member 2-Dr.Rajeev Kumar Singh -Member 3-Dr. Riddhi Jaiswal -Member 4-Dr. Mohammad Kaleem Ahmad -Member 5-Dr. Rahul Kumar -Member 6-Dr.Sujita Kumar Kar -Vice Dean & Member 7-Dr. D.N. Upadhyaya -Additional Member-Secretary, IEC 8-Dr.Hardeep Singh Malhotra -Convener
IA	**Action Taken**
1	Clarification of research proposal entitled ***"Assessment of midterm estimated GFR (EGFR) by different formula (24 hrs. CREATININE CLEARANCE, MDRD, CKD-EPI & NANRA) in patients of hypertensive disorders of pregnancy and its association with fetomaternal outcomes"*** submitted by Dr. Priya Agarwal, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/2082/22 dated 3rd October, 2022. **Previous Comment:** • The study variables and study parameters should be identified. • The research hypothesis should be properly formulated in terms of study parameters. • The sample size calculation is arbitrary. It can be done only after defining the research hypothesis. Statistical Analysis section is missing. • The study design is mentioned as "prospective case control study".

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• It should be properly mentioned as case-control study is retrospective study. • Statistical analysis section is missing. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XIV-PGTSC-II***
2	Clarification of research proposal entitled ***"Role of diet and lifestyle in colorectal cancer (CRC) - A case control study in Lucknow"*** submitted by Dr. Christopher James, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1457/CM/24 dated 13th March, 2024. **Previous Comment:** • Identify one primary objective; the rest should be put into secondary objectives. • Convert the primary objectives into a proper research hypothesis using the parameters of the study population. • The sample size is arbitrary. Mention the formula used. • How the cases will be matched with controls? • What will be the ratio of matching (1:1 or 1:K)? • The statistical analysis will be for matched study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XVII-PGTSC-II***
3	Clarification of research proposal entitled ***"A comparative study of ozone therapy and photodynamic therapy as an adjunct to scaling and root planning in chronic periodontitis"*** submitted by Dr. Shilpi Mangal, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 4242/P-24 dated 19th April, 2024. **Previous Comment:** • As indicated in annexure 1: is the risk reasonable? Please indicate. • The design of study is Randomized controlled trial. No method of randomization or allocation is indicated. • Sample size calculation needs to be detailed- the formula used and step wise calculation. • The clinical outcomes need further detailing in context with analysis. Kindly list all the anticipated outcomes (Clinical and microbiological). • Arrange the description of proposal in PICO format with emphasis on comparison and outcome, the anticipated STATISTICAL ANALYSIS needs to be

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	summarised. • Being randomised controlled trial involving PDT, the other formalities need to be completed as per RCT. • Patient information sheet in both English and Hindi needs to be submitted as per the SOP of EC KGMU. • Who will fund the project? Kindly indicate? ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **PGT Declaration received.** **Decision:** Approved ***Ref. code: XIX-PGTSC-II***
4	Clarification of research proposal entitled ***"Effect of USG guided intra-articular prolotherapy versus steroid injection for sacroiliac joint dysfunction- A randomized controlled trial"*** submitted by Dr. Ruth Kikon, JRI, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 5816/24 dated 16th April, 2024. **Previous Comment:** • Please attach properly filled Patient Information Sheet ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Previous decision:** • It is unclear whether the desired interventions are approved interventions/standard-of-care, if yes; please include a statement in the proposal. **PGT Declaration received.** **Decision:** Approved ***Ref. code: XIX-PGTSC-IIA/P27***
5	Clarification of research proposal entitled ***"Roles of preoperative and early postoperative electrodiagnosis in brachial plexus injury patients undergoing nerve transfer operations"*** submitted by Dr. Gourav Jain, SR, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 50/23 dated 23rd April, 2024. **Previous Comment:** The scientific committee's decision statement needs to be ticked. • The role of investigators is not defined. • The aim and objectives of this study seem to be interchanged. ***role of preoperative and early postoperative electrodiagnosis in brachial plexus injury patients undergoing nerve transfer operations and its association with***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	electrodiagnostic parameters. • The duration of the study is written as January 2023 to October 2025 • Will the researcher get 34 months for the study? • Is the study started? • Variable no of sample size is written 20 (Checklist & protocol -see materials and methods)/ 31 (in protocol on same pg)? • Hindi ICF may be written in a more comprehensive language. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XIX-PGTSC-IIA/P57***
6	Clarification of research proposal entitled ***"To assess the efficacy of platelet rich plasma (PRP) in patients with partial thickness facial burns as compared to conventional facial burn care"*** submitted by Dr. Shrivats Mishra, SRI, Department of Plastic & Reconstructive Surgery, King George's Medical University, U.P., Lucknow vide letter no. 427/2024 dated 30th March, 2024. **Previous Comment:** • The study design is retrospective as well as prospective. • It cannot be both. Each type of study uses different methodology and analysis and sample size calculation. • It has to be split into two different parts. • Each type shall use different subjects. • Sample size calculation is missing. • From the Case series form, it is not clear: How the disease free survival shall be measured. • Statistical analysis section is very general. It should be specific to the objectives of the study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XIX-PGTSC-IIA/P73***
7	Clarification of research proposal entitled ***"To study the effect of curcumin on inflammatory markers and microbial flora in hemimaxillectomy patients with obturator prosthesis: A randomized controlled trial"*** submitted by Dr. Yangchin Drema, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 995/24 dated 30th March, 2024. **Previous Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• As stated in Annexure 1 this study involves a (herbal) medicine of Indian system of medicine. So it would be better to include an ayurvedic co investigator. • This is stated to be double blind RCT. Kindly mention the technique of allocation, randomization & double blinding. Is placebo not indicated here? • Who will bear the cost of curcumin & tests. Do you plan to register this RCT.?? • Summarize the anticipated outcome variables and anticipated statistical analysis of the same. • Kindly mention the dose, duration , brand and mode of administering curcumin. • No need to submit the SOP guidelines of Pt information sheet. Instead kindly submit the actual patient information sheet both in English & Hindi accordingly. • Kindly revise "purpose of study" & "Study procedure" in ICF in such a language that the patient may understand. • In annexure 1 regarding use of biological specimen it is indicated as "NA" while lower down 'Yes' in indicated for the use of infectious & biohazardous specimen. This is contrasting statement. Also no indication of blood collection is mentioned for IL &TNF? • Kindly refer to CONSORT guidelines for RCT before resubmitting ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P3***
8	Clarification of research proposal entitled ***"Study of sentinel lymph node in gallbladder cancer using indocyanine green dye - A pilot study"*** submitted by Dr. Shiva, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 485/24 dated 27th February, 2024. **Previous Comment:** • Annexure 1 indicates that risk is not reasonable - Explain • Elaborate regarding DSMB as per annexure 1. What are the anticipated adverse events that need to be reported to IEC. • Kindly revise 'purpose of study' & 'Study 'procedure' in ICF in such a way for the patient to understand (Simple Language) • Revise patient information sheet for the patient to understand ESP points 4,6,7,9,13,14, 17. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P18***
9	Clarification of research proposal entitled ***"Assessment of osteoprotegerin (OPG) and***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	implant stability through the topical application of UV irradiated "Vitamin D" on implant surface during placement: A randomized controlled study" submitted by Dr. Singh, JRI, Department of Prosthodontics Crown & Bridges, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 984/24 dated 27th March, 2024. **Previous PGTSC Comment:** • Kindly modify the title *"A randomized control study"* in place of ***"Randomized controlled trial".*** ***The aforementioned comments were sent to the Principal-Investigator, the response to which was reviewed by the Member-Secretary, IEC.*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P21***
10	Clarification of research proposal entitled ***"Analysis of outcome amongst survivors of isolated moderate and severe head injury patients managed conservatively and surgically - A retrospective study"*** submitted by Dr. Biman Chandra Sinha, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 571/NS/24 dated 16th March, 2024. **Previous Comment:** • In Annexure 1 the sample size indicated is 80, while the sample size mentioned inside is 900-1000. Kindly resolve the discrepancy : • Kindly present the steps of sample size calculation. • In annexure 1 the duration of study is stated as 1year while inside it is stated as 2 yrs - kindly rectify. • This is retrospective study. Will retrospective records also be analyzed.? If prospective analysis is to be done then how can it be considered only respective study. Kindly submit a flowchart of patient recruitment with study procedure (Methodology) so as to make methodology more clear. • Kindly revise patient information sheet (esp point 13,15,17,18) and include language that patient can easily understand. • In scientific review committee the HOD seal is missing. • As per annexure1, is the risk not reasonable as compared to anticipated benefits (point no. 10) ? • Kindly elaborate the role of DSMB (point No.11). What sort of adverse events are anticipated that need to be submitted to IEC. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the newly reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P24***
11	Clarification of research proposal entitled ***"A comparison between solitary IMF dental***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	cleat technique with ersnt ligatures and conventional erich arch bars for intermaxillary fixations: a randomized controlled study" submitted by Dr. Rangeet Bhadra, JRI, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 273/OMSD/24 dated 20th March, 2024. **Previous Comment:** • It this is RCT kindly elaborate technique of allocation & randomization. • Kindly refer CONSORT guidelines for better refinement. • Elaborate about DSMB. What about adverse events Kindly indicate in annexure 1(point 11). • If sample size of each group is 17 then why only 15 cases will be recruited in 1st group. • Summarize the anticipated statistical analysis. • Kindly submit Pt information sheet both in English & Hindi. • Kindly indicate the various outcome variables and that should reflect in case sheet. • The ICF should include study procedure in simple language understandable to the patient. It should also include the follow-up protocol. • If this study is of 3 yrs duration then kindly include time line of action in terms of Pt recruitment, data collection, follow-up , analysis etc. • Kindly modify the title ***"A randomized control study"*** in place of ***"Randomized control trial"*** ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the newly reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P25***
12	Clarification of research proposal entitled ***"A comparative study of endoxifen and divalproex in patients with bipolar disorder (Manic Episode)"*** submitted by Dr. Alisha Raj, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 561/Pharm/23 dated 27th July, 2023. ***Previous Comment:*** • Kindly seek PGT declaration form ***The aforementioned comments were sent to the Principal-Investigator, the response to which was reviewed by the Member-Secretary, IEC.*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P29***
13	Clarification of research proposal entitled ***"Study to compare fluorography versus cineangiography at reducing radiation exposure during single vessel PCI"*** submitted by Dr. Pawan Kumar Chaudhary, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 1104/Cardio/24 dated 11th March, 2024. **Previous Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Clarification of research Pages of proposal are disorganized and page nos. are also missing, Pages need to be arranged in an order and protocol to be written following the IEC form point no 4 i.e. Brief description of the proposal. • In material and methods section text needs to be modified as at some of the sentences are written in past tense. • Pt. Information sheet to be adapted and submitted as per the proposal. • ICF to be written in simple and understandable language. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P35***
14	Clarification of research proposal entitled ***"Impact of newer heart failure therapies on health-related quality of life (hrQOL)"*** submitted by Dr. Sidharth Sharma, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 688/24 dated 29th February, 2024. **Previous Comment:** • The patient information sheet needs to be modified as per the study protocol. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P36***
15	Clarification of research proposal entitled ***"Correlation of tumour infilterating lymphocytes (TIL's) as a potential predictive marker for response to neoadjuvant chemotherapy in breast cancer"*** submitted by Dr. Rajat Qanoongo, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 560/SY/24 dated 6th March, 2024. **Previous Comment:** • While the samples will be collected from 2015 to 2022, as indicated in sample analysis, the study sample duration is mentioned till 2023. Kindly resolve the discrepancy. • What is P1 and P2 in sample size? Kindly include the steps of sample size calculation. • Kindly include a copy of semi structured self administered proforma that will be used to extract details. • Kindly explain the short-term survival and how does it include febrile neutropenia / chemo toxicity • How and when will you assess febrile neutropenia and chemo toxicity? Kindly incorporate in your submission.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• In point 10 of annexure 1, do you think that the risk here is not reasonable as compare to anticipated benefits. • Kindly elaborate on DSMB. What are the anticipated adverse events that need to be reported to IEC. • If patient information sheet is attached then where is informed consent form? How will you obtained informed consent retrospectively? There is no consent waiver application either. • Kindly revise the patient information sheet specially points 479 13 14, 1517 and submit English and Hindi version both • By which parametres will you assess the response to neo adjuvant chemotherapy? Is it just the pathological response? Also includes the RECIST criteria. • Kindly summarize the anticipated continuous variables and proportional data that would be analyzed. • The scientific review committee report has not does not have a seal of chairperson. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P49***
16	Clarification of research proposal entitled ***"A study of fasting and postprandial total serum bile acids (TSBA) levels in term pregnant women and it's associated neonatal outcome"*** submitted by Dr. Anshu Choudhary, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/670/24 dated 14th March, 2024. **Previous Comment:** • Vulnerable subjects has been ticked a no and pregnant women as yes. • Reasonable risk has been ticked as No. • Sample size is mentioned as 120 cases in IEC form and 200 cases in the synopsis. • Patient information sheet is incomplete. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P60***
17	Clarification of research proposal entitled ***"Evaluation of psychological symptoms and quality of life amongst women with natural menopause versus surgical menopause - A cross-sectional study"*** submitted by Dr. Khushtar Jabeen, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/626/24 dated 4th March, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Previous Comment: • IEC form to be filled properly. • The introduction of the study needs to be written properly along with appropriate references. • Psychological symptoms include a broad range of indicators that need to be defined. • Will there be any criteria for menopausal patients or any of the female patients consulting OBG/ psychiatry OPD will be taken? And, if so why in exclusion criteria pt. with psychiatric disorders will to be excluded? • The study description needs to be written as point no 4 of the IEC proforma. • The Hindi consent form need to be written in a simple and understandable language. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P65***
18	Clarification of research proposal entitled ***"Study of fever in pregnancy at a tertiary care teaching Hospital"*** submitted by Dr. Deep Shikha, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/561/24 dated 27th February, 2024. **Previous Comment:** • The inclusion criteria include all pregnant females with fever on any occasion while HPE of placenta will be done in selected cases with fever in any trimester. So what are those selected indications? • Summarize all the outcome variables and brief the anticipated statistical annulus. • Rewrite the patient information sheet specially points 11,13,14,15. • Elaborate on DSMB as indicated in Annexure 1. What are the anticipated adverse events that need to be reported to IEC. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P67***
19	Clarification of research proposal entitled ***"A retrospective study of clinic-radiological profile and outcome of medulloblastoma at KGMU, Lucknow for the last five years"*** submitted by Dr. Jason, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 561/NS/24 dated 15th March, 2024. **Previous Comment:** • The study duration in annexure 1 is quoted as 1yr while in methodology section it

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	is quoted as 2yrs? Kindly resolve. • Kindly elaborate regarding DSMB for this retrospective study as mentioned in annexure 1. What are the anticipated adverse events that may be reported to IEC. • The stamp of HOD in annexure1 (last page) in missing. • While annexure 1 indicates written informed consent and ICF is attached accordingly, the data collection section in methodology indicated only "telephone consent "- Kindly resolve. • ICF needs to be revised as text mentioned in " purpose of study." and "study procedure." does not make sense. Kindly revise in the language understandable to the patient. • Kindly re-write the patient information sheet as per SOP of EC KGMU and specially consider points 2,3,4,5,7,9,11,13,14,17 that do not make any sense. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P70***
20	Clarification of research proposal entitled ***"To study oxidative stress and antioxidant status in adolescents and young women with primary dysmenorrhea"*** submitted by Dr. Monika Singh, JRI, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/45/24 dated 12th January, 2024. **Previous Comment:** 1. Methodology incomplete Biochemical estimations (oxidative stress parameters) protocol not provided. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P72***
21	Clarification of research proposal entitled ***"An observational study to estimate the efficacy of statins for LDL-C reduction in acute coronary syndrome and non-acute coronary syndrome patients Indian population"*** submitted by Dr. Saket Ramraika, SRI, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 870/Cardio/24 dated 16th March, 2024. **Previous Comment:** • In annexure 1. the duration of study in 18 m as well as 2yr. Kindly resolve and finalize. • Kindly submit the steps of sample size calculation. • In undertaking by PI, the other members of research team are missing. • In plan of study the follow-up at one place is after 3 months (as per NICE

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	guidelines) While at other place it is stated as monthly for 3 months. Kindly make this clear. • Summarize the anticipated outcome variables. • The ICF does not mention the contact of investigator. • The Hindi version of ICF should be retyped and hind text needs to be corrected. • The patient information sheet should be as per SOP of EC KGMU only. • No need to attached SOP guidelines for patient information sheet. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXI-PGTSC-IIA/P78*
22	Clarification of research proposal entitled ***"Outcome analysis and clinic-radiological profile of patients with intraventricular tumours treated at KGMU"*** submitted by Dr. Mohit Mangla, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 560/NS/24 dated 15th March, 2024. **Previous Comment:** • Kindly define the roles of guides & co guides as per protocol . • If no side effects are expected then what is the role of DSMB, or reporting of adverse events and interim analysis as per annexure 1. • If the aim is to study patients of last 12 years then how can it be a prospective study and how will the consent be obtained - Will the patient be called to decide his/her participation? and rest others excluded ?. • Pt information sheet indicates that it is both retrospective & prospective. Kindly indicate the inclusion of patients (retrospective & prospective) in methodology preferably via flow chart. • Ethical approval is primarily for prospective intervention and not for past procedures. • What is the anticipated sample size (not indicated in annexure 1)-kindly show sample size calculation. • Kindly rectify language for points 5,6,13,15,17 in patient information sheet. • Kindly rectify language in ICF for patient participation as per design of study (prospective or retrospective.) ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXI-PGTSC-IIA/P80*
23	Clarification of research proposal entitled *"Effect of mindful meditation an anxiety,*

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	haemodynamic parameters and inflammatory markers on patients undergoing surgery for varicose veins" submitted by Dr. Chaitanya Gahlot, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/627/24 dated 5th March, 2024. **Previous Comment:** • The project is written in a sketchy way. To write a proposal a proper description of the problem statement along with a relevant review of literature, existing research gap, relevance of the study along with objectives to be there, which is missing? Further, there is a need for suitable methods to address the concerns. The introduction of the study barely talks about the research gap as per the topic chosen for the study. Methodology also not gives any clue about the strategy that is to be adopted for mindful meditation. • Who will guide modification techniques? ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** According to the clarification, the Sr. Chief PI will be responsible for the mediation procedure. Approval to the study may be provided in consensus with the learned committee members. **Decision:** To be put-up in the IEC Meeting scheduled on 13-05-2024. *Ref. code: XXI-PGTSC-IIA/P81*
24	Clarification of research proposal entitled ***"A retrospective study of epidemiology, clinical presentation, surgical intervention and outcome of patients who underwent surgery for aneurysmal SAH from 2015 till 2023"*** submitted by Dr. Shubhrit Tyagi, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 531/NS/24 dated 24th February, 2024. **Previous Comment:** • The Study design indicates that it is a retrospective study & ethical approval is primarily for prospective interception & not for post procedures. • Kindly define the roles of guides & co guides as per protocol . • If no side effects are expected then what is the role of DSMB, or reporting of adverse events and interim analysis as per annexure 1. • If the aim is to study patients of last 8 years then how can it be a prospective study and how will the consent be obtained - Will the patient be called to decide his/her participation? and rest others excluded ?. • Kindly rectify language for points 5,7,13,15,16,17 in patient information sheet. • Kindly rectify language in ICF for patient participation as per design of study (prospective or retrospective.) ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P82***
25	Clarification of research proposal entitled ***"Extensive lymph node dissection in predicting survival in patients with Gallbladder cancer - preliminary data from a tertiary care Hospital in Northern India"*** submitted by Dr. Shiva, JRI through his Mentor Prof. A.A. Sonkar, Head, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 484/24 dated 27th February, 2024. **Previous Comment:** • IEC form is improperly filled. • Use of biological/hazardous material is ticked as 'No' • Sample size calculation has not been done. • Methods sections mentions the design as retrospective, but patient information sheet mentions the study as prospective. Please clarify? • Patient information sheet is incomplete. • Informed consent form in Hindi is incompletely attached. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-II B IMR-R/P2***
26	Clarification of research proposal entitled ***"Evaluation of aloe vera loaded nanofibrous scaffold in vital pulp therapy: A randomized controlled trial"*** submitted by Dr. Anjali Mall, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1004/Cons&Endo/24 dated 28th February, 2024. **Previous Comment:** • It is unclear whether aloe vera loaded nanofibrous scaffold in vital pulp therapy is and approved intervention/standard-of-care. If yes, Please include a statement in the proposal. • Kindly state if AYUSH clearance ID required for the conduct of this study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXII-PGTSC-IIA/P1***
27	Clarification of research proposal entitled ***"Prevalence of aspergillus sensitization and ABPA in asthmatic patients"*** submitted by Dr. Vishal Shukla, JRI, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	786/24 dated 18th March, 2024. **Previous Comment:** • The Scientific review committee does not have seal of Chairperson. • Annexure 1 point 7 states that 'no body fluids or tissue' is to be taken. Then how will 1gE be measured? • Is the risk not reasonable as compared to anticipated benefits? (Annexure 1 point 11) • What are the anticipated adverse events that need to be reported to IEC? (Annexure 1 point 11) • Revise the ICF so that patient may better understand specially the study procedures. • Patient information sheet is for pleural effusion (point 4 & 5)? What is the role of biopsy? If biopsy is to be under taken then kindly mention in annexure 1 point 6 does not make any proper sense. Kindly re-write the entire Patient information sheet (both English & Hindi version) • Kindly indicate in which body tissue 1gE will be estimated. • Kindly given details of ACT 7 GINA 16 ptom control. • Kindly summarize the various outcome variables and statistical analysis as those variables. • Kindly summarize methodology in PICO format. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXII-PGTSC-IIA/P19*
28	Clarification of research proposal entitled ***"Efficacy of olanzapine versus lorazepan for management of breakthrough chemotherapy-induced vomiting in childhood cancer patients: An open label, quasi-randomized, pilot study"*** submitted by Dr. Meenakshi, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 254/Ped/24 dated 21st February, 2024. **Previous Comment:** • This is a prospective cohort comparative study. Everything should be planned accordingly. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXII-PGTSC-IIA/P22*
29	Clarification of research proposal entitled *"To study the association of serum*

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	immunoglobulin-G levels with outcome of hospitalized cases of WHO defined severe community acquired pneumonia" submitted by Dr. Aaradhya Shukla, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 600/Ped/2024 dated 1st April, 2024. **Previous Comment:** • The Scientific Committee report in unsigned. • The Principal guide Dr.S.Awasthi has superannuated and since Dr. Mala Kumar is new Principal-Investigator guide the submitted documents need to reflect the same. • The consent form in Hindi is incomplete. • The Patient information sheet needs to be submitted as per SOP of EC, KGMU. • The details of Patient Information Sheet need to be filled up in Annexure 1. • Kindly enclose details of PRISM -3 severity scoring. • Since this study on children involves even revise & re-submit of 2m age, an assent form needs to be submitted. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXII-PGTSC-IIA/P30*
30	Clarification of research proposal entitled *"Utility of molecular over traditional diagnostic method in diagnosis and management of ventilator-associated pneumonia caused by gram negative bacteria in intensive care unit"* submitted by Dr. Krishna Priya Agrawal, SRI, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/116/24 dated 23rd February, 2024. **Previous Comment:** • While duration of study in Annexure 1 is indicated as 2 years while elsewhere it is 1 year. Kindly resolve/clarify. • Patient information sheet (both English & Hindi version) need to be re-written as per the SOP of K.G's Medical University. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXII-PGTSC-IIA/P40*
31	Clarification of research proposal entitled *"Mechanical power (MP) as a predictor of outcome in patients with moderate to severe traumatic brain injury (TBI): a prospective observational study"* submitted by Dr. Neeraj Kumar, SRI, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/90/24 dated 12th February, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Previous Comment: • IEC form mentions selection of vulnerable subject like mentally challenged, illiterate and terminally ill patients. In this case the consent of an LAR will be required. • Section on Biological material mentions 'banking for future research'. What will be stored for future research? • Section on Data Monitoring mentions presence of DSMB. The University has no DSMB. Where will adverse events be reported? • Sample size in IEC form is mentioned as 80-120, whereas in the synopsis it is mentioned as 120. Please specify. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXII-PGTSC-IIA/P41*
32	Clarification of research proposal entitled *"A comparative evaluation of concentrated platelet rich fibrin and calcium silicate based cement in pulpotomy of permanent teeth using laser - A randomized control trial"* submitted by Dr. Himi Rathore, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 1005/Coms&Endo/24 dated 28th February, 2024. **Previous Comment:** • Seal of Chairperson in Scientific Committee report is missing. • Patient 4 of Annexure 1 should be elaborated as required in protocol-Kindly rewrite. • While patient age group is mentioned as 15-25 years, on the other hand age criteria are stated as 18-45 years-Kindly clarify. • Kindly mention the references study on the basis of which sample size calculation is done. • Kindly mention the allocation & randomization methods used in this RCT. • What will be the outcome variables? • As the PI has submitted the project as RCT involving drug & device, kindly make sure to register this trial. • Refer to CONSORT guidelines before submitting revised version. • How can vulnerable subjects especially foetus & terminally ill be included in this RCT. (Annexure 1 patient 5 (VI)? • Fill in the left out blanks of annexure 111, 12, 13) • What the anticipated serious adverse events are as mentioned in patient 15 of Patient information sheet. These should be elaborated and mentioned in ICF as well. Who will be responsible to pay for treatment of these SAEs. ***The aforementioned comments were sent to the Principal-Investigator, the response to***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	which was forwarded to the reviewer. ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXII-PGTSC-IIA/P47*
33	Clarification of research proposal entitled ***"One stop fertility assessment using advanced ultrasound 3D"*** submitted by Dr. Laxmi, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/740/24 dated 7th March, 2024. **Previous Comment:** • Guide signature and date is missing on the undertaking. • ICF and Pt Information sheet to be written in simple and understandable language. Items/ statements of pt information sheet that is not applicable for the project to be indicated as NA. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXII-PGTSC-IIA/P48*
34	Clarification of research proposal entitled ***"Clinico-epidemiological outcome study of CVJ, cervical, thoracic, lumbar and sacral spinal tuberculosis in tertiary care hospital"*** submitted by Dr. Balabhadra Samantary, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 450/SY/23 dated 8th April, 2024. **Previous Comment:** • Seal of Chairperson of Scientific Committee is missing. • Is the risk not reasonable as compared to anticipated benefits? (annexure 1 patient 10) • Elaborate on Data & Safety monitory board. What are the anticipated adverse events, that need to be reported to IEC (Annexure 1 patient II). Such possibility need to be mentioned in patient information sheet & ICF. • While annexure 1 patient 5 indicates duration of study as 1 year, the time line mentions it as 26 m Kindly resolve. • Undertaking by PI is incomplete & unsigned. • ICF (English version) is incomplete & mentions subjects name as study title-Kindly rewrite & resubmit. • ICF (Hindi version) is illegible. Kindly retype clearly & resubmit. • It this is a retrospective study of records from past 10 years? Then will the living patients be called for consent? Please resolve this confusion. • Kindly submit your "Predesigned quantitative tools" used to collect data-is it different from VAS?

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Kindly correct points 7 & 14 in patient information sheet. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXII-PGTSC-IIA/P49*
35	Clarification of research proposal entitled ***"The role of T-Cell TH 17 levels in patients undergoing laparoscopic/open cholecystectomy and its effect on gastro-intestinal immunity- A prospective cross-sectional study"*** submitted by Dr. Akash Nikhil Srivastav, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 632/SY/24 dated 18th March, 2024. **Previous Comment:** • Several sections of the IEC form are incomplete. • Title of the study does not adequately reflect the aim of the study. • Sample size calculated has been split between cases and controls. • Kindly clarify the study design; is it a "cross-sectional study" or a "prospective case-control" or a "prospective cohort design". ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXIII-PGTSC-IIA/P2*
36	Clarification of research proposal entitled ***"Assessment of quality of life after reduction of limb volume by compression therapy in lower limb lymphedema patients: A prospective observational study"*** submitted by Dr. Mithlesh Kumar, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 742/SY/24 dated 12th March, 2024. ***Previous Comment:*** • Kindly complete the left out blanks in Annexure 1. • Seal of Chairperson in scientific review committee is missing. • Is the risk not reasonable compared to benefits? (See annexure 1 point 10) • If there is a plan to report adverse events (Annexure 1 point 11) then incorporate them in ICF & patient information sheet. • Kindly incorporate statistical analysis mentioning the various anticipated outcome measures. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Ref. code: XXIII-PGTSC-IIA/P3
37	Clarification of research proposal entitled *"Early onset neonatal sepsis in neonates born through preterm pre-labor rupture of membrane: A prospective cohort study"* submitted by Dr. Anita Gautam, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 350/Ped/24 dated 2nd March, 2024. ***Previous Comment:*** • The objective of the study should be mentioned in the title. • There are too many objectives. Identify one primary objective and the rest should be clubbed into secondary objectives. • Make a list of the study variables and population parameter. • Convert the primary objective into research hypothesis using the population parameters. • Sample size is not given. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation** of reviewer:-* Provisionally approved **Decision:** Approved *Ref. code: XXIII-PGTSC-IIA/P4*
38	Clarification of research proposal entitled *"Prevalence of ionized hypocalcaemia in trauma patients and its role in predicting mortality at level I trauma center - A prospective observational study"* submitted by Dr. Mohd Tahir, JRI, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. TS/270/24 dated 29th February, 2024. **Previous Comment:** • In SOP-Checklist point no.-7 (use of biological samples) -ticked as 'NO' but samples will be taken, Point no.-10 (Risk & benefit)-ticked as not reasonable-PI to correct or revise SOP-Checklist. • Informed consent form /Guardian consent form -English/Hindi versions not similar -please resend and as all age group patients will be recruited therefore Child Assent form should also be submitted • Case record form not included ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation** of reviewer:-* Provisionally approved **Decision:** Approved *Ref. code: XXIII-PGTSC-IIA/P5*
39	Clarification of research proposal entitled *"A comparison of treatment decision for adhesive restorations using different clinical diagnostic criteria in high caries risk children"* submitted by Dr. Simran Shivhare, JRI, Department of Paediatrics & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	U.P., Lucknow vide letter no. Pedo/80/24 dated 16th March, 2024. **Previous Comment:** • What is the meaning of treatment decision? • Make a list of the study variables and population parameter • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is arbitrary. It should be specific to the research hypothesis. • Statistical analysis section is very general. It should be specific to the research hypothesis. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P15***
40	Clarification of research proposal entitled ***"Comparison of clinical outcome in Doppler guided hemorrhoidal artery ligation versus laser hemorrhoidoplasty in symptomatic hemorrhoids: A randomized controlled study"*** submitted by Dr. Lalit Pandey, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1403/SY/23 dated 25th September, 2023. **Previous Comment:** • Is the risk not reasonable compared to benefits? (See annexure 1 point 10)- Kindly clarify. • What are the anticipated adverse events that are planned to be reported to IEC. Kindly state then in ICF/Patient information sheet. • It is expected that sample size consideration are finalized with the help of a statistician. • Kindly incorporate the questionnaire used in study as stated in check list of annexure 1. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was reviewed by the Member-Secretary, IEC.*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P16***
41	Clarification of research proposal entitled ***"Comparative evaluation of clinical and Radiographic success of lesion sterilization tissue repair (LSTR), modified LSTR with triple antibiotic paste and metapex pulpectomy in primary molars: A randomized controlled study"*** submitted by Dr. Ayisha Beevi T P, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/69/2024 dated 1st March, 2024. **Previous Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• The numbers of objective are 6 in number (synopses) at one place & only 2 at other. Kindly consolidate 6 to 2. • The 'Study procedures" in ICF needs to be in a patient friendly language. • Annexure 1 point 8 indicate that healthy volunteers will be recruited. This is not indicated in the text. Kindly clarify. • Kindly complete left over blanks in annexure 1. • It is expected that sample size allocation in each group has been finalized by a statistician. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P21***
42	Clarification of research proposal entitled ***"Clinical and radiographic evaluation of three different indirect pulpcapping materials in primary molars: A randomized clinical study"*** submitted by Dr. Bhawana Kumari, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/68/24 dated 1st March, 2024. **Previous Comment:** • In Title the study design mentioned as Randomized Controlled Clinical Study, but in Protocol it is mentioned as Randomized Controlled Clinical Trial -PI to clarify. • If this is RCT study then outcome measures should also be included in Protocol apart from method of randomization, blinding and flow chart of the study. • In Inclusion criteria heading -Age and sex of the patients not mentioned (age and sex mentioned in Participants heading)-PI to include it in Inclusion criteria as well. • As 4-9 yrs. age group patients to be recruited in the study therefore, Guardian consent form should also be submitted. • If this is RCT study then Clinical trial registry document should be submitted (after ethical approval)-PI to clarify about study design. • In Tools- FRANKL rating criteria should be attached. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P23***
43	Clarification of research proposal entitled ***"Factors associated with acute kidney injury in Children with diphtheria and its impact on outcome: An observational study"***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	submitted by Dr. Vanshika, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no.350/Ped/24 dated 9th March, 2024. **Previous Comment:** • The consent is to be taken from the parent or the guardian and that need to be written accordingly. Patient information sheet also needs modification accordingly. • In both languages consent and assent forms for children to be written with similar content. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P25***
44	Clarification of research proposal entitled ***"Evaluation of use of fresh frozen plasma and cryoprecipitate in surgical patients"*** submitted by Dr. Rajeev Kumar, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 735/24 dated 29th February, 2024. **Previous Comment:** • The scientific committee report should be in a proper prescribed format with specific decision and countersigned by Chairman with proper seal. • If anticipated adverse events are planned to be reported to IEC then kindly state those adverse events in IEC & patient information sheet. • Kindly include age in inclusion criteria. • Enumerate the anticipated outcome measures used in statistical analysis. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P29***
45	Clarification of research proposal entitled ***"Assessment of bedside blood transfusion practices in hematological disorder patients"*** submitted by Dr. Manigandan S, JRI, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 582/24 dated 13th March, 2024. **Previous Comment:** • Signature, name of the chairperson is not there on the SRC. • As the topoc of the study is to assess bedside blood transfusion practices in hematological disorder patients which is to be followed at each step. However, details are not provided accordingly. The protocol need to be reviewed thoroughly for aim, objectives and methodology. Also, the pt information sheet and ICF to be written accordingly.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• IEC needs to be filled properly. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P31***
46	Clarification of research proposal entitled ***"Therapeutic drug monitoring of anti-fungal drug voriconazole in cases of invasive aspergillosis among adult hemato-oncological patients"*** submitted by Dr. Saurabh Kumar Nande, JRI, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 428/23 dated 23rd October, 2023. **Previous Comment:** • In SOP-Checklist, Point no.-10 (Risk & benefit) -ticked as not reasonable -PI to correct. • Study design should be elaborated as Prospective observational study • In inclusion /Exclusion criteria Sex specification and pregnant & lactating women criteria not mentioned • In Tools- EORTC/MSG revised guidelines should be included • Where TDM for Voriconazole concentrations will be performed-PI to clarify. • In addition, details of TDM have not been appropriately provided in the proposal. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P32***
47	Clarification of research proposal entitled ***"Low dose emicizumab prophylaxis in patients with hemophilia a with or without inhibitors - A single center, prospective observational study"*** submitted by Dr. Gaurav Datta, SRI, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. 158/CH/24 dated 11th March, 2024. **Previous Comment:** • Scientific review committee should be revised as the name and signature of three Co-investigators (Dr. S P Verma, Dr. A K Tripathi and Dr. Swasti Sinha) are present. • In SOP-Checklist-Point no. 6 (confidential handling of data) ticked as No and Point no.-10 (Risk & benefit) -ticked as not reasonable -PI to correct. • Sample size calculation not done (only total no. of patients-36 is given) • In Inclusion /Exclusion criteria Sex specification and pregnant & lactating women criteria not mentioned

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• As the age of recruited subjects are from 2 years onwards, the Child Assent form (in English /Hindi versions) should also be submitted. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P35***
48	Clarification of research proposal entitled ***"Comparative evaluation of effectiveness of green tea polyphenoles, triphala, Morinda citrifolia and 5% sodium hypochorite as intracanal irrigants against isolated microorganisms from infected root canal - An interventional study"*** submitted by Dr. Daulat Kumar, JRI, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. Pedo/103/24 dated 2nd April, 2024. **Previous Comment:** • In scientific committee report the seal of chairperson is missing. • Since this study includes testing of an ayurvedic product i.e. Triphala, an ayurvedic Co-Investigator may be added. • Regarding preparation of test solutions the references concerning recommended concentration for endodontic irrigation need to be added. • If samples for bacterial load assessment from root canal is to be collected then it should be indicated in annexure 1 (point 7) • Annexure 1 indicates that healthy volunteers will be recruited but this is not indicated in the plan. • Is the risk not reasonable compared to benefits (annexure 1 point 10) • In ICF the 'Study procedure' & 'Benefits from study' sections need to be in a more patient-friendly language. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P37***
49	Clarification of research proposal entitled ***"Prognostic utility of ratio of central venous-to-arterial carbon-dioxide tension difference to arterial-to-venous oxygen content difference combined with arterial lactate clearance rate in early resuscitation of septic shock"*** submitted by Dr. Rahul Kanjilal, SRI, Department of Critical Care Medicine, King George's Medical University, U.P., Lucknow vide letter no. DCCM/1184/2024 dated 15th April,2024. **Previous Comment:** • The protocol is incomplete. • Actually, the title itself is not clear.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• The primary objectives and secondary objectives give a list of study variables. • Make a list of the study variables and population parameters required for adherence, therapeutic outcomes, quality of life etc. • Convert the primary objective into research hypothesis using the population parameters. • There is no methodology section. • There is no study design. • Sample size calculation has no meaning in the absence of properly defined objectives. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P39***
50	Clarification of research proposal entitled ***"Diagnostic utility of contrast enhanced ultrasonography along with grey scale ultrasound and real time elastography in predicting the malignancy risk in Bethesda 3,4,5 lesions - An interventional study"*** submitted by Dr. Meghana V. Shetty, SR, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. EndoSurg/141/2024 dated 21st March, 2024. **Previous Comment:** • Section on Biological materials has been answered as 'No' but cytopathology and excision biopsy of the lesion is being done. This needs to be corrected. • Kindly defend the title of the study "an interventional study" vis-à-vis "an exploratory analysis" as the type of study. Actually, the denotation "Diagnostic utility" is sufficient to define the type of study. • Title does not include the site of evaluation; kindly correct. • Should be in ICF corrections. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P40***
51	Clarification of research proposal entitled ***"Reliability of on-site surgeon performed fine needle aspiration cytology with toluidine blue staining in thyroid and breast diseases - An interventional study"*** submitted by Dr. Asiya Zehra, SR, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. EndoSurg/142/2024 dated 21st March, 2024. **Previous Comment:** • In Inclusion /Exclusion criteria pregnant & lactating women criteria not

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	mentioned. • How PI will assess the learning curve of surgeon performing FNAC across the study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P41***
52	Clarification of research proposal entitled ***"Outcome assessment after surgical intervention (Angioplasty with catheter guided thrombolysis and stenting) in infra-inguinal peripheral arterial vascular disease – a prospective observational study"*** submitted by Dr. Kumar Kaushik, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 743/SY/24 dated 12th March, 2024. **Previous Comment:** • In scientific committee report the seal of chairperson is missing. • In annexure 1 point 8. What will be the role of healthy volunteers as stated? • In the risk not reasonable compared to benefits (see annexure 1 point 10) • If there is a plan of reporting adverse events to the IEC, kindly include them in ICF & patient information sheet. • Kindly eneumerate the outcome variables as per the objectives & the methodology to assess them. • In ICF, kindly detail the 'Study procedure' section in a patient friendly language. Make similar correction in Hindi version. • Point 7 of patient information sheet seems out of context indicating 'Students'. Kindly clarify. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P43***
53	Clarification of research proposal entitled ***"A study of sleep difficulties in children with autism spectrum disorder"*** submitted by Dr. Sonu Maddheshiya, JR, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 2520/Psy/24 dated 5th March, 2024. **Previous Comment:** • Vulnerable subjects section is ticked as 'No' but children are being used as subjects. • ICF is not signed by the Investigator. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Recommendation of reviewer:- Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P44***
54	Clarification of research proposal entitled ***"Follow up study of drug resistant TB patient enrolled under NTEP on all oral bedaquiline based regimen at nodal DR-TB center, KGMU"*** submitted by Dr. Vineet Kumar Yadav, JR, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 260/24/24 dated 28th February, 2024. **Previous Comment:** • Make a list of the study variables and population parameters required for follow up study of drug resistant TB patients enrolled under NTEP on all oral bedaquiline based regimen. • Convert the primary objective into research hypothesis using the population parameters. • Study design says "prospective study". What kind of prospective study? • Sample size calculation is not given. It just says 100 cases approximately. • Statistical analysis section is very general. It should be specific to the research hypothesis. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P45***
55	Clarification of research proposal entitled ***"Study of SLR (Sentinel LN Identification Rate) in patients undergoing sentinel lymph node biopsy in post-NACT breast cancer patients using dual dye technique - A pilot study"*** submitted by Dr. Vivek Rav Prashantkar, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 741/SY/24 dated 12th March, 2024. **Previous Comment:** • In scientific review committee report the seal of chairperson is missing. • While one document indicates 4 Co-Investigators, the other shows 6 Co-Investigators including 2 additional, Dr. Patwa & Dr. Mala Sagar. Kindly resolve. • In annexure 1 kindly fill up the empty responses and state the sample size. • Is the risk not reasonable compared to benefits (annexure 1 point 10)? • If there is a plan of reporting adverse events to IEC then kindly include the adverse events in ICF & patient information sheet as indicated in annexure 1 point 11. • In under taking by PI the date is missing. • Regarding primary objectives, kindly eneumerate the anticipated short term

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	outcomes that will be analysed. • How will the quality of life be assessed. Kindly include the questionnaire. • In the inclusion criteria state whether all or any specific stage of breast cancer will be included. • Whether pregnant females be also included. If not then show them in exclusion criteria (Since the safety of SLNB in pregnant ladies is not fully established) • How will drug safety be analysed in enrolled patients as indicated in statistical analysis section. • In ICF the study procedure section need to be detailed and as per patient-understandable language. • Kindly revise patient information sheet especially points 6 & 7 as they are totally irrelevant. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P46***
56	Clarification of research proposal entitled ***"Evaluation of perioperative outcomes of pulmonary hydatid cyst with special emphasis on bronchopleural fistula: A retrospective observational study"*** submitted by Dr. Chinmoy Chakraborty, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 562/24 dated 29th February, 2024. **Previous Comment:** • The title and aim/objective do not match. • The "quality of life" instrument is required. • Its reliability, validity, utility have to be assessed. • The title says: retrospective observational study. The study type says: Prospective observational study. • Sample size calculation is arbitrary in the absence of proper research hypothesis. • Statistical analysis section is missing. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P51***
57	Clarification of research proposal entitled ***"Autologous platelet rich fibrin versus normal saline dressings in chronic venous leg ulcer patients in ulcer size reduction and quality of life: A randomized controlled study"*** submitted by Dr. Pallaprolu Jyothirmai, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Dated 13th May, 2024

	letter no. 640/SY/24 dated 23rd March, 2024. **Previous Comment:** • Section on PIS incomplete ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P53***
58	Clarification of research proposal entitled ***"Role of diagnostic laparoscopy in abdominal penetrating trauma in stable patients: A prospective analytical study"*** submitted by Dr. Arpita Shukla, JRI, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. 260/TS/24 dated 1st March, 2024. **Previous Comment:** • There are too many objectives. Identify one primary objective and the rest should be clubbed into secondary objectives. • Make a list of the study variables and population parameters to define the role of Diagnostic laparoscopy in treatment of stable penetrating abdominal trauma. • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is arbitrary in the absence of proper research hypothesis. • Statistical analysis section is missing. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P54***
59	Clarification of research proposal entitled ***"To investigate the prevalence of various single nucleotide polymorphism on COL11A1 gene coding for collagen XI α1 chain in primary angle closure glaucoma (PACG), a neuro-degenerative disease, at a tertiary healthcare center in northern India"*** submitted by Dr. Farheen Parveen, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 541/OP/24 dated 5th March, 2024. **Previous Comment:** • Primer sequence of PCR has not been mention ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Ref. code: XXIII-PGTSC-IIA/P55
60	Clarification of research proposal entitled ***"Quality of life of dacryocystitis patients: An observational study"*** submitted by Dr. Anji Jain, JRI, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 540/OP/24 dated 5th March, 2024. **Previous Comment:** • Only the sign of the chairperson is given on the SRC; the seal and name is missing. Also, 2 of the members are Co-Investigators in the project. • IEC needs to be filled properly ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P56***
61	Clarification of research proposal entitled ***"Incidence of development of lymphedema in carcinoma breast patients undergoing modified radical mastectomy using axillary reverse mapping (ARM)"*** submitted by Dr. Akshay, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 563/24 dated 29th February, 2024. **Previous Comment:** • Make a list of the study variables and population parameters to measure and study the incidence of development of lymphedema in carcinoma breast patients. • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is not given. • Statistical analysis section is very general. It should be specific to the research hypothesis. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P57***
62	Clarification of research proposal entitled ***"Adjunctive photodynamic therapy in management of periodontal intrabony defects"*** submitted by Dr. Sheetal Sharma, JRI through her Mentor Prof. Rameshwari Singhal, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow funded by Office of Dean, Research & Development, KGMU vide letter no. 4166/P/23 dated 5th March, 2024, 2024. **Previous Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• In SOP-Checklist-Point no-10 (Risk & benefit)-ticked as not reasonable-PI to correct. • In Inclusion criteria Sex specification not mentioned. • Study design mentioned is RCT, but CONSORT guidelines are not followed. • (Randomization method, blinding and Outcome measures are not given in Protocol), therefore PI is requested to change the study design as Randomized Controlled study and mention the randomization method. • The sample size per group given is 20 and total patients no. given as 40, but PI made three groups in methodology (Gp-1, Gp-2 and Gp-3 as control group)-PI to clarify ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-II B IMR-R/P1***
63	Research proposal entitled ***"A prospective evaluation of outcomes of emergency laparotomy using NELA Data Set"*** submitted by Dr. Swapnil Singh, JRI, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 541/Ortho/2024 dated 5th April, 2024. **Previous Comment:** • The duration in point 5 annexure 1 is 2 yrs as well as 1.5 yrs. Kindly rectify. • Is the risk not reasonable compared to anticipated benefits? (Annexure 1 point 10) • In patient information sheet, point 6 relates to breast cancer while point 7 is totally unacceptable. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P1***
64	Clarification of research proposal entitled ***"A prospective comparative cohort study of combined intravenous and intra-articular versus intravenous administration of tranexamic acid in patients of total knee arthroplasty"*** submitted by Dr. Deepak Chawda, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 561/Ortho/24 dated 22nd March, 2024. **Previous Comment:** • Following sections of IEC form are incomplete/incorrectly filled-type of subjects/special group subject, patient information sheet, risk and benefits. • Calculation of sample size has not been shown as per formula. • Patient information sheet is incorrectly filled. • Same information is repeated in different sections/headings. • Kindly submit the PGT Declaration form ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Recommendation of reviewer:- Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P2***
65	Clarification of research proposal entitled ***"Functional outcome of fracture posterior wall acetabulum managed by spring plate using kocher-langenbeck approach"*** submitted by Dr. Ankur Maan, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 530/Ortho/24 dated 16th March, 2024. **Previous Comment:** • In SOP-Checklist- point no.10 (Risk & benefit)-ticked as not reasonable-PI to correct or revise SOP-Checklist. • In Inclusion criteria sex specification not mentioned • Informed consent form-as the age group of patients to be recruited starts from 16 yrs., therefore Child Assent form should also be submitted. • PI should also clarify that how will he take consents of subjects taken retrospectively? Whether he will submit Human Subject Review Waiver Form (HSRWF) for retrospective part of the study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P3***
66	Clarification of research proposal entitled ***"Prediction of hamstring graft thickness for anterior cruciate ligament reconstruction by anthropometric measurement: A prospective study"*** submitted by Dr. Amit Kumar, JRI, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 1104/Ortho/23 dated 6th December, 2023. **Previous Comment:** • There are 2 sets of annexure 1 where in sample sizes are indicated as 48 and 100 respectively. Kindly correct. • Is the risk not reasonable compared to benefits (Annexure 1 point 10). Kindly complete the left out blanks. • If there is a plan to report adverse events (annexure 1 pt 11) then what are those events? They need to be stated in ICF and patient information sheet as well. • What is the role of healthy volunteers as indicated in annexure 1 (pt 8). There needs to be separate ICF & information sheet for them. • Kindly enumerate the various outcome variables and summarize their statistical analysis in that context. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P4***
67	Clarification of research proposal entitled ***"Assessment of 'probable surgical" traumatic brain injury (TBI) patients"*** submitted by Dr. Samarthan SL, SRI, Department of Neurosurgery, King George's Medical University, U.P., Lucknow vide letter no. 2304/NS/23 dated 8th December, 2023. **Previous Comment:** • Kindly include the study design in the title. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was reviewed by the Member-Secretary, IEC.*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P6***
68	Clarification of research proposal entitled ***"To elucidate the role of serum nogo-a as a predictor of neurological recovery in spinal cord injury (SCI):A prospective study"*** submitted by Dr. Akash Singh, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 523/Ortho/24 dated 16th March, 2024. **Previous Comment:** • In SOP-Checklist point no. 10 (Risk & benefit)-ticked as not reasonable and point no.7 (Use of biological samples) ticked as NO but samples will be taken-PI to correct the SOP-Checklist. • SCIM tool is not attached-please include. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P7***
69	Clarification of research proposal entitled ***"Knee self efficacy and patient satisfaction post anterior cruciate ligament reconstruction: A prospective and retrospective study"*** submitted by Dr. Manjul Gupta, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 556/Ortho/2024 dated 20th March, 2024. **Previous Comment:** • The design of the study, as mentioned in the title, may be modified to "An ambispective study". • The sample size in annexure 1 point 5 is 95, while in methodology mention it is 105. Kindly correct. • Is the risk not reasonable compared to anticipated benefits? (Annexure 1 pt 10) • What is the role of healthy volunteers (Annexure 1 pt 8) Separate ICF & information sheet to be included for them?

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• What are the anticipated adverse events that need notification (Annexure 1 pt 11) • The latter part of methodology is in past tense. It needs correction. • Kindly enumerate all the anticipated outcome variables & summarize the statistical analysis based upon those variables. • Since this also has a retrospective component, how will the consent be obtained from them? Also kindly reformate 'Study procedure' section of ICF in a more patient friendly Language. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P12***
70	Clarification of research proposal entitled ***"A prospective comparative study to evaluate the results of anterior cruciate ligament reconstruction using hamstrings versus quadriceps tendon graft"*** submitted by Dr. Ayush Kumar, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 560/Ortho/24 dated 22nd March, 2024. **Previous Comment:** • In SOP-Checklist, point no.10 (Risk & benefit) ticked as not reasonable-PI to correct. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P13***
71	Clarification of research proposal entitled ***"A prospective study to evaluate the results of correction of angular deformities around the knee using computer assisted indigenous hexapod fixator system"*** submitted by Dr. Vivek Kumar, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 531/Ortho/24 dated 16th March, 2024. **Previous Comment:** • IEC to be filled properly- specially point no. 5, 8, 10, 11. • As it is a follow up of OPD patients with angular deformity; title should reflect the same. • In study population patients with angular deformity attending OPD to be written. • If patients 12 years and above age are to be taken there should be guardian consent and patient assent form. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P15***
72	Clarification of research proposal entitled ***"A study on effects of organo-chlorine pesticide exposure on progression of chronic myeloid leukemia"*** submitted by Dr. Syed Mohd. Abuturab Rizvi, JRI, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/1333/2024 dated 22nd March, 2024. **Previous Comment:** • In SOP-checklist, point no.10 (Risk & benefit) ticked as not reasonable-PI to correct. • In inclusion criteria-Age and sex specifications of the patients not mentioned-PI to include. • Detailed sample size calculation is missing-Discrepancy in total sample size given (75) and in grouping (25/50) but in calculation n=31 is mentioned PI to clarify. • As this is a comparative cross-sectional study-flow chart of methodology is needed. • The title of the study mentions "progression of chronic myeloid leukemia" while the design of the study is cross-sectional; how will you achieve your objective/s? • Case record form is not attached. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P17***
73	Clarification of research proposal entitled ***"Role of strain and shear wave ultrasound elastography in chronic kidney disease patients"*** submitted by Dr. Suryang Chaurasia, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 426/RD/23 dated 20th March, 2024. **Previous Comment:** • This is prospective comparative cohort study. • The two cohorts (Treatment and control) should be explicitly defined. • The sample size formula is inappropriate. It is for prevalence study. • After stating the research hypothesis (involving study variables and parameters) properly, right sample size formula should be used. • The statistical hypothesis section is very general. It should be specific to the research hypothesis. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Ref. code: XXIV-PGTSC-IIA/P18
74	Clarification of research proposal entitled ***"Validation of open injury scores in predicting salvageability of limb in type IIIB open tibial fractures"*** submitted by Dr. Utkarsh Bansal, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 540/Ortho/24 dated 5th April, 2024. **Previous Comment:** • Informed consent mentions the study as Case control study. Please correct this. • Informed consent in Hindi not present. • Kindly clarify **"Study design"** • Title is different in the section on "Role of responsibilities" ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved
	Ref. code: XXIV-PGTSC-IIA/P21
75	Clarification of research proposal entitled ***"Evaluation of patient reported outcome in arthroscopically reconstructed anterior cruciate ligament tear using autologous tendon grafts"*** submitted by Dr. Sagar Meena, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 882/Ortho/24 dated 20th March, 2024. **Previous Comment:** • Role of supervisors are missing • IEC to be filled properly point no. 5.vi (elderly?), 8, 10, 11 • Tools to be applied should be mentioned in the proposal. • Both Hindi/ English ICF to be written properly. • If patients 16-50 years of age are to be taken there should be guardian consent and patient assent form. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved
	Ref. code: XXIV-PGTSC-IIA/P22
76	Clarification of research proposal entitled ***"Computed tomographic evaluation of normal and variant anatomy of craniovertebral junction in northern India population at a tertiary health care center"*** submitted by Dr. Shiv Kumar Yadav, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 732/ANAT/2024 dated 22nd March, 2024. **Previous Comment:** • If investigator wishes to analyse only the CT scan without patient contact and accordingly has submitted consent waiver from, then why has the PI submitted

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	ICF 7 patient information sheet? Kindly clarify. Corresponding corrections need to be made in annexure 1. • Also clarify if this is a retrospective study or a prospective study and if any other clinical data will be collected or not? • Is the risk not reasonable compared to anticipated benefits? (Annexure 1 pt 10) • Kindly summarize statistical analysis in context of the anticipated outcome variables. • The patient information sheet should not mention the guidelines. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P28***
77	Clarification of research proposal entitled ***"Stress cytogenetic study of patients of aplastic anemia at a tertiary healthcare centre"*** submitted by Dr. Bedana Gautam, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 551/Ped/2024 dated 5th April, 2024. **Previous Comment:** • The Seal of the chairperson on SRC is missing. • In the study inclusion criteria age groups to be written precisely. Inclusion criteria do not indicate age group; PI wishes to include up to the age of 40 years; please clarify and prepare the ICF accordingly. • Procedural details are to be written accordingly. • PI states another blood sample will be taken from the control subject. Needs clarification? Who will be the control subject? Should be written properly in the methodology section. • Who will bear the cost of the investigations? ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P29***
78	Clarification of research proposal entitled ***"Role of biomarkers, serum IL 8 and GM-CSF, to predict short-term outcomes in term neonates with perinatal asphyxia"*** submitted by Dr. Mukul Goel, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3269/Ped/23 dated 5th October, 2023. **Previous Comment:** • The sample size calculation is not given • Statistical analysis section is very general. It should be specific to the study research hypothesis.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• The title of the proposal may be revised to include the design of the study ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P31***
79	Clarification of research proposal entitled ***"Pediatric DR-TB: resistance pattern, treatment outcome and side-effect profile"*** submitted by Dr. Palepu Sai Krishna Kaushik, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3567/Ped/23 dated 29th November, 2023. **Previous Comment:** • Kindly enumerate the anticipated outcome variables. • The consent process in pediatric cases should include guardian/legal representative signature. Kindly modify the respective forms. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P34***
80	Clarification of research proposal entitled ***"Comparison of loading dose alone versus standard pritchard regimen in severe preeclampsia patients for prevention of eclampsia - A randomized controlled study"*** submitted by Dr. Divya, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/952/24 dated 20th March, 2024. **Previous Comment:** • Seal of the chairperson on SRC is missing. • The Chairperson of the SRC is chief supervisor. • IEC to be filled properly. Same duration to be mentioned on the IEC and protocol. • ICF and Patient information sheet needs to be written with clarity so that a lay person (participants) can understand the purpose and procedure before giving the consent. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P35***
81	Clarification of research proposal entitled ***"Clinical presentation and outcome of post-infectious broncholitis obliterans in children"*** submitted by Dr. Noopur Gupta, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	no. 426/24 dated 23rd March, 2024. **Previous Comment:** • The aim says: "To determine the clinical features of PIBO in children. This is just a description of study variables. • The objective should mention the use of these clinical features. • Research hypothesis should be stated in terms of study parameters (such as proportion, mean, standard deviation etc.). • Sample size calculation is not given. • The statistical analysis section is very general. It should be specific to the research hypothesis. • Assent form from parents is required. • The title of the proposal may be revised to include the design of the study ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P37***
82	Clarification of research proposal entitled ***"Role of FABP 1 and FABP 4 in detection of diabetic nephropathy in geriatric type 2 diabetes mellitus patients"*** submitted by Dr. Chitranshi Hyanki, JRI, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 274/Pharma/24 dated 5th April, 2024. **Previous Comment:** • Kindly fill up the blanks in annexure 1 (pt (i) & (ii). • On one hand investigator states that no body fluids will be collected (annexure 1 pt 7), while on the other hand he wishes to collect 5 ml blood. Kindly rectify. • Is the risk not reasonable compared to anticipated benefit? • Kindly enumerate the outcome variables & summarize the statistical analysis based on those anticipated variable. • In ICF the PI is Chief Supervisor & this should be rectified. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P40***
83	Clarification of research proposal entitled ***"Prevalence of psychological distress and its risk factors in patients with primary bone tumors - A cross sectional single centre study"*** submitted by Dr. Sujita Kumar Chaudhary, JRI, Department of Orthopaedics Surgery, King George's Medical University, U.P., Lucknow vide letter no. 522/Ortho/24 dated 16th March, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Previous Comment: • This is basically observational study to find the prevalence of depressive and anxious symptomatology in cancer patients. • Since a cross-sectional study can only measure a distribution at a single time point, demographic, anthropometric, paraclinical, bioimpedance and genetic variables (not parameters) centered on dynamic or time-dependent quantities will introduce detection bias. • In view of the above comments, the title of the proposal may be revised suitably. • This cannot be used for making causal inference (risk factors). • Statisticians generally prefer to make causal inferences from randomized controlled experiments. • Data analysis section is incomplete. It just mentions the name of software to be used. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P41***
84	Clarification of research proposal entitled ***"Evaluation of anorectal manometry parameters in patients with active and quiescent inflammatory bowel diseases"*** submitted by Dr. Saurabh Kumar Mishra, SR, Department of Medical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. 3302/MedGastro/24 dated 21st March, 2024. **Previous Comment:** • In Inclusion /Exclusion criteria–Sex specification not mentioned. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P46***
85	Clarification of research proposal entitled ***"Clinical profile and short-term outcome of status epilepticus in children and risk factors for the development of refractory status epilepticus"*** submitted by Dr. Kirti Tripathi, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 360/Ped/2024 dated 30th March, 2024. **Previous Comment:** • Sample size is given as 190 at one place, 200 at another and 236 where sample size calculation has been done. Please clarify. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Recommendation of reviewer:- Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P47***
86	Clarification of research proposal entitled ***"A prospective follow-up study on the development of new-onset prediabetes and diabetes mellitus after an episode of acute pancreatitis"*** submitted by Dr. Gaya Prasad Shukla, SR, Department of Medical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. 3306/MedGastro/2024 dated 23rd March, 2024. **Previous Comment:** • ICF to be written in an understandable language. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P48***
87	Clarification of research proposal entitled ***"Profile of pulmonary infections in acute leukemia patients during induction phase"*** submitted by Dr. P Raghuveer, SRI, Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. 350/24 dated 9th April, 2024. **Previous Comment:** • IEC form incompletely/incorrectly filled. Difficult to read due to format issues. Please correct and submit complete form in legible print. • Tile of Co-PI, Prof A.K Tripathi is wrong since he has superannuated. This needs to be corrected. • Sample size calculation has not been done. • Summary is incomplete/poorly written. • PIS is in wrong format/incomplete/poorly written • ICF translation into Hindi is poor. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P50***
88	Clarification of research proposal entitled ***"Anatomical study of anterior tibial artery and its perforators"*** submitted by Dr. Arun Kumar, JRIII, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 19/ANAT/24 dated 10th April, 2024. **Previous Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• The project can be approved but the left blank spaces be filled in annexure 1 (points 2,5,9,13) ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P51***
89	Clarification of research proposal entitled ***"A study on national quality assurance standard (NQAS) compliance in medical gastroenterology ward in a tertiary care Government teaching hospital, Lucknow, India"*** submitted by Dr. Rajnish MP Singh under the guidance Dr. Nitin Dutt Bhardwaj, Professor Junior Grade & Head, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/164/24 dated 20th March, 2024. **Previous Comment:** • It seems that information are to be extracted from the records of Gastroenterology ward; if so IEC to be filled accordingly and protocol need correction. • Further, if only records are to be extracted and analyzed there is no need of patient information sheet and for ICF; PI may apply for waiver of the study. • Also, if the PI has to interview staff and patients as written in the protocol; number of staff patients to be interviewed should be clearly mentioned. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-II B-MHA/P1***
90	Clarification of research proposal entitled ***"A study on the level of compliance with national quality assurance standard (NQAS): musqan in department of paediatrics in tertiary care government teaching hospital, Lucknow"*** submitted by Dr. Vishika Singh under the guidance Dr. Nitin Dutt Bhardwaj, Professor Junior Grade, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/163/24 dated 20th March, 2024. **Previous Comment:** • If information is to be taken from the records there is no need for patient information sheet and ICF. The IEC to be filled properly and proposal to be written accordingly. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Ref. code: XXIV-PGTSC-II B-MHA/P2
91	Clarification of research proposal entitled ***"Effectiveness of exercise-based regimen on symptoms of chemotherapy-induced peripheral neuropathy (CIPN), among patients undergoing chemotherapy, admitted in medical oncology, K.G.M.U, Lucknow"*** submitted by Mr. Malay Kumar Rai through his guide Dr. Suchana Roy Bhowmik, Assistant Professor, Department of College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.585/24 dated 8th April, 2024. **Previous Comment:** • In ICF study process to be written in simple and understandable language so that the participant could understand it. Hindi/ English both consent should have the same meaning. • CIPN scoring key needs revision; how a score of zero be treated as mild symptoms. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXIV-PGTSC-IIC/P1*
92	Clarification of research proposal entitled ***"Impact of maternal teaching regarding newborn danger signs on knowledge among mothers of newborn admitted in NICU and NNU at KGMU"*** submitted by Ms. Amrita Singh through her guide Dr. Suchana Roy Bhowmik, Assistant Professor, Department of College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4049/X.51/24 dated 1st January, 2024. **Previous Comment:** • Following sections of IEC form are incomplete/incorrectly filled-type of subjects/special group subject, patient information sheet, risk and benefits. • Calculation of sample size has not been shown as per formula. • Patient information sheet is incorrectly filled. • Same information is repeated in different sections/headings. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved *Ref. code: XXIV-PGTSC-IIC/P2*
93	Clarification of research proposal entitled ***"Effectiveness of educational bundle knowledge regarding antenatal care and family planning among antenatal mothers"*** submitted by Ms. Smriti Singh through her guide Mr. Subin S., Assistant Professor, Department of Obstetrics & Gynaecology, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.697/23 dated 22nd April, 2024. **Previous Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• In SOP-Checklist-point no-6 (Confidential handling of data)-not ticked and point no.13–Conflict of interest not ticked –PI to correct. • In Inclusion criteria –Age range of subjects to be recruited- not mentioned • Tool–Questionnaire's validation has not been done-it is awaited ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIC/P4***
94	Clarification of research proposal entitled ***"Effectiveness of nurse-led education on knowledge and expressed practice regarding prevention of urinary tract infection among postnatal mothers in selected health centers"*** submitted by Ms. Kajal Mishra through her guide Mr. Rohitash Kumar, Assistant Professor, Department of Community Health Nursing, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.629/PF/24 dated 13th April, 2024. **Previous Comment:** • Proposal cover letter not signed by the Guide. • Direct identifiers being used and confidential handling is ticked as 'No' • Section on consent all boxes is not ticked. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIC/P5***
95	Clarification of research proposal entitled ***"Effectiveness of reverse pressure softening technique on the level of breast engorgement and breast feeding among postnatal mothers at Queen Mary Hospital, KGMU, Lucknow"*** submitted by Ms. Nidhi Dwivedi through her guide Mr. Subin. S, Assistant Professor, Department of Obstetrics & Gynaecology, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.680/24 dated 19th April, 2024. **Previous Comment:** • As annexure 1, both patients & healthy volunteers are included in the study, accordingly separate ICF & information sheet need to be generated. • What will be the role of healthy volunteer and what will be their inclusion criteria. • Kindly define clearly the control & experimental groups. • Kindly submit a flow chart for methodology of this study starting from recruitment to final outcome. • Kindly enumerate the outcome variables & summarize the statistical analysis based upon those variables. ***The aforementioned comments were sent to the Principal-Investigator, the response to***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	which was forwarded to the reviewer. ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIC/P6***
96	Clarification of research proposal entitled ***"A study to assess the effectiveness of video assisted teaching programme on knowledge and practice regarding metered dose inhaler among patients diagnosed with bronchial asthma in a tertiary care hospital, Lucknow"*** submitted by Ms. Akanksha Yadav through her guide Dr. Rashmi P. John, Department of Medical & Surgical Nursing, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no. nil dated 9th April, 2024. **Previous Comment:** • As per annexure 1, both patients & healthy volunteers are included in the study. Accordingly separate ICF & information sheet need to be generated. • What will be the role of healthy volunteer and what will be their inclusion criteria. • The hypotheses H1 & H2 are same. Kindly explain or rectify. • Kindly enumerate the anticipated outcome variables that will be analyzed & summarize the statistical analysis based upon those variables. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIC/P9***
97	Clarification of research proposal entitled ***"Effect of community-based education program on knowledge regarding prevention of minor stroke among middle age adults in selected urban areas"*** submitted by Ms. Komal through her guide Mr. Rohitash Kumar, Department of Community Health Nursing, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.596/24 dated 10th April, 2024. **Previous Comment:** • In SRC–The Seal of Chairperson is missing • In SOP-Checklist-point no-6 (Confidential handling of data)-ticked as – • No-PI to correct • In Inclusion criteria sex specification not mentioned. Tool-Lesson Plan-Hindi version–not submitted. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIC/P11***
98	Clarification of research proposal entitled ***"Assessment of the awareness and perceived***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	barriers regarding vasectomy among male population residing in a selected rural area of Lucknow" submitted by Mr. Mohammad Aquib Ansari through her guide Mr. Rohitash Kumar, Department of Community Health Nursing, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.595/24 dated 10th April, 2024. **Previous Comment:** • Kindly modify the title of the study to "Assessment of the awareness…." • The study uses direct identifiers and confidential handling is ticked as 'No' • Sections on consent-all boxes are not ticked. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIC/P12***
99	Clarification of research proposal entitled ***"Assessment of intimate partner violence, coping and psychological distress among spouses of patient with alcohol use disorder"*** submitted by Ms. Smriti through her guide Miss. Sudha Mishra, Assistant Professor, Department of Mental Health Nursing, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.4058/X.51/24 dated 1st January, 2024. **Previous Comment:** • The sample size formula is inappropriate. It is for prevalence study. • The sample size formula shall be based on "reliability coefficient", since this is an assessment of an instrument on violence, coping and psychological distress. • The statistical analysis section is very general. It should be specific to the objective of the study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIC/P14***
100.	Clarification of research proposal entitled ***"Prevalence of AKI in neonates, with birth weight below 1800 grams, receiving nephrotoxic drugs in NICU"*** submitted by Dr. Abhay Singla, JRII, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 624/Ped dated 4th April, 2024. **Previous Comment:** • The proposal needs discussion during the meeting. • The title of the proposal may be revised to avoid the use of abbreviations and include the design of the study. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Provisionally approved **Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P52***
101	Clarification of research proposal entitled ***"Efficacy of tissue engineered scaffold in recession coverage: A randomized clinical trial"*** submitted by Dr. M. Priyadarshini, JRI, Department of Periodontology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 4262/P/24 dated 3rd May, 2024. **Previous Comment:** • Kindly modify the title to "Randomized controlled study" • Kindly provide PGT declaration form **Previous Decision:** • **Pending, subject to submission of PGT Declaration form and response to comments in a tabular format.** ***The aforementioned comments were sent to the Principal-Investigator, the response recieved from PI on 7th May, 2024.*** **Decision:** Approved ***Ref. code: XIX-PGTSC-IIA/P3***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"Comparison of various prognostic scores in predicting outcome in alcohol related acute on chronic liver failure: prospective observational study"*** submitted by Dr. Arvind Kumar, SR, Department of Medical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. 3228/MedGastro/24 dated 18th January, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXV-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Prevalence and correlation of sarcopenia and hepatic osteodystrophy with etiology and severity of underlying liver cirrhosis"*** submitted by Dr. Krishna Pal Kohli, SR, Department of Medical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. 3213/MedGastro/24 dated 10th January, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXV-PGTSC-IIA/P2***
4.	Research proposal entitled ***"Effect of metabolic control and IL6 on bone mineral density in children with type 1 diabetes"*** submitted by Dr. Sejal Agrawal, JRI, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 3774/Ped/23 dated 21st December, 2023. ***Recommendation of reviewer:*** • Who will bear the financial burden of the investigations (hematological and radiological) which are not a part of standard work-up of diabetes mellitus?

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Who will bear the financial burden of investigations of controls? • It is expected that the cost of these investigations are NOT passed on to the cases/ controls enrolled in the study. • Kindly mention the name of funding agency, if involved. **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission. ***Ref. code: XXV-PGTSC-IIA/P4***
5.	Research proposal entitled ***"A prospective randomized study on therapeutic strategies in non-muscle invasive bladder cancer: gemcitabine + docetaxel vs. BCG - analysis of efficacy and side effects"*** submitted by Dr. Avinash Chandra Mishra, SRI, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 25/24 dated 19th January, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXV-PGTSC-IIA/P5***
6.	Research proposal entitled ***"A comprehensive evaluation of the impact of oral health education during pregnancy: A Hospital-based intervention study"*** submitted by Dr. Khushboo Arif, SR, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 100/PHD/24 dated 13th February, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXV-PGTSC-IIA/P6***
7.	Research proposal entitled ***"Prevalence of rib anomalies in pediatric cancer patients - A radiological study"*** submitted by Dr. Supratik Pal, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 608/ANAT/24 dated 27th January, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXV-PGTSC-IIA/P7***
8.	Research proposal entitled ***"Knowledge, attitude and practice regarding pharmacovigilance and adverse drug reaction among dental postgraduate students and interns in Lucknow: A cross sectional study"*** submitted by Dr. Sonalika Srivastava, SR, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 79/OM&R/24 dated 28th February, 2024. ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Approved, waiver may be granted if the data is completely anonymized. **Decision:** 'Waiver of consent' granted ***Ref. code: XXV-PGTSC-IIA/P8***
9.	Research proposal entitled ***"Circulatory levels of oxidative stress markers in patients of benign parotid gland tumours"*** submitted by Dr. Sachin Kumar, JRII, Department of Oto-Rhino-Laryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 500/ENT/24 dated 6th February, 2024. ***Recommendation of reviewer:*** • IEC form section 7 (Consent) is incomplete. • Who will bear the cost of the blood investigation for patients and controls? The cost incurred in the research should not be passed on to the subjects. • Kindly state if a funding agency is involved. **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P9***
10.	Research proposal entitled ***"Evaluation of quality of life after placement of glabellar region implant supported prosthesis in maxillectomy cases"*** submitted by Dr. Tanvi, JRI, Department of Oral & Maxillofacial Surgery, King George's Medical University, U.P., Lucknow vide letter no. 18/OMSD/24 dated 11th January, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXV-PGTSC-IIA/P10***
11.	Research proposal entitled ***"Management of nasal bone fractures - open vs. closed treatment: A comparison"*** submitted by Dr. Bhawna, JR, Department of Oral & Maxillofacial Surgery, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 43/OMSD/24 dated 23rd January, 2024. ***Recommendation of reviewer:*** • Type of study design is not mentioned in the title/proforma. • Method of allocating patients in both the groups is not mentioned in proforma • Details of assessment of healing are not mentioned in follow-up visits. • How would the groups be compared especially when the severity of injury might not be comparable in the two groups. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P11***
12.	Research proposal entitled ***"Impact of caries initiation site on the efficacy of vital pulp therapy in mature mandibular molars with symptomatic irreversible pulpitis: A prospective clinical study"*** submitted by Dr. Prabha Shristha, JRI, Department of

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 930/Coms&Endo/24 dated 5th February, 2024. ***Recommendation of reviewer:*** • In SOP-Checklist, point no.-10 (Risk & benefit) - ticked as not reasonable -PI to correct. • Is this study a randomised clinical trial? If yes, method of randomization, allocation concealment and blinding has not been mentioned. • Details of various study groups (number and how the treatment groups are different) have not been given. • Details of various caries initiation sites not mentioned. • Details of follow-up period not mentioned. • Criteria for clinical and radiological evaluation at baseline and follow-up visits not provided. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P12***
13.	Research proposal entitled ***"Evaluation of splenic stiffness compared to liver stiffness as non-invasive predictors for esophageal varices in patients with liver cirrhosis"*** submitted by Dr. Akriti Bhardwaj, SR, Department of Medical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. 540/GS/24 dated 30th January, 2024. ***Recommendation of reviewer:*** • In the SOP-checklist, point no. 3. iv) "Is it an Investigational new drug" not ticked. PI to correct. • Also point no. 5. v) Type of subjects not ticked. PI to correct. • In SOP-Checklist, point no.-10 (Risk & benefit) - ticked as not reasonable -PI to correct. • There are multiple objectives. It is suggested to identify one primary objective and the rest should be clubbed into secondary objectives. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P13***
14.	Research proposal entitled ***"Visual evoked potential parameter (P100 latency and amplitude) in recently diagnosed type II diabetic patients and patients with diabetic history of more than 10 years"*** submitted by Dr. Deepak Chowdhary, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3758/PHY/24 dated 19th February, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Recommendation of reviewer: • Scientific review committee should be revised as the name and signature of two Co-investigators (Dr. Nar Singh Verma and Dr. Shraddha Singh) are present. • Kindly provide the details of formulas used in sample size calculations. **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P14***
15.	Research proposal entitled ***"Respiratory fitness and happiness index in morning and evening walkers"*** submitted by Dr. Priyanka Singh, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3757/PHY/24 dated 19th February, 2024. ***Recommendation of reviewer:*** • Scientific review committee should be revised as the name and signature of three Co-investigators (Dr. Nar Singh Verma, Dr. Shraddha Singh and Dr. Dileep Kumar Verma) are present. • In SOP-Checklist, point no.-10 (Risk & benefit) - ticked as not reasonable -PI to correct. • In material and methods, two different age groups are mentioned (18-45 years and 18-26 years). • It is not mentioned how and from which place morning/evening walkers will be selected. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P15***
16.	Research proposal entitled ***"To study compliance of NABH standards in a tertiary care Government Teaching Hospital, Lucknow"*** submitted by Dr. Shallu Yadav, Department of Hospital Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/83/24 dated 15th February, 2024. ***Recommendation of reviewer:*** • SOP-checklist is incomplete. Point no. 8-11 is missing. • Kindly process the proposal for 'waiver of consent'. **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P16***
17.	Research proposal entitled ***"To study awareness & utilization of ESI scheme benefits among insured persons working in a Tertiary Care Government Teaching Hospital, Lucknow"*** submitted by Dr. Dhirendra Kumar Verma, Department of Hospital

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Administration, King George's Medical University, U.P., Lucknow vide letter no. HA/80/24 dated 14th February, 2024. ***Recommendation of reviewer:*** • Signature of PI is missing in Annexure-1 • In SOP-Checklist, point no.-10 (Risk & benefit) - ticked as not reasonable -PI to correct. • There is more than one objective. It is suggested to identify one primary objective and the rest should be clubbed into secondary objectives. **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P17***
18.	Research proposal entitled ***"Burden of depression, anxiety, stress among school-going adolescents and factors affecting utilization of mental health services by school-going adolescents of Lucknow district - A cross-sectional study"*** submitted by Dr. Abhinav Kumar, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1306/CM/24 dated 14th February, 2024. ***Recommendation of reviewer:*** • There are multiple objectives. It is suggested to identify one primary objective and the rest should be clubbed into secondary objectives. **Comment:** As above **Decision:** Level 1: Approved – with or without suggestions or comments ***Ref. code: XXV-PGTSC-IIA/P18***
19.	Research proposal entitled ***"Immunohistochemical, morphological and behavioural comparison of preinvasive and invasive cervical lesions with reference to human papilloma virus infection"*** submitted by Dr. Mitali Rawat, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 134/24 dated 19th February, 2024. ***Recommendation of reviewer:*** • In SOP-Checklist, point no.-10 (Risk & benefit) - ticked as not reasonable -PI to correct. **Comment:** As above **Decision:** Level 1: Approved – with or without suggestions or comments ***Dr. Sujita Kumar Kar did not take part in the discussion and making decision.*** ***Ref. code: XXV-PGTSC-IIA/P19***
20.	Research proposal entitled ***"Estimation of plasma levels of sFLT-1 and PLGF and its correlation with histopathological grading in women with placenta accrete spectrum"*** submitted by Dr. Arpita Singh, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/440/24 dated 16th

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	February, 2024. ***Recommendation of reviewer:*** • SOP-checklist is incomplete. Part of point no. 7 is missing. • In SOP-Checklist, point no.-10 (Risk & benefit) - ticked as not reasonable -PI to correct. • There are multiple objectives. It is suggested to identify one primary objective and the rest should be clubbed into secondary objectives. **Comment:** Sponsor information is incorrect. Kindly modify. **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Dr. Mohammad Kaleem Ahmad did not take part in the discussion and making decision.*** ***Ref. code: XXV-PGTSC-IIA/P20***
21.	Research proposal entitled ***"Characterisation of B Cells in newly diagnosed immune thrombocytopenia (ITP) patients and their correlation with response to steroid therapy"*** submitted by Dr. Harshita Singh, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 136/24 dated 19th February, 2024. ***Recommendation of reviewer:*** • Very clear planning and writing • Point no 19 in Patient Information sheet to be corrected **Decision:** Level 1: Approved – with or without suggestions or comments. ***Ref. code: XXV-PGTSC-IIA/P21***
22.	Research proposal entitled ***"An observational study on estimation and correlation of serum Vitamin B12, serum Vitamin D3 and lipid profile along with assessment of hearing in tinnitus patients"*** submitted by Dr. Ravi Kumar Rawat, JRI, Department of Oto-Rhino-Laryngology & Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 528/ENT/24 dated 3rd February, 2024. ***Recommendation of reviewer:*** • Estimation of vitamins and lipids is not justified in the title as there is no protocol for lab tests in the methodology; hence title may be re-framed • Introduction-13th last line, 'all patients…PTA' should be deleted. It is giving an impression of the study already being over • If all patients with CKD and HTN are excluded, will there be any significant number of participants showing derangement in vitamin B12, D3 or lipid profile? • Under METHODS, matter related to vitamin D level should be in future tense • Under ROL, every paper is copied as 'we', 'our'. Please rectify • Under ROL, Reference McKenna *et al* (2014) describes another factor, not pertaining to the topic. It may be removed. • Goyal *et al* (2015) is INCOMPLETE. Either complete or remove it from the list.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Clarification regarding funding is required. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P22***
23.	Research proposal entitled ***"Outcomes of vital pulp therapy in permanent teeth using nanofibrous scaffolds and I-PRF: A randomized controlled study"*** submitted by Dr. Muskan Jain, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 931/Cons&Endo/24 dated 5th February, 2024. ***Recommendation of reviewer:*** • Point no 11 on data monitoring is incomplete • Study design is RCT, please ensure the guidelines are followed in terms of outcome measures, blinding, etc. • Statistical tests are not mentioned **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P23***
24.	Research proposal entitled ***"Role of antimicrobial photodynamic therapy during non surgical root canal treatment of teeth having apical periodontitis in individuals with type 2 diabetes mellitus-A clinical and radiographic evaluation"*** submitted by Dr. Abinia Vaishna VI.N, JRI, Department of Conservative Dentistry & Endodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 963/Cons&Endo/24 dated 10th February, 2024. ***Recommendation of reviewer:*** • Approved **Decision:** Approved ***Ref. code: XXV-PGTSC-IIA/P24***
25.	Research proposal entitled ***"Out of pocket expenditure in tuberculosis patients: An observational study at tuberculosis units in Lucknow district"*** submitted by Dr. Aqsa Arif, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1381/CM/24 dated 29th February, 2024. ***Recommendation of reviewer:*** • Is there a comparison group to estimate the proportions mentioned under objectives? If yes, please mention. • 2.Mention the statistical parameters to be used • How will the questionnaire be pre-validated and inter observer bias be handled? **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Ref. code: XXV-PGTSC-IIA/P25
26.	Research proposal entitled ***"Retrospective and prospective study on image guided celiac ganglion block for pain relief in cases of pancreatitis and hepatobiliary malignancies"*** submitted by Dr. Vikas Singh, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 1341/RD/24 dated 30th January, 2024. ***Recommendation of reviewer:*** • Study duration is 2 years in IEC proforma and 1 year in Material and Methods. Please correct • Study design is INCOMPLETE; it seems that it is a mixed-method cohort design or an ambispective study • How will the retrospectively enrolled patients receive celiac block? • Will the patients be randomly selected for each imaging modality? Please clarify • Will the procedure be repeated if there may be a need or is it a one-time process? • Mention the statistical tools to be used. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P26***
27.	Research proposal entitled ***"Laboratory markers of hematoma expansion in acute intra cerebral haemorrhage patients: A prospective observational study"*** submitted by Dr. Saritesh Kumar Thakur, SR, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 109/Neuro/24 dated 6th March, 2024. ***Recommendation of reviewer:*** • The plan of study is very clear • However, the entire Introduction under PROJECT SUMMARY is a mismatch to the proposal. To be re-written • In annexure 7, point no 20, name of Member secretary, IEC to be removed **Comment:** As above **Decision:** Level 1: Approved – with or without suggestions or comments ***Ref. code: XXV-PGTSC-IIA/P27***
28.	Research proposal entitled ***"The determinants of health-related quality of life in obstructive airway disease patients: A Hospital based study"*** submitted by Dr. Theepan Kumar S, JRII, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1429/CM/24 dated 12th March, 2024. ***Recommendation of reviewer:*** • Please write the reference numbers uniformly and properly • Kindly keep just one primary objective, based on which the sample-size calculation is to be done; rest should be labeled as secondary objectives. • How will the investigators meet and measure outcomes of their third objective? **Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P28***
29.	Research proposal entitled ***"Fracture of hyoid bone in cases of mechanical asphyxia death resulting from hanging and strangulation"*** submitted by Dr. Mohd Irfan, JRI, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 70/FMT/24 dated 22nd February, 2024. ***Recommendation of reviewer:*** • Topic does not give idea of the proposed methodology or study design. To be reframed • Points number 4-7 in patient information sheet to be edited in accordance to a corpse • ROL: Serial numbers and year of study to be corrected • References to be re-written in a standard format like Vancouver • Language of background and justification is inappropriate and ambiguous. Please rectify. • Kindly elaborate on the procedure adopted towards ensuring consent viz. LAR, police official, etc. **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P29***
30.	Research proposal entitled ***"Ambispective study of management of may-thurner syndrome and its outcomes"*** submitted by Dr. Avanjala Singh, JRI, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 186/RD/24 dated 22nd February, 2024. ***Recommendation of reviewer:*** • Point numbers 2, 13 to be completed in the IEC proforma • Point no 7 of patient information sheet to be completed • Study is quoted as an ambispective cohort study that carries forward patients from a retrospective cohort. Kindly clarify if the methodology conforms to the study design? • What is the baseline detection rate? Is the sample size of 54 applicable to pre and post intervention same set of patients or do you have a control/ comparison group? • Referring to the point above, what shall be the follow up period? **Comment:** • Kindly provide PGT declaration form. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P30***
31.	Research proposal entitled ***"Effect of educational intervention on practices, prevention***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Dated 13th May, 2024

	& management of animal bite amongst community level healthcare workers at Government health facilities of Lucknow district" submitted by Dr. Gurutheja H. C, JRI, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1347/CM/24 dated 22nd February, 2024. ***Recommendation of reviewer:*** • Resubmit the scientific review committee sheet and provide specific comments to the headings c, d,f, and g. • The Annexure 1 Q4–brief description of the proposal as per the heading is missing. • In the patient information sheet, Q13 please provide an answer to the question asked. • The executive summary for the study is missing. Please provide as per the heading in the ethical format. **Comment:** • Signature is missing of Dr. O.P. Singh in Scientific Review Committee. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P31***
32.	Research proposal entitled ***"Analysis of serum testosterone levels in men with stricture urethra and its effect on surgical outcome"*** submitted by Dr. Ujjawal Jain, SRI, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 151/URO/24 dated 4th March, 2024. ***Recommendation of reviewer:*** • Annexure 1 (Sponsor Information) Q1. Mentions funding from a Government agency; kindly clarify and submit the details. • Annexure 1 Q5iii. Correct the recruitment of sexes in the study. • Annexure 1 Q7ii. Please specify how will you measure serum testosterone by taking blood from the patients. • Annexure 1 Q8, please tick the necessary blocks for the patient information sheet. • The executive summary for the study is missing. please provide as per the heading in the ethical format. • The Annexure 1 Q4 – brief description of the proposal as per the heading is missing. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P32***
33.	Research proposal entitled ***"Characterization of T cell subsets in newly diagnosed ITP patients and their correlation with response to steroid therapy"*** submitted by Dr. Md Sultan Ahamad, JRI, Department of Pathology, King George's Medical University, U.P., Lucknow vide letter no. 156/24 dated 20th February, 2024. ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• The Annexure 1 Q4 – brief description of the proposal as per the heading is missing. • The executive summary for the study is missing. Please provide as per the heading in the ethical format. • Annexure 1 Q7. Please check for the use of body fluids in the study and mention why? **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission *Ref. code: XXV-PGTSC-IIA/P33*
34.	Research proposal entitled *"Flipped classroom paradigm facilitate the learning of physiology in medical students"* submitted by Dr. Shalini Lal, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3764/PHY/24 dated 20th February, 2024. ***Recommendation of reviewer:*** • Annexure1 Q3 ii. What is the clinical trial that is used in the study being approved in the Indian market? • Annexure 1 Q4. Please write a brief description according to the heading mentioned. • Annexure 1 Q5ii. Mention the duration of subject participation. • The executive summary for the study is missing. Please provide as per the heading in the IEC format. **Comment:** The title of the study needs to be modified to reflect an analysis/study instead of a statement and should also include the study design. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission *Ref. code: XXV-PGTSC-IIA/P34*
35.	Research proposal entitled *"Study of chromosomal aberrations and polymorphism of GSTT1 & GSTM1 gene in cases with acute lymphoblastic leukemia in North Indian population"* submitted by Dr. Varda Mateen, JRI, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 680/ANAT/24 dated 1st March, 2024. ***Recommendation of reviewer:*** • Point no.4 of Annexure 1- brief description of the proposal- is not found. • Annexure Q5ii b Duration of subject participation • Explain the need for special groups Q5 vii. For subject selection in study? • Details of body fluid in Q7 ii is not found. • Please check Q8 and mark all the necessary blocks. • Patient Information sheet in both languages is missing. • Scientific review committee is missing. • In the inclusion criteria, the age group of the patients to be enrolled is missing.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	And on what basis the severity of the disease will be determined to recruit patients in the study. • The informed consent in both English and Hindi languages for cases and control is missing. • The location to carry out the PCR-RFLP is missing in the study. • What is the role of Dr. Sushma Tomar and Dr Gyanendra Sonkar in patient selection? Please specify. • The executive summary for the study is missing. Please provide as per the heading in the ethical format. **Comment:** • Kindly disclose the source of funding and clarify the financial implications. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P35***
36.	Research proposal entitled ***"To estimate the prevalence of drug sensitive and drug resistance extrapulmonary tuberculosis at tertiary care center"*** submitted by Dr. Akash Sharma, JRI, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 265/24 dated 26th February, 2024. ***Recommendation of reviewer:*** • Annexure 1 Q4. the Brief description of the study as per the heading is missing in the proposal. • Annexure 1 Q8, please tick the necessary blocks for the patient information sheet. • In the Patient information sheet, Q4, explain why you have chosen the subject for the study. • In the Patient information sheet, Q7, mention the dos and don'ts subject enrolled in the study must follow. • In the Patient information sheet, Q13, provide how you will deal with the new information available in the study. • How was sample size calculated? • The executive summary for the study is missing. Please provide as per the heading in the ethical format. **Comment:** Title of the study may be modified to ***"Estimation of prevalence of drug sensitive and drug resistance extrapulmonary tuberculosis at tertiary care center"*** *AND* should include the study design. As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P36***
37.	Research proposal entitled ***"Assessment of cardiac autonomic function and anxiety sensitivity in different phases of menstrual cycle"*** submitted by Dr. Gulnaaz Khanam, JRI, Department of Physiology, King George's Medical University, U.P., Lucknow vide letter no. 3765/PHY/24 dated 20th February, 2024. ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Annexure 1 Q4. Please write a brief description according to the heading mentioned. • SRC needs to be revised. • Mention the study design in the title as well as in the manuscript. • Kindly provide executive summary according to the heading of ethical format. **Comment:** The objectives should be divided into primary and secondary objectives. There should be one primary objective (to be used for calculating the sample size) while the remaining objectives may be grouped as secondary objectives. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P37***
38.	Research proposal entitled ***"A naturalistic comparative study of transcranial direct current stimulation and repetitive transcranial magnetic stimulation in the management of generalized anxiety disorder"*** submitted by Dr. Tayyaba Haseen, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 2450/Psy/24 dated 26th February, 2024. ***Recommendation of reviewer:*** • Annexure1 Q3 ii. What is the clinical trial that is used in the study being approved in India, UK & European markets? • Annexure 1 Q4. Please write a brief description according to the heading mentioned. • In the English informed consent, please re-write the purpose of the study. • Please provide the executive summary according to the heading provided in the form. • Mention the study design. • How is the sample size of the study calculated? **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission. ***Dr. Sujita Kumar Kar did not take part in the discussion and making decision.*** ***Ref. code: XXV-PGTSC-IIA/P38***
39.	Research proposal entitled ***"Analgesic effectiveness of pudendal nerve block for postoperative pain management in anorectal surgery-randomized comparative study"*** submitted by Dr. Marnanjal Kumar, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/226/24 dated 21st February, 2024. ***Recommendation of reviewer:*** • Annexure 1 Q4, provide brief summary of the proposal according to the heading. • Annexure 1 Q5 ii provide the duration of subject participation in the study. • In the patient information sheet, please re-answer Q4, 7, and 13 in the study. • Kindly add an executive summary of the study as per the heading in the ethical

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	annexure. **Comment:** • The title may be modified to "…anorectal surgery – a randomized controlled study" • Kindly provide PGT declaration stating whether the interventions/combinations are approved or not; if yes, are they approved for the given indication. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P39***
40.	Research proposal entitled ***"Immunohistochemical expression of PCNA in pleomorphic adenoma of parotid gland"*** submitted by Dr. Farazmed, JRI, Department of ENT Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 527/ENT/24 dated 27th February, 2024. ***Recommendation of reviewer:*** • Annexure 1 Q4, provide brief summary of the proposal according to the heading. • Annexure 1 Q5 ii provide the duration of subject participation in the study. • In the patient information sheet, please re-answer Q4 in the study. • Kindly add an executive summary of the study as per the heading in the annexure. • Why is the margin of error taken 15%? Re-calculate the sample size? **Comment:** The design of the study is unclear. The study should be included in the title of the study. Do you wish to proceed as a pilot assessment? **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P40***
41.	Research proposal entitled ***"Systemic immune inflammation index as a prognostic factor in patients of sub mucous fibrosis and its correlation with dysplasia"*** submitted by Dr. Shubhi Goel, JRI, Department of ENT Head & Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 528/ENT/24 dated 27th February, 2024. ***Recommendation of reviewer:*** • Annexure 1 Q4, provide brief summary of the proposal according to the heading. • Annexure 1 Q5 ii provide the duration of subject participation in the study. • Annexure 1 Q7ii please mention details of organ or body fluid used in the study. • In the patient information sheet answer to the Q -what are the alternatives for diagnosis and treatment? The sequences of questions are not according to the format of patient information sheet. • Kindly modify the title to include the study design. • Why is the margin of error taken 15%? Re-calculate the sample size? • Kindly add an executive summary of the study as per the heading in the annexure. **Comment:** The objectives should be divided into primary and secondary objectives. There should be

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	one primary objective (to be used for calculating the sample size) while the remaining objectives may be grouped as secondary objectives. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P41***
42.	Research proposal entitled ***"Non-anaemic iron deficiency in pregnancy and its association with maternal and fetal outcomes"*** submitted by Dr. Aditi Singh, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/509/24 dated 21st February, 2024. ***Recommendation of reviewer:*** • Annexure 1 Q4, provide brief summary of the proposal according to the heading. • Annexure 1 Q7ii please mention details of organ or body fluid used in the study. • In the patient information sheet, please re-answer Q4, 5,7, 9, 13, and 15 in the study. • Kindly add an executive summary of the study as per the heading in the annexure. **Comment:** • Clarification on Iron supplementation in Group 1 is required • Kindly modify the title to include the study design. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P42***
43.	Research proposal entitled ***"Combined perioperative versus postoperative mitomycin C instillation in non-muscle invasive bladder cancer – A randomized controlled study"*** submitted by Dr. Jitender Yadav, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 179/URO/24 dated 13rd March, 2024. ***Recommendation of reviewer:*** • Is this a "Randomized Controlled Trial" or "Randomized Controlled Study", as you have used both terms in title. • In Patient Information Sheet point 16, you mentioned "records may be inspected by company sponsoring" while in SOP Checklist, no information was provided regarding sponsor. Kindly provide the details. **Comment:** • It is unclear whether adverse events will be reported under post-marketing surveillance. • Kindly elaborate on the sample size and its calculation. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P43***
44.	Research proposal entitled ***"Clinical utility of laryngeal mask airway blockbuster® and supreme™ supraglottic devices for airway management in post-burn injury contracture neck patients under general anaesthesia: A randomized comparative study"*** submitted by Dr. Govind Agarwal, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/229/24 dated 21st February, 2024. ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Patient Information Sheet is not informative • In SOP-Checklist point no.10 (Risk & benefit)-ticked as not reasonable. It should be reasonable. **Comment:** • The title of the study may be modified as "…neck patients undergoing general anaesthesia: A …" **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Dr. D.N. Upadhyaya did not take part in the discussion and making decision.*** ***Ref. code: XXV-PGTSC-IIA/P44***
45.	Research proposal entitled ***"Study on short-term prognostic accuracies of CLIK-C ACLF score in acute-on-chronic liver failure patients"*** submitted by Dr. Vishal Gupta, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 592/MED/24 dated 14th March, 2024. ***Recommendation of reviewer:*** • In SOP-Checklist point no. 5 (vi) (Vulnerable subjects)-ticked as No, but Elderly ticked Yes. • PI to correct the checklist. • It is not clear how the comparison of scores would be done, and whether it is truly represented by the sample size. **Comment:** **Decision:** Level 3: Revision with major modifications for resubmission ***The opinion of Dr. G.G. Agarwal needs to be taken for sample size calculation.*** ***Ref. code: XXV-PGTSC-IIA/P45***
46.	Research proposal entitled ***"Comparison of peguero-lo presti, sokolow-lyon and cornell voltage electrocardiographic criteria for the diagnosis of left ventricular hypertrophy in patients with hypertension"*** submitted by Dr. Prashant Meena, JRI, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 607/MED/24 dated 15th March, 2024. ***Recommendation of reviewer:*** • In Inclusion criteria – Age and gender specification of the patients not mentioned- PI to include. • The title may be revised to include the study design. • Sample size calculation needs elaboration. **Comment:** **Decision:** Level 3: Revision with major modifications for resubmission ***The opinion of Dr. G.G. Agarwal needs to be taken for sample size calculation.*** ***Ref. code: XXV-PGTSC-IIA/P46***
47.	Research proposal entitled ***"Efficacy of injection iron isomaltoside for treatment of anaemia in pregnant women in a tertiary care center"*** submitted by Dr. Anzia Ansari, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/473/24 dated 20th February, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Recommendation of reviewer: • If it is not a clinical trial, you have to mention **NA** against SOP-Checklist, Point no. 3. Clinical Trials. • It is unclear how adverse event reporting shall be handled **Comment:** **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P47***
48.	Research proposal entitled ***"Fetal fibronectin - A new tool for prediction of successful induction of labor in cases of previous cesarean section"*** submitted by Dr. Rajni Kharkwal, JRI, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/470/24 dated 19th February, 2024. ***Recommendation of reviewer:*** • If it is not a clinical trial, you have to mention **NA** against SOP-Checklist, Point no.- 3.Clinical Trials • Sample size calculation needs elaboration. **Comment:** The objectives should be divided into primary and secondary objectives. There should be one primary objective (to be used for calculating the sample size) while the remaining objectives may be grouped as secondary objectives. **Decision:** Level 3: Revision with major modifications for resubmission ***The opinion of Dr. G.G. Agarwal needs to be taken for sample size calculation*** ***Ref. code: XXV-PGTSC-IIA/P48***
49.	Research proposal entitled ***"Correlation of clinical profile of nasopharyngeal angiofibroma with vascular endothelial growth factor expression and serum levels-identifying surrogate factor for anti-VEGF therapy"*** submitted by Dr. Suvigya Jain, JRI, Department of Otorthinolaryngology & Head Neck Surgery, King George's Medical University, U.P., Lucknow vide letter no. 538/ENT/24 dated 29th February, 2024. ***Recommendation of reviewer:*** • In SOP-Checklist, Point no.-5 (ii) b) (Subject participation) -you mentioned Young Adult males, While in Materials and Methods section of your proforma (Inclusion Criteria) "All patients" is mentioned (without any age and gender specifications) PI to correct. **Comment:** The objectives should be divided into primary and secondary objectives. There should be one primary objective (to be used for calculating the sample size) while the remaining objectives may be grouped as secondary objectives. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission. ***Ref. code: XXV-PGTSC-IIA/P49***
50.	Research proposal entitled ***"Efficacy of a novel chitosan hydrogel delivered biomimetic self-assembling peptide (P11-4) for remineralization of 'hypomineralized enamel lesions' in Paediatric patients: A randomized clinical trial"*** submitted by Dr. Agarwal Abhilasha Kishanlal, SR, Department of Paediatric & Preventive Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Dated 13th May, 2024

	Pedo/25/24 dated 24th January, 2024. ***Recommendation of reviewer:*** • As per title it is a clinical trial, but you have mentioned NA against SOP-Checklist, Point no.- 3. Clinical Trials. Kindly clarify. If this is not a trial, then the title should be modified to "A randomized controlled study" in place of "A randomized controlled trial". **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P50***
51.	Research proposal entitled ***"Assessing post mastectomy pain relief; A randomized comparative study of USG guided erector spinae block and mid transeverse pleura block"*** submitted by Dr. Ashu, JR, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/233/24 dated 21st February, 2024. ***Recommendation of reviewer:*** • In SOP-Checklist, Point no.-5 (i) Number of subjects not mentioned • In SOP-Checklist, Point no.-5 (ii) Duration b) (Subject participation), you have to mention the duration of subject participation. • In SOP-Checklist, Point no.-5 (vi) Subject Vulnerability- not ticked • In SOP-Checklist point no.10 (Risk & benefit)-ticked as not reasonable. It should be reasonable. • PI to correct the checklist. **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P51***
52.	Research proposal entitled ***"Diastolic dysfunction in type 2 diabetes mellitus"*** submitted by Dr. Nikita Jani, JR, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 596/MED/24 dated 14th March, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: XXV-PGTSC-IIA/P52***
53.	Research proposal entitled ***"Lower genito-urinary tract injury in female: single centre experience"*** submitted by Dr. Mughakato H Sema, SR, Department of Urology, King George's Medical University, U.P., Lucknow vide letter no. 130/URO/24 dated 13th March, 2024. ***Recommendation of reviewer:*** • Kindly include the study design in the title of the study. • The objectives of the study should be divided into primary and secondary objectives. There should be one primary objective while the remaining objectives

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	may be grouped as secondary objectives. • Clarify the sample size (with justification, if the enrollment is not based on duration). • The management options and the expected outcome analysis is unclear. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P53***
54.	Research proposal entitled ***"Comparison of efficacy of suprascapular nerve block, platelet rich plasma and exercise program for the treatment of adhesive capsulitis of shoulder joint-A randomized controlled study"*** submitted by Dr. Harshit Tripathi, JR, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 5551/24 dated 22nd February, 2024. ***Recommendation of reviewer:*** • In SOP-Checklist, Point no.-5 (ii) Duration of study and Subject participation, both mentioned 18 months, please explain. • In SOP-Checklist, Point no.-5 (vi) Vulnerable subjects ticked No, while Age group mentioned as 40-70 years in Inclusion criteria. • In SOP-Checklist, Point no.-8,9,10,11,12 are missing. • Patient information Sheet, English version not attached. Only guidelines are attached. **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P54***
55.	Research proposal entitled ***"Planter fascia stretching exercises versus ultrasound guided local corticosteroid injection for planter fasciitis: A randomized controlled trial"*** submitted by Dr. Neelam Kumari, JR, Department of Physical Medicine & Rehabilitation, King George's Medical University, U.P., Lucknow vide letter no. 5679/24 dated 23rd March, 2024. ***Recommendation of reviewer:*** • In SOP-Checklist, Point no.-5 (ii) Duration of study and Subject participation, both mentioned 18 months, please explain. • Patient information Sheet, English version not attached. Only guidelines are attached. **Comment:** • Kindly modify the title ***"A randomized controlled study"*** in place of ***"A randomized controlled trial"*** **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P55***
56.	Research proposal entitled ***"A comparative study of impulse oscillometry (IOS)***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	parameters between patients with usual interstitial pneumonia (UIP) and non UIP pattern diffuse parenchyma lung disease (DPLD) diagnosed on high resolution computed tomography (HRCT)" submitted by Dr. Manisha Chandra, JR, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 674/24 dated 27th February, 2024. ***Recommendation of reviewer:*** • Following sections of the IEC form ar incomplete-8, 10. • Section 5 mentions subjects as both patients as well as volunteers. Please explain. • Sample size has not been justified please calculate the sample size. **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P56***
57.	Research proposal entitled ***"To study the effect of 5% lignocaine patch in attenuating spinal needle puncture pain in patient posted for ano-rectal surgery under spinal anaesthesia: A prospective randomized control study"*** submitted by Dr. Shrikant Kushwaha, JR, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/220/24 dated 21st February, 2024. ***Recommendation of reviewer:*** • Following sections of the IEC form are incomplete-7 • Section 3 mentions that the study is a drug trial. Please clarify. **Comment:** • Kindly provide the PGT declaration. • The title of the study may be modified to "A randomized controlled study" instead of "A prospective randomized control study". **Decision:** Level 3: Revision with major modifications for resubmission. ***Ref. code: XXV-PGTSC-IIA/P57***
58.	Research proposal entitled ***"To study vitamin B12 deficiency anemia and its correlation with clinical, hematological and electrophysiological parameters"*** submitted by Dr. Shubham Verma, JR, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 589/MED/24 dated 14th March, 2024. ***Recommendation of reviewer:*** • There are multiple objectives. It is suggested to identify one primary objective and the rest should be clubbed into secondary objectives. **Comment:** • It is important to define the participants as per standard definition/ terminology. • Kindly improve upon the use of tense in the proposal; the study has been planned and is yet to be conducted. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P58***
59.	Research proposal entitled ***"The effects of ketofol, ketamine and etomidate anesthesia***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	for modified ECT on neuropsychological outcome in major depressive disorders patients: A randomized, comparative study" submitted by Dr. Arushi Jaiswal, JR, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/211/24 dated 21st February, 2024. ***Recommendation of reviewer:*** • Introduction is written in points (page 18). Kindly write the introduction in running text. • Method of allocation concealment not mentioned. **Comment:** • Kindly modify the title to ***"A randomized controlled study"*** in place of ***"A randomized comparative study"*** **Decision:** Level 3: Revision with major modifications for resubmission ***Dr. Sujita Kumar Kar did not take part in the discussion and making decision.*** ***Ref. code: XXV-PGTSC-IIA/P59***
60.	Research proposal entitled ***"Effect of oral melatonin on postoperative analgesia in mandibular fracture fixation surgery-A randomized controlled study"*** submitted by Dr. DineshKumar. P, JR, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/202/24 dated 21st February, 2024. ***Recommendation of reviewer:*** • In SOP-Checklist, point no.-10 (Risk & benefit) - ticked as not reasonable -PI to correct. • Kindly mention method of randomization and allocation concealment • Kindly clarify if the proposal actually qualifies for "A randomized placebo-controlled study". **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P60***
61.	Research proposal entitled ***"Evaluation of serum Vitamin D3 level with perioperative outcome in chronic empyema thoracis: A prospective observational study"*** submitted by Dr. Nitin Nishad, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 465/24 dated 24th February, 2024. ***Recommendation of reviewer:*** • The attached proposal title page and Hindi Patient Information Sheet are of another candidate Dr Neetu Singh, and has been signed by Dr Nitin Nishad. Highly unacceptable. • Spellings to be checked in ROL • None of the studies quoted under ROL, talk of correlation between Vit D and empyema thoracis, rather only wound healing. Please expand literature search. • There is disparity in study duration mentioned at the two places.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• What is the timeline of pre and post operative periods for sample collection to estimate Vitamin D levels? **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P61***
62.	Research proposal entitled ***"Video-assisted thoracoscopic surgery versus intra-pleural streptokinase instillation: A randomized, controlled clinical trial for optimum treatment of post-traumatic retained hemothorax"*** submitted by Dr. Archana Singh, JR, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. TS/194/24 dated 27th February, 2024. ***Recommendation of reviewer:*** • ROL is too brief. Kindly expand. • The 2 studies quoted under ROL are not mentioned in references. **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P62***
63.	Research proposal entitled ***"Role of citicholin and cerebrolysin combination in the management of severe traumatic brain injury: A prospective randomized study"*** submitted by Dr. Obili Manoj, JR, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/227/24 dated 21st February, 2024. ***Recommendation of reviewer:*** • Please mention same spelling in all the text, of the drug under trial • Reference numbers 4 and 25 are incomplete • Disparity in study design under informed consent and the title. Please correct • Mention sample size calculation and the statistical tools to be used • Kindly clarify if the intervention in question has been approved by DCGI or not. If yes, please furnish the approval letter/list. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P63***
64.	Research proposal entitled ***"A study of applicability of IPS clinical practice guidelines in adolescents with functional neurological disorder"*** submitted by Dr. Sandhya Verma, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 2462/Psy/24 dated 28th February, 2024. ***Recommendation of reviewer:-*** • Make a list of the study variables and population parameters required for managing functional neurological disorder.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is not given. It should be specific to the research hypothesis. • Discuss a little bit about the reliability and validity of the scales being used. Are these scales usable/applicable in the present context. • Statistical analysis section is missing. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Dr. Sujita Kumar Kar did not take part in the discussion and making decision.*** ***Ref. code: XXV-PGTSC-IIA/P64***
64.	Research proposal entitled ***"A study of applicability of IPS clinical practice guidelines in adolescents with functional neurological disorder"*** submitted by Dr. Sandhya Verma, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 2462/Psy/24 dated 28th February, 2024. ***Recommendation of reviewer:-*** • Make a list of the study variables and population parameters required for managing functional neurological disorder. • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is not given. It should be specific to the research hypothesis. • Discuss a little bit about the reliability and validity of the scales being used. Are these scales usable/applicable in the present context. • Statistical analysis section is missing. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Dr. Sujita Kumar Kar did not take part in the discussion and making decision.*** ***Ref. code: XXV-PGTSC-IIA/P64***
65.	Research proposal entitled ***"To study the effectiveness of melatonin supplementation on sleep and cognition in children with ADHD experiencing sleep disturbances"*** submitted by Dr. Ritwick Tripathi, JRI, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 2473/Psy/24 dated 28th February, 2024. ***Recommendation of reviewer:-*** • This is an effectiveness study. The control group and treated group should be explicitly defined. • Make a list of the study variables and population parameters required for investigating the effect of melatonin treatment.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is not given. It should be specific to the research hypothesis. • Discuss a little bit about the reliability and validity of the scales being used. Are these scales usable/applicable in the present context. • Statistical analysis section is missing. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Dr. Sujita Kumar Kar did not take part in the discussion and making decision.*** ***Ref. code: XXV-PGTSC-IIA/P65***
66.	Research proposal entitled ***"Comparision of efficacy of cranial vs cervical approach of ultrasound guided greater occipital nerve block in patients undergoing posterior fossa craniotomy: A randomized controlled study"*** submitted by Dr. Sandhya, JR, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/205/24 dated 21st February, 2024. ***Recommendation of reviewer:-*** • Make a list of the study variables and population parameters required for investigating the effect of melatonin treatment. • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is arbitrary in the absence of proper research hypothesis. It should be specific to the research hypothesis. • Statistical analysis section is arbitrary. It should be specific to the research hypothesis. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P66***
67.	Research proposal entitled ***"A study of sensory processing emotional & behavioural profile among preschool children exposed to screen"*** submitted by Dr. Arif Khan, JR, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 2488//Psy/24 dated 29th February, 2024. ***Recommendation of reviewer:-*** • The objectives of the study are not given. • Make a list of the study variables and population parameters required for studying sensory processing, emotional & behavioural profile. • Convert the primary objective into research hypothesis using the population parameters.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Sample size calculation is not given. It should be specific to the research hypothesis. • Discuss a little bit about the reliability and validity of the scales being used. Are these scales usable/applicable in the present context. • Statistical analysis section is missing. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P67***
68.	Research proposal entitled ***"A study of naltrexone and topiramate combination versus naltrexone alone in craving in alcohol dependence"*** submitted by Dr. Ayush Maheshwari, JR, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 2492//Psy/24 dated 29th February, 2024. ***Recommendation of reviewer:-*** • This is an effectiveness study. The control group and treated group should be explicitly defined. • Make a list of the study variables and population parameters required for comparing the two treatment groups. • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is arbitrary in the absence of proper research hypothesis. It should be specific to the research hypothesis. • Discuss a little bit about the reliability and validity of the scales being used. Are these scales usable/applicable in the present context. • Statistical analysis section is missing. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P68***
69.	Research proposal entitled ***"A study of add-on rTMS on craving in patients with opioid dependence"*** submitted by Dr. Sanjana Bhasin, JR, Department of Psychiatry, King George's Medical University, U.P., Lucknow vide letter no. 2491//Psy/24 dated 29th February, 2024. ***Recommendation of reviewer:-*** • Make a list of the study variables and population parameters required for comparing the two treatment groups. • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is arbitrary in the absence of proper research hypothesis. It should be specific to the research hypothesis.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Discuss a little bit about the reliability and validity of the scales being used. Are these scales usable/applicable in the present context. • Statistical analysis section is arbitrary. It should be specific to the research hypothesis. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Dr. Sujita Kumar Kar did not take part in the discussion and making decision.*** ***Ref. code: XXV-PGTSC-IIA/P69***
70.	Research proposal entitled ***"Comparison of clinical performance of i-GEL versus i-GEL plus in adult patients going for laparoscopic cholecystectomy under general Anaesthisesia: A prospective randomized control study"*** submitted by Dr. Tanvi Shukla, JR, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/195/24 dated 21st February, 2024. ***Recommendation of reviewer:-*** • Make a list of the study variables and population parameters required for comparing the two groups. • Convert the primary objective into research hypothesis using the population parameters. • Sample size calculation is arbitrary in the absence of proper research hypothesis. It should be specific to the research hypothesis. • Statistical analysis section is arbitrary. It should be specific to the research hypothesis. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P70***
71.	Research proposal entitled ***"Prevalence of osteoporosis in diabetes mellitus and impact of glycemic control and duration of diabetes ob bone mineral density"*** submitted by Dr. Vivek Kumar Chauhan, JR, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 591/MED/24 dated 14th March, 2024. ***Recommendation of reviewer:-*** Approved **Decision:** Approved ***Ref. code: XXV-PGTSC-IIA/P71***
72.	Research proposal entitled ***"Profile of patients attending ophthalmology emergency services at a tertiary care centre in a Government medical university- A descriptive study"*** submitted by Dr. Shalvi Chandra, JR, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. 8692/OHP/24 dated 29th February 2024. ***Recommendation of reviewer:-***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Approved **Decision:** Approved ***Ref. code: XXV-PGTSC-IIA/P72***
73.	Research proposal entitled ***"Evaluation of peri-operative and short term outcomes in patients undergoing roux-en-y hepatico jejunostomy in post cholecystectomy bile duct injury: A prospective observational study"*** submitted by Dr. Ashish Yadav, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 467/24 dated 24th February 2024. ***Recommendation of reviewer:-*** • Reference numbers 3,8,10 are incomplete • Sample size estimation is not provided • Mention the statistical tools to be used **Comment:** As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXV-PGTSC-IIA/P73***
74.	Research proposal entitled ***"Evaluation of stem cell based therapy in diabetic foot ulcer: A prospective observational study"*** submitted by Dr. Neetu Singh, JR, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 466/24 dated 24th February 2024. ***Recommendation of reviewer:-*** • There is disparity in the names of co-supervisors under proposal title and IEC proforma • Purpose of study under informed consent, and point 16, 17 under annexure 7 are vaguely written. Please correct • Disparity in study duration as well as sample size under IEC proforma and Material & Methods section • Under 'steps of extraction of mesenchymal cells', there is no detail of extraction itself • Spellings are to be corrected, particularly after the flowchart • Heading of the flow chart to be changed from STUDY DESIGN to WORK FLOW. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXV-PGTSC-IIA/P74***
75	Research proposal entitled ***"The role of patient education and video session of fiber optic bronchoscopy intubation in anticipated difficult airway patients for reduction of procedural stress and anxiety: A prospective randomized control study"*** submitted by Dr. Shivang Kumar, JR, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/218/24 dated 21st February 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Recommendation of reviewer:- *mendation of reviewer:-* • In SOP-Checklist, Point no.-5 (ii) Duration b) (Subject participation), you have to mention the duration of subject participation. • In SOP-Checklist, Point no.-5 (v), (vi) remained unticked. Need to be mentioned. • In SOP-Checklist point no.10 (Risk & benefit)-ticked as not reasonable. It should be reasonable. • Patient information Sheet, Hindi version not attached. Only guidelines are attached. PI to correct. **Comment:** • Kindly clarify the measures of evaluation • The title of the study may be modified to "The role of …A randomized controlled study". **Decision:** Level 2: Revision with minor modifications/amendments for resubmission *Ref. code: XXV-PGTSC-IIA/P75*
	MHPE students
III	Research proposal entitled *"Emotional intelligence and its relation it academic stress and performance among undergraduate medical and dental students"* submitted by Dr. Dipti Shastri, Additional Professor, Department of Orthodontics, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow. *Recommendation of reviewer:-* • Sponsor mentioned as Government but budget as NA. Explain • In SOP-Checklist, Point no.-5 (vi), ticked elderly but study is on UG students. Explain • In SOP-Checklist point no.10 (Risk & benefit)-ticked as not reasonable. It should be reasonable. • PI to correct. **Comment:** As above **Decision:** Level 1: Approved – with or without suggestions or comments *Ref. code: XXV-PGTSC-MHPE-III/P1*

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 132nd IEC Meeting held on 29th May, 2024

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the 132nd Institutional Ethics Committee Meeting held on **29th May, 2024 from 02:30 P.M. till 5:00 P.M.** at 3rd Floor, Seminar Hall, Central Library, King George's Medical University, U.P., Lucknow in ***hybrid mode.***

The following Members were present in the Meeting:

- Dr. J.S. Srivastava -Chairman
- Hon'ble Justice K.L.Sharma -Member
- Dr. Ritu Karoli -Member
- Dr. Meenakshi Pawha -Member
- Mr. Jayant Krishna -Member
- Dr. Rahul Kumar -Member
- Dr. Sujita Kumar Kar -Member & Vice Dean
- Dr. Hardeep Singh Malhotra -Member-Secretary, ex-officio

IB	Action Taken of IEC
1-	Clarification of research amended protocol no. EX6018-4758 Study Phase: 3a entitled **"ZEUS - *Effects of ziltivekimab versus placebo on cardiovascular outcomes in participants with established atherosclerotic cardiovascular disease, chronic kidney disease and systemic inflammation*"** sponsored by Novo Nordisk India Private Ltd. submitted by Prof. Rishi Sethi, Department of Cardiology King George's Medical University, U.P., Lucknow vide letter no. 686/Cardio/Res/24 dated 8th February, 2024. **Previous EC Comment:** • Being a modification, it is understood that the prior version had a valid IEC approval and that all related documents are in place. • It is noted that the insurance are in place. • CTRI documents & DCGI documents is expected to be appropriate. • The modification documents need to be filed. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved ***The following documents were reviewed in its Meeting:-*** S.No. | Document 1. | Protocol V11.0 dated 17 May 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

2.	Protocol Signature Page for Protocol VIA
3.	1) SIIC a) English i.SIIC_Adult_IN_EN_V5.0_dated 26 July 2023 ii.SIIC_DTP_IN_EN_3.0_Dated 26 July 2023 iii. SIIC_Optional Pre-screening_IN_EN5.0_Dated 26 July 2023 b) Hindi Front Translations i) SIIC_Adult_IN_HI_5.0_dated 30 Aug 2023 ii)SIIC_DTP_IN_HI.3_ Dated' 30 Aug 2023 iii)SIIC_ Optional Pre_ H1_5.0 Dated 30 Aug 2023 ➢ Back Translations SIIC_ Adult IN HI_5.0 BT dated 30 Aug 2023 ii) SIIC DTP_IN_HI_3.0 BT dated 30 Aug 2023 iii)SIIC_ Optional Pre-screening_IN_HI_5.0 dated 30 Aug 2023 SIIC Translation Certificates (HI)
4.	SRR a) English i) Other Info to Subjects 4758_Patient study booklet-version 4_EN_Dated_18 April 2023 ii) Other Info to Subjects 4758-hq-srr-ZEUS-Patient study book EN 18 April 2023 april 2023 iii) Subject Information Sheet ZEUS Device Instruction storyboard EN- Dated May 2023 iv) Subject Information Sheet ZEUS Patient Pen Injector leaflet HI_ Dated 18 May 2023 b) Hindi i)Other Info to-Subjects 4758_Patient study booklet version 41-11_Dated 18 April 2023 ii) Other Info-to-Subjects 4758-hq-srr-ZEUS-Patient study book HI_ Dated iii)Subject Information Sheet ZEUS Device Instruction storyboard_HI_Dated Sep 2023 iv) Subject Information Sheet ZEUS Patient Pen Injector leaflet HI_Dated 8 Sep 2023.
5.	1) DFO i.DFU V4.0_HI ii.DFU_V4.0_EN SRR Translation certificates (HI)

Decision: Approval subject to fulfillment of Administrative formalities.

Ref. code: 116th ECMIIC/P1

2. Clarification of research protocol no. OPX-PR-03 entitled "***Randomized, double-blinded, placebo-controlled study to evaluate the safety, tolerability, and efficacy of intravenous varespladib followed by oral varespladib in addition to standard of care in subjects bitten by venomous snakes***" sponsored by M/s Ophirex, Inc submitted by Dr. Medhavi Gautam, Assistant Professor, Department of Medicine, King George's Medical University, U.P., Lucknow, vide letter no. CT/RM/31/2024 dated 9th April, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Previous comment:

- Sponsor is Ophirex Inc. Contract research organization is Syneos Health. CDSCO approval has been sought by M/S InVentiv International Pharma Services Pvt. Ltd. CTA is with Syneos?
- CDSCO letter does not mention KGMU site.
- Insurance policy is lapsing in June 2024. Please get it renewed & inform the IEC.
- It is unclear who would fund the project and how expenses would be managed.

The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of reviewer:

Provisionally Approved

The following documents were reviewed in its Meeting:-

1. Study Protocol, Version 3.0 dated 01 Dec 2022
2. Investigator's Brochure, Version 1.3 dated 24 Feb 2023
3. Copy of submission of Clinical Trial Application cover letter along with the email confirmation and Snapshot of DCGI Submission dated 16 Dec 2022
4. Main Site-Specific ICD (Site SB3-225_Medhavi Gautam), Version 3.0 dated 25 Feb 2023 in
   a) English
   b) Hindi
   c) Hindi to English
   d) Certificate of Translation (Hindi) dated 15 Mar 2023
5. Dosing Instructions and Dosing Calendar, Version 2.0 dated 03 Feb 2023 in
   a) English
   b) Hindi
   c) Hindi to English
   d) Certificate of Translation (Hindi) dated 20 Feb 2023
6. Subject ID Card, Version 1.1 dated 08 Dec 2022 in
   a) English
   b) Hindi
   c) Hindi to English
   d) Certificate of Translation (Hindi) dated 28 Dec 2022
7. Patient Related Outcomes/ Patient Scales/ Questionnaires:
   a) Columbia-Suicide Severity Rating Scale (C-SSRS)- Baseline, dated 14 Jan 2009 in
      i. English
      ii. Hindi
      iii. Certificate of Translation (Hindi) dated 09 May 2018
   b) Columbia-Suicide Severity Rating Scale (C-SSRS)- Since Last Visit, dated 14 Jan 2009 in
      i. English
      ii. Hindi
      iii. Certificate of Translation (Hindi) dated 05 Jul 2018
   c) Patient Global Impression of Change (PGIC) Scale: version 1976
   d) Patient Specific Functional Scale (PSFS): version 1995
   e) Numeric Pain Rating Scale (NPRS): version 2006

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	f) Patient Family Brochure, Version 1.0 dated 07 Feb 2023 i. English ii. Hindi iii. Certificate of Translation (Hindi) dated 11 May 2023 8. Physician Scales/ Questionnaires: a) Clinical Global Impression – Severity of Illness (CGI-S) Scale: version 1976 b) Clinical Global Impression – Global Improvement (CGI-I) Scale: version 1976 c) Modified Global Snakebite Severity Score (SSS) 9. Clinical Trial Insurance Certificate dated 28 Apr 2023 10.Case Report Form (CRF), Version 0.3 dated 14 Nov 2022 11. Data Safety Monitoring Board (DSMB) Charter, Version1.0 dated 22 Nov 2022 12. Draft Clinical Trial Agreement 13. CV of Principal Investigator dated 09 Jan 2023 14. ML of Principal Investigator No.3907 dated 31 Jul 2012 15.GCP Training Certificate of Principal Investigator 09 Jan 2023 16.Protocol Signature Page dated 25 Jan 2023 17.Investigator's Brochure, Acknowledgment of Receipt (IB AoR) dated 18 Jul 2023 18.Investigator Undertaking dated 15 Mar 2023 19.FDA 1572 dated 15 Mar 2023 20.Financial Disclosure Form (FDF) of Principal Investigator dated 15 Mar 2023 21.DCGI NOC Dated 29-08-2023 22.Import Export License Dated 29-08-2023. 23.SEC Recommendation dated 12 Jul 2023: Refer page 4 of 4, item 16, yellow highlighted section states that the study has been approved by CDSCO. 24.CTRI ref no: REF/2023/07/070655 dated 20 Jul 2023. 25. Main Site-Specific ICD (Site SB3-225_Medhavi Gautam), Version 3.1 dated 21 Jun 2023 in 26.a) English 27.b) Hindi 28.c) Hindi to English 29.d) Certificate of Translation (Hindi) dated 27 Jul 2023 **Decision:** Approval subject to fulfillment of Administrative formalities. ***Ref. code: 130th ECM IIC/P2***
3.	Clarification of research protocol no. PB016-03-01 entitled ***"A randomized, double-blind, multicenter phase 3 study in patients with moderately to severely active ulcerative colitis (UC) to compare the efficacy, safety and immunogenicity of PB016 and entyvio® for the induction and maintenance of clinical response and remission (UCESIVE)"*** sponsored by M/s Polpharma Biologics S.A. Trzy Lipy submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SGE/CT/28/24 dated 6th May, 2024. **Previous comment:** • IEC form Section 3 (iii) not completed. • Section 7 of IEC form mentions no biological materials being used, but section 7(ix) mentions that samples will be sent abroad. Permission obtained from competent

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

authorities.

- Section 8 on consent is incompletely filled.
- Section 5(v) of IEC form mentions subject as those with constipation, however the study is being done on subjects with ulcerative colitis.

The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of reviewer:

Provisionally Approved

The following documents were reviewed in the Meeting:-

Sr. No.	Documents type	Version and Date
1.	Protocol PB016-03-01	V1.1, 10-Oct-2023
2.	Protocol PB016-03-01_Tracked	V1.1, 10-Oct-2023
3.	Protocol PB016-03-01_Summary Of Changes	V1.1, 10-Oct-2023
4.	Investigator Brochure PB016	V3.0, 16-May-2023
5.	Investigator Brochure PB016_Tracked	V3.0, 16-May-2023
6.	Investigator Brochure PB016	V4.0, 16-Jun-2023
7.	Investigator Brochure PB016_Tracked	V4.0, 16-Jun-2023
8.	Main Patient ICF India_English	V2.1.1, 20-Oct-2023
9.	Main Patient ICF India_Hindi	V2.1.1, 20-Oct-2023
10.	Main Patient ICF India_Hindi to English	V2.1.1, 20-Oct-2023
11.	Translation, BT and Verification Certificate_ Main Patient ICF India_Hindi	-
12.	Principle Investigator Undertaking (PA V1.1)	12-Oct-2023

Decision: Approval subject to fulfillment of Administrative formalities.

Ref. code: 130th ECM IIC/P5

4. Clarification of research protocol no. HCR/IV/TRUMAB/05/2022 entitled "***A phase IV multi-centric, post-marketing study evaluating the safety, immunogenicity and efficacy of the marketed formulation of hetero-trastuzumab in female patients with HER2+ breast cancer***" sponsored by M/s Hetero Biopharma Limited submitted by Dr. Naseem Akhtar, Additional

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/954/24 dated 16th April, 2024. **Previous comment:** • Justification of sample size of 200 not provided. • KGMU site not mentioned in DCGI letter. Letter mentioning KGMU site may be sent to IEC. ***The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** Provisionally Approved ***The following documents were reviewed in Its Meeting:-*** 1. Clinical Study Protocol Version 1.0 dated 14-May-2022 2. Investigator Brochure version 1.0 dated 02 Sep 2016 3. Inform Consent Form (ICF) English version 1.0 dated 14 May 2022. 4. Inform Consent Form (ICF) version 1.0 dated 14 May 2022 Translated from English to Hindi on 03 May 2023. 5. ICF Translation Certificate dated 03 May 2023. 6. Inform Consent Form (ICF) version 1.0 dated 03 May 2023 Back Translated from Hindi to English on 17 May 2023 7. ICF Back Translation Certificate dated 17 May 2023 8. DCGI Submission Acknowledgment 9. DCGI Approval Letter dated 18 Apr 2023 10. Insurance Policy dated 09 Feb 2024 11. Investigator Undertaking dated 18 May 2022 12.Investigator Signature Page dated 18 May 2022 13.Principal Investigator's CV & MRC 14.Draft electronic Case Report Form (CRF) Version 3.0 dated 04 Oct 2022 15.Draft CT **Decision:** Approval subject to fulfillment of Administrative formalities. ***Ref. code: 130th ECM IIC/P9***
5.	Clarification of research protocol no. #: R3918-PNH-2050 entitled ***"An open-label extension study to evaluate the long-term safety, tolerability, and efficacy of pozelimab and cemdisiran combination therapy in patients with paroxysmal nocturnal hemoglobinuria"*** sponsored by M/s Regeneron Pharmaceuticals Inc submitted by Dr. S.P. Verma, Additional Professor & Head,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Department of Clinical Hematology, King George's Medical University, U.P., Lucknow vide letter no. CH/CT/04/24 dated 12th April, 2024.

Previous comment:

- Under Sponsor information in IEC form, section 3 (Industry) is incomplete.
- Section on Clinical trial (3(i)) mentions that the study is for device/vaccines.
- DCGI approval mentions the name of Dr A K Tripathi as the PI. Insurance certificate has the name of Dr S. P. Verma. Kindly submit an amendment and ensure that the Insurance is valid.
- This study is a continuation of a study under Dr A K Tripathi, ex-Head, Department of Clinical Hematology. Kindly get the same amended.

The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

Recommendation of reviewer:

Provisionally Approved

The following documents were reviewed in the Meeting:-

Sr. No.	Name of the document	Version No.	Version date
1.	Protocol including Protocol synopsis	Amendment no. 2	30 March 2023
1.1	Dr. _Protocol Signature page signed on 08 June 2023	Amendment no. 2	24 Jan 2024
2.0	R3918-PNH-2050_Protocol_Amendment 3_AAA_Source_ 24AUG2023	Amendment no. 3	24 Aug 2023
2.1	Dr. Upendra Sharma_ 356504_Protocol Signature page signed on	Amendment no. 3	23 Jan 2024
3.0	Investigator Brochure Edition 8_Cemdisiran	Edition 8	22 November 2022
3.1	REGN3918_IB_6_Original_Source_Pozelimab	Edition 6	25 Apr 2023
4.0	ALN-CC5 Investigator Brochure Edition 8_Cemdisiran Receipt	Edition 8	20 Jan 2024
4.1	REGN3918_IB_6_Original_Source_Pozelimab Receipt	Edition 6	20 Jan 2024

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

5.0	R3918-PNH-2050 India Site 356507 Dr.Shailendra Prasad Verma Main ICF English V1.0 dated 19 Dec 2023 based on _India Main ICF English V2.1 Dated 19 Dec 2023	V.1	19 DEC 2023
6.0	R3918-PNH-2050 India Site 356507 Dr.Shailendra Prasad Verma Main ICF English V1.0 dated 19 Dec 2023 based on India Main ICF English V2.1 Dated 19 Dec 2023	V1.0	19 Dec 2023
7.0	R3918-PNH-2050 India Site 356507 Dr.Shailendra Prasad Verma Main ICF English V1.0 dated 19 Dec 2023 based on_India Main ICF English V2.1 Dated 19 Dec 2023Translated from Hindi to English on 10Jan2024	V1.0	19 Dec 2023
8.0	356507 Main ICF V1 _HI-IN_TCert	NA	10 Jan 2024
10.	R3918-PNH-2050 _India 356507 Dr.Shailendra Prasad Verma FBR ICF English_V1.0_dated 12 Dec 2023_based on India FBR_ICF English _V1.0_Dated 17 Jul 2023	V1.0	12 Dec 2023
11.	R3918-PNH-2050_India 356507 Dr. Shailendra Prasad Verma FBR ICF English_ V1.0_dated 12 Dec 2023_based on India FBR_ICF English _V1.0_Dated 17 Jul 2023Translated from Hindi to English on 10Jan2024	V1.0	12 Dec 2023
12.	R3918-PNH-2050 _India 356507 Dr. Shailendra Prasad Verma FBR ICF English_V1.0_dated 12 Dec 2023_based on India FBR_ICF_English_V1.0_Dated 17 Jul 2023 Translated from English to Hindi on 10Jan2024	V1.0	12 Dec 2023
13.	356507 FBR Dated 12 Dec 2023_HI-IN_TCert	NA	10 Jan 2024

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

14.	R3918-PNH-2050 India_Site 356504 Dr.Shailendra Prasad Verma Pharmacogenomics ICF English V1.0 dated 12 DEC 2023_ based on India Pharmacogenomics ICF V1.0_Dated 17 Jul 2023	V1.0	12 Dec 2023
15.	R3918-PNH-2050 India_Site 356507 Dr.Shailendra Prasad Verma Pharmacogenomics ICF English V1.0 dated 12 DEC 2023_based on India Pharmacogenomics ICF V1.0_Dated 17 Jul 2023 Translated from English to Hindi on 10Jan2024	V1.0	12 Dec 2023
16.	R3918-PNH-2050 India_Site 356507 Dr.Shailendra Prasad Verma Pharmacogenomics ICF_ English V1.0 dated 12 DEC 2023_based on India Pharmacogenomics ICF V1.0_Dated 17 Jul 2023 Translated from Hindi to English on 10Jan2024	V1.0	12 Dec 2023
17.	15.356507 PGX Dated 12 Dec 2023_HI-IN_TCert	NA	10 Jan 2024
18.	R3918-PNH-2050 India Site _ 356507 Dr.Shailendra Prasad Verma Pregnant Partner ICF English V1.0 dated 12 DEC 2023 based onIndia Pregnant Partner ICF English v1.0 dated 17 Jul 2023	V1.0	12 Dec2023
19.	R3918-PNH-2050 India Site _ 356507 Dr.Shailendra Prasad Verma Pregnant Partner ICF English V1.0 dated 12 DEC 2023 based on India Pregnant Partner ICF English v1.0 dated 17 Jul 2023 Translated from English to Hindi on 10Jan2024	V1.0	12 Dec 2023
20.	R3918-PNH-2050 India Site _ 356507 Dr.Shailendra Prasad Verma Pregnant Partner ICF English V1.0 dated 12 DEC 2023 based	V1.0	12 Dec 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

		on India Pregnant Partner ICF English v1.0 dated 17 Jul 2023 Translated from Hindi to English on 10Jan2024		
	21.	R3918-PNH-2050_PP ICF_356507_HI-IN_TCert	NA	10 Jan 2024
	22.	R3918-PNH-2050_eCOA Subject Facing Screen Report_India (English)_v1.0_2MAR2023	V1.0	2 march 2023
	23.	Certification_R3918-PNH-2050_eCOA Subject Facing Screen Report_India (English)_v1.0_20MAR2023	NA	20 March 2023
	24.	.R3918-PNH-2050_eCOA Subject Facing Screen Report_India (Hindi)_v1.0_20MAR2023	V1.0	20 March 2023
	25.	Certification_R3918-PNH-2050_eCOA Subject Facing Screen Report_India (Hindi)_v1.0_20MAR2023	NA	20 March 2023
	26.	R3918-PNH-2050_IN_Patient Emergency Card_Master_V1.0_Final	V1.0	3 JAN 202
	27.	R3918-PNH-2050_IN_Patient Emergency Card_Master_V1.0_Final_3Jan2024_HI-IN	V1.0	3 JAN 2024
	28.	R3918-PNH-2050_IN_Patient Emergency Card_Master_V1.0_Final_3Jan2024_HI-IN_TCert	NA	
	29	R3918-PNH-2050_Subject Safety_Participation Card Pozelimab-Cemdisiran - 26dec2023_IN FINAL	V1.0	26 DEC 2023
	30	.R3918-PNH-2050_Subject Safety_Participation Card Pozelimab-Cemdisiran - 26dec2023_IN FINAL_3Jan2024_HI-IN	V1.0	26 DEC 2023
	31.	31.R3918-PNH-2050_Subject Safety_Participation Card Pozelimab-Cemdisiran - 26dec2023_IN FINAL_3Jan2024_HI-IN_TCert	NA	
	32.	Annotated Case Report Form (aCRF) - V03 -	V3.0	11 July 2023

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

		11 Jul 2023		
	33.	R3918-PNH-2050 Insurance		
	34.	276439 IND 20231123 RA Approval-CDSCO Import License for Study Drugs	NA	23 Nov 2023
	35.	276439 IND 20231123 RA Approval-CDSCO Initial Clinical Trial Application	NA	23 Nov 2023
	36.	36.PI CV Dr. S.P Verma	NA	08 Jan 2024
	37.	GCP Dr. S.P Verma	NA	06 june 2023
	38.	MRC Dr.shailendra Parasad Verma	NA	
	39.	39.276439 R3918-PNH-2050 IND 356007 CSA 20230731 1	NA	
	40.	40..276439 R3918-PNH-2050 IND 356007 Budget 20230731 1	NA	
	41	Investigator Undertaking	NA	

Decision: Approval subject to fulfillment of Administrative formalities.

Ref. code: 130th ECMIIC/P10

6. Clarification of research protocol no. EX601/-4979 entitled ***"ARTEMIS Effects of ziltivekimab versus placebo on cardiovascular outcomes in patients with acute myocardial infarction"*** sponsored by M/s Novo Nordisk submitted by Prof. Rishi Sethi, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no. 35/Cardio/Res/24 dated 22nd April, 2024.

Previous comment:

- In sponsor information on IEC form, UN Agencies has been ticked.
- Contact address of sponsor is missing from IEC form. Send the contact address to IEC
- Details of 'organs and body fluids' mentioned under section on Biological materials not given.
- Adverse events reporting are being done to DSMB as per the IEC form. This needs to be corrected.
- DCGI application has been attached, not approval. Kindly submit the approval letter to IEC.
- Insurance cover is expiring in April, 2024.
- Sample size is mentioned as 10,000 in protocol and as 20 in the IEC form.
- Has the study been approved at any other site? If yes, kindly submit the same.

The aforementioned comment was sent to the Principal-Investigator, the response to which was forwarded to the reviewer.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Recommendation of reviewer:

Provisionally Approved

The following documents were reviewed:-

S. No.	Study documents
1	Protocol Clinical Trial Protocol -EX6018-4979, Version 1.0, dated 04 Dec 2023 Protocol Attachment I,Version 2.0, Dated 05 Dec 2023 Protocol Attachment II,Version 1.0 dated 11Jan2024 Agreement on Protocol signed on 12 Dec 2023 General guidance Tuberculosis risk factors Version 1.0 dated 28 Nov 2023
2	Investigator's Brochure Investigator's Brochure - Ziltivekimab subcutaneous administration NN6018Edition6, Version 1.0 dated 01 June 2023 IB Receipt Form signed on 11 Dec 2023
3	**e-CRF** 1. EX6018-4979 (ARTEMIS) CRF Requirements V1.0 dated 8 Dec 2023 2. Sample CRF/Add. pages for EC version 1.0 dated 30-Nov-2023
4	**Patient Information Sheet and Informed Consent Form** **English** 1. EX6018-4979, Patient Information Sheet and Informed Consent Form: Main, Version 1.0_IN_EN Dated 01-Dec-2023, Status: Final 2. EX6018-4979, Patient Information Sheet/Informed Consent Form: Male Partner of a Female Patient, Version 1.0_IN_EN Dated 01-Dec-2023, Status: Final 3. EX6018-4979, Patient Information Sheet/Informed Consent Form: Direct to 4. Patient (DTP), Version 1.0_IN_EN Dated 01-Dec-2023, Status: Final **Hindi** EX6018-4979, Patient Information Sheet and Informed Consent Form: Main, Version 1.0_IN_HI Dated 12 Jan 2024, Status: Final EX6018-4979, Patient Information Sheet and Informed Consent Form: Main, Version 1.0_IN_HI_BT Dated 12 Jan 2024, Status: Final EX6018-4979, Patient Information Sheet/Informed Consent Form: Male Partner of a Female Patient, Version 1.0_IN_HI Dated 12 Jan 2024, Status: Final EX6018-4979, Patient Information Sheet/Informed Consent Form: Male Partner of a Female Patient, Version 1.0_IN_HI_BT Dated 12 Jan 2024, Status: Final EX6018-4979, Patient Information Sheet/Informed Consent Form: Direct to Patient (DTP), Version 1.0_IN_HI Dated 12 Jan 2024, Status: Final EX6018-4979, Patient Information Sheet/Informed Consent Form: Direct to Patient (DTP), Version 1.0_IN_HI_BT Dated 12 Jan 2024, Status: Final Translation Certificates – Forward and Back Translations
5	**Patient Materials** **English** EX6018-4979 ARTEMIS Device instruction storyboard IN EN Master V

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

			1.0_Final_04-Oct-2023 EX6018-4979_Certificate of achievement_IN_EN_Master_V 1.0_Final_04-Oct-2023 EX6018-4979_Dosing diary_IN_EN_Master_V 2.0_Final_04-Oct-2023 EX6018-4979_Informed consent FAQ_IN_EN_V 1.0_Final_24-Nov-2023 EX6018-4979_Participant ID-visit reminder card_IN_EN_V 1.0_Final_24-Nov-2023 EX6018-4979_Participant newsletter 1_IN_EN_V 1.0_Final_24-Nov-2023 EX6018-4979_Participant newsletter 2_IN_EN_V 1.0_Final_24-Nov-2023 EX6018-4979_Participant newsletter 3_IN_EN_V 1.0_Final_24-Nov-2023 EX6018-4979_Participant newsletter 4_IN_EN_V 1.0_Final_24-Nov-2023 EX6018-4979_Participant study booklet_IN_EN_V 1.0_Final_24-Nov-2023 EX6018-4979_Participant support network leaflet_IN_EN_V 1.0_Final_24-Nov-2023 EX6018-4979_Participant thank you letter_IN_EN_Master_V 1.0_Final_23-Nov-2023 EX6018-4979_Participant visit overview pocket version_IN_EN_V 1.0_Final_24-Nov-2023 EX6018-4979_Participant visit overview_IN_EN_V 1.0_Final_24-Nov-2023 EX6018-4979_Participant welcome letter_IN_EN_Master_V 1.0_Final_23-Nov-2023 EX6018-4979_Recruitment advertisement - digital_IN_EN_V 1.0_Final_24-Nov-2023 EX6018-4979_Recruitment advertisement - poster_IN_EN_V 1.0_Final_24-Nov-2023 EX6018-4979_Recruitment advertisement - trifold_IN_EN_V 1.0_Final_24-Nov-2023 Translation Certificate Other Info to Subjects ARTEMIS Greeting Cards_A6_Firework Other Info to Subjects ARTEMIS Greeting Cards_A6_Flower Other Info to Subjects ARTEMIS Greeting Cards_A6_Gift Other Info to Subjects ARTEMIS Greeting Cards_A6_Snow Other Info to Subjects ARTEMISPatient ItemsVersion 1.0 dated 11 December2023 Other Info to Subjects Health tracker sample report ARTEMIS_MASTER EN Video, EN subtitles Other Info to Subjects EX6018-4979_ARTEMIS Study Intro Movie **Hindi** EX6018-4979_ARTEMIS Device instructionstoryboard_IN_HI_V1.0_Final_04-Oct-2023 EX6018-4979_Certificateofachievement_IN_HI_V1.0_Final_04-Oct-2023 EX6018-4979_Dosing diary_IN_HI_V 2.0_Final_04-Oct-2023 EX6018-4979_Informed consent FAQ_IN_HI_V 1.0_Final_23-Nov-2023 EX6018-4979_Participant ID-visit reminder card_IN_HI_V 1.0_Final_23-Nov-2023 EX6018-4979_Participant newsletter 1_IN_HI_V 1.0_Final_23-Nov-2023 EX6018-4979_Participant newsletter 2_IN_HI_V 1.0_Final_23-Nov-2023	

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	EX6018-4979_Participant newsletter 3_IN_HI_V 1.0_Final_23-Nov-2023 EX6018-4979_Participant newsletter 4_IN_HI_V 1.0_Final_23-Nov-2023 EX6018-4979_Participant study booklet _IN_HI _V 1.0 _Final _23-Nov-2023 EX6018-4979_Participant support network leaflet _IN_HI _V 1.0 _Final _23-N ov-2023 EX6018-4979_Participant thank you letter_IN_HI_V 1.0_Final_23-Nov-2023 EX6018-4979_Participant visit overview pocket version_IN_HI_V 1.0_Final_23-Nov-2023 EX6018-4979_Participant visit overview_IN_HI_V 1.0_Final_23-Nov-2023 EX6018-4979_Participant welcome letter_IN_HI_V 1.0_Final_23-Nov-2023 EX6018-4979_Recruitment advertisement - digital_IN_HI_V 1.0_Final_23-Nov-2023 EX6018-4979_Recruitment advertisement - poster _IN_HI _V 1.0 _Fin al_23-Nov-2023 EX6018-4979_Recruitment advertisement - trifold_IN_HI_V 1.0_Final_23-Nov-2023 Translation Certificate EX6018-4979_ARTEMIS Study Intro movie_HI_IN_V 1.0_Final_27-Nov-2023 EX6018-4979_ARTEMIS Study Intro movie_HI_IN_V 1.0_Final_27-Nov-2023_TCert
6	**Site Materials** EX6018-4979_Contact personchecklist_EN_Master_V 1.0_Final_29-Aug-2023 EX6018-4979_Discussion guide on infection risk handling_EN_Master_V 1.0_Final_29-Aug-2023 EX6018-4979_Guidance for supporting HCPs_EN_Master_V 1.0_Final_29-Aug-2023 EX6018-4979_Inclusion & exclusion criteria quickguide_EN_Master_V2.0_Final_08-Dec-2023 EX6018-4979_Managing infection risk_EN_Master_V 1.0_Final_29-Aug-2023 EX6018-4979_Treatment action plan_EN_Master_V 1.0_Final_29-Aug-2023 IP Instructions DTP_pharmacy instruction version_1.0_dated 06 Oct 2023 IP Instructions MarkenDTP_booking Process_ARTEMIS_final_23 Nov 2023 EX6018-4979_ARTEMIS SRR Materials Catalogue_EN_Master_V2.0_Final_23-Jan-2024
7	**DFU** DFU_DV3430SDD_A V4.0_IN(EN) DFU_DV3430SDD_A V4.0_IN(HI)
8	**Patient Reported Outcome** **English** IN Subject Questionnaire EQ-5D-5L Paper Self-Complete v1.1 Effective_India (English) IN Subject Questionnaire EQ-5D-5L Translation Certificate dated Feb 2012

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Dated 29th May, 2024

		EX6018-4979_End Text_IN_EN_Master_V 1.0_Final_04-Oct-2023 EX6018-4979_Instruction to Investigator_IN_EN_Master_V 1.0_Final_04-Oct-2023 EX6018-4979_Investigator AE signature_IN_EN_Master_V 1.0_Final_04-Oct-2023 EX6018-4979_Paper PRO Study Participant Cover Letter_IN_EN_Master_V 1.0_Final_04-Oct-2023 Subject Questionnaire -Translation Certificate dated 4 Oct 2023 **Hindi** IN Subject Questionnaire EQ-5D-5L Paper Self-Complete v2.0 Effective_India (Hindi) IN Subject Questionnaire EQ-5D-5L Translation Certificate dated 28 Jul 2023 EX6018-4979_End Text_IN_HI_V 1.0_Final_04-Oct-2023 EX6018-4979_Instruction to Investigator_IN_HI_V 1.0_Final_04-Oct-2023 EX6018-4979_Investigator AE signature_IN_HI_V 1.0_Final_04-Oct-2023 EX6018-4979_Paper PRO Study Participant Cover Letter_IN_HI_V 1.0_Final_04-Oct-2023 Subject Questionnaire -Translation Certificate dated 4 Oct 2023
	9	**PI Documents** CV, MRC & GCP Investigator Undertaking dated18 Dec 2023
	10	**DCGI Submission Letter dated 12 Jan 2024**
	11	**Clinical Trial Insurance** Local Insurance Certificate - Policy No: P0124200001/9999/100060 dated 20 Dec 2023 Global Insurance Certificate - Policy No: 390–08654942-30078 dated 31 Mar 2023
	12	**Draft Clinical Trial Agreement**
	13	**Draft CTRI -REF/2024/01/077666**
	14	**Lab Documents** Lab Manual - ARTEMIS (EX6018-4979)_Final_V1.0_dated 04 Dec 2023 Blood Volumes -ARTEMIS (EX6018-4979)_v4.00_dated 15 Nov 2023 Flowchart Summary Collection Guide - ARTEMIS (EX6018-4979)_Final_V1.0_dated 04 Dec 2023 End Use Certificate(IN) dated 26 Oct 2023 Letter of Acceptance for Central Lab-Material transfer acceptance (IN) dated 26 Oct 2023 Memo on Sample Retention and Destruction of Samples at ICON Laboratory Services - ARTEMIS (EX6018-4979)_dated 09 Nov 2023 Lab Certificate -Central Lab (ICON Farmingdale) - New York State Department of Health Lab Certificate - Central Lab (ICON Farmingdale) - College of American Pathologists Lab Certificate - Central Lab (ICON Singapore) -Ministry of Health Singapore

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

		CV Head of Laboratory (ICON Farmingdale) dated 25 Aug 2023 CV Head of Laboratory (ICON Singapore) dated 11 Apr 2023
	15	Method of Patient Recruitment – Indoor patients

Decision: Approval subject to fulfillment of Administrative formalities.

Ref. code: 130th ECMIIC/P12

IB **Minutes of ADR Subcommittee Meeting**

Minutes of the **"ADR Sub Committee"** Meeting of the **"Institutional Ethics Committee"** held on 29-05-2024 from 02:00 P.M. till 02:30 p.m. at 3rd Floor, Seminar Hall, Central Library, K.G's Medical University, U.P., Lucknow in hybrid mode.

The following Members were present in the Meeting:

- Dr. J.S. Srivastava -Chairman
- Hon'ble Justice K.L.Sharma -Member
- Dr. Meenakshi Pawha -Member
- Mr. Jayant Krishna -Member
- Dr. Rahul Kumar -Member
- Dr. Sujita Kumar Kar -Member & Vice Dean
- Dr. Hardeep Singh Malhotra -Member-Secretary, ex-officio

1a- ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 85/Neuro/24 dated 6th March, 2024 ***preliminary email dated 06th March, 2024 at 11:38 A.M.***

Patient ID & age and gender: S-45-3-3031(MML)/42 years & 2 month/Male
Subject Initial: M-F
Patient Diagnosis: Right intracranial (Basal ganglia) bleed

Patient enrollment date: 03-03-2024
Patient enrollment Arm: Control
Patient follow up under study-NA
Follow up visit completed-NA

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	SAE detected on-06-03-2024 **SAE (Death) occurred on date:** Expired on 06-03-2024 **Follow up visit remaining:** No **24 hours, notified to EC, Sponsor**-Yes **14 days analysis report submitted to EC**-No **Subject History:-** A letter was received in the Office of the Ethics Committee on 6th March, 2024 from PI. The above mentioned patient was recruited in this clinical trial after fulfilling due checklist and informed consent. His clinical details are as follows patients with subject ID-S-45-3-3031, 42 years /Male admitted on 03.03.2024 in Neurology emergency with case of sudden onset weakness of left side of the body diagnosed to have right interacerebral (basal ganglia)bleed, volume approximately 19.87 ml. He was randomized to the control arm and was given standard treatment. The patients had h/o of hypertension and presented with uncontrolled blood pressure. The patient recived treatment as follows -Labetalol infusion Indepamide 2.5mg/BD infusion and Telmisarten +Amlodepin 40/5mg/BD. He was also on inj. Manitol. Despite of the mentioned treatment,patient had uncontrolled Blood pressure. On 05.03.2024,around 11 am the patient was transferred to Neurology ICU for close monitoring of Blood pressure.There patient received treatment for Blood pressure management, he was put on inj. Labetalol continuous infusion and metoprolol 25mgBD was also started, along with antibiotics Ceftriaxone 1gm/BD. On 06.03.2024, patient's condition gradually deteriorated despite the treatment, the patient developed sudden onset respiratory distress,on examination he had feeble pulse, decreased oxygen saturatioiin and anisocoria, GCS fell to EIVIMI for that patient was intubated. Despite all these efforts, the patient's condition worsened. Patient landed into sudden cardiac arrest on 06.03.2024 at 11.45 pm, CPR was given according to ACLS protocol. Despite all methods of CPR the patient couldn't be received. The patient was declared dead at 01.30 am on 06.03.2024. *Recommendation of Primary reviewer:* **a-Enrolment date**-03-03-2024 **b-Patient enrolment arm-Control arm-** Control arm. **c-SAE detected on 06-03-2024** **d-Notification to IEC 06-03-2024.14 day causality assessment is not attached in the documents.** **e. The SAE (death) doesn't appear to be related to the study and appears to be an outcome of the disease process. The patient died during the first admission from the complications of the disease process itself.** **f- Number of patients in the study-57. number of SAE-12. Number of deaths-7** **Comments:** • Discrepancy in typing • 14th day report missing reporting done or not to be clarified. Pharmacovigilance, Check for notification. **Decision:** Clarification from PI. ***Ref. code: 115th ECMIIA/P5***
1b	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 118/Neuro/24 dated 30th March, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Patient ID & age and gender: S-45-3-2638(MML)/74 years Male
Subject Initial: J-P
Patient Diagnosis: Leftintracranial (Thalamic) bleed

Patient enrollment date: 01-01-2024
Patient enrollment Arm: Control
Patient follow up under study-Yes
Planning on visit-No
SAE detected on-26-03-2024
SAE (Death) occurred on date: Expired on 10-02-2024
Follow up visit remaining: No
24 hours, notified to EC, Sponsor-NA
14 days analysis report submitted to EC-NA
Subject History:-
A letter was received in the Office of the Ethics Committee on 30th March, 2024 from PI. The above mentioned patient was recruited in this clinical trial after fulfilling due checklist and informed consent. His clinical details are as follows. Patient with subject ID-S-45-3-2638, 74 years/Male, was admitted on 0101.2024 in the Neurology emergency ward with c/o sudden weakness of right side of the body diagnosed to have Left Thalamic bleed with Intraventricular Extension, volume approximately 10.75 ml. He was randomized in the control arm and was given standard treatment. The patient had no h/o of HTN, no h/o of T2DM, no h/o of Seizure, no h/o of fever. On admission patient GCS was E4V5M6, BP - 180/110 mmhg, PR-86 min, SPO2 was 98% CNS Pupil-NSNR B/L Plantar Flexion on the left side, extensor on right side Power 1/5 on right side and 5/5 on left side. Patient was admitted for 10 days (01.01.2024 to 10.01.2024). Patients was treated with antihypertensive medicines and other supportive treatment, the patient had responded to the treatment and was treatment and was discharged with stable vitals on 10.01.2024. On discharge patients GCS was E4V5M5, BP -124/86 mmhg, PR-86/ min, SPO2 was 98%,CNS pupil - NSNR B/L plantar Flexion in the left side flexor right side Power 1/5on right side. Patient's condition during discharge was stable. As the patient was in INTRINSIC TRAIL, the randomized patient's follow -up was due on day 90th (10 days +/-) i.e 3 months on telephone. Hence, was called on 26.03.2024 for the follow-up visit reminder due on 01.04.2024 but we came to know that the patient had already **expired** on 10.02.2024 at his home. Reason for death is UNKNOWN.
Recommendation of Primary reviewer:
a. Enrolment date-01-01-2024
b- Patient enrolment arm-Control arm.
c-SAE occurred on -10-12-2024
d-SAE detected on 26-03-2024.
e. Notification to IEC by letter on 30-03-2024. 24-hour notification and 14-day causality assessment is not attached in the documents.
f- The SAE (death) doesn't appear to be related to the study and appears to be an outcome of the disease process. The patient died at home; no autopsy reports are available.
g. Number of patients in the study-58. Number of SAE-13. Number of deaths-8
Comments:

- Discrepancy in typing

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• 14th day report missing reporting done or not to be clarified. Pharmacovigilance, Check for notification. **Decision:** Clarification from PI. ***Ref.code: 115th ECMIIA/P5***
1c-	ADR of research proposal entitled ***"Indian trial of Tranexamic acid in Spontaneous intracerebral haemorrhage (INTRINSIC TRIAL)*** submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, K.G's Medical University, U.P., Lucknow vide letter no. 147/Neuro/24 dated 23rd April, 2024. **Patient ID & age and gender:** S-45-3-3267/55 years /Female **Subject Initial:** N-D **Patient Diagnosis:** Left intracranial (Basal ganglia) bleed **Patient enrollment date:** 16-04-2024 **Patient enrollment Arm:** INTERVENTION **Patient follow up under study-**NA **Follow up visit completed-**NA **Planning on visit-**NA **SAE (Death) occurred on date:** Expired on 21-04-2024 **Follow up visit remaining:** No **24 hours, notified to EC, Sponsor-**Yes **14 days analysis report submitted to EC-**No **Subject History:-** A letter was received in the Office of the Ethics Committee on 23rd April, 2024 from PI. The above mentioned patient was admitted on 16th April, 2024 in Neurology emergency with c/sudden weakness of right side of the body diagnosed to have left midbrain and left thalamus bleed with intraventricular extension, volume approximately 16.09ml. She was randomized to the Intervention arm and tranexamic acid drug 2 grams were given along with other standard treatments. The patient had no history of DM2 or hypertension. The patient's blood pressure was controlled on oral medications but she gradually developed hyperventilation. She later on landed in circulatory failure and was started on inotropes support and her GCS fell to E1V1M4. Despite all these efforts, the patient's condition worsened. The patient landed into sudden cardiac arrest on 21st April, 2024 at 4:30 am, CPR was given accordingly to ACLS protocol. Despite all methods of CPR, the patient couldn't be revived. The patient was declared **dead** at 5:00 am on 21-04-2024. *Recommendation of Primary reviewer:* **a. Enrolment date-**16-04-2024 **b. Patient enrolment arm-**Intervention arm **c.SAE occurred on-**21-04-2024 **d. SAE detected on** 21-04-2024 **e. Notification to IEC by letter on 23-04-2024.** 24-hour notification and 14-day causality assessment is not attached in the documents. **f.The SAE (death) doesn't appear to be related to the study and appears to be an outcome of the disease process. The patient died during the first admission from the complications of the disease**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	process itself. **g- Number of patients in the study**-60 Number of SAE-14. Number of deaths-9 **Comments:** • PI to provide missing documents. **Decision:** Clarification from PI ***Ref.code: 115th ECMIIA/P5***
IIa	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial"*** submitted by Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 787/Cardio/Res/2024 dated 21st March, 2024 & preliminary email dated 7th March, 2024 at 3:26 PM. **Death** **Site no.: 109** **Patient ID & age and gender:** S-069/ 39 years/Female **Patient Diagnosis:** RHD/Sev-MS/MVA 1.0 cm. **Patient enrollment date:** 17-12-2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up & 6-months follow-up **Planning on visit-** 12th Month **Subject expired on 01-07-2023** **SAE detected on 01-03-2024** **Follow up visit remaining:** 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor**-07-03-2024 **14 days analysis report submitted to EC**-21st March, 2024 **Subject History:** A letter was received in the office of the Ethics Committee on 21st March, 2024 by PI, The subject last visited the site on 30th June, 2023 for 06-months actual on site visit. The subject was last called on 30th September for a 9 month telephonic follow-up call. But, the subject didn't answer the call. The subject was again contacted on 12th December, 2023 for 12 months actual site visit reminder call. The contact numbers provided by the subject were not reachable. Despite repeated reminder calls the subject did not answer the calls. The subject was again contacted on 7th March, 2024 for a reminder call, where the subject's LAR informed that she had complaints of breathlessness and discomfort and she passed away on 1st July 2023 around 2:00 P.M. at home. A local practitioner came and confirmed the patient's death and no autopsy was done. As per the information given by the patient's LAR, it seems to be a case of worsening of heart failure. Despite multiple reminders the subject's LAR was unable to provide the death certificate of the subject. The SAE is not related to the investigational drug. *Recommendation of reviewer:* a) **Enrolment date** – 17-12-2022 b) **SAE (death) occurred on**– 01-07-2023 c) **SAE detected date** – 07-03-2024

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	d) **Details of events**– The subject's LAR informed that subject had complaints of breathlessness and discomfort and she passed away on 1st July 2023 around 2:00 P.M. at home. A local practitioner came and confirmed the patient's death and no autopsy was done. e) **24 hrs notification by email**–07-03-2024 f) **14 day analysis submitted on**–21-03-2024 g) **Causal relationship and Compensation**– The SAE (death) doesn't appear to be related to the study, and appears to be an outcome of the disease process. The patient died at home and no autopsy was done. The causal relationship of SAE with intervention cannot be established and no compensation is warranted. **Comments:** Whether other options including surgical/alternative therapies have been offered to the participant or not? **Decision:** To clarify from the PI. ***Ref. code: 102nd ECM IIA/P24***
IIb	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial"*** submitted by Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 780/Cardio/Res/24 dated 13th March, 2024 &:preliminary email dated 28th February, 2024 at 2:56 PM. Death **Site no. 109** **Patient ID & age and gender:** K-030,31 years, Male **Patient Diagnosis:** RHD/Sev-MS/MVA 0.8 cm. **Patient enrollment date:** 07-07-2022 **Patient enrollment arm-**Digoxin **Patient follow up under study-**6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed-**Enrolment & Baseline & 06 month **Planning on visit-** 18th Month **SAE detected on date:** 28-02-2024 **Date of death:** 25-05-2023 **Follow up visit remaining:** 12th Month, 18th Month, 24th Month, 30th Month, 36th Month. **24 hours, notified to EC, Sponsor-**28-02-2024 **14 days analysis report submitted to EC-**13th March, 2024 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 13th March, 2024 from PI. The subject didn't answer the call. Despite further multiple reminder calls made to the subject, the calls were not answered from any of the numbers provided by the subject. The subject's 18 month visit was overdue so again repeated calls were made to the subject for 18 month visit completion. None of the calls were answered. The subject's was again contacted telephonically on 28th February, 2024 for a reminder call. The subject's LAR informed that the subject had complained of breathlessness since 24th May 2023. His

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	condition worsened on the next day he passed away on 25th May, 2023 at home around 1:00 P.M. As per the information given by the patient's LAR, it seems to be a case of worsening of Heart failure. A local practitioner came and confirmed the patient's death and no autopsy was done. Despite multiple reminders the subject's LAR was unable to provide the death certificate of the subject. The SAE is not related to the investigational drug. *Recommendation of reviewer:* a) **Enrolment date**–07-07-2022 b) **SAE date**–25-05-2023 c) **SAE detected date**–28-02-2024 d) **Details of events**– The subject's was again contacted telephonically on 28th February, 2024 for a reminder call. The subject's LAR informed that the subject had complained of breathlessness since 24th May 2023. His condition worsened on the next day he passed away on 25th May, 2023 at home around 1:00 P.M. A local practitioner came and confirmed the patient's death and no autopsy was done. e) **24 hrs notification by email**–28-02-2024 f) **14 day analysis submitted** on–13-03-2024 g) **Causal relationship and Compensation**– The SAE (death) doesn't appear to be related to the study, and appears to be an outcome of the disease process. The patient died at home and no autopsy was done. The causal relationship of SAE with intervention cannot be established and no compensation is warranted. **Comments:** Whether other options including surgical/alternative therapies have been offered to the participant or not? **Decision:** To clarify from the PI. ***Ref. code: 102nd ECM IIA/P24***
IIc	ADR of research proposal entitled ***"Digoxin in patients with rheumatic heart disease-a randomized placebo controlled trial"*** submitted by Prof. Rishi Sethi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no. 817/Cardio/Res/24 dated 1st April, 2024 & preliminary email dated 18th March, 2024 at 3:52 PM. **Death** **Site no. 109** **Patient ID & age and gender:** R-D-025,35 years, Female **Patient Diagnosis:** RHD/Sev-MS/MVA 1.5 cm. **Patient enrollment date:** 20-06-2022 **Patient enrollment arm**-Digoxin **Patient follow up under study**-6th Month ,12th Month , 18th Month, 24th Month, 30th Month, 36th Month. **Follow up visit completed**-Enrolment & Baseline Follow-up & 6 months follow-up **Planning on visit**- 18th Month **SAE detected on date:** 18-03-2024 **Date of death:** 22-12-2023 **Follow up visit remaining:** 18th Month, 24th Month, 30th Month, 36th Month.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	24 hours, notified to EC, Sponsor-18-03-2024 **14 days analysis report submitted to EC**-01-04-2024 **Subject History:** A letter of PI was received in the Office of the Ethics Committee on 1st April, 2024 from PI. The subject last visited the site on 19th Dec, 2023 for 12 months actual on site visit. The subject was contacted telephonically on 9th March, 2024 for a 15 month telephonic follow-up call. The subject did not answer the call. Despite multiple repeated reminders, the calls were not answered. The subject was again contacted telephonically on 18th March, 2024, where the subject's LAR informed that the subject had complaints of breathlessness and she passed away on 22nd December, 2023 around 6:00 P.M. at home. A local practitioner came and confirmed the patient's death and no autopsy was done. As per the information given by the patient's LAR, it seems to be a case of worsening of heart failure. The SAE is not related to the investigational drug. The death certificate has been provided by the subject's LAR. *Recommendation of reviewer:* a) **Enrolment date**–20-06-2022 b) **SAE date**–22-12-2023 c) **SAE detected date**–18-03-2024 d) **Details of events**– the subject's LAR informed that the subject had complaints of breathlessness and she passed away on 22nd December, 2023 around 6:00 P.M. at home. A local practitioner came and confirmed the patient's death and no autopsy was done. e) **24 hrs notification by email**–18-03-2024 f) **14 day analysis submitted on**–01-04-2024 g) **Causal relationship and Compensation**– The SAE (death) doesn't appear to be related to the study, and appears to be an outcome of the disease process. The patient died at home and no autopsy was done. The causal relationship of SAE with intervention cannot be established and no compensation is warranted. **Comments:** Whether other options including surgical/alternative therapies have been offered to the participant or not? **Decision:** To clarify from the PI ***Ref. code: 102nd ECM IIA/P24***
IIIa	ADR of research protocol ***ISCHEMIA*** entitled ***"International study of comparative health effectiveness with Medical and invasive approaches"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no.822/Cardio/Res/24 dated 4th April, 2024. Death **Site no. 091019** **Patient ID & age and gender:** R-K/013,70 years/Male **Patient Diagnosis:** Coronary Artery Disease/Chronic Stable Angina

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Patient enrollment date: 28-04-2015 **Patient follow up under study**-Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic Follow up till 5 year. **Follow up visit completed**-Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18 **Planning on visit-** Telephonic Follow-up Visit of month of March, 2024. **SAE detected on date:** 22-Mar-2024 **Follow up visit remaining:** Telephonic Visits (Every Month) till 2025 **Date of death:** 14-Feb-2024 **24 hours, notified to EC, Sponsor**-22-Mar-2024 **14 days analysis report submitted to EC**- 05-04-2024 **Subject History:** A letter was received in the office of the Ethics Committee on 4th April, 2024 by PI. Subject was randomized in Invasive Arm. Study Coordinator made a scheduled monthly follow up call to the subject on 22nd March, 2024 at 11:30 AM. After several calls, Subject's son picked the call and informed to PI that the subject passed away on 14th February, 2024 at around 01:10 AM in night. LAR informed to PI that one day prior to the death, the subject had dry cough and the next day in the afternoon he complained of chest pain, Subject's son took him to the hospital (SGPGI) and the Doctors there informed about the subject's death. Since there was no medical care given, PI has no documents related to the Patient's death. No autopsy was done. **Death Certificate provided by LAR.** *Recommendation of reviewer:* • The patient enrollment date was 28-04-2015. The study is having a follow-up period of 5 years. The SAE occurred in the year 2024 (9 years after enrollment to study) which is outside the study period. What is the relevance of reporting it? Mismatch of dates (14th-day report submitted to EC on 4th April or 5th April 2024?) As the project has been extended, the patient's follow up under study may be amended appropriately. • The death seems unrelated to the adverse effect of the intervention. **Comments:** As above **Decision:** To clarify from the PI. ***Ref. code: 60th ECM II-A/P13***
IIIb	ADR of research protocol ***ISCHEMIA*** entitled ***"International study of comparative health effectiveness with Medical and invasive approaches"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, K.G's Medical University, U.P., Lucknow vide letter no.816/Cardio/Res/24 dated 1st April, 2024. **Death** **Site no. 091019** **Patient ID & age and gender:** M-S/058,69 years/Male **Patient Diagnosis:** Coronary Artery Disease/Chronic Stable Angina **Patient enrollment date:** 15-10-2016

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Patient follow up under study-Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18, every month telephonic Follow up till 5 year. **Follow up visit completed**-Randomization visit, Month 1.5, Month 3, Month 6, Month 12, Month 18 **Planning on visit-** Telephonic Follow-up Visit of month of March, 2024. **SAE detected on date:** 20-Mar-2024 **Follow up visit remaining:** Telephonic Visits (Every Month) till 2025 **Date of death:** 03-Feb-2024 **24 hours, notified to EC, Sponsor**-20-Mar-2024 **14 days analysis report submitted to EC-** 03-04-2024 **Subject.History:** A letter was received in the office of the Ethics Committee on 1st April, 2024 by PI. Subject was randomized in Invasive Arm. Study Coordinator made a scheduled monthly follow up call to the subject on 20th March, 2024 at 11:50 AM. Subject's brother picked the call and inform to the PI that subject passed away on 3rd February, 2024 at 01:00 AM. LAR informed that Subject had cold from 04 days and on 2nd February, 2024 in evening; subject was having chest pain, for which subject was taken to the nearest hospital, where they came to know that subject had died. There is no documents related to the death and No autopsy was done,. **Death Certificate was also not provided by LAR.** *Recommendation of reviewer:* • The patient enrollment date was 15-10-2016. The study is having a follow-up period of 5 years. The SAE occurred in the year 2024 (8 years after enrollment to study) which is outside the study period. What is the relevance of reporting it? As the project has been extended, the patient's follow up under study may be amended appropriately. • The death seems unrelated to the adverse effect of the intervention. **Comments:** • Consent form-says- Cost to be burned by the participant. • Clarify-extension of study. **Decision:** To clarify from the PI. ***Ref. code: 60th ECM II-A/P13***
IV	Research Protocol no.PreQuest-01 entitled "Prospective, multi-centric, single arm post marketing surveillance of PRISTINE, everolimus eluting cobalt chromium coronary stent system to assess its continued safety and efficacy" sponsored by Relisys Medicine Devices Ltd. submitted by Prof. Pravesh Vishwakarma, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 12/Cardio/Res/24 dated 13th April, 2024. Death **Site no.** KGMU **Patient ID & age and gender:** KGMU113/78 Year/Male **Patient Diagnosis:** N on-ST elevation Myocardial Infarction/LLB dated 27th February, 2023 **Patient enrollment date:** 03-03-2023 **Patient enrolled in Arm: PRISTENE Registry** **Patient follow up under study**-Follow up 2 (6 month)

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Follow up visit completed-Enrolment & Follow-up 1 (1 month) & Follow-up 2 (6 month) **Planning on visit-** Follow up 3 (9 month). **SAE detected on date:** 29-Mar-2023 **Follow up visit remaining:** Follow up 3 (9 month) **Date of death:** 29-Jan-2024 **24 hours, notified to EC, Sponsor**-30-Mar-2023 **14 days analysis report submitted to EC-** 13-04-2024 **Subject History:** A letter was received in the office of the Ethics Committee on 13th April, 2024 by PI. Subject was randomized on 03-Mar-2023 in the study. The subject underwent OCT procedure on 24th November, 2023 after which he got discharged. The subject missed his 9 month follow-up visit that was scheduled on 04-12-2023. Despite multiple reminder calls, the subject did not answer the calls. The subject's LAR informed on 29-Mar-2024 that the subject had complained of abdominal pain and discomfort since 29-Jan-2024, in the morning. The subject's condition deteriorated further. He was not hospitalized and he passed away on 29th January, 2024 at home around 1.00 PM. A local practitioner came and confirmed the patient's death and no autopsy was done. Despite multiple reminders the subject's LAR was unable to provide the death certificate of the subject. The SAE is not related to the investigational device. **Death Certificate was also not provided by LAR.** *Recommendation of reviewer:* • There is a lot of mismatch of date of SAE and date of death. How SAE can be detected March 29 th when the patient died on 29th January? • The death seems unrelated to the adverse effect of the intervention. **Comments:** • Consent form says-cost to be burned by the participant. Why so? **Decision:** Forwarded to main Committee. ***Ref. code: 110th ECM IIC/P1***
II-C	**Review of New Drug Trial**
1.	Research protocol no. CXXB750A12201 entitled ***"A multi-center, randomized, placebo-and active-controlled, parallel-group, 24 week proof of concept and dose-finding study to evaluate efficacy, safety, and tolerability of XXB750 in patients with heart failure"*** sponsored by M/s Novartis Healthcare Private Limited submitted by Prof. S. K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no. 753/Cardio/Res/2024 dated 27th February, 2024 & 17/Cardio/Res/24 dated 16th April, 2024. ***Recommendation of reviewer:*** • DCGI approval -yes • Site/ PI approval by DCGI – yes **Comment:** • Kindly provide the Aadhar no. of each patient. • LAR-File complaint-Consumer forum

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• Here the present jurisdiction is of Mumbai which may be changed to Lucknow • Insurance need to be corrected. PI-Insurance from KGMU Cannot be allowed. Sponsor should deal with insurance. Insurance document should be submitted to IEC. • Kindly provide the CTRI registration • Vulnerable subjects have not been mentioned. • Kindly modify the IEC form-Phase II, however under 3.ii-if has been mentioned that it is approved. • Samples are sent abroad. Do the Investigators have MTA for the same & genetics testing? **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECMIIC/P1***
2.	Research protocol no. CT-CE-CREAVALVE-2023 entitled ***"A prospective, multi-centre, single arm, pivotal clinical study to determine the safety and effectiveness of crea aortic valve for use as a replacement aortic heart valve"*** sponsored by M/s Onecrea Medical India Pvt. Ltd submitted by Prof. S. K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 758/Cardio/Res/2024 dated 14th March, 2024. ***Recommendation of reviewer:*** • PI form- Risk Benefit Ratio- Not properly filled IEC form section 10 • DCGI clarification letter is present but letter stating that device similar to it is already in use- could not be seen, clarification from sponsor is present. Seek letter, which is the predicate device?, Payment transfer (1.68L) to PI account. Clarification as all funds to be transferred to KGMU account. • Insurance will end in October 2024. **Comment:** • Life explanatory-1 Year, Vulnerable subjects. • Is baseline data sufficient to approve the study on this device? Only 3 cases reported. • Mechanism of compensation to LAR, needs to be detailed. • Kindly remove the name of Member-Secretary from ICD: In case of injury free of cost treatment to be provided. • Cardiothorasic Surgeon to be included in decision making process for valve replacement. • Insurance-I crore/person, Aggregate 1 crore. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECMIIC/P2***
3.	Research protocol no. D798EC00001 entitled ***"A phase III, randomized, open-label, multi-centre, global study of volrustomig (MEDI5752) as sequential therapy versus observation in participants with unresected locally advanced Head and Neck squamous cell carcinoma, who have not progressed following definitive concurrent chemoradiotherapy (eVOLVE-HNSCC)"*** sponsored by M/s Astra Zeneca submitted by Prof. Vijay Kumar, Department of Surgical

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Oncology, King George's Medical University, U.P., Lucknow, vide letter no. SONC/1066/2024 dated 24th April, 2024. ***Recommendation of reviewer:*** • Following documents are required • Site/ PI approval by DCGI/CTRI/CTA/CSA study. • Budget/MTA for Genetics & clarification. • Kindly confirm the statement in section 10 for risk & benefits • Discrepancy …… duration of study 60 vs 80 • Indemnity Pg 17- Clause II-CSA **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 131st ECMIIC/P3***
III-A	**Modification**
1.	Modification of research protocol no. NN9838-4942 entitled ***"REDEFINE 3: The cardiovascular safety and efficacy of cagrilintide 2.4 mg.s.c. in combination with semaglutide 2.4 mg s.c. (CagriSema 2.4 mg/2.4 mg) once-weekly in participants with established cardiovascular disease"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 725/Cardio/24 dated 22nd February, 2024. ***Recommendation of reviewer:*** • The insurance period ended on 30-04-2024. The investigator need to clarify whether the insurance has been renewed as the study period is extended. Kindly send the letter to IEC. ***The following documents were reviewed in the Meeting:-***

Sl.No.	Documents
1.	**PROTOCOL** a. Protocol version 6.0 dated 14 Sep 2023 b. Protocol Signature Page for Protocol version 6.0 c. Protocol attachment I version 3.0 dated 22 Sep 2023
2.	**SIIC** **English:** a. NN9838-4942, Subject Information/Informed Consent Form – Main Version 4.0_IN_EN Dated

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

			30 Oct 2023, Status: Final b. NN9838-4942, Subject Information/Informed Consent Form - Male Partner of Female Participant Version 2.0_IN_EN Dated 09 Oct 2023, Status: Final c. NN9838-4942, Subject Information/Informed Consent Form – Future Research Version 2.0_IN_EN Dated 09 Oct 2023, Status: Final d. NN9838-4942, Subject Information/Informed Consent Form – Genotyping Version 2.0_IN_EN Dated 09 Oct 2023, Status: Final e. NN9838-4942, Subject Information/Informed Consent Form – Direct to Patient Version 2.0_IN_EN Dated 09 Oct 2023, Status: Final **Hindi:** a. NN9838-4942, Subject Information/Informed Consent Form – Main Version 4.0_IN_HI Dated 04 Nov 2023, Status: Final b. NN9838-4942, Subject Information/Informed Consent Form – Main Version 4.0_IN_HI_BT Dated 04 Nov 2023, Status: Final c. NN9838-4942, Subject Information/Informed Consent Form - Male Partner of Female Participant Version 2.0_IN_HI Dated 04 Nov 2023, Status: Final d. NN9838-4942, Subject Information/Informed Consent Form - Male Partner of Female Participant Version 2.0_IN_HI_BT Dated 04 Nov 2023, Status: Final e. NN9838-4942, Subject Information/Informed Consent Form – Future Research Version 2.0_IN_HI Dated 04 Nov 2023, Status: Final f. NN9838-4942, Subject Information/Informed Consent Form – Future Research Version 2.0_IN_HI_BT Dated 04 Nov 2023, Status: Final g. NN9838-4942, Subject Information/Informed Consent Form – Genotyping Version 2.0_IN_HI Dated 04 Nov 2023, Status: Final h. NN9838-4942, Subject Information/Informed Consent Form – Genotyping Version 2.0_IN_HI_BT Dated 04 Nov 2023, Status: Final i. NN9838-4942, Subject Information/Informed Consent Form – Direct to Patient Version 2.0_IN_HI Dated 04 Nov 2023, Status: Final j. NN9838-4942, Subject Information/Informed Consent Form – Direct to Patient Version 2:0_IN_HI_BT Dated 04 Nov 2023, Status: Final Translation certificates: a. Translation certificate Main SIIC v4.0_IN_HI

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

		b. Translation certificate Main SIIC v4.0_IN_HI_BT c. Translation certificate Male partner SIIC v2.0_IN_HI d. Translation certificate Male partner SIIC v2.0_IN_HI_BT e. Translation certificate Future research SIIC v2.0_IN_HI f. Translation certificate Future research SIIC v2.0_IN_HI_BT g. Translation certificate Genotyping SIIC v2.0_IN_HI h. Translation certificate Genotyping SIIC v2.0_IN_HI_BT i. Translation certificate DTP SIIC v2.0_IN_HI j. Translation certificate DTP SIIC v2.0_IN_HI_BT
		Hindi: a. NN9838-4942, Subject Information/Informed Consent Form – Main Version 4.0_IN_HI Dated 04 Nov 2023, Status: Final b. NN9838-4942, Subject Information/Informed Consent Form – Main Version 4.0_IN_HI_BT Dated 04 Nov 2023, Status: Final c. NN9838-4942, Subject Information/Informed Consent Form - Male Partner of Female Participant Version 2.0_IN_HI Dated 04 Nov 2023, Status: Final d. NN9838-4942, Subject Information/Informed Consent Form - Male Partner of Female Participant Version 2.0_IN_HI_BT Dated 04 Nov 2023, Status: Final e. NN9838-4942, Subject Information/Informed Consent Form – Future Research Version 2.0_IN_HI Dated 04 Nov 2023, Status: Final f. NN9838-4942, Subject Information/Informed Consent Form – Future Research Version 2.0_IN_HI_BT Dated 04 Nov 2023, Status: Final g. NN9838-4942, Subject Information/Informed Consent Form – Genotyping Version 2.0_IN_HI Dated 04 Nov 2023, Status: Final h. NN9838-4942, Subject Information/Informed Consent Form – Genotyping Version 2.0_IN_HI_BT Dated 04 Nov 2023, Status: Final i. NN9838-4942, Subject Information/Informed Consent Form – Direct to Patient Version 2.0_IN_HI Dated 04 Nov 2023, Status: Final j. NN9838-4942, Subject Information/Informed Consent Form – Direct to Patient Version 2.0_IN_HI_BT Dated 04 Nov 2023, Status: Final Translation certificates:

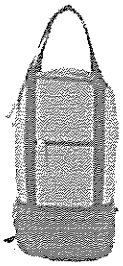
(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

		k. Translation certificate Main SIIC v4.0_IN_HI l. Translation certificate Main SIIC v4.0_IN_HI_BT m. Translation certificate Male partner SIIC v2.0_IN_HI n. Translation certificate Male partner SIIC v2.0_IN_HI_BT o. Translation certificate Future research SIIC v2.0_IN_HI p. Translation certificate Future research SIIC v2.0_IN_HI_BT q. Translation certificate Genotyping SIIC v2.0_IN_HI r. Translation certificate Genotyping SIIC v2.0_IN_HI_BT s. Translation certificate DTP SIIC v2.0_IN_HI t. Translation certificate DTP SIIC v2.0_IN_HI_BT
	3.	**SUBJECT DIARIES** **English:** a. Subject Diary Master NRS diary v2.0_IN_EN dated 10 Nov 2023 b. Subject Diary Master Dosing Visit 7 to Visit 12 v1.0_IN_EN dated 10 Nov 2023 c. Subject Diary Master Dosing Visit 13 to Visit 24 v1.0_IN_EN dated 10 Nov 2023 d. Subject Diary Master Dosing Visit 25 v1.0_IN_EN dated 10 Nov 2023 **Hindi:** a. Subject Diary Master NRS diary v2.0_IN_HI dated 23 Nov 2023 b. Subject Diary Master Dosing Visit 7 to Visit 12 v1.0_IN_HI dated 23 Nov 2023 c. Subject Diary Master Dosing Visit 13 to Visit 24 v1.0_IN_HI dated 23 Nov 2023 d. Subject Diary Master Dosing Visit 25 v1.0_IN_HI dated 23 Nov 2023
	4.	**CRF** a. Sample CRF for EC v2.0 dated 08 Sep 2023 b. e-CRF completion guidelines version 3.0
	5.	**Cooler Bag Specification:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Retention Item: Physical Activity		
Cooler bag	Cooler bag to be used for transporting study medicine. Colour: grey Bag pack with 2 cooling bricks incl. (Neutral – without Novo logo or text) Volume : 19 litres Dimensions : 45cm x 17cm x 19cm	 Price: 107 DKK / 14.40 EUR / 15 USD

Decision: Approval subject to fulfillment of Administrative formalities

Ref. code: 123rd ECMIIC/P4

2. Modification version 2 of research protocol no. CKJX839B12302 entitled ***"A randomized, double-blind, placebo-controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT)"*** submitted by Prof. S.K. Dwivedi, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 723/Cardio/24 dated 22nd February, 2024.

Recommendation of reviewer:

Approved

The following documents were reviewed in the Meeting:-

Sl.No.	Documents
1.	Clinical Trial Protocol (Version Number:02; dated: 10-Jul-2023)
2.	Summary of Changes Clinical Trial Protocol (Version Number: 02; Dated : 10 Jul- 2023
3.	Patient Information and Informed Consent Form (Version 3.0, Dated 20 Jul 2023)
4.	Patient Information and Information Consent Form (Version 3.0, Dated 20 –Jul-2023) translated form English to Hindi on 22-Jul-2023
5.	Patient Information and Informed Consent Form (Version 3.0, dated 20- Jul-2023) Back translated from Hindi to English on 27 Jul 2023
6	Translated and back translated certificate for Patient Information and Informed consent from

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

		(Version 3.0 Dated 20- Jul-2033): • Hindi
	7.	DGCI submission for Approval Protocol Amendment Version 02 dated 10 Jul 2023

Decision: Approval subject to fulfillment of Administrative formalities

Ref. code: 114th ECMIIC/P4

3. Modification of research updated protocol version 3.1.1 entitled ***"Evaluate the effectiveness, safety and tolerability of various doses of linezolid in combination with bedaquiline and pretomanid in adults with Pre-extensively drug-resistant)PRE-XDR),or treatment intolerant/non-responsive multidrug-resistant (MDRTi/NR) pulmonary tuberculosis in India"*** Sponsored by ICMR-NIRT submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 735/24 dated 7th March, 2024.

Recommendation of reviewer:
Approved

Decision: Approved

Ref. code: 109th ECM IB/P7

4. Modification of research updated protocol version 3.2 entitled ***"Evaluate the effectiveness, safety and tolerability of various doses of linezolid in combination with bedaquiline and pretomanid in adults with Pre-extensively drug-resistant)PRE-XDR),or treatment intolerant/non-responsive multidrug-resistant (MDRTi/NR) pulmonary tuberculosis in India"*** Sponsored by ICMR-NIRT submitted by Prof. Surya Kant, Head, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 736/24 dated 7th March, 2024.

Recommendation of reviewer:
Approved

Decision: Approved

Ref. code: 109th ECM IB/P7

5. Modification of research protocol no. ITI-007-501 entitled ***"A randomized, double-blind, placebo-controlled, multicenter study to assess the efficacy and safety of lumateperone as adjunctive therapy in the treatment of patients with major depressive disorder"*** submitted by Prof. Adarsh Tripathi, Department of Psychiaty, King George's Medical University, U.P., Lucknow vide letter no. 2562/Psy/24 dated 22nd March, 2024.

Recommendation of reviewer:
Approved

Decision: Approved

Ref. code: 124th ECMIIC/P2

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

6.	Modification of research protocol no. EX6018-4915 entitled ***"Effects of ziltivekimab versus placebo on morbidity and mortality in patients with heart failure with mildly reduced or preserved ejection fraction and systemic inflammation"*** sponsored by M/s Nova Nordisk India Pvt. Ltd. submitted by Prof. Monika Bhandari, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 5/Cardio/Res/24 dated 9th April, 2024. ***Recommendation of reviewer:*** • The insurance period ended on 30-04-2024. The investigator need to clarify whether the insurance has been renewed as the study period is extended. Kindly submit the renewed insurance certificate to IEC. • Is it approved by DCGI? Kindly submit the approval letter to IEC. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 126th ECMIIC/P1***
7.	Modification of research proposal entitled ***"Elucidation of novel prognostic markers and their role in progression of diabetes mellitus-associated neurocognitive disorder (DMAND)"*** submitted by Prof. Shailendra Kumar Saxena, Department of Center for Advance Research, King George's Medical University, U.P., Lucknow vide letter no. CFAR/16/24 dated 3rd April, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Approved ***Ref. code: 122nd ECM IB/P1***
IV	**Missing document**
1.	Submission of study documents (missed in the initial dossier) to the Ethics Committee for review under the research protocol no. PB016-03-01 entitled ***"A randomized, double-blind, multicenter phase 3 study in patients with moderately to severely active ulcerative colitis (UC) to compare the efficacy, safety and immunogenicity of PB016 and entyvio® for the induction and maintenance of clinical response and remission (UCESIVE)"*** sponsored by M/s Polpharma Biologics S.A. Trzy Lipy submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SGE/CT/25/24 dated 22nd April, 2024. ***Previous Comment:-*** • Senior resident cannot be a Co-PI in sponsored trial. The Institution policy to be followed. • What biological sample will be sent abroad is not specified. • Section 8 of consent form is incomplete. 3 • Section 5(v) of IEC form mentions subject as those with constipation, however the study is being done on subjects with ulcerative colitis. Some patients of UC may have constipation. Clarify the inclusion criteria. • IEC form section 3 is not incomplete. ***Recommendation of reviewer:*** • The documents submitted by the Investigator are adequate and appropriate. If the

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

proposal submitted by the Investigator is considered appropriate by the initial reviewer) it may be approved.

The following documents were reviewed in the Meeting:-

Sr. No.	Documents type	Version and Date
1	Pregnancy Follow up ICF_English	V1.1 13-Mar-2023
2	Pregnancy Follow up ICF_Hindi	V1.1 13-Mar-2023
3	English Back Translation from Hindi Pregnancy Follow up ICF	V1.1 13-Mar-2023
4	Translation, BT and Verification Certificate (Pregnancy Follow up ICF)	-
5	Pregnant Partner ICF_English	V1.1 13-Mar-2023
6	Pregnant Partner ICF_Hindi	V1.1 13-Mar-2023
7	English Back Translation from Hindi Pregnant Partner ICF	V1.1 13-Mar-2023
8	Certificate of Translation, BT and Verification (Pregnant Partner ICF)	-
9	Patient Card_English	V1.0, 19-Oct-2022
10	Patient Card_Hindi	V1.0, 19-Oct-2022
11	Patient Card_Hindi to English	V1.0, 19-Oct-2022
	Certificate of Translation, BT and Verification (Patient Card)	-
12	Patient Diary_English	V1.0, 09-Nov-2022
13	Patient Diary_Hindi	V1.0, 09-Nov-2022
14	Patient Diary_Hindi to English	V1.0, 09-Nov-2022
15	Certificate of Translation, BT and Verification (Patient Diary)	-
16	GP Letter (Template)	V1.0 28-Nov-2022
17	Mayo score	V1.0 03-Feb-2023
18	Certificate of Analysis-PB016	24-05-2022
19	Certificate of Analysis- Entyvio	26-07-2022

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	20	SmPC of Entyvio	--

Decision: Approval subject to fulfillment of Administrative formalities

Ref. code: 130th ECMIIC/P5

V	**Other Matter with the permission of Chairman**
1-	Regarding a notification for Urine pregnancy test was performed at baseline (Visit-1) of patients with Subject ID:06-001,06-002 and 06-004, as per Investigator discretion after informing the patient and documenting the same to ensure the patient's safety-Product leaflet attached under the research protocol no.GPL/CT/2022/011/1V entitled "***An open label single arm, multicentric, prospective, post marketing study to evaluate the safety and effectiveness of fluticasone Furoate/Vilanterol (FF/VI) DPI in the management of asthma patients (Promise OD)***" submitted by M/s Glenmark Pharmaceuticals Ltd. submitted by Dr. Ankit Kumar, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. RM/12/CT/24 dated 12th April, 2024. **Comment:** Protocol need to be verified for better clarification. **Decision:** Noted *Ref. code: 128th ECM IIC/P1*
2-	Regarding notification for not implementing Assent 7-11 years according to National Ethical Guidelines for Biomedical and Health Research involving Human participants 2017 (ICMR Ethical guidelines 2017), page no. 64, Box 6.6.under considerations for assents it is mentioned that- "For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded". In view of this ICMR ethical guidelines as referred above, all the below listed assent ICF's for the age group of 7-11 years is not required. Since the EC has approved the Assent 7-11 years within the initial approval letter dated 16th March, 2024 under the research protocol no. DEN302 entitled "***A randomized, double-blind, placebo-controlled, phase 3 trial to investigate the safety and immunogenicity of a dengue tetravalent vaccine (Live Attenuated) (TDV) administered subcutaneously to healthy subjects aged 4 to 60 years in India***" sponsored by M/s Takeda Vaccines, Inc. submitted by Dr. D. Himanshu, Additional Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/35/2022 dated 28th December, 2022. **Decision:** Noted *Ref. code: 121st ECM IIC/P2*
3-	Regarding corrections in Patient information sheet and Informed consent form, Assent Form, Subject Diary visit-1, subject diary visit-2 under "***An open label single arm, multicentric, prospective, post marketing study to evaluate the safety and effectiveness of fluticasone Furoate/Vilanterol (FF/VI) DPI in the management of asthma patients (Promise OD)***" submitted by M/s Glenmark Pharmaceuticals Ltd. submitted by Dr. Ankit Kumar, Assistant

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. RM/13/CT/24 dated 12th April, 2024. **Comment:** • Kindly clarify why this document should not be considered an amendment? **Decision:** Level 2: Revision with minor modifications/amendments for resubmission *Ref. code: 128th ECM IIC/P1*
4-	Regarding **ICF Erratum**" for subject information sheet and consent form in English, version 02 for India dated 24-01-2023 adapted from the master subject information sheet version 7.0 dated 17th November, 2022 protocol TILD-19-19 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF naive subjects with active psoriatic arthritis II (INSPIRE 2)***" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/58/24 dated 4th April, 2024. **Comment:** • Justification for the change in number of subjects from 472 to 292. • Were these changes made by the sponsor parse or by intermediacy? • The charges made qualify for an amendment fee. **Decision:** Level 3: Revision with major modifications for resubmission *Ref. code: 122nd ECM IIC/P6*
5-	Regarding notification that KGMU Lucknow and Dr. P.K. Sharma names have been added as new site and as PI from KGMU Lucknow respectively in updated proposal in STENOSIS TRIAL under the research proposal entitled "***Longterm single versus dual antiplatelet therapy in patients with ischemic stroke due to intracranial atherosclerotic disease: A randomized trial***" submitted by Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 83/Neuro/24 dated 5th March, 2024. **Comment:** To obtain a letter from MC, Medicine sponsor to include Dr. P.K. Sharma as PI. **Decision:** Noted *Ref. code: 125th ECM IIA/P11*
6-	Regarding translation certificate for Langland & visit cards extension under the research protocol no. CLNA043A12202 entitled "***A 5-year, randomized, double-blind, placebo-controlled, multi-center study assessing the efficacy, safety and tolerability of intra-articular regimens of LNA043 versus placebo in patients with symptomatic knee osteoarthritis (ONWARDS)***" sponsored by M/s Novartis Healthcare Pvt. Ltd. submitted by Dr. Shah Wali Ullah, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no.1076/OS/24 dated 30th April, 2024. **Decision:** Noted

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	Ref. code: 114th ECM IIC/P3
7-	Regarding addendum budget included in CTA for DXA scans, travel reimbursement for unscheduled visit & equipment at site 20210025 Romosozumab (EVENITY®) entitled "***An open-label, single-arm, multicenter phase 4 study to evaluate safety and tolerability of romosozumab (EVENITY®) in postmenopausal women in India with osteoporosis and a high risk of fracture***" sponsored by M/s One Amgen Center Drive Thousand Oaks submitted by Prof. Ashish Kumar, Department of Orthopaedic Surgery, King George's Medical University, U.P., Lucknow vide letter no.1076/OS/24 dated 30th April, 2024. **Comment:** • Sponsor approval is required. • Signature of sponsor is missing. • Why was the protocol modified? • The said modifications qualify for an amendments fee. **Decision:** Approval subject to modification
	Ref. code: 121st ECMIIC/P3
8-	Regarding change in collection procedure for ADA and PK testing under the research protocol no. TILD-19-07 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF experienced subjects with active psoriatic arthritis I (INSPIRE 1)***" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow, vide letter no. Rh/CT/74/24 dated 4th May, 2024. **Comment:** • Signature of sponsor is missing. • To be submitted as modification of protocol? • Why there is a need to change procedure? **Decision:** Level 3: Revision with major modifications for resubmission
	Ref. code: 122nd ECMIIC/P5
9-	Regarding change in collection procedure for ADA and PK testing under the research protocol no. TILD-19-19 entitled "***A phase III, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and safety to tildrakizumab in Anti-TNF naive subjects with active psoriatic arthritis II (INSPIRE 2)***" sponsored by M/s Sun Pharmaceutical Industries Limited submitted by Prof. Urmila Dhakad, Head, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/CT/75/24 dated 4th May, 2024. **Comment:** • Signature of sponsor is missing. • Why there is a need to change procedure?

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• To be submitted as modification of protocol) **Decision:** Level 3: Revision with major modifications for resubmission *Ref. code: 122nd ECMIIC/P6*
10-	**Discussion on policy matters:** • Regarding reporting of SAE related to Phase IV/non-DCGI trials, it was unanimously approved that such events should mandatorily be reported to the Pharmacovigilance Committee of KGMU, a designated Adverse Drug Reaction Monitoring Centre (AMC), besides being reported to IEC. Their report will then be annexed to the minutes of ADR-subcommittee. • To meet the additional staff requirement in the Ethics Cell, it was decided that the currently levied overhead charges (10%) be increased to 25% in line with those applicable in AIIMS-New Delhi, SGPGIMS-Lucknow and RMLIMS-Lucknow.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

King George's Medical University, U.P., Lucknow

Institutional Ethics Committee Meeting,

OFFICE OF THE ETHICS COMMITTEE

Administrative Block

Minutes of 133rd ECM held on 15th June, 2024

(Registration No.: ECR/262/Inst/UP/2013/RR-19)

Minutes of the 133rd Institutional Ethics Committee Meeting held on **15th June, 2024 from 02:30 P.M. till 05.00 P.M.** in the Medical Education, Administrative Block, King George's Medical University, U.P., Lucknow ***in hybrid mode.***

The following Members were present in the Meeting:-

- Dr. J.S. Srivastava -Chairman
- Hon'ble Justice K.L.Sharma -Member
- Dr. Ritu Karoli -Member
- Dr. Pradeep Maurya -Member
- Mr. Jayant Krishna -Member
- Dr. Rahul Kumar -Member
- Dr. Rajeev Kumar Singh -Member
- Dr. Mohammad Kaleem Ahmad -Member
- Dr. Riddhi Jaiswal -Member
- D.N. Upadhyaya -Additional Member-Secretary
- Dr. Sujita Kumar Kar -Member & Vice Dean
- Dr. Hardeep Singh Malhotra -Member-Secretary, ex-officio

The following Members were not present in the Meeting:-

- Dr. Amit Goel -He has given his written comment
- Dr. G.G. Agarwal
- Dr. Meenakshi Pawha

I-	Action taken
a	Clarification of research proposal entitled "***Multidimensional analysis of pain in burning mouth syndrome: A questionnaire based study***" submitted by Dr. Akhilanand Chaurasia, Additional Professor, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 314/OMSR/24 dated 2nd May, 2024. **Previous comment:-**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

	• The design of the study lacks clarity. The proposal should clearly define the study design and whether the evaluation would be prospective or not. • IEC Proforma to be filled properly. • Sample size is to be calculated and written as per the study requirement. The protocol-related details are to be given in a sequence. • Methods to be written properly and tense of sentences to be checked. • ICF to be prepared in an understandable language. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** • Provisionally approved **Decision:** Approved ***Ref. code: 130th ECM IIA/P8***
b.	Clarification of research proposal entitled "***Analysis of expression and polymorphism in miRNA target genes associated with gall bladder cancer***" submitted by Prof. Navin Singh, Department of Radiotherapy, King George's Medical University, U.P., Lucknow vide letter no. 1052/RT/24 dated 3rd June, 2024. **Previous comment:-** • Sample size calculation not provided. • Methodology and references page missing • Name of micro RNA genes not mentioned. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:*** • Provisionally approved **Decision:** Approved ***Ref. code: 124th ECM IIA/P4***
II-	**New Proposal**
1.	Research proposal entitled "***The Indian sjogren's syndrome registry: A metabolic syndrome registry: A multicentre observational study of sjogren's syndrome in India***" submitted by Dr. Kriti Kishor, Assistant Professor, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/505/24 dated 7th May, 2024. ***Recommendation of reviewer:*** • Reply awaited **Comment:** • It is unclear if the registry complies with the Government of India's "The Digital Personal Data Protection Act, 2023". • The methodology suggests that a "Biorepository" would be formed. It may be noted that a biorepository and registry are by nature & design entirely different and have different set of rules. Kindly clarify. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 133rd ECM IIA/P1***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

Dated 15th June, 2024

2.	Research proposal entitled "***The annual cost of illness in Indian systemic lupus erythematosus patients: A cross-sectional study***" submitted by Dr. Kriti Kishor, Assistant Professor, Department of Clinical Immunology & Rheumatology, King George's Medical University, U.P., Lucknow vide letter no. Rh/506/24 dated 7th May, 2024. ***Recommendation of reviewer:*** • Sample size calculation not provided to justify the scientific need. Approximately 500 subjects to be recruited in a duration of 12 months. • It is unclear how the 3-monthly cost would translate into an annual estimate. Kindly clarify. • How would the PI standardize exacerbations/intercurrent illness and admission cost vis-à-vis the cost estimate in stable patients? **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 133rdECM IIA/P2***
3.	Research proposal entitled "***Management of pancreatic trauma at tertiary care centre in North India- single centre experience***" submitted by Prof. Abhijit Chandra, Head, Department of Surgical Gastroenterology, King George's Medical University, U.P., Lucknow vide letter no. SG/333/24 dated 6th May, 2024. ***Recommendation of reviewer:*** • Objective of the study is not mentioned in the protocol submitted to IEC.. • Outcome has not been defined what her survival or otherwise.. • It seems from the documents that the study has already been completed and now the investigators are asking for the IEC approval before publication. • Waiver of consent documents mentions a different topic for the study. • Past tense used in project especially in statistical analysis. • Project name-discordant in the consent waiver form. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 133rdECM IIA/P3***
4.	Research proposal entitled "***Unlocking the secrets of age: exploring elbow joint fusion for accurate estimation***" submitted by Dr. Mousami Singh, Additional Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 178/FMT/24 dated 7th May, 2024. ***Recommendation of reviewer:*** • Objective of the study is not clear. • How the outcome (objective of the study) will be measured and defined? Kindly clarify. • Mode of recruitment/inclusion? Reason for students to come for age estimation • Most participants would fall below 18 years category. Need consent from parents and assent from subjects. • The proposal has been written in the past tense; the same is reflected in the title of the study. It seems that the approval is being sought after the study has been performed/conducted/completed. Thus, retrospective approval of the proposal

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	cannot be granted. **Comment:** As above **Decision:** Level 4: Not approved ***Ref. code: 133rd ECM IIA/P4***
5.	Research proposal entitled "***Single stage nasolabial flap reconstruction for carcinoma of oral cavity- An institutional experience***" submitted by Dr. Naseem Akhtar, Additional Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/955/24 dated 16th April, 2024. ***Recommendation of reviewer:*** • Objective of the study is not clear. • How the cosmetic outcome (objective of the study) will be measured and defined. **Comment:** • Retrospective study design: Should be submitted for "waiver of consent" or it should be explicitly defined how consent would be obtained. • No ROL or recent publications are available in the proposal. Kindly review the study by Ganguly et al; (2023) in Oral Oncology report. Where the technique was described in 1833 • SPSS-23: Is it available with the PI? • It is unclear what this study would add to the existing literature Why would a 13 year-retrospective data collection need a sample number? This is simply a duration-based data collection; thus, all available patients' records have to be included. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 133rd ECM IIA/P5***
6.	Research proposal entitled "***Surgical outcomes of penile cancer- An institutional experience***" submitted by Dr. Naseem Akhtar, Additional Professor, Department of Surgical Oncology, King George's Medical University, U.P., Lucknow vide letter no. SONC/953/24 dated 16th April, 2024. ***Recommendation of reviewer:*** **Comment:** • Retrospective study: Should be submitted for "waiver of consent" or it should be explicitly defined how consent would be obtained. • Outcome criteria regarding recurrence versus disease-free survival versus with-disease survival should be clearly defined. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 133rd ECM IIA/P6***
7.	Research proposal entitled "***Fetomonitoring- to develop and validate an artificial***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

Dated 15th June, 2024

	intelligence based voice application to support delivery room staff in documenting fetal heart rate readings, improving intrapartum care*"** submitted by Prof. Anjoo Agarwal, Head, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1253/24 dated 10th May, 2024. ***Recommendation of reviewer: Approved **Decision:** Approved ***Ref. code: 133rd ECM IIA/P7***
8.	Research proposal entitled **"*A double blinded single centered study for the evaluation of synergistic herbal formulation versus conventional treatment for gout*"** submitted by Dr. Shah Waliullah, Additional Professor, Department of Orthopedic Surgery, King George's Medical University, U.P., Lucknow vide letter no. 972/OS/24 dated 11th May, 2024. ***Recommendation of reviewer:*** • In SOP-Checklist, point no.-10 (Risk & benefit) - ticked as not reasonable. • 15-60 years patient will be included in the study. But in SOP checklist, children not ticked in vulnerable patients. Sample size calculation to be justified.. • Children Assent form not provided. **Comment:** • SRC does not have ~~a~~ an expert related to the intervention. • Co-Investigators do not include an expert related to the intervention. • Phase-I data should be provided to document the safety of the ~~study~~ product/formulatio **Decision:** Level 4: Not approved ***Ref. code: 133rd ECM IIA/P8***
9.	Research proposal entitled **"*The diagnostic and prognostic role of vascular endothelial growth factor-A in patients with early sepsis*"** submitted by Prof. Zia Arshad, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. 132/CCU/24 dated 13th May, 2024. ***Recommendation of reviewer:*** *Reply awaited* **Comment:** • Definition of early sepsis not clear. When early sepsis occurs.? • The proposal contains analysis of samples. It seems that the approval is being sought after the study has been performed/conducted/completed. Thus, retrospective approval of the proposal cannot be granted. • Criteria for prognostic value evaluation. • Patient information sheet. Amount of blood and frequency to be given. • Separate Guardian sheet needed. **Decision:** Level 4: Not approved ***Ref. code: 133rd ECM IIA/P9***
10.	Research proposal entitled **"*Resuscitation & Amp; survival analysis of cardiac arrest***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	practices in India: prospective observational multicenter study (RESUSCITATE Study)*"** submitted by Dr. Ankit Kumar, Assistant Professor, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1050/ResP/24 dated 16th May, 2024. ***Recommendation of reviewer: *Reply awaited* **Comment:** • Their seems to be an error in the title "Resuscitation & Amp…". Kindly review. What does Amp. mean? Budgetary break-up is required. • PIS and LAR consent: It is unclear at what time-point consent process will ~~this~~ be done. Is it possible to predict cardiac arrest and take consent? • Vulnerable subject listing needs revision • Sponsor information is incorrect. • Co-investigators-Different centres: Is there an existent MoU? **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: 133rd ECM IIA/P10***
11.	Research proposal entitled **"*Prevalence and pattern of infertility in India: A multicentric nationwide Hospital-based cross-sectional study (India "FertiHope" Study)*"** submitted by Prof. Anjoo Agarwal, Head, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1271/24 dated 13th May, 2024. ***Recommendation of reviewer:*** *Reply awaited* **Comment:** • It is suggested that the Hindi word "banjh/banjhpan" be substituted by "nisantaan" to avoid stigmatized referral to the state of being "infertile". • List of investigators and budgetary break-up is required. • Define the diagnostic criteria of "infertility" • It is not clear which tests would be used to assess infertility and who and how the financial burden be borne. • It is unclear of PI would be able to fulfil the committed sample size. **Decision:** Level 3: Revision with major modifications for resubmission. ***Ref. code: 133rd ECM IIA/P11***
12.	Research proposal entitled **"*A prospective cohort observational study to evaluate the project on breastfeeding and newborn care*"** submitted by Dr. Shalini Tripathi, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 874/Ped/24 dated 17th May, 2024. ***Recommendation of reviewer:*** *Reply awaited* **Comment:** • Is there a MoU with the Sponsor/PI's institute? Whether IECs of those centers approved? • Is there an agreement where KGMU is listed as a collaborating centre? A Foreign collaborator from RICE, Austin, USA HMSC clearance may be needed. • Role & responsibilities of Co-PI • Program evaluation at the Co-PI level is unclear

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

Dated 15th June, 2024

	• Funding/financial implications are unclear. It seems there is no provision of funding to the KGMU but PI is from KGMU. **Decision:** Level 3: Revision with major modifications for resubmission. ***Ref. code: 133rd ECM IIA/P12***
13.	Research proposal entitled "***Glycogen storage diseases (GSDs) in Indian children-establishing an Indian GSD (I-GSD0 registry)***" submitted by Dr. Sanjeev Kumar Verma, Additional Professor, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 911/Ped/24 dated 25th May, 2024. ***Recommendation of reviewer:*** *Reply awaited* **Decision:** Defer to the next meeting because the primary reviewer is yet to submit his recommendation. ***Ref. code: 133rd ECM IIA/P13***
14.	Research proposal entitled "***Evaluation of the safety & efficacy of Ganga Water phage therapy plus standard medical therapy as compared to standard medical therapy alone for helicobacter pylori-related dyspepsia: a randomized control trial***" submitted by Prof. Ajay Kumar Patwa, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 14445/MED/24 dated 24th May, 2024. ***Recommendation of reviewer:*** • What is the evidence to support that GWPT is effective against HP? In lack of preliminary data, it will be unethical to conduct an RCT. • It is written as a multicentric study- please mention all the study centers. • Why it is a phase II study? Kindly provide DCGI OR ayush approval along with data generated from the phase I study. • Sample size calculation is grossly wrong. • Mention the name, dose, dosing frequency, and duration of antibiotics included in intervention. • Though the title talks about safety but no data/information are collected on safety. • If safety of GWPT is in doubt then it is unethical to conduct an RCT. • How the GW will be collected, transported, and stored without compromising its quality. • How it will be ensured that the used GW contained bacteriophage? • How the nature and quantity of bacteriophage in GW will be ascertained? • Outcome is assessed at 2 weeks after starting the therapy. The common practice in HP therapy is to assess the eradication at 4-6 weeks after stopping the therapy. **Comment:** • Phage therapy? Is this approved by CDSCO? • Are there Co-PIs from IITR-Co/PI or other departments who would assess heavy metals/bacteriology? **Decision:** Level 3: Revision with major modifications for resubmission.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

Ref. code: 133rd ECM IIA/P14

15. Research proposal entitled "***Comparison of clinic-radiological outcome of supracndylar fracture humerus with well perfused hand and supracondylar fracture humerus with pink-pulseless hand-A retrospective study***" submitted by Dr. Syed Faisal Afaque, Assistant Professor, Department of Padeatrics Orthopaedics, King George's Medical University, U.P., Lucknow vide letter no. 3015/PaedOrtho/24 dated 11th May, 2024.

Recommendation of reviewer:

- When it is a retrospective study, how will the consent be obtained from the patient? Waiver of consent is applicable here. The investigator needs to attach the waiver of the consent form (appropriately filled).
- In this retrospective study, how advertisement will be done to recruit the patients? The investigator ticked YES for the item number 9 in IEC proforma.
- If it is a retrospective study, then why the investigators are limiting the sample to 40?
- Statistical analysis segment need to be improved. As there are two groups and as per the objective of the study two groups will be compared for the outcome measures. For this appropriate statistical test need to be discussed as the data is likely to be non-parametric (due to small sample size).

Comment:

- The SRC needs to review this study afresh and the proposal too needs a fresh submission.

Decision: Level 4: Not approved

Ref. code: 133rd ECM IIA/P15

16. Research proposal entitled "***Comparative evaluation of intensified short course regimen and standard regimen for adults TB meningitis: Open label randomized controlled trial (INSHORT trial)***" submitted by Dr. Imran Rizvi, Associate Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 274/Neuro/24 dated 3rd June, 2024.

Recommendation of reviewer:

- IEC proforma: Sponsor information: Budget amount is not mentioned.
- IEC proforma: 5.vi: Vulnerable subjects are ticked NO. And the inclusion criteria mentions enrollment of patients above 18 years of age with no upper cut off. It indicates that vulnerable subjects like elderly and seriously ill will be included. Kindly do appropriate corrections.
- IEC proforma: item number 8 (Consent): Kindly tick all the relevant items.
- IEC proforma: Checklist items are not ticked.
- The investigator has mentioned that the pharmacokinetic parameters of ATT regimen in plasma and CSF will estimated. It means that biological sample will be taken from the patient. However, the investigator has not mentioned about it in the IEC proforma item number 7 (all the elements under use of biological material is ticked NO).

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

Dated 15th June, 2024

	• The title of the project in the Hindi patient information sheet and Hindi informed consent do not match. • Is there any drop out criteria for the patients who die during the course treatment because of any cause)? ← ? • Is there any provision of insurance or compensation? **Comment:** • As above **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: 133rd ECM IIA/P16***
II-B	**New Ph. D Proposal**
1.	Research proposal entitled **"*Pulmonary rehabilitation program for patient with chronic obstructive pulmonary disease*"** sponsored by CIPLA submitted by Mr. Shivam Srivastava, Ph.D Scholar under the guidance Prof. Surya Kant, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 1051/ResP/23 dated 16th May, 2024. ***Recommendation of reviewer:*** **Decision:** Defer to the next Meeting primary reviewer has not given his comment. **Decision:** ***Ref. code: 133rd ECMIIB-Ph.D/P1***
II-C	**Review of New Drug Trial**
1.	Research protocol no. J3L-MC-EZEF entitled **"*A phase 3, randomized, double-blind, placebo-controlled study to investigate the effect of lepodisiran on the reduction of major adverse cardiovascular events in adults with elevated lipoprotein (a) who have established atherosclerotic cardiovascular disease or are at risk for a first cardiovascular event-ACCLAIM-Lp(a)*"** sponsored by M/s Eli Lilly and Company Indianapolis, Indiana submitted by Prof. S. K. Dwivedi, Head, Department of Cardiology, King George's Medical University, U.P., Lucknow, vide letter no. 103/Cardio/Res/24 dated 18th May, 2024. ***Recommendation of reviewer:*** *Reply awaited* **Decision:** Defer to the next Meeting because quorum was incomplete ***Ref. code: 133rd ECMIIC/P1***
III A-	**Additional Document**
1.	Additional of research protocol no. DEN-302 entitled ***"A randomized, double-blind, placebo-controlled, phase 3 trial to investigate the safety and immunogenicity of a dengue tetravalent vaccine (Live Attenuated) (TDV) administered subcutaneously to healthy subjects aged 4 to 60 years in India"*** sponsored by M/s Takeda Vaccines, Inc. submitted by Prof. D. Himanshu, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. MED/CT/35/24 dated 29th May, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Defer to the next Meeting because quorum was incomplete

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	Ref. code: 121st ECMIIC/P2
III-B	**Modification**
1.	Modification of research protocol no. CKJX839D12303 entitled "***A multi-center, randomized, double-blind, placebo-controlled, parallel-group IIIb study evaluating the effect of inclisiran on atherosclerotic plaque progression assessed by coronary computed tomography angiography (CCTA) in participants with a diagnosis of non-obstructive coronary artery disease without previous cardiovascular events (VICTORION-PLAQUE)***" sponsored by M/s Nshovartis Healthcare Private Limited submitted by Prof. S. K. Dwivedi, Head, Department of Cardiology, King George's Medical University, U.P., Lucknow vide letter no. 74/Cardio/Res/24 dated 4th May, 2024. ***Recommendation of reviewer:*** Approved **Decision:** Defer to the next Meeting because quorum was incomplete
	Ref. code: 124th ECMIIC/P1
2.	Modification of research protocol no. GO42784 entitled "***A phase III, randomized, open-label, multicenter study evaluating the efficacy and safety of adjuvant giredstrant compared with physician's choice of adjuvant endocrine monotherapy in patients with estrogen receptor-positive, HER2-negative early breast cancer***" sponsored by M/s F. Hoffmann-La Roche Ltd. Prof. Anand Mishra, Head, Department of Endocrine Surgery, King George's Medical University, U.P., Lucknow vide letter no. ES/27/24 dated 4th May, 2024. ***Recommendation of reviewer:*** *Reply awaited* **Decision:** Defer to the next Meeting because quorum was incomplete
	Ref. code: 115th ECMIIC/P2
3.	Modification of research proposal entitled "***Prospective global platform to evaluate and enhance cognitive and functional trajectories after stroke (PROSPECT)***" submitted by Hamilton Health Sciences through its Population Health Research Institute Hamilton General Hospital under supervision of Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 183/Neuro/24 dated 16th May, 2024. ***Recommendation of reviewer:*** *Reply awaited* **Decision:** Defer to the next Meeting because quorum was incomplete.
	Ref. code: 127th ECMIIA/P16
3.	Modification of research proposal entitled "***Prospective global platform to evaluate and enhance cognitive and functional trajectories after stroke (PROSPECT)***" submitted by Hamilton Health Sciences through its Population Health Research Institute Hamilton General Hospital under supervision of Dr. Praveen Kumar Sharma, Additional Professor, Department of Neurology, King George's Medical University, U.P., Lucknow vide letter no. 183/Neuro/24 dated 16th May, 2024. ***Recommendation of reviewer:***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	Reply awaited **Decision:** Defer to the next Meeting because quorum was incomplete. ***Ref. code: 127thECMIIA/P16***
IV	**Brought to Ethics Committee after XXVI-PGTSC held on 6th June, 2024**
	Minutes of XXVI-PG Thesis sub Committee" of "Institutional Ethics Committee" M held on 06th, June, 2024 from 11.00 AM. in the Board Room, Administrative Block George's Medical University, U.P., Lucknow. ***The following Members were present in the Meeting:*** • Dr. G.G. Agarwal -Member • Dr. Rajeev Kumar Singh -Member • Dr. Rahul Kumar -Member • Dr. Riddhi Jaiswal -Member • Dr. Kaleem Ahmad -Member • Dr. D.N. Upadhyaya -Member & Additional Member-Secretary • Dr. Sujita Kumar Kar -Member & Vice Dean • Dr. Hardeep Singh Malhotra -Member-Secretary, ex-officio
I-A	**Action Taken**
1.	Clarification of research proposal entitled ***"A pilot randomized controlled trial comparing visually aided nicotine replacement therapy and standard nicotine replacement therapy in smokeless tobacco users"*** submitted by Dr. Aman Rajput, JRI, Department of Public Health Dentistry, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 360/PHD/24 dated 18th May, 2024. **Previous Comment:** • It seems to be well planned study. Why it is being called pilot study? • If it is really, RCT, all the fundamentals are missing. • For example, (i) proper formulation of research hypotheses, (ii) study variables, (iii) primary and secondary outcome measures, (iv) method used to generate the random allocation sequence, including details of any restrictions (blocking, stratification etc.), (v) How double blinding is done, (vi) how the success of masking assessed.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	• The sample size calculation is arbitrary in the absence of proper research hypothesis. The different quantities used in the formula are not clear. There is no design effect for this study. It is for cluster-randomized trial. • The statistical methods used to compare groups for primary outcomes, methods for additional analyses, such as subgroup analyses and adjusted analyses. • How the results will be presented: (i) Participants flow, (ii) baseline data, (iii) outcomes and estimation, (iv) adverse events, etc. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXI-PGTSC-IIA/P13***
2.	Clarification of research proposal entitled ***"The expression of prevotella ORIS, neissera flava, neisseria flavescens/subflava, fusobacterium nucleatum, aggregatibacter segnis, streptococcus mitis, porphyromonas and candida albicans in oral potential malignant disorder and oral cancer - A histopathological correlation"*** submitted by Dr. Hrithik Kaushal Jain, JRI, Department of Oral Medicine & Radiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 315/OMSR/24 dated 2nd May, 2024. **Previous Comment:** • The PI is investigating correlation of eight pathogens with oral potentially malignant disorder. This may be scientifically unsound since the minimum sample size will be distributed amongst all these sub-types of patients and correlation of result will be difficult. It is suggested that the PI choose one pathogen and observe its association with OPM lesions for the study to be scientifically relevant. • Project is REJECTED till it is suitably modified. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **Decision:** Approved ***Ref. code: XXIII-PGTSC-IIA/P59***
3.	Clarification of research proposal entitled ***"Role of simvastatin as an adjunct to non-surgical periodontal therapy in chronic peridontitis patients"*** submitted by Dr. Jayant Gupta, JRI, Department of Peridontology, Faculty of Dental Sciences King George's Medical University, U.P., Lucknow vide letter no. 4288/P/24 dated 14th May, 2024. **Previous comment:-** • Kindly fill in the blanks (Annexure-1 point 3 (iii) & point II) • Kindly eneumerate the specific objectives point wise & don't describe methodology in 'aims' section.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	• The title of the proposal may be revised to include the design of the study. • Regarding exclusion criteria how you will exclude the suspected allergy to simavastin. • In patient information sheet kindly exclude the initial guidelines. • Is the risk not reasonable compared to anticipated benefits? • Kindly provide PGT declaration form. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved **EC Decision:** Approved ***Ref. code: XXIV-PGTSC-IIA/P44***
4	Clarification of research proposal entitled ***"Assess the quality of life of patients diagnosed with idiopathic generalized epilepsy at KGMU Hospital, Lucknow"*** submitted by Ms. Mansi Verma through her guide Dr. Suchana Ray Bhawmik, Assistant Professor, Department of Medical Surgical, College of Nursing, King George's Medical University, U.P., Lucknow vide letter no.630/24 dated 13th April, 2024. **Previous Comment:** • Kindly modify the title of the study to "Assessment of the quality…." • The sample size formula is inappropriate. It is for prevalence study. • The sample size formula shall be based on "reliability coefficient", since this is an assessment of an instrument on quality of life. • The statistical analysis section is missing. ***The aforementioned comments were sent to the Principal-Investigator, the response to which was forwarded to the reviewer.*** ***Recommendation of reviewer:-*** Provisionally approved. **EC Decision:** Approved ***Dr. Hardeep Singh Malhotra did not take part in the discussion & making decision.*** ***Ref. code: XXIV-PGTSC-IIC/P7***
II-A	**New Thesis-Resident**
1.	Research proposal entitled ***"Prevalence of trauma patients in ICU at level one trauma center: A prospective observational single centre study"*** submitted by Dr. Mahek Verma, JRI through her guide Dr. Vaibhav Jaiswal, Additional Professor, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. TS/195/24 dated 28th February, 2024. ***Recommendation of reviewer:-*** • Sponsor information: Inaccurate • As the study includes patients above 15 years of age and there is no upper limit. • In the vulnerable subjects category, children and elderly need to be ticked.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	• IEC proforma. point number 8 (consent): Information provided are incorrect. Why would a counsellor obtain consent for the study of the PG resident? • The checklist is incomplete. • Consenting below the age of 18 years is not clear. The investigator need to enclose assent form and guardian consent form for participants below 15 years of age. • The title of the study may be modified to incorporate the specific outcome of interest **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXVI-PGTSC-IIA/P1***
2.	Research proposal entitled ***"Comparison of purse-string wound closure vs conventional closure in reducing the risk of wound infection after stoma reversal-A prospective comparative study"*** submitted by Dr. Mohd. Nasir, JRI through his guide Dr. Saumya Singh, Additional Professor, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 479/24 dated 27th February, 2024. ***Recommendation of reviewer:-*** • The title of the study should not include abbreviations • Data collection heading starts with "be sharply taken...." The sentence started from an incomplete sentence. Kindly check it. • Kindly mention whether these techniques are approved techniques of stomal closure. • The investigator need to mention the points of assessment as it is a prospective study. • What will be end point of assessment, in case of death need to be mentioned? • In timeline, why six month is taken for review of literature? • How the outcome variables will be measured? • **Kindly provide the PGT declaration.** **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/P2***
3.	Research proposal entitled ***"Non invasive assessment of liver fibrosis using bard score, FIB 4 score and elastography in type 2 diabetes mellitus patients"*** submitted by Dr. Rajat Agarwal, JRI through his guide Prof. K. K. Sawlani, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 608/MED/24 dated 15th March, 2024. ***Recommendation of reviewer:-*** • Subjects include elderly, but there is no tick on vulnerable patients • Case report form is not attached • Sample size is different in IEC proforma and Method section **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P3***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

4.	Research proposal entitled ***"Study of comparison of prognostic efficacy of log odds ratio of lymph nodes vs lymph node ratio in oral cancers"*** submitted by Dr. Simon Batta, JRI through his guide Dr. Parijat Suryavanshi, Additional Professor, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 483/24 dated 27th February, 2024. ***Recommendation of reviewer:-*** • Case report form is not attached **Comment:** • The methodology, including the design of the study, needs more clarity. Defining the flow of the study in the form of an algorithm would be beneficial. • Sample size calculation needs a review • The follow-up period does not seem to do justice with the mean survival observed in patients with oral cancers. Kindly clarify. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P4***
5.	Research proposal entitled ***"Impact of renal replacement therapy on serum ammonia levels in patients of acute liver failure and acute on chronic liver failure"*** submitted by Dr. Kanishka Bharti, JR through her guide Dr. Medhavi Gautam, Associate Professor, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 609/MED/24 dated 15th March, 2024. ***Recommendation of reviewer:-*** • Annexure 1 Q5, In the subject selection point vi, you have marked vulnerable subjects as No and elderly subjects as Yes. Please explain. • Annexure 1 Q7ii, please specify the details and the mark the appropriate option. • In the informed consent, elaborate the study procedures, in both English and Hindi consent. • In the patient information sheet, re-answer Q4, Q7, and Q8, in both English and Hindi. • Please attach Q4 of Annexure 1. • The executive summary for the proposal is missing • How can you consider the prevalence to be 50% for calculating the sample size for the study? • Why is the margin of error 10%, instead of 5%? **Comment:** • Kindly clarify sample size calculation **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P5***
6.	Research proposal entitled ***"Plasma exchange in acute or acute on chronic liver failure: A systematic review and meta-analysis of randomized controlled studies"*** submitted by Dr. Tarun Chauhary, JR through his guide Prof. D. Himanshu,

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no..690/MED/24 dated 14th March, 2024. ***Recommendation of reviewer:-*** • As the investigator mentioned that the proposed study will be an systematic review and meta-analysis, what is the relevance sample size, study design, subject selection, exclusion criteria of the subjects as the study is not going to recruit subjects directly. It is a secondary research, the investigator should focus more on the nature of studies to be included for analysis. • Kindly refer to the study type. The investigators have ticked single centre study. What is its relevance in a systematic review and meta-analysis? • Statistical analysis should discuss about the analysis planned in meta-analysis • What is the relevance of consent form here? • What side effects the investigator is going to report to IEC (it is ticked in the IEC proforma)? • Going through the IEC preform and proposal, it looks that the investigator is doing a study on independent sample than doing a secondary research. I would recommend the investigators to refer to EQUATOR network - PRISMA guideline and checklist for developing the proposal. The proposal is grossly is erratic and need to be re-written. • Waiver of consent form to be attached. • Roles and responsibilities of the investigator page contains grossly erratic information. **Comment:** • Kindly refer to ICMR's "National Ethical Guidelines for Biomedical and Health Research involving Human Participants" whose scope is applicable to ***primary research*** pertaining to all biomedical, social and behavioural science involving human participants. Thus, the grant of approval to the submitted proposal seems to be out of purview of the Institutional Ethics Committee. To be put-up in full IEC scheduled on 15th June 2024 for further discussion. **Decision:** ***Dr. Hardeep Singh Malhotra did not take part in the discussion & making decision.*** ***Ref. code: XXVI-PGTSC-IIA/ P6***
7.	Research proposal entitled ***"Serial Electrophysiological Changes in Peripheral Nerves in Newly Diagnosed Patients with Drug Sensitive and Drug Resistant Pulmonary Tuberculosis"*** submitted by Dr. Dheeraj Kumar, JR through his guide Prof. Rajiv Garg, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 683/Res/24 dated 28th February, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/ P7***
8.	Research proposal entitled ***"Feasibility analysis of early stoma closure in trauma***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	patients: A prospective observational study at level 1 trauma centre" submitted by Dr. Prajjwal Gupta, JRI through his guide Dr. Narendra Kumar, Additional Professor, Department of Trauma Surgery, King George's Medical University, U.P., Lucknow vide letter no. TS/193/24 dated 27th February, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/ P8***
9.	Research proposal entitled ***"Prevalence of Rhesus(Rh) antigen and Kell(K1) antigen among blood donors in northern India"*** submitted by Dr. Vijay Pratap, JRI through his guide Prof. Ashutosh Singh, Department of Transfusion Medicine, King George's Medical University, U.P., Lucknow vide letter no. 805/24 dated 22nd February, 2024. ***Recommendation of reviewer:-*** • It is not clear whether the consent is for blood donation alone or participation in the study as the sample size is 56,000 • 'Yes' is the answer to data monitoring in point no 11, but to whom, is not mentioned **Comment:** • Use of "98% CI" needs justification • Sample size calculation needs clarification • The proposal should include a statement as to which guidelines they would comply, including those for the storage of samples **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P9***
10.	Research proposal entitled ***"To study the impact on ovarian reserve by laparoscopy vs open surgery in benign ovarian cysts"*** submitted by Dr. Shivani Rai, JR-1 through her guide Dr. Pushp Lata Sankhkwar, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. 805/24 dated 22nd February, 2024. ***Recommendation of reviewer:-*** • Title is inappropriate. It looks as if it is the aim. The title should be "A study on the impact of laparoscopy vs open surgery on ovarian reserve in benign ovarian cysts". In addition, abbreviations are best avoided in the title of the study. • Scientific review form is not signed by all the members. • In the IEC form the investigator has ticked that no biological material, blood and tissue sample will be taken. However, the first aim of the study is to serially measure serum anti-mullerian hormone... How this will be done without biological sample? • Inclusion criteria is inaccurate. What do you mean by all patients? Exclusion criteria are mentioned under inclusion criteria. • Patient information sheet: item number 8 to 13: Inaccurate. Mention the appropriate responses for it. **Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	• The proposal needs a review by a formal statistician including a statement on the use of stated version of SPSS. This should range from sample size calculation to statistical methodology, used achieve the stated outcomes. • There is lack of clarity on the cut-off for AMH; will this be a post-hoc assessment. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P10***
11.	Research proposal entitled ***"Deciphering the Molecular Landscape of MexA and MexC Genes in Burkholderia cepacia complex from Clinical and Environmental Sources"*** submitted by Dr. Shiv Sundar Kumar, JRI through his guide Dr. Sheetal Verma, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1546/24 dated 22nd February, 2024. ***Recommendation of reviewer:-*** • Annexure Q5ii b Duration of subject participation • Annexure 1 Q5vi, please mark the vulnerable subject as yes. • In the informed consent, the purpose of the study is answered as the title of the study? Please re-answer it. Along with it, re-answer the study procedures that you can explain to patients while enrolling them in you study. • In the patient information sheet, re-answer Q4, Q13 and Q14, in both English and Hindi. • In the informed consent sheet, while stating the benefits of the study, could you elaborate how MexA and MexC notable presence will provide benefit to patient? • Provide the reference for 11% prevalence used for calculating the sample size. Also, how have you decided to enroll 30 isolates from environmental sources? • Annexure 1 Q7ii, how will you perform molecular experiments without any use of body fluids? • Please attach Q4 of Annexure1. • The executive summary for the proposal is missing **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P11***
12.	Research proposal entitled ***"A Study to estimate circulating level of serum osteoprotegerin and analysis of it's gene expression in type 1 diabetes mellitus among children"*** submitted by Dr. Sadia Nomani, JRI through her guide Dr. Kalpana Singh, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/1230/24 dated 21st February, 2024. ***Recommendation of reviewer:*** • Please clarify compensation to injury as it is ticked in both points no. 8 and 12. • Sample size calculated is 58, taken is 35+35=70 with 20% dropouts; kindly clarify

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

Dated 15th June, 2024

	• Point no 10; will there be direct benefit to the patient with this study? **Comment:** • Healthy Controls: Forms are missing • Follow-up: Kindly provide the detail • Why have been drop-outs calculated? Is there a provision of follow up estimation that the PI wishes to perform? Please clarify. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Dr. Mohammad Kaleem Ahmad did not take part in the discussion and making decision.*** ***Ref. code: XXVI-PGTSC-IIA/ P12***
13.	Research proposal entitled ***"Exploring the role of Lipid metabolizing genes in Non-Alcoholic Fatty Liver Disease (NAFLD)"*** submitted by Dr. Sana Shareefa, JRI through her guide Dr. Shweta Kumari, Department of Biochemistry, King George's Medical University, U.P., Lucknow vide letter no. Bio/1231/24 dated 21st February, 2024. ***Recommendation of reviewer:-*** • In the IEC proforma the sample size mentioned is 54, whereas in the proposal it has been mentioned as 124 (62 cases and 62 controls). Kindly clarify it. • Clarify the subject age-range selection and whether they qualify as vulnerable subjects? • IEC proforma point no 10.i (Risks and benefits): The response should be yes. The investigator has ticked "No". Similarly point number 1 (sponsorer information), why the investigators ticked government? Are you getting any sponsorship from any government agency? **Comment:** • How would the cost of investigations be handled? Kindly submit details of funding. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P13***
14.	Research proposal entitled ***"Prospective study of patients satisfaction in Thyroid Surgical patients using PSAQ score"*** submitted by Dr. Niharika Kusawatia, JRI through her guide Dr. Kushagra Gaurav, Associate Professor, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 448/24 dated 22nd February, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/ P14***
15.	Research proposal entitled ***"Prognostic role of Serum CEA, CA 125, AFP, CA"-3 & CA 19-9 in patients of Carcinoma Breast and its correlation with known IHC marke"*** submitted by Dr. Priyansh Tandon, JRI through her guide Prof. Surender Kumar, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 450/24 dated 23rd February, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	Recommendation of reviewer:- • Annexure1 Q5ii and Q5vii, Q6i please mark the appropriate boxes. • In the patient informed consent, please write the answers keeping in mind the perspective to explain patients about the study. Re-answer the purpose of the study, study procedures that you will follow, and benefits the volunteered patient will have after participating the study, in both English and Hindi. • In the patient information sheet, re-answer Q2, 13,14, and 17, in both English and Hindi. • Re-calculate the sample size using the recent prevalence data provided by Globocan or any internationally accepted site. • The referencing in the proforma -introduction does not match with the references provided in the end. The references in the introduction start from 32. • Please attach Q4 of Annexure1. • The executive summary for the proposal is missing **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P15***
16.	Research proposal entitled ***"Comparative Analysis of Metabolic Syndrome in PRISm VS COPD Patients"*** submitted by Dr. Garima Mishra, JR through her guide Dr. Anand Srivastava, Department of Respiratory Medicine, King George's Medical University, U.P., Lucknow vide letter no. 242/24 dated 21st February, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/ P16***
17.	Research proposal entitled ***"Comparative Autopsy Based study of Skull Fracture Pattern among Pedestrians, Bike Riders and Car Drivers in Road Traffic Accidents"*** submitted by Dr. Mushir Ahmad, JR through his guide Prof. Anoop Kumar Verma, Department of Forensic Medicine, King George's Medical University, U.P., Lucknow vide letter no. 69/FMT/24 dated 22nd February, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/ P17***
18.	Research proposal entitled ***"Comparison of Central Corneal Thickness Measured by Corneal Topography and Anterior Segment Optical Coherence Tomography"*** submitted by Dr. Purushottam Gupta, JRI through his guide Dr. Pramod Kumar, Department of Ophthalmology, King George's Medical University, U.P., Lucknow vide letter no. nil dated 29th February, 2024. ***Recommendation of reviewer:-*** • Scientific review form is not signed by all the members. • Chairperson should be a member of scientific review committee. • The investigator and co-investigator of the study cannot be a part of scientific review committee of the given study.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	• Co-supervisor Dr. Sandeep Saxena has not signed the proposal. • Checklist IEC incomplete. • Patients above 40 years of age are included in the study, then in IEC proforma vulnerable group need to be ticked and elderly population to be ticked under it. • Why 5ml blood will be taken? In IEC proforma under biological material it has been mentioned that 5 ml blood will be taken. **Comment:** • The title should include the design of the study. • Methodology is grossly incomplete. Kindly clarify the sample size and whether an absolute or a pilot assessment is planned. • There is no mention of outcome measures, outcome assessment and what statistical methods would be used. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P18***
19.	Research proposal entitled ***"Randomized Comparative Study to Assess the Efficacy of 0.5%, Hyperbaric Bupivacaine, 0.5% Hyperbaric Levobupivacaine and 0.5% Isobaric Levobupivacaine for Spinal Anaesthesia in total Knee Replacement Surgery"*** submitted by Dr. Ankita Rai, JRI through his guide Dr. Aparna Shukla, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/230/24 dated 21st February, 2024. ***Recommendation of reviewer:-*** • Checklist incomplete, • Sample size mentioned in IEC proforma is incorrect. It is also important to clarify the denotation used for "k" in sample size calculation. What do drop-outs mean in your study; kindly specify? • Sample size calculation should be referenced. • Participants up to the age of 70 years are included. So, the investigator should tick elderly in the vulnerable group. • Objectives are not clear and too many. • Patient information sheet is incorrect (in most places the investigator had mentioned NA or None). Appropriate responses to be mentioned for each question. • Procedure and statistical analysis plan are complete missing in the proposal. **Comment:** • The title of the study can be shortened by generalizing the intervention. • Kindly submit PGT declaration form. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P19***
20.	Research proposal entitled ***"Evaluation of Optic nerve Sheath Diameter/Eyeball Transverse Diameter (ONSD/ETD) Ratio for Predicting Neurological outcome in patients undergoing Supratentorial Craniotomy: Comparison of use and CT***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	Measurements" submitted by Dr. Arun Unnithan, JRI through his guide Dr. Hemlata, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/222/24 dated 21st February, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/ P20***
21.	Research proposal entitled ***"Factors associated with road traffic injuries among the adults admitted in tertiary care hospital: A hospital based study"*** submitted by Dr. Akhilesh Kumar Patel JRII through his guide Dr. Anish Khanna, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1483/CM/24 dated 19th March, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/ P21***
22.	Research proposal entitled ***"Status of newborn care services at government primary and secondary level delivery facilities in Lucknow district"*** submitted by Dr. Vivek Singh JRI through his guide Dr. Monika Agarwal, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1354/CM/24 dated 22nd February, 2024. ***Recommendation of reviewer:-*** • IEC proforma, point no.8 consent form: Why nurse/counsellor will take consent? • Is it a qualitative study? • How the data will be analysed? Analysis plan is missing. • How did you arrive at the given sample size? Kindly clarify. • What will be the structure and content of interview? **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P22***
23.	Research proposal entitled ***"Spectrum of Congenital anomalies in fetus at a tertiary care center"*** submitted by Dr. Somya Singh, JR through her guide Dr. Shalini Singh, Associate Professor, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/521/24 dated 22nd February, 2024. ***Recommendation of reviewer:-*** • Inappropriate answers in PIS • Minimal sample size is 150? **Comment:** • The title of the study may be modified to ***"Spectrum of "fetal congenital anomalies at a tertiary care center".***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	Decision: Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P23***
24.	Research proposal entitled ***"Determinants of utilization antenatal care services among recently delivered women residing in Urban slums of Lucknow: A cross sectional study"*** submitted by Dr. Preeti Kumari JR-II through her guide Prof. Anish Khanna, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1461/CM/24 dated 14th March, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/ P24***
25.	Research proposal entitled ***"A Cross-sectional study of Age-Related Changes in Symphysial Surface of pubis observed in patients undergoing 3D Computed Tomography Scan"*** submitted by Dr. Rahul Mishra, JRI through his guide Dr. Shiuli, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 65/FMT/24 dated 22nd February, 2024. ***Recommendation of reviewer:-*** • EC proforma point no 10.i (Risks and benefits): The response should be yes. The investigator has ticked "No". • Data analysis segment is insufficient. • In the IEC proforma under the heading of vulnerable subjects, children and elderly need to be ticked. • As the investigator is including participants below 18 years of age, there is a need to submit additional forms for Guardian as well as children differently (both in English and Hindi). **Comment:** • It is unclear how outcome measures are related to FMT department. • A justification of (200) sample size is required • Financial implications need to be elaborated • Pregnancy? • Data collection method does not seem to match the cross-sectional design of the study **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P25***
26.	Research proposal entitled ***"Comparison of Erector Spine Plane Block with Intercostal Nerve Block for Post-Operative Analgesia in patient Undergoing Thoracotomy for Decortication: A Randomised Comparative Study"*** submitted by Dr. Ajay Kumar Gautam JRI through his guide Dr. Sateesh Verma, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/200/24 dated 21st February, 2024. ***Recommendation of reviewer:-*** • Decision of scientific review committee is not marked.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	• Relevant details under clinical trials to be filled (IEC proforma) as it is an interventional study. • Items included under consent form and Patient information Sheet are not ticked in the IEC form. • IEC form point no 10.i: Risk & benefits: It should be yes. • IEC proforma checklist is incomplete. • Undertaking of the principal investigator is not signed by the PI. • Patient information sheet is grossly erratic. • Objectives are poorly written. They should be specific, measurable and self-explaining. • Patients with age more than 60 years are included under the point number 5 of IEC proforma, the investigator should tick the vulnerable subjects and elderly. • Statistical analysis: Paired t test is not a test for inter-group comparison. Kindly correct it. For inter-group comparison of categorical variables chi-square test or Fisher's exact test is used and for continuous variables, unpaired t test is used. **Comment:** • Kindly submit PGT declaration • K=1 needs elaboration • How do you mean by drop-outs? Do you plan a follow-up estimation? It seems that the PI is referring to "potential errors related to total testing process". **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P26***
27.	Research proposal entitled ***"Co-Relation of Serum Adropin Level in Type 2 Diabetes Mellitus with and without Diabetic Nephropathy and also with Chronic Heart Failure"*** submitted by Dr. Madhusudan Agarwal JRII through his guide Prof. Satyendra Kumar Sonkar, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 786/MED/24 dated 3rd April, 2024. ***Recommendation of reviewer:-*** • There are two co-supervisors outside KGMU. Kindly enclose their CVs as per the format given in the SoP of IEC proforma (available at KGMU website). • Section 4 of IEC: Missing • Section 5 of IEC proforma: due to cutting and overwriting it is not clear, what is the sample size and duration of study. • There is no information about study, methodology, review of literature, aims & objectives, selection criteria, design of the study, sample size estimation, statistical analysis plan. • IEC proforma is grossly incomplete. • Patient information sheet in Hindi and English are inaccurate. **Comment:** • Algorithm of the study should be added in the proposal. • The title of the study needs modification with appropriate mention of the study design (Case-control, as per details)

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	• Define one primary objective and club the rest as secondary objectives. • Sample size estimation is required. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P27***
28.	Research proposal entitled ***"Gross & Histopathological Changes in Heart, Kidneys, Adrenals and Skin of Bite Site in Case of Snake Envenomation in Northern India – An Observational study"*** submitted by Dr. Vivek Mahendra, JRI through his guide Dr. Sangeeta Kumari, Additional Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 63/FMT/24 dated 22nd February, 2024. **Comment:** • Please provide the sampling method/frame. • The proposal needs to be processed for "Waiver of consent". **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Dr. Riddhi Jaiswal did not take part in the discussion and making decision.*** ***Ref. code: XXVI-PGTSC-IIA/ P28***
29.	Research proposal entitled ***"Effect of thermal softening of double lumen endobronchial tube on post operative sore throat in patients undergoing one lung ventilation: A randomized comparative study"*** submitted by Dr. Kavinraj P, JRI through his guide Dr. Shefali Gautham, Professor Junior Grade, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/202/24 dated 16th February, 2024. ***Recommendation of reviewer:*** • Prospective randomized study: Is it with or without control? • Modify the proposal to comply with CONSORT checklist. • Outcome appears to be an ordinal measure • The statistical methods are inappropriate for the design and conduct of the study; these need review by a formal statistician. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P29***
30.	Research proposal entitled ***"Evaluation of inflammation based prognostic scores in patients with Carcinoma Gall Bladder"*** submitted by Dr. Aashna Mahendru, JRI through his guide Prof. A. A. Sonkar, Department of General Surgery, King George's Medical University, U.P., Lucknow vide letter no. 455/24 dated 24th February, 2024. ***Recommendation of reviewer:*** • Clarify the design of the study. • Kindly provide a modified algorithm of the study.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	Comment: • Which survival measure and statistical method has been selected, is unclear. • The follow up period needs a relook vis-a-vis the survival pattern of patients with CaGB. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P30***
31.	Research proposal entitled ***"Investigating presepsin as a novel biomarker for catheter-Related bloodstream infections in intensive Care Unit Patients"*** submitted by Dr. Aditi Tenguria, JRI through his guide Prof. Vimala Venkatesh, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1555/Micro/24 dated 22nd February, 2024. ***Recommendation of Primary reviewer:-*** • Executive summary is too short and INCOMPLETE. Study details, methodology, sample size etc are not provided • Why are 2 types of consent forms attached? • Subject selection with reference to vulnerable patients is incomplete while study participants are ICU patients • Please clarify 'direct benefit to patients' as statements differ in point 12 of PIS and point 10 of IEC proforma • Please clarify whether it is a Descriptive (prevalence) or Diagnostic study? **Comment:** • Define one primary objective and club the rest as secondary objectives. • Who will bear the cost of investigations (including presepsin and the rest)? Kindly justify the financial implications. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/ P31***
32.	Research proposal entitled ***"Characterization of coaagulase negative staphylococcus from neonatal blood cultures at a Tertiary Care Center: A descriptive study"*** submitted by Dr. Navneeth Krishnan. S, JRI through his guide Prof. Vimala Venkatesh, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1559/Micro/24 dated 22nd February, 2024. ***Recommendation of Primary reviewer:-*** • Subject selection is incomplete particularly when subjects are neonates but vulnerable subjects is neither answered as YES nor NO • Is the study providing direct benefit to the enrolled participant as mentioned in point no. 10 of IEC proforma? • Please expand the answers to questions no. 2 and 4 in PIS **Comment:** • Kindly justify the selected study design • Subject selection needs elaboration • Clarify 'virulence gene presence' and the involved statistics **Decision:** Level 2: Revision with minor modifications/amendments for resubmission

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

Dated 15th June, 2024

	Ref. code: XXVI-PGTSC-IIA/ P32
33.	Research proposal entitled ***"Identification of non- tuberculous mycobacteria from clinical specimens using MALDI-TOF MS; a hospital based study"*** submitted by Dr. Prashant Khare, JRI through his guide Prof. Amita Jain, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 1564/Micro/24 dated 22nd February, 2024. ***Recommendation of Primary reviewer:*** • Kindly detail the specimens being used. • Provide justification for the selected sample size. **Comment:** • It would be appropriate to state the overall sample from which these will be derived. **Decision:** Level 3: Revision with major modifications for resubmission
	Ref. code: XXVI-PGTSC-IIA/ P33
34.	Research proposal entitled ***"Microbiological profile in clinically suspected cases of osteomyelitis"*** submitted by Dr. Pyare Lal Patel, JRI through his guide Prof. Gopa Banerjee, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 841/24 dated 21st May, 2024. ***Recommendation of Primary reviewer:*** • Timeline 3 years while study duration 1 year? • Point no. 8, there's a tick on both benefits and compensation; how will the PI compensate? • In Assent form, no compensation is written • Scientific committee form bears only 4 signatures **Comment:** • Time line may be corrected-3 years to 1 year **Decision:** Level 1: Approved – with or without suggestions or comments
	Ref. code: XXVI-PGTSC-IIA/P34
35.	Research proposal entitled ***"Assessing testicular stiffness in varicocele [atients: the utility of shear wave elastography and comparative analysis of pre and post treatment stiffness"*** submitted by Dr. Prabhav Mishra, JRI through his guide Dr. Anil Rawat, Associate Professor, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 593/RD/24 dated 22nd May, 2024. ***Recommendation of Primary reviewer:*** • Checklist is not appropriately ticked • Define one primary objective and club the rest as secondary objectives. • Point no. 7 in Hindi PIS needs correction • The current proposal seems to be a replication of a study referenced in the proposal. Kindly clarify what your proposal adds to the current literature. over and above the study by Ahmad et al. **Comment:**

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/P35***
36.	Research proposal entitled ***"A study on carbapenemase genes in frequently isolated non fermenters from respiratory samples of ventilated patients"*** submitted by Dr. Sushmita Verma, JR through her guide Prof. Vimala Venkatesh, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 208/24 dated 22nd May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P36***
37.	Research proposal entitled ***"Molecular characterization of biofilm formation and antibiotic susceptibility in stenotrophomons maltophilia in Hospitalized Patients"*** submitted by Dr. Pushpa Chaudhary, JR through her guide Dr. Sheetal Verma, Additional Professor, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 206/24 dated 22nd May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P37***
38.	Research proposal entitled ***"Evaluation of ceftazidime- avibactam susceptibilty in multiddrug- resistant enterobacterales in a tertiary Hospital setting"*** submitted by Dr. Nandaputhra Das S, JRII through his guide Prof. Vimala Venkatesh, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 225/24 dated 22nd May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P38***
39.	Research proposal entitled ***"Serotypes causing dengue fever and dengue encephalopathy-A descriptive study"*** submitted by Dr. Netra Chakravarty, JRIII through her guide Prof. Amita Jain, Head, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 224/24 dated 22nd May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P39***
40.	Research proposal entitled ***"Prescribing trends of antihypertensive medications and profile of adverse drug reactions: An observational study in a tertiary care hospital in India"*** submitted by Dr. Karan Suneja, JR through his guide Prof. Sarvesh Singh, Department of Pharmacology, King George's Medical University, U.P., Lucknow vide letter no. 357/Pharm/24 dated 22nd May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P40***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

41.	Research proposal entitled ***"Evaluation of Vitamin D supplementation on serum AMH levels in infertile women with decreased ovarian reserve and Vitamin D deficiency"*** submitted by Dr. Ankita Jaiswal, JR through her guide Dr. Vandana Solanki, Additional Professor, Department of Obstetrics & Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/940/24 dated 22nd May, 2024. ***Recommendation of reviewer:*** • Kindly add the study design in the title of the proposal. • What are the diagnostic criteria of infertility that would be adopted? • What is the vitamin D supplementation regime that will be used? • Previously advised formatting has not been paid attention to-still needs to be done • PIS is poorly filled • Inappropriate clarification of the previous comments **Comment:** • Reference is required for the supplementation regime to replenish vitamin D, along with actual details of supplementation. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/P41***
42.	Research proposal entitled ***"Evaluation and comparison of the diagnostic performance of MALDI-TOF-MS directly from urine samples with conventional method for identification of pathogens in catheter associated urinary tract infections in ICU admitted patients"*** submitted by Dr. Soham Bhattasali, JR through his guide Prof. Raj Kumar Kalyan, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 226/24 dated 24th May, 2024. ***Recommendation of Primary reviewer:*** • Is Government the sponsor, as mentioned? Please provide details. • Points no. 10,11,12 in IEC proforma are unanswered • Numbering in PIS needs correction • It appears to be a diagnostic performance study. However, there is no mention of appropriate statistical tools like sensitivity, specificity etc. Kindly label the gold standard adopted for reference. **Comment:** • Kindly revise the title of the study to make it succinct and with a mention of study design. • Sample size estimation needs a review • Assent form is required. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/P42***
43.	Research proposal entitled ***"A cross-sectional study for clinical and sonological characterization of uterine myometrial lesions"*** submitted by Dr. Rashmi Vishwakarma, JR through her guide Prof. Nisha Singh, Department of Obstetrics &

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	Gynaecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1333/24 dated 21st May, 2024. ***Recommendation of Primary reviewer:*** • Please clarify the mention of study being government sponsored, budget self? Provide details of the sponsor information/scheme. • Malignant myometrial lesions are neither mentioned in inclusion nor exclusion criteria though the topic characterizes myometrial lesions in all. Please specify the PICO in detail with special emphasis on participants/patients. **Comment:** As above **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/P43***
44.	Research proposal entitled ***"Sepsis in acute on chronic liver failure: cause or consequence"*** submitted by Dr. Umang Maheshwari, JR through his guide Prof. Ajay Kumar Patwa, Department of Medicine, King George's Medical University, U.P., Lucknow vide letter no. 595/MED/24 dated 14th March, 2024. ***Recommendation of Primary reviewer:*** • At Point no.10 in IEC proforma, both Yes and No are ticked • Sample size is 150 while in SS calculation is 226. Please clear the disparity. In addition, it does not seem to match the study design; please review this with a statistician. • Title appears to be that of a publication/chapter; it is advised to be modified including the study design in the title. • There should be one primary objective, while the rest may be clubbed under secondary objectives. **Comment:** • It seems that the PI wishes to look at prevalence of sepsis in liver diseases while the title suggests ACLF. Kindly specify the diagnostic criteria considering the actual patient population. **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/P44***
45.	Research proposal entitled ***"Utilization of postnatal care services among mothers residing in Lucknow district: A community based cross- sectional study"*** submitted by Dr. Disha Chawla, JRII through her guide Prof. Monika Agarwal, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 1465/CM/24 dated 14th March, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P45***
46.	Research proposal entitled ***"Analysis of non-metric dental traits using dental casts for ethnicity identification in a mixed population using stereomicroscope, radiographs and 3d printing"*** submitted by Dr. Priya Devi, JR through her guide Prof. Shalini

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	Gupta, Department of Oral Pathology & Microbiology, Faculty of Dental Sciences, King George's Medical University, U.P., Lucknow vide letter no. 3173/OP/24 dated 22nd May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P46***
47.	Research proposal entitled ***"To determine maternal and neonatal cytomegalovirus positivity with viral load estimation in neonates born with pre-mature delivery/ Intrauterine growth restriction/congenital defects"*** submitted by Dr. Harshit Kumar, JR through his guide Prof. Raj Kumar Kalyan, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 232/24 dated 24th May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P47***
48.	Research proposal entitled ***"Study on etiology of atypical pneumonia with special reference to chlamydia, mycoplasma, legionella in community acquired pneumonia adult patients"*** submitted by Dr. Reena Yadav, JR through her guide Prof. Prashant Gupta, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 231/24 dated 24th May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P48***
49.	Research proposal entitled ***"Evaluation of cause of death in obscure autopsy cases among postmortem cases: An observational study"*** submitted by Dr. Saurav Suman Prajapati, JRI through his guide Prof. Anoop Kumar Verma, Head, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 197/FMT/24 dated 18th May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Dr. Riddhi Jaiswal did not take part in the discussion and making decision.*** ***Ref. code: XXVI-PGTSC-IIA/P49***
50.	Research proposal entitled ***"A study to analyse current prescription pattern of Anti-diabetic drugs in a tertiary care teaching hospital"*** submitted by Dr. Naim Akhtar, JR through his guide Dr. Suyog Sindhu, Associate Professor, Department of Pharmacology & Therapeutics, King George's Medical University, U.P., Lucknow vide letter no. 360/Pharma/24 dated 24th May, 2024. **Comment:** • The exclusion criteria are redundant and do not add any meaning to the inclusion criteria. **Decision:** Level 1: Approved – with or without suggestions or comments ***Ref. code: XXVI-PGTSC-IIA/P50***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

51.	Research proposal entitled ***"Role of shear wave ultrasound elastography in evaluating superficial soft tissue masses"*** submitted by Dr. Nida Fatma, JR through her guide Dr. Sukriti Kumar, Associate Professor, Department of Radiodiagnosis, King George's Medical University, U.P., Lucknow vide letter no. 179/RD/24 dated 22nd February, 2024. **Comment:** • Please specify if the follow up is applicable? o If yes, will it be diagnostic/comparative in nature? o Also state if it is a pre- and post-evaluation method? • Discrepancy in study design (Prospective Cohort) versus diagnostic value of shear elastography **Decision:** Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/P51***
52.	Research proposal entitled ***"Prevalence and determines of Malnutrition and Anaemia in Children with global Developmental delay"*** submitted by Dr. Arushi Gautam, JR through her guide Prof. Chandrakanta, Department of Paediatrics, King George's Medical University, U.P., Lucknow vide letter no. 179/RD/24 dated 22nd February, 2024. ***Recommendation of Primary reviewer:-*** • Please modify the study title to "***Prevalence and determinants of malnutrition and anaemia in children with global developmental delay"*** • The IEC form is not properly filled. o In sponsor information, Government is ticked whereas NA is ticked in contact address of sponsor and budget. o Point no.12; Is there compensation for injury is left unticked. o In Brief summary, secondary objectives no.1 and 2 are repetitions. **Comment:** • Sample size estimation: Kindly elaborate the reason to set CI limits at 90%? • Blood samples are used; kindly clarify the financial implications. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXVI-PGTSC-IIA/P52***
53.	Research proposal entitled ***"Age Related Histological changes in the Human Brain"*** submitted by Dr. Hardic Bhattacharya, JR through his guide Prof. Archana Rani, Department of Anatomy, King George's Medical University, U.P., Lucknow vide letter no. 656/ANAT/24 dated 21st February, 2024. ***Recommendation of Primary reviewer:-*** • There are multiple objectives. It is suggested to identify one primary objective and the rest should be clubbed into secondary objectives. • Sample size is not determined. It is mentioned that sample size will be determined based on the availability of suitable specimen meeting the inclusion criteria. Kindly clarify.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

	Decision: Level 1: Approved – with or without suggestions or comments. Waiver of consent may be granted subject to appropriate response to reviewer's comments ***Ref. code: XXVI-PGTSC-IIA/P53***
54.	Research proposal entitled ***"Analysis of perinatal death in a tertiary care referral and teaching hospital"*** submitted by Dr. Manisha Mahana, JR through his guide Prof. Amita Pandey, Department of Obstetrics & Gynecology, King George's Medical University, U.P., Lucknow vide letter no. OG/1367/24 dated 25th May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P54***
55.	Research proposal entitled ***"Prevalence and determinants of common mental disorders (CMDs) among antenatal women in rural Lucknow"*** submitted by Dr. Humra Rizwan Ansari, JRII through her guide Prof. Monika Agarwal, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 271/CM/24 dated 24th May, 2024. ***Recommendation of reviewer:-*** • IEC Proforma: Sponsor information: As there is no sponsor for this study, why the investigator has ticked Govt./National? • IEC proforma: item number 8: All relevant items are not ticked. • IEC proforma: Risk & benefits are incorrectly ticked. • Kindly clarify 10% non-response rate • The investigator used Vancouver style of referencing at places and Harvard style of referencing at places. Kindly follow a uniform style of reference. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXVI-PGTSC-IIA/P55***
56.	Research proposal entitled ***"Cognitive functions among diabetic retinopathy patients attending the ophthalmology out-patient department–A hospital based study"*** submitted by Dr. Merin Mary John, JR through her guide Prof. Shivendra Kumar Singh, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 278/CM/24 dated 25th May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P56***
57.	Research proposal entitled ***"An observational study on rickettsioses in paediatric patients at a Tertiary care center"*** submitted by Dr. Kumari Karishma, JR through her guide Prof. Raj Kumar Kalyan, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 188/24 dated 17th May, 2024.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IE

64.	Research proposal entitled ***"Evaluation of the efficacy of concurrent versus sequential administration of rifaximin and probiotics in patients with irritable bowel syndrome: an observational prospective study"*** submitted by Dr. Vishal Tiwari, JR through his guide Prof. Rahul Kumar, Department of Pharmacology, King George's Medical University, U.P., Lucknow vide letter no. 366/Pharm/24 dated 30th May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Dr. Rahul Kumar did not take part in the discussion & making decision.*** ***Ref. code: XXVI-PGTSC-IIA/P64***
65.	Research proposal entitled ***"Prevalence of atherosclerotic changes in coronary arteries in young population – An autopsy based study"*** submitted by Dr. Himanshu Patel, JR through his guide Dr. Mausami Singh, Additional Professor, Department of Forensic Medicine & Toxicology, King George's Medical University, U.P., Lucknow vide letter no. 208/FMT/24 dated 29th May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P65***
66.	Research proposal entitled ***"Assessment of physical and psychological health status of children living in orphanage homes in Lucknow"*** submitted by Dr. Vedika Singh, JR through her guide Prof. Reema Kumari, Department of Community Medicine & Public Health, King George's Medical University, U.P., Lucknow vide letter no. 293/CM/24 dated 29th May, 2024. ***Recommendation of reviewer:-*** • IEC proforma: As there is no sponsor, why the investigator has marked GOVT/National under sponsor information? • Participants are children in orphanages, then why the investigator mentions under the patient information sheet that you are a caretaker of orphanage so you are included in the study? • Who will give consent for the study? Elaborate more in details as the participants are below 18 years of age. • Include assent form for the participants and guardian/caregiver consent form. • As the participants are orphans, who will be legally held responsible to give consent? Kindly elaborate about it. • Source of participants is orphanage homes. Do you have access to 294 sample between 11 to 18 years of age at Lucknow? • Statistical analysis plan is missing. • Elaborate more about study tools. **Comments:** • There are multiple objectives. It is suggested to identify one primary objective and the rest should be clubbed into secondary objectives. • The algorithm used does not reflect true multistage sampling. It is unclear what extra meaning does it convey.

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC

Dated 15th June, 2024

	Decision: Level 3: Revision with major modifications for resubmission ***Ref. code: XXVI-PGTSC-IIA/P66***
67.	Research proposal entitled ***"Assessment of USG- Guided M-TAPA blockversus external Oblique Intercostal block in providing analgesia for Peadiatric Laproscopic Surgery"*** submitted by Dr. Subhi Ojha, JR through her guide Prof. Prem Raj Singh, Department of Anesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/727/24 dated 25th May, 2024. **Decision:** Defer to the next meeting because primary reviewer is yet to submit his recommendation. ***Ref. code: XXVI-PGTSC-IIA/P67***
68.	Research proposal entitled ***"Microbiological profile of patients with endophthalmitis admitted in a Tertiary care center"*** submitted by Dr. Rovina Melisha Dsouza, JR through her guide Prof. Gopa Banerjee, Department of Microbiology, King George's Medical University, U.P., Lucknow vide letter no. 247/24 dated 29th May, 2024. ***Recommendation of reviewer:-*** • Sample size calculation is not provided. Please include it. **Decision:** Level 2: Revision with minor modifications/amendments for resubmission ***Ref. code: XXVI-PGTSC-IIA/P68***
II-A	**Modification**
	Modification of research proposal entitled ***"Comparison of LMA proseal, ambu aurgagain, baska mask and LMA protector for airway management in laparoscopic surgeries: A randomized comparative, an open label study"*** submitted by Dr. Ayur Verma, JRI, Department of Anaesthesiology, King George's Medical University, U.P., Lucknow vide letter no. Anaes/736/23 dated 29th May, 2024. ***Recommendation of reviewer:-*** • IEC proforma: As there is no sponsor, why the investigator has marked GOVT under sponsor information? • All the relevant headings in the consent need to be ticked in the IEC proforma item number 8. **Decision:** Level 1: Approved – with or without suggestions or comments ***Ref. code: XXI-PGTSC-IIA/P61***

(Hardeep Singh Malhotra)
Member-Secretary, IEC

(J.S. Srivastava)
Chairman, IEC