KING GEORGE'S MEDICAL UNIVERSITY, UTTAR PRADESH, LUCKNOW

MEETING CELL

In exercise of the powers conferred under sub-section (1) of section 45 of the King George's Medical University, Uttar Pradesh Act, 2002 (U.P. Act No. 8 of 2002) and in supersession of all existing orders on the subject, the Executive Council of the King George's Medical University makes the following regulations relating to the conduct and procedure to be followed at its meetings and other matters related or incidental thereto :-

The KING GEORGE'S MEDICAL UNIVERSITY (Conduct and Procedure of Meeting of Executive Council) REGULATIONS, 2018.

CHAPTER – I
PRELIMINARY

Short title & commencement

1.01 These regulations may be called the King George's Medical University (Conduct and Procedure of Meeting of Executive Council) Regulations, 2018.

Definitions

1.02 In these regulations, unless there is anything repugnant in the subject or context-

(a) '**Act**' means the King George's Medical University, Uttar Pradesh Act, 2002 as amended from time to time;

(b) '**Council**' means the Executive Council of the University;

(c) '**Meeting**' means a meeting of the Executive Council;

(d) '**Secretary**' means the Secretary to the Executive Council;

(e) '**Member**' means a member of the Executive Council duly specified under section 24 read with section 8 and includes the Chairperson;

(f) '**Special Invitee**' includes the Finance Officer, the Controller of Examinations and any other Statutory Officer of the University, invited by the Council having no voting right;

(g) '**Statutes**' means the King George's Medical University, Uttar Pradesh First Statutes, 2011 as amended from time to time; and

(h) words and expressions used but not defined in these regulations shall have the meanings assigned to them in the Act and the Statutes.

Term of the members
Statute 3.01(2)

1.03 (1) Subject to the conditions contained in sub-section (2) of section 50 of the Act, the term of the office of the members of the Executive Council, other than *ex-officio* members, shall be three years, commencing from the date of its upcoming meeting.

(2) In the meeting of the Council, the member shall declare that he/she does not falls under the provisions of sub-section (3) of section 24 of the Act.

CHAPTER – II
GENERAL

The Secretary

2.01 The Registrar of the University shall be *ex-officio* Secretary of the Council. In his absence the Deputy Registrar or an officer nominated by him, with the prior approval of the Vice-Chancellor, shall act as the Secretary of the Council.

2.02 It shall be the duty of the Secretary of the Council to attend its meeting and to maintain the relevant records, registers and other documents provided for this purpose. In addition, the Secretary shall have -

(a) to ensure compliance of the provisions of the regulations alongwith all directions and resolutions passed by the Council;

(b) to bring to the notice of the Council any irregularity, illegality or omission on its part;
(c) to provide every information asked for by the Council and
(d) other functions as may be entrusted to him from time to time.

Venue of meeting

2.03 The meeting of the Executive Council shall generally be held in the premises of the University, but the Vice-Chancellor may, in consultation with the members, call a meeting at a venue other than the University premises in special circumstances to be mentioned in the NOTICE to Members.

Category of meetings

2.04 The meeting of the Executive Council shall be of three categories:-
(a) Regular Meeting,
(b) Special Meeting, and
(c) Emergency Meeting.

2.05 (a) **REGULAR MEETINGS** of the Council may be held at such intervals as may be considered necessary but shall not be less than four in a calendar year.
(b) A **SPECIAL MEETING** of the Council may be called to resolve any urgent matter requiring the attention of the Council.
(c) In an emergent situation, that could not have been reasonably foreseen and which requires immediate attention and quick action to deal with it, by the Council, an **EMERGENCY MEETING** may be called by the Vice-Chancellor without providing any formal notice or agenda to the members as the meeting is unexpected and immediate by its nature.

CHAPTER – III

SUMMONING OF MEETING

3.01 The meetings, other than an Emergency Meeting of the Council, shall be called by the Registrar under the directions of the Vice-Chancellor either on his own initiative or on a written request SIGNED BY atleast one-third of the effective members of the Council.

Special Meeting

3.02 In case of a Special Meeting, the Vice-Chancellor may call a meeting to deal with any urgent matter requiring the attention of the Council at any time after giving *prior* notice of atleast three days to the members. It may be done by communicating the agenda by-circulation to each member, through special messenger:

Provided that, no resolution shall be deemed to have been duly approved by the Executive Council by circulation, unless the resolution has been circulated in draft, together with the necessary papers, if any, to all the members of the Council, at their addresses registered with the University, preferably by hand delivery or by Speed Post or by e-mail, or through such electronic means as may be resolved from time to time and has been approved by a majority of the members:

Provided also that, where not less than one-third of the total number of members require that any resolution under circulation must be decided at a meeting, the Chairperson shall put forth the resolution to be decided at a regular or special meeting of the Executive Council as the occasion requires:

Provided further that a resolution shall be noted at a subsequent meeting of the Council and made part of the minutes of such meeting.

Emergency Meeting

3.03 An Emergency Meeting may be held by personal contacts (members assembled at a physical location) or e-mail or other electronic methods like video-conferencing. However, written consent or dissent of members on the PROCEEDING shall be necessary which may be transmitted electronically. Once a quorum is present, emergency action can be approved by a majority of members participating in the meeting.

Regular Meeting

3.04 Every notice calling a meeting of the Council shall specify the venue, date and the hour of the meeting and shall contain a list of point-wise agenda-items of the business to be transacted at such meeting. The notice shall be served on

members of the Council including Special Invitees and Associated Persons, as may be applicable, by the Registrar atleast seven days previous to each meeting.

3.05 Proposals relating to vote of thanks, messages of congratulation or condolence, addresses and other matters of like nature may be moved with the permission of the Chair and no *prior* notice of such a proposal will be necessary.

3.06 Subject to the provisions contained in section 51 of the Act, any accidental omission to give notice to, or the non-receipt of such notice by any member or other person who is entitled to such notice for any meeting shall not invalidate the proceedings of the meeting.

Agenda Items

3.07 (1) With the notice of the meeting mentioned hereinabove, point-wise agenda items shall be circulated to members, special invitees and other relevant persons, as he thinks necessary, by the Registrar with the *prior* approval of the Vice-Chancellor.

(2) Such notice shall be served personally on the local members of the Council, failing which, it may be served on any adult member of his family.

(3) In other cases the notice shall be communicated by Speed Post or e-mail or any other electronic methods, whichever is feasible. In any condition, the successful communication will be ensured.

Framing the Agenda

3.08 Agenda of the meeting may be framed in the following sequence:-

(1) Pre-Agenda Items– Greeting to members (including new members), introduction by new members, message of congratulation etc, as applicable.

(2) Main Agenda Items –

(a) Confirmation of previous minutes,

(b) Action Taken Reports (A.T.R.) of previous minutes (datewise/itemwise)- if not complied, with reasons thereof, in detail and sequence,

(c) Other items as per the agenda to be considered,

(d) Last Agenda Item – Thanks to outgoing members, condolence etc.

Proposal to add on

3.09 A member who wants to move any matter, not included in the agenda, shall give a notice to the Registrar to be included in the agenda of the meeting, not less than seven days before the date fixed for the said meeting. The Registrar will include it in the agenda after attaining approval of the Vice-Chancellor thereon.

Final Agenda

3.10 The Registrar will circulate Final Agenda Items and Agenda Notes thereon with annexure, if any, to members jointly signed by the Vice-Chancellor and the Registrar before three clear days of the meeting. Supplementary agenda with notes may be communicated atleast 24 hours before the starting of the meeting.

3.11 At a special or emergency meeting, the subject for the consideration of which the meeting has been called for, shall only be discussed.

Quorum of meeting

3.12 At all the meetings of the Council, five members, inclusive of the Chairperson, shall form a quorum:

Provided that no quorum shall be necessary for an adjourned meeting.

Adjournment of the meeting

3.13 (1) At the appointed time or during a meeting, the Secretary shall take notice whether quorum is present. If the quorum is not present, the meeting shall be adjourned for fifteen minutes, and if necessary, further for another fifteen minutes. If still there is no quorum, the Chairperson may declare that the meeting shall be adjourned to a later hour on the same day or to a future date as he thinks fit. Accordingly, the notices shall be issued.

(2) At all adjourned meetings, no business other than that on the agenda of the original meeting shall be considered.

3.14 No matter, which had not been on the agenda of the meeting, shall be discussed at any meeting except with the prior permission of the Chairperson.

3.15 The Participation of members in a regular meeting of the Council shall be in person but in special circumstances and in rare cases, to be recorded in writing, video conferencing or other audio-visual means, as may be applicable, may be arranged. Video Conferencing should be capable of recording and recognising the participation of the members and of recording and storing the proceedings of

such meetings along with date and time.

CHAPTER – IV

CONDUCT OF BUSINESS

Presiding officer

4.01 The Vice-Chancellor shall, preside over meetings of the Council. In his absence from any meeting, the members present shall elect one of the members from amongst themselves, to preside over that meeting.

Transaction of business

4.02 (1) The business of the meeting shall be transacted in the order in which it is entered in the agenda unless otherwise resolved in the meeting with the permission of the Chairperson.

(2) The Secretary shall put forth the factual position of the subject as per the Statutory provisions/orders in order to resolve the issue in the Council. The views of the Registrar may be recorded in the minutes of the Council distinctly, if he so desires.

(3) Provisions mentioned hereinabove shall *mutatis mutandis* apply to 'Special Invitees', in case of matters related to them.

4.03 (1) All matters which come up before the Council shall be resolved by a majority of the votes of the members present and voting at the time and, in the event of an equality of votes, the Chairperson or in his absence, the person presiding shall have a casting vote or second vote:

Provided that the Council shall obtain the opinion of the Finance Officer before passing a resolution involving financial implications. The views of the Finance Officer shall be recorded in the minute prepared under Chapter VI of these regulations.

(2) The number of members "**FOR**" and "**AGAINST**" the item may be recorded in the minutes and the resolution shall be taken accordingly.

4.04 An Audio-Video recording of the proceeding of a meeting will be ensured and maintained by the Registrar for three years unless-otherwise directed by any Authority or a Court of Law.

Association of an expert

4.05 (1) The Council may associate with itself any expert whose assistance or advice, it may thinks necessary in carrying out any of the provisions of the Act, statutes or ordinances or government orders without any right to vote.

(2) A person associated by the Council under sub-regulation (1) shall have a right to take part in the discussions relevant to that purpose.

(3) Preference may be given to the Agenda-Item in which assistance or advice of an Associate Member is required. After the discussion, he may be requested to leave the venue.

Re-opening of any matter

4.06 No matter once decided by the Council shall be re-opened within six months except with the consent of two-thirds of the members of the Council through a regular agenda item.

4.07 (1) During the course of a meeting, no person other than the members will remain in the meeting place unless called or permitted by the Chairperson.

(2) The concerned dealing officer/employee will be present alongwith concerned documents/records/files etc at anteroom during the discussion on the subject related to him. The Council may seek his assistance at any time, it thinks necessary and thereafter he may leave the place.

CHAPTER – V

PROCESS OF DISCUSSIONS

Bar of participation

5.01 Where any matter is related to a member, the member concerned will not participate in the discussions of that particular item and leave the meeting place before starting of that agenda item, for the period discussion on that agenda-item is not over, otherwise the resolution passed on that agenda-item shall be *void*. This will be mentioned in the minutes accordingly.

Point of order

5.02 Any member may, at any time in the course of discussion, rise and call the

attention of the Chairperson to a point of order. If the Chairperson is of opinion that the point of order has been raised for the purpose of mere obstruction or of interruption to the discussion or to the business of the meeting, he will so declare which shall be complied with.

5.03 The Chairperson shall be the sole judge of any point of order and may, of his own instance or at the instance of a member, call to order any member who is speaking. If the member so called to order disregards such call, the Chairman may direct him to sit down which shall be complied with.

Question to Chair

5.04 (1) A question may be asked by a member of the Council for the purposes of obtaining information on a matter relating to the affairs of the University.

(2) The question shall be addressed to the Chair:

Provided that no question will be asked which does not satisfy the following conditions, namely:

(i) It shall be so framed as to be a request for information,

(ii) It must not contain arguments, inferences, ironical expressions or defamatory statements,

(iii) It must not ask for an expression of opinion or the solution of hypothetical proposition,

(iv) It must not refer to the character, competence or conduct of any person except in his official capacity.

(v) It must not refer to a matter which in the opinion of the Chairperson is of a confidential nature.

Admissibility of a question

5.05 (1) The Chairperson shall decide on the admissibility of a question and may disallow any question which, in his opinion, contravenes the above provisions, but in that case he shall give his reasons for disallowance to the member concerned.

(2) Reply shall be made by the Secretary or the Chairperson as the occasion requires.

Ruling by the Chair

5.06 The Chairperson shall decide all points of order on procedure or disputes which may arise in any meeting and his decision thereon shall be final.

CHAPTER –VI

MINUTES OF MEETING

Draft minutes

6.01 The draft minutes of the meeting as drawn up by the Secretary and the Chairperson shall be circulated amongst the members of the Council at the earliest, preferably within a week:

Provided that in case, one of these is not in service of the University or have gone out-side for atleast a week or in other unavoidable circumstances, the minutes may be authenticated by any of these officers present in the meeting as on date.

6.02 Within a fortnight of the issue of the draft minutes, members may communicate to the Secretary indicating any correction or suggestions etc therein. The Secretary will take cognizance of the same and seek approval of the Chairperson thereon.

Compliance of resolution

6.03 After the period mentioned hereinabove, if no suggestions or corrections have been received, the resolutions passed by the Council may be complied with:

Provided that in compliance of the court orders or in other urgent cases the resolution will be complied immediately, as the occasion requires.

Confirmation of minutes

6.04 The minutes alongwith amendment suggested, if any, shall be placed for confirmation at the next regular meeting of the Council as the first item in the agenda.

6.05 (1) After the minutes are confirmed by the Council, they shall be placed in the MINUTE-BOOK and the website of the University and circulated to all concerned for compliance and necessary action.

(2) Printed minutes of the meetings in book form shall be maintained and

preserved permanently in easy volumes.

CHAPTER – VII
MISCELLANEOUS

Residuary powers **7.01** All such matters not specifically provided for in these regulations and all questions relating to detailed working of these rules shall be regulated in such manner as the Chairperson may from time to time direct.

Payment of TA, DA etc **7.02** Members, other than the University employees, of the Council shall be entitled to actual travelling expenses and daily allowance for attending the meetings of the Council or any of its committee at the rates laid down by the Council in consultation with the Finance Committee:

Provided that the members who are employees under the Central Government or the State Government shall be governed by their respective departmental rules or orders for travelling expenses.

Constitution of committees **7.03** (1) The Council may constitute Committee(s) for the purpose, it thinks necessary fit and may associate expert(s) to the Committee for specific purpose(s) in advisory capacity.

(2) The meeting of a Committee shall be held in private and its report shall be confidential.

(3) The committee will submit its report to the Vice-Chancellor who will place it before the Council, through the agenda.

(4) The Chairperson of the Committee may be invited by the Council to express his views regarding the recommendations of the Committee.

Delegation of powers **7.04** The Council may delegate such of its powers, as it deems proper, to an officer or authority of the University, or to a committee appointed by it subject to such conditions as may be specified in the resolution.

Section 25(8)

Amendment in these regulations **7.05** Amendment in these regulations may be made by the Council by the majority of two-third of its members.

Removal of hardship **7.06** If operation of any provision of these regulations causes undue hardship in any particular case, the Vice-Chancellor, as the Chairperson may, in consultation with the Registrar, for reasons to be recorded in writing, dispense with or relax the requirement of that provision in a just and equitable manner.

Rajesh Kumar Rai
Secretary.

Prof. M.L.B. Bhatt
Chairman.

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

Institutional Ethics Committee for Human Research

Standard Operating Procedure

Research Cell
Administrative Block
King George's Medical University, UP,
Lucknow

King George's Medical University, UP, Lucknow

Institutional Ethics Committee for Human Research

Standard Operating Procedure (SOP)

Rev. Ver.-1/2019

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Standard Operating Procedure (SOP)

1. Objective

The objective of this Standard Operating Procedure (SOP) is to ensure quality and consistency in review of clinical research proposals and to contribute to the effective functioning of the Institutional Ethics Committee (IEC) so that a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the Committee as prescribed by the Ethical guidelines for biomedical research on human subjects and to follow the current ICMR and national ethical guidelines for biomedical research on human subjects.

2. Scope

This SOP applies to the review and assessment of all protocols submitted for initial review and approval from the IEC. The specific points in the guidelines attached to the assessment form for initial review must be adequately addressed in the protocol itself and/or protocol related documents under review. Relevant comments made during discussion and deliberation about a specific protocol should be recorded in the minutes of the meeting. The decision reached by the IEC will be communicated to the PI.

3. Role & Functions of Institutional Ethics Committee (IEC)

- IEC will review and approve all research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of research participants irrespective of the source of funding. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.
- The IEC will ensure that all the cardinal principles of research ethics viz, autonomy, beneficence, non–malfeasance and justice are taken care of in planning, conduct and reporting of a proposed study.
- It will look into the aspects of informed consent process, risk benefit ratio, distribution of burden/benefit and provisions for appropriate compensations wherever required.
- It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through periodic reports, final report and site visits etc.
- The committee will also ensure compliance with all regulatory requirements, applicable guidelines and laws.

4. Composition of IEC

- IEC shall be constituted in accordance with ICMR norms & GCP guidelines for a

period of 3 years.

- IECs should be multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of an IEC.
- The Chairperson of the Committee will be a person of eminence from outside the Institution to maintain the independence of the Committee.
- The number of members in the committee shall be between 7 to 15 members.
- Faculty Incharge, Research Cell will be the Member Secretary of Institutional Ethics Committee and it will be an ex-officio post. The Member Secretary shall conduct the business of the Committee. Other members will be a mix of medical and non-medical scientific and non-scientific persons including general public to reflect the differed viewpoints.
- The composition may be as follows:

Structure	**Time Period**
Chairperson (From outside the University)	3 Years
Basic Medical Scientist of the University and Basic Medical Scientist from a reputed Institution (Member)	3 years
Senior Clinicians from various departments of the University (Member)	3 Years
Legal Expert or retired Judge (Member)	3 years
Social Scientist/ Representative of NGO (Member)	3 years
Philosopher/ Ethicist/ Theologian (Member)	3 years
Lay person (Member)	3 years
Member Secretary from the University	Ex-officio

- External members could be drawn from any public or private institute from anywhere in the country. There shall be adequate representation of age, gender, community etc. in the Committee to safeguard the interests and welfare of all sections of the society.

5. Authority under which IEC is constituted:

- The Vice Chancellor, KGMU, Lucknow shall constitute the IEC, in consultation with the Faculty Incharge, Research Cell.
- The Vice Chancellor will be appellate authority for any issues arising during the proceeding of review process.
- The committee will be normally reconstituted every 3 years

6. Membership Duration and Responsibilities

- The duration of the membership will be 3 years

- There will be no bar on the members serving for more than one term but it is desirable to have around one third fresh members.
- A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member. Authority to replace the member shall be with the Vice Chancellor.
- A member can tender resignation from the committee with proper reasons to do so.
- Members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.
- Conflict of interest if any shall be declared by members of the IEC before the start of proceedings of the meeting.

7. Quorum Requirements

- A minimum of 5 members including at least three outside members is required for quorum. All decisions should be taken in meetings and not by circulation of project proposals.
- The ethics committee approving drug trials should have in the quorum at least one representative from the following groups:
  1. One basic medical scientist (preferably one pharmacologist).
  2. One clinician
  3. One legal expert or retired judge Ethical Review Procedures
  4. One social scientist/ representative of non-governmental organisation/ philosopher/ ethicist/theologian or a similar person
  5. One lay person from the community.

8. Offices/Conduct of the Meeting

- The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected by the members present from among themselves.
- The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the PI.

9. Independent Consultants

- IEC may call upon subject experts as consultants for review of selected research protocols.
- These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities.
- They will not take part in the decision making process.

10. Application Procedure

- All proposals should be submitted in the prescribed application form, copies of which will be available with the Member Secretary.
- All relevant documents should be enclosed with application.
- The required number of copies of the proposal along with the application and documents in prescribed format duly signed by the PI and Co-investigators/Collaborators should be forwarded by the Head of the Department.
- The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.
- The date of meeting will be intimated to the PI who should be available to offer clarifications if necessary.
- The decision of IEC will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication.

11. Documentation

All research proposals should be submitted with the following documents:

- Title of the project
- Names of the PI and Co-investigators with designation.
- Name of any other Institute/Hospital/Field area where research will be conducted.
- Approval of the Head of the Department.
- Protocol of the proposed research.
- Ethical issues in the study and plans to address these issues.
- Proposal should be submitted with all relevant annexure like proforma, case report forms, questionnaires, follow–up cards, etc. to be used in the study.
- Patient information sheet and informed consent form in English/Hindi and local language(s) should be enclosed. The patient information sheet should provide adequate and complete information in understandable lay man language. It should also assure that any new information that becomes relevant during the trial and is related to their participation will be given to them. The consent form should be as per schedule Y published in Gazette of India (2005).
- For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country/other countries, if available.
- Any regulatory clearances required. Copy of clearances if obtained. This is necessary for new drug/device not approved for marketing in India, justification for sending of biological samples outside India and use of radioactive pharmaceuticals in clinical studies.
- Source of funding and Budget along with the supporting documents.

- Indemnity issues including insurance for the compensation to the participants etc.
- An undertaking to ensure free treatment for research related injury (disability, chronic life-threatening disease and congenital anomaly or birth defect) and if required, payment of compensation over and above medical management by the investigator and/institution and sponsor(s), as the case may be.
- An undertaking to immediately report Serious Adverse Events (SAE) to IEC.
- Statement of conflicts of interest, if any.
- Plans for publication of results–positive or negative–while maintaining the privacy and confidentiality of the study participants.
- Any other information relevant to the study.
- Agreement to submit annual progress report and final report at the end of study.
- The PI should provide the details of other ongoing research projects (Title of the project, Date of starting and duration, source and amount of funding).

12. Waiver of Consent

A researcher cannot decide that her/his proposal falls in the exempted, expedited or full review category. All research proposals must be submitted to the EC. The decision on the type of review required rests with the EC and will be decided on a case-to-case basis. Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.

The researcher can apply to the EC for a waiver of consent if the research involves less than minimal risk to participants and the waiver will not adversely affect the rights and welfare of the participants

The EC may grant consent waiver in the following situations:

- research cannot practically be carried out without the waiver and the waiver is scientifically justified;
- retrospective studies, where the participants are de-identified or cannot be contacted;
- research on anonymized biological samples/data;
- certain types of public health studies/surveillance programmes/programme evaluation studies;
- research on data available in the public domain; or
- research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

13. Review Procedure

- Meetings of IEC shall be held on scheduled intervals as prescribed (once in 2 months or even earlier, for which the dates will be decided at the end of previous meeting). Additional meetings will be held as and when necessary.
- The proposals will be sent to members at least 2 weeks in advance.
- Decisions will be taken by consensus after discussions, and voting will be done if necessary.
- PI should be available during the meeting and may be invited to offer clarifications.
- Independent consultants/Experts may be invited to offer their opinion on specific research proposals.
- The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with signature of Chairperson at each page.

14. Element of Review

- Scientific design and conduct of the study.
- Approval of scientific review committee and regulatory agencies.
- Assessment of predictable risks/harms and potential benefits.
- Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
- Management of research related injuries, adverse events and compensation provisions.
- Justification for placebo in control arm, if any.
- Availability of products to the trial subjects after the study, if applicable.
- Patient information sheet and informed consent form in English/Hindi and local language.
- Protection of privacy and confidentiality of subjects.
- Involvement of the community, wherever necessary.
- Protocol and proforma of the study including the consent form.
- Plans for data analysis and reporting.
- Adherence to all regulatory requirements and applicable guidelines.
- Competence of investigators, research and supporting staff.
- Facilities and infrastructure.

15. Expedited Review

- Proposals which are recommended for minor revisions will be reviewed by a sub committee appointed by the IEC for clearance and approved by the Chairperson. The approvals will be reported in the next IEC meeting by Member Secretary.

- Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review.
- The revised form of proposals requiring major changes will be reviewed at the next ethics committee meeting.
- Rejected proposals may be reconsidered only if a very strong background is there.

16. Decisions Making

- A member shall recuse himself from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.
- Only members will make the decision. The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.
- Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- Revised proposals may be subjected to an expedited review.
- All approved proposals will be subject to the following standard conditions. Additional conditions may be added by the IEC.
  - PI should submit annual report of the ongoing project on format prescribed by the Institute, to the IEC.
  - The final report of the completed study should be submitted by PI.
  - The PI should highlight the changes in the protocols/brochures/informed consent form etc. being amended from the previous documents while submitting amended documents to IEC.

17. Communicating the Decision

- Decision will be communicated to Principal Investigator by the Member Secretary in writing.
- Suggestions for modifications and reasons for rejection will be communicated to the Principal Investigator.

18. Memorandum of Understanding and Indemnity Agreement for sponsored Drug/Device/ Collaborative Trials

- After the approval from IEC, the sponsor/CRO will submit the clinical trial agreement/Memorandum of Understanding and Indemnity Agreement document on Rs. 100 stamp paper separately (two copies) to the Institute which will be signed by sponsor, Principal Investigator and the Faculty In-charge, Research Cell after the approval of Hon'ble Vice Chancellor.
- As per existing policy of the Institute, there will be 25% overhead charges to the total cost of the trial/per patient cost.

- The drug trial shall be started by the PI after the agreement is signed by all the parties as well as required regulatory approvals from DCGI etc. are available for the concerned trial.

19. Follow up Procedures

- Annual report should be submitted by the PI on prescribed format along with comments.
- Final report should be submitted at the end of study on prescribed format including a copy of the report which has been sent to sponsoring agency.
- All SAEs and the interventions undertaken should be intimated immediately to IEC. The PI should submit the SAEs reported by other centers from time to time to the Member Secretary for information to IEC along with comments if any action is required in the current study.
- Protocol deviation, if any, should be informed with adequate justifications.
- Any amendment to the protocol should be submitted for approval.
- Any new information related to the study should be communicated to IEC.
- Change of investigators should be done with the approval of IEC.
- Premature termination of study should be notified with reasons along with summary of the data obtained so far.

20. Record Keeping and Archiving

- Curriculum Vitae (CV) of all members of IEC.
- Minutes of all meetings duly signed by the Chairperson.
- Copy of all correspondence with members, researchers and other regulatory bodies.
- All study related documents (study protocols with enclosed documents, progress reports, and SAEs.)
- A copy of filled CRF (Case Report Forms) shall remain with the PI.
- Final report of the approved projects.
- Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
- All documents should be archived for minimum of five years after the completion of study.

21. Site Monitoring and Post-monitoring activities

- Routine monitoring for a site may be decided at the time of approval of the project by the Full Board. This is recorded in the IEC minutes.

21.1 Before the visit

- Irrespective of the cause for conducting monitoring the following procedure will be followed:
- The IEC will identify and select one or more IEC members (henceforth referred to as monitors) to conduct monitoring of a site.
- The selected member/members will be given a letter in this regard.
- The agenda of monitoring will be decided by the identified monitors in consultation with the Member Secretary and Chairperson.
- The Member Secretary will decide the date of the monitoring in consultation with the monitors and the PI.
- The final date will be communicated to the PI and monitors.
- Monitors will carry with them Site Monitoring Visit Report Forms

21.2 During the visit

- The Monitor will follow the check list and oversee the progress of the study will ensure that the study conduct and data handling comply with the protocol, GCPs and applicable ethical and regulatory requirements.

21.3 After the visit

- The Monitor will submit the completed Site Monitoring Visit Report to the IEC within 7 working days of conducting a site monitoring visit or at the time of full board meeting (whichever is earlier).
- The report should describe the findings of the monitoring visit.
- The Member-Secretary will present the monitoring report at the next full board IEC meeting and the concerned Monitor will provide additional details/ clarifications to members, as required.
- The IEC will discuss the findings of the monitoring process and take appropriate action.
- The IEC will convey the decision to the Principal Investigator in writing within 14 working days of the meeting.
- The IEC will place the copy of the report in the protocol file.

22. Updating IEC Members

- All relevant information on ethics will be brought to the attention of the members of IEC by the Member Secretary.

- Members will be encouraged to attend national and international training programs/conferences/seminars in the field of research ethics to help in improving the quality of research protocols/ethics committee submissions and review.

23. Bibliography

- Good Clinical Practices for Clinical Research in India by Central Drugs Standard Control Organization, New Delhi, (Available at: http://www.cdsco.nic.in/html/GCP1.html)
- National Ethical guidelines for biomedical and health research involving human participants. Indian Council of Medical Research 2017. (Available at: http://ncdirindia.org/Ethics/Download/ICMR_Ethical_Guidelines_2017.pdf)

KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

FORM TO BE FILLED BY THE PRINCIPAL INVESTIGATOR (PI) FOR SUBMISSION TO INSTITUTIONAL ETHICS COMMITTEE (IEC)

(for attachment to each copy of the proposal)

* **Ref.** Code No. of IEC:

* to be filled by Office of IEC

Proposal Title:

_____

_____

_____

_____

_____

	Name, Designation & Qualifications	Departmental Tel Nos. email ID	Signature
PI			
Co-PI/Collaborators 1.			
2.			
3.			

Please attach Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years) not working at KGMU. The investigators should sign their CV.

_____

Sponsor Information

1. Indian	a) Government ☐ b) Private ☐	Central ☐	State ☐	Institutional ☐
2. International	a) Government ☐	Private ☐		UN Agencies ☐
3. Industry	a) National ☐	Multinational ☐		
4. Contact address of sponsor				
5. Budget				

1. Type of study	Epidemiological ☐ Clinical ☐	Basic Sciences ☐ Single Centre ☐	Behavioral ☐ Multicentric ☐
2. Status of review	New ☐	Revised ☐	
3. Clinical Trials Drug/Vacancies/Device/Herbal Remedies i. Does the study involve use of Drugs ☐ Devices ☐ Vaccines ☐ Indian systems of Medicines / or Alternate systems of Medicine ☐ Any other ☐ None ☐			
ii. Is it approved and marketed In India ☐ UK & Europe ☐ USA ☐ Other countries, specify			
iii. Does it involve a change in use, dosage, route of administration? **if yes**, whether DCGI's/Any other Regulatory Authority's permission obtained? **If yes,** copy of permission attached.			Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐
iv. Is it an Investigational New Drug? **If yes,** a. Investigator's Brochure enclosed b. Preclinical studies data available (if yes, provide summary) c. Clinical studies data available (if yes, provide summary) d. Clinical study is Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ e. DCGI's permission obtained **If yes,** copy of letter enclosed			Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ Yes ☐ No ☐

4. Brief description of the proposal-aim(s) and objectives, justification for study, methodology describing the potential risks and benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words)

5. Subject selection

i. Number of subjects

ii. Duration of a) Study: b) Subject participation

iii. Will subjects from both sexes be recruited 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 ☐	

6. Privacy and confidentiality

i. Study Involves
- Direct Identifiers ☐
- Indirect Identifiers/Coded ☐
- Completely Anonymised / 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 ☐

iii. Use of recombinant / gene therapy products Yes ☐ No ☐

if yes, has Institutional Biosafety Committee 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 ☐

If yes, has Institutional Biosafety Committee approval for Radioactive Isotopes been obtained? Yes ☐ No ☐

vii. Use of Infectious / biohazardous specimens Yes ☐ No ☐

viii. Proposal disposal of material Yes ☐ No ☐

ix. Will any sample collected from the patients be sent abroad? Yes ☐ No ☐
If yes, give details and address of collaborators

a. Sample will be sent abroad because (Tick appropriate box)
Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed ☐
If so, reasons
b. Has necessary clearance been obtained Yes ☐ No ☐

8. **Consent** *** Written** ☐ **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	☐
Compensation for participation	☐	Benefits if any on future commercialization e.g. Genetic basis for drug development	☐
Compensation for study related injury	☐		

Translation of information sheet in local language ☐

ii. If healthy volunteers will be included, information sheet for them attached Yes ☐ No ☐

iii. Consent form in English	☐	Hindi	☐
iv. Who will obtain consent (PI/Co-PI)	☐	Nurse / Cousellor	☐
Research Staff	☐	Any other	☐

* If written consent is not obtained, giver reasons:

9. **Will any advertising be done for recruitment of Subjects?**
(Posters, flyers, brochure, websites – if so attach a copy) Yes ☐ No ☐

10. **Risks & benefits**

i. Is the risk 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?	Yes ☐	No ☐
		Direct ☐	Indirect ☐
	b) to the society?	Yes ☐	No ☐

11. Data monitoring

i. Is there a data & safety monitoring committee/Board (DSMB)?	Yes ☐	No ☐
ii. Is there a plan for reporting of adverse events?	Yes ☐	No ☐

if yes, reporting will be done to Sponsor ☐ IEC ☐ DSMB ☐ iii. Is there a plan for interim analysis of data?				Yes ☐	No ☐
12. Is there compensation for injury? **If yes,** by Sponsor ☐ Investigator ☐ Insurance Company ☐ Any other ☐				Yes ☐	No ☐
13. Do you have conflict of interest? **(Financial / Non financial)** If yes, specify				Yes ☐	No ☐

Check list for attached documents:

Project proposal – 05 copies

Curriculum Vitae of non KGMU Investigators	☐
Brief description of proposal/summary	☐
Copy of the Protocol / Project and questionnaire (if any)	☐
Investigator's Brochure	☐
Copy of Patient information sheet & Consent form in local language	☐
Copy of Advertisements/Information brochures	☐
DCGI/DBT/BARC clearance if obtained	☐
Copy of Insurance Policy	☐
Copy of Clinical trial agreement	☐
Copy of IEC proforma	☐
Copy of PI undertaking	☐
Copy of Case Report Form	☐

Signature of PI with stamp

Date

Signature of HOD with stamp

UNDERTAKING BY THE PRINCIPAL INVESTIGATOR

1 **NAME OF THE PROJECT**

2 **NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL INVESTIGATOR**

3 **OTHER MEMBERS OF THE RESEARCH TEAM**

4 **NAME AND ADDRESS OF ANY OTHER MEDICAL INSTITUTE, HOSPITAL OR INSTITUTION WHERE PARTS OF THE STUDY WILL BE DONE**

5 **NUMBER OF ONGOING PROJECTS/CLINICAL TRIALS IN WHICH YOU ARE PI.**

- I confirm that I will initiate the study only after obtaining all regulatory clearances.
- I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IEC at the earliest.
- I confirm that the CO PI and other members of the study team have been informed about their obligations and are qualified to meet them
- I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under ICMR and National Regulatory Guidelines are adhered to.
- I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IEC, Regulatory authorities, Sponsors or their authorized representatives.
- I will inform the IEC and the Sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence.
- I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.
- I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.
- I will inform IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IEC within 4 weeks of the due date.

Signature of Principal Investigator **Date**

ONE PAGE CV FOR NON-KGMU INVESTIGATORS

Last Name	First Name	Middle Initial
Date of Birth (dd/mm/yy):		**Sex**
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordination		
Professional Mailing Address (Include institution name)	**Study Sited Address (Include institution name)**	
Telephone (office):	**Mobile Number:**	
Telephone (Residence):	**Email:**	
Academic Qualifications (Most current qualification first)		
Degree / Certificate	**Year**	**Institution, Country**
Current and Previous Relevant Positions Including Academic Appointments (Most current position first)		
Month and Year	**Title**	**Institution / Company, Country**
Brief Summary of Relevant Clinical Research Experience:		
Signature: **(Signature Required)**	**Date:**	

FORMAT FOR COMMUNICATION TO THE PRINCIPAL INVESTIGATOR BY THE MEMBER SECRETARY, INSTITUTIONAL ETHICS COMMITTEE

Dated: _____

To,
Prof./Dr. _____

_____

Dear Prof./Dr. _____

The Institutional Ethics Committee in its meeting held on _____, has reviewed and discussed your application. submitted vide letter no. _____ dated _____, to conduct the clinical trial/project entitled "_____
_____"
sponsored by _____ Ref. Code no._____

The following documents were reviewed:

a. Trial protocol (including protocol amendments/project) dated _____ Version no (s) _____
b. Investigator's Brochure, dated _____, Version no. _____
c. Patient information Sheet and Information Consent Form (including updates if any) in Hindi, English and/or vernacular language.
d. Proposed methods for patient accrual including advertisement (s) proposed to be used for the purpose.
e. Current CV of investigator from outside KGMU.
f. Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation.
g. Investigator's Agreement with the Sponsor.
h. Investigator's Undertaking.
i. Ethics Committee Proforma.
j. DCGI approval letter/ submission letter.
k. Case Report Form
l. Any other/additional documents

Comments of Committee:

Decision of Committee:

Member Secretary
Institutional Ethics Committee

INTIMATION OF START OF STUDY

1. Project/Trial Reference Code Number
2. Title of the drug/multicentric trial
3. Principal Investigator (Name & Department)
4. Sponsor
5. Contract Research Organization (CRO) if any
6. Date of sanction by IEC
7. Date of start

(Signature of Principal Investigator)

Date:

PROGRESS REPORT (ANNUAL)/FINAL REPORT

1. Project/Trial Reference Code Number
2. Title of the Research Project/drug/multicentric trial
3. Principal Investigator (Name & Department)
4. Sponsor
5. Contract Research Organization (CRO) if any
6. Date of sanction by IEC
7. Date of start
8. Objectives of the study
9. Progress report as per objectives (attach separate sheet)
10. Serious Adverse Events if any with details (in summary form)
11. Protocol deviation if any with reasons/justifications
12. Report/publications/conference presentation
13. Awards/recognition

Date: **(Signature of Principal Investigator)**

(Signature of Head of the Department)

KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

GUIDELINES FOR PATIENT INFORMATION SHEET

Potential recruits to your research/trial study must be given sufficient information to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below where appropriate, and preferably in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs.

1. Study Title

Is the title self explanatory to a lay person? If not, an additional simplified title may also be included.

2. Invitation Paragraph

You should explain that the patient is being asked to take part in a research/trial study. The following is an example:

"You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?

The background and aim of the study should be given here

4. Why have I been chosen?

You should explain how and why the patient was chosen and how many other patients will be studied.

5. Do I have to take part?

You should explain that taking part in the research/trial is entirely voluntary. You could use the following paragraph:

"It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."

6. What will happen to me if I take part?

You should say how long the patient will be involved in the research/trial, how long the research/trial will last (if this is different), how often they will need to visit the hospital/lab or a clinic (if this is appropriate) and how long these visits will be. You should explain if the patient will need to visit the doctor (or clinic) more often than for the usual treatment and if travel expenses are available. What exactly will happen e.g. blood tests, x-rays, interviews etc? Whenever possible you should draw a simple flow chart or plan indicating what will happen at each visit. What are the patient's responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the clinic at 9.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research/trial methods you

intend to use – the following simple definitions may help.

Randomized Trial: Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer, which has no information about the individual – i.e. by chance. Patients in each group then have a different treatment and these are compared. This way, the chances of something happening as a result of our choosing to put you in a specific group or bias is reduced. You should tell the patients what chance they have of getting the study drug/treatment: e.g. a one in four chance.

Blind Trial: In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you not your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so). This is done to ensure that the trial is carried out without a bias that may result from knowing which group you are in, which can adversely affect the results.

Cross-over Trial: In a cross-over trial both the groups have the different treatments in turn. There may be a break between treatments, a washout period, so that the effects of the first drug or treatment are cleared from your body before you start the new treatment.
Placebo: A placebo is a dummy treatment such as a pill, which looks like the real thing but is not. It contains no active drug, chemical or ingredient.

7. What do I have to do?

Are there any lifestyle restrictions? You should tell the patient if there are any dietary restrictions. Can the patient drive? Drink? Take part in sport? Can the patient continue to take his/her regular medication? Should the patient refrain from giving blood? What happens if the patient becomes pregnant? Explain (if appropriate) that the patient should take the medication regularly.

8. What is the drug or procedure that is being tested?

You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration. Patients entered into drug trials should preferably be given a card (similar to an identify card) with details of the trial they are in. They should be asked to carry it at all times.

9. What are the alternatives for diagnosis or treatment?

For therapeutic research/trial the patient should be told what other treatment options are available.

10. What are the side effects of taking part?

For any new drug or procedure you should explain to the patients the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned or in case of emergency. The known side effects should be listed in terms the patient will clearly understand (e.g. 'damage to the heart' rather than 'cardiotoxicity'; 'abnormalities of liver tests' rather than 'raised liver enzymes'). For any relatively new drug it should be explained that there may be unknown side effects.

11. What are the possible disadvantages and risks of taking part?

For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study, the following (or similar) should be said:

"It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator.

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of foetal damage.

If future insurance status, e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the patients have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should clearly state what will happen if you detect or find a condition of which the patient was unaware. It is treatable? What are you going to do with this information? What might be uncovered (e.g. high blood pressure, HIV status)?

12. What are the possible benefits of taking part?

Where there is no intended clinical benefit to the patient from taking part in the trial this should be stated clearly.

It is important not to exaggerate the possible benefits to the patient during the course of the study, e.g. saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:

We hope that (all the treatments will help you. However, this can not be guaranteed. The information we get from this study may help us to treat future patients with (name of condition) better.

13. What if new information becomes available?

If additional information becomes available during the course of the research/trial you will need to tell the patient about this. You could use the following:

"Sometimes during the course of a research project/trial, new information becomes available about the treatment/drug that is being studied. If this happens, your research/trial doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research/trial doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Also, on receiving new information your research/trial doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue."

14. What happens when the research/trial study stops?

If the treatment will not be available after the research/trial finishes this should be

explained to the patient. You should also explain to them what treatment will be available instead. Occasionally the company sponsoring the research/trial may stop it. If this is the case the reasons should be explained to the patient.

15. What if something goes wrong?

You should inform patients how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from patients as to their treatment by members of staff (doctors, nurses etc) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event.

16. Will my taking part in this study be kept confidential?

You will need to obtain the patient's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. A suggested form of words for drug company sponsored research/trial is:

"If you consent to take part in the research/trial any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research/trial for purposes of analyzing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/clinic/laboratory"

"All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory will have 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?

You should be able to inpatients what will happen to the results of the research trial. You might add that they will not be identified in any report publication.

18. Who is organizing and funding the research/trial?

The answer should include the organization or company sponsoring or funding the research/trial

(e.g. Govt. agency, pharmaceutical company, NGO, academic institution).

The patient should be told whether the doctor conducting the research/trial is being paid for including and looking after the patient in the study. This means payment other than that to cover necessary expenses such as laboratory tests arranged locally by the researcher, or the costs of a research nurse.

19. Who has reviewed the study?

You may wish to mention that IEC has reviewed and approved the study (you should not however list the members of the Committee).

20. Contact for further information

You should give the patient a contact address for further information. This can be your name or that of another doctor/nurse involved in the study. **(Name of the PI, Address, Telephone Numbers and Name of the Member Secretary of Ethics Committee and**

address with telephone numbers)

Remember to thank your patient for taking part in the study!

The patient information sheet should be dated and given a version number.

The Patient Information Sheet should state that the patient will be given a copy of the information sheet and the signed consent form.

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.

Date **Signature of PI**

किंग जार्ज चिकित्सा विश्वविद्यालय, उ0प्र0, लखनऊ

सूचित सहमति पत्र

अध्ययन का शीर्षक ——————————————————————————

अध्ययन का नम्बर——————————————————————————

अन्वेषक का सम्पर्क विवरण——————————————————————

सहभागी का पूरा नाम ——————————————————————————

जन्म तिथि/उम्र ——————————————————————————

पता ——————————————————————————

भाग–1

अध्ययन का उद्देश्यः–

अध्ययन की प्रक्रियाएंः–

अध्ययन से जोखिमः–

अध्ययन से लाभः–

सम्भावित जटिलताएंः–

क्षतिपूर्तिः–

गोपनियताः–

प्रतिभागी के अधिकारः–

अध्ययन मे भागीदारी के विकल्पः–

भाग–2

1. मेरी पुष्टि है कि मैने उपरोक्त परीक्षण हेतु जानकारी पत्र दिनांक————————को पढ़ व समझ लिया है, तथा मुझे प्रश्न पूछने के अवसर प्रदान किये गये।

   अथवा

   मुझे अध्ययन अन्वेषक ने विस्तार से सब तथ्यों को समझा दिया है तथा मुझे प्रश्न पूछने का अवसर प्रदान किया।

2. मैंने समझ लिया है कि इस अध्ययन में मेरी प्रतिभागिता स्वैच्छिक है, तथा यह कि मै बिना कोई कारण बताए किसी भी समय अपनी चिकित्सीय देखभाल या कानूनी अधिकारों पर प्रभाव पडे बिना हट जाने के लिए स्वतंत्र हूं।

3. मैंने समझ लिया है कि चिकित्सीय प्रायोजक की ओर से काम करने वाले अन्य, नैतिकता समिति तथा विनियामक प्राधिकारियों का चालू अध्ययन तथा इससे सम्बन्धित हो सकने वाले किसी अनुसंधान से सम्बन्धित मेरे स्वास्थ्य अभिलेखों को देखने के लिए मेरी अनुमति की आवश्यकता नही होगी, भले ही मैं इस परीक्षण से हट ही क्यों न जाऊं। तथापि मैंने समझ लिया है कि तृतीय पक्ष

को दी गई या प्रकाषित की गई किसी जानकारी में मेरी पहचान को उजागर नही किया जाएगा।

4. इस अध्ययन में प्राप्त किन्ही आकडों या परीक्षणों के प्रयोग पर पाबंदी न लगाने के लिये मै सहमत हूं बशर्ते कि ऐसे प्रयोग मात्र वैज्ञानिक प्रयोजन/नों के लिये ही हों।
5. उपर्युक्त अध्ययन में भाग लेने के लिये मैं सहमत हूं।

सहभागी के हस्ताक्षर या अगूंठे का निशान/कानूनी रूप से स्वीकार्य प्रतिनिधि ——————————

हस्ताक्षर करने वाले का नाम —————————— दिनांक ——————

सहभागी से सम्बन्ध ——————————

मैं, अधोहस्ताक्षरी ने सहभागी/कानूनी रूप से स्वीकार्य प्रतिनिधि को सरल, उनको समझ मे आने वाली भाषा मे, अध्ययन में पालन होने वाली प्रक्रियायें और जोखिम एवं लाभों से अवगत करा दिया है।

अध्ययन अन्वेषक के हस्ताक्षर —————————— दिनांक ——————

अध्ययन अन्वेषक का नाम —————————— दिनांक ——————

गवाह के हस्ताक्षर —————————— दिनांक ——————

गवाह के हस्ताक्षर————————————————— दिनांक ——————

KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

INFORMED CONSENT FORM

Study Title_____

Study Number_____

Contact details of Principal-Investigator: _____

Subject's Full Name _____

Date of Birth/Age_____

Address _____

PART 1

1. Purpose of the study:
2. Study procedures:
3. Risk from the study:
4. Benefits from the study:
5. Complications:
6. Compensation:
7. Confidentiality:
8. Rights of the participants:
9. Alternatives to participation in the study:

PART 2

Consent

1 I confirm that I have read and understood the information sheet dated _____for the above study and have had the opportunity to ask questions.

OR

I have been explained the nature of the study by the Investigator and had the opportunity to ask questions

2 I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3 I understand that the sponsor of the clinical trial/project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my

health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4 I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)

5. I agree to take part in the above study

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____

Signatory's Name:_____

Date:_____

Relationship with subject:_____

Investigator's statement:-

I, the undersigned have explained to the parent/guardian in a language she/he understands the procedures to be followed in the study and risks and benefits.

Signature of the Investigator: ***Date:***

Name of the Investigator:

Signature of the Witness: ***Date:***

Name of the Witness:

CV OF MEMBERS OF THE INSTITUTIONAL ETHICS COMMITTEE

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

First Name	:	
Middle Initial	:	
Last Name	:	
Organizational Title	:	
Professional Mailing Address (Include Institution Name)	:	
Telephone (Office)	:	
Mobile No.	:	
Email Address		
Member's Specialty (Primary, Scientific, Non Scientific)	:	
Role in K.G.M.U. Ethics Committee	:	

Academic Qualifications (Most current qualification first)

Degree/Certificate	Year	Institution, Country

Professional Experience:

Month / Year	Title	Institution, Country

Experience in Bioethics:

S.No.	Course/Workshops/ Conferences/ Meeting Attended	Organized by	Place	Duration

Members of the other Institutional Ethics Committee / Bioethics Societies with duration:

Signature:

Date:

KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

SECRECY UNDERTAKING CONFIDENTIALITY AGREEMENT FORM FOR IEC MEMBERS

In recognition of the fact, that I, _____

_____

(Member's name, and his/her affiliation) herein referred to as the "undersigned", have been appointed as a member of the KGMU-Institutional Ethics Committee (IEC) and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines;

Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants;

The undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Signature of IEC Member _____ Date _____

Name of IEC Member _____

KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

AGREEMENT ON CONFIDENTIALITY

(Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to you for your records.)

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.

I, _____ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature of IEC Member Date

_____ _____

Chairperson's Signature Date

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

_____ _____

Signature of IEC Member Date

KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

CONFLICT OF INTEREST FORM/ DECLARATION FOR IEC MEMBERS

(Voluntary disclosure regarding COI by IEC member - The IEC member should determine whether he/she has a COI before reviewing research and declare all certain or potential conflicts of interest prior to engaging in any review process.)

I am aware of the policy of the IEC regarding conflict of interest and that no reviewer may participate in the review, comment or participate in decision making of any activity in which he/she has actual/potential conflict of interest except to provide information as requested by the IEC.

I declare _____ (actual or potential COI) in relation to the proposal entitled "_____ _____" submitted for review to the IEC. The reason for COI is_____

I will refrain from the review process and /or discussion at the IEC meeting / and also will not take part in ongoing and periodic review and monitoring of this study.

_____ _____

Signature of IEC Member Date

_____

Name of IEC Member

_____ _____

Chairperson's Signature Date

KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

CONFLICT OF INTEREST

IEC members should not participate in discussing, or decision making on research proposals applications reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by the IEC.

a) If an IEC member has a COI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the Research Cell and return the documents.

b) If an IEC member has a COI for a study for which he or she has been assigned as a primary reviewer, he or she will inform the Research Cell so that the review is re-assigned to other members.

c) If an IEC member has a COI for review of research study at a meeting, he or she will inform the Chairperson and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research. This is applicable also for IEC meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed.

d) Recusal - IEC member who declares COI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a *recusal*, not an abstention or an absence.

_____ _____

Signature of IEC Member Date

_____

Name of IEC Member

MEMORANDUM OF UNDERSTANDING

This Memorandum of understanding (hereinafter called MoU) between King George's Medical University U.P., Lucknow, U.P., India through Faculty Incharge, Research Cell (herein after called KGMU UP), the Principal investigator of the Project (the Second Party _____ (herein after called_____) and the sponsoring Agency (the third Party _____ (herein after called_____) of the Project entered into on this _____ (day) _____ (month)_____(year).

Preamble:

Whereas KGMU UP is a Medical University, established by Govt. of Uttar Pradesh, as a centre of excellence for providing medical care, education and research of high order.

Whereas (the third Party) _____

_____

_____

Whereas KGMU UP and (the second party) _____ _____are willing to jointly participate in the development of _____ _____

The coordinator of the project will be _____ _____ (name and designation of the faculty member responsible from KGMU UP, Lucknow) (Second Party). The other coordinator of the project will be _____ (name and designation of person responsible for third party).

Scope of MoU

This MoU will cover the joint efforts of King George's Medical University U.P., Lucknow (First Party), the Principal investigator of the Project) Second Party) and _____ (third party) in the area of _____

_____

(specify the area of work jointly to be done)

Furnish full details of the work to be done:

1.
2.
3.
4.

Responsibilities of KGMU UP

1.
2.
3.
4.

Responsibilities of Second Party

1.
2.
3.
4.

Responsibilities of Third Party

1.
2.
3.
4.

Administration:

Joint responsibilities of the project will be with KING GEORGE'S Medical University U.P., Lucknow (first Party), the Principal investigator of the Project (Second Party) and _____(third party)

Financial Arrangements:

Funds for the projects will be from _____

_____

_____ (name the funding agency) and the proportion of the funds to be released to KGMU UP will be Rs. _____ (specify the amount).

The following equipment/consumables/supplies will be provided to KGMU UP by (third Party) _____

(This is for MoU's involving grant of equipment/consumables/supplies)

1.

2.

3.

4.

Intellectual Property Rights:

1. The R & D information generated shall be shared by both the collaborating parties.
2. Any publication shall be by mutual consent of second and third party.
3. Patents and other benefits, arising out of the project if any, shall be shared between all three parties.
4. For projects identified as having a distinct potential of generating know how leading to commercial applications NRDC (National Research Development Corporation of India) Guidelines will be followed.

NRDC Guidelines:

1. To bring to the notice of the Investigator, prospective user of the technology being developed.
2. To do market research about the product and bring out a comprehensive study about the market potential for attending entrepreneur.
3. For effective coordination between the laboratory generating the know how and the entrepreneur.
4. To take such other steps as may facilitate the communication of know how.
5. NRDC will retain 40% of the royalty/premia and the remaining 60% will be sent to the KGMU UP, generating the knowhow. The sharing of 60% between the KGMU UP and the project investigator team may be decided by the KGMU UP.

Duration of MoU :

This MoU will be in force for a period of _____(years) from the date of its signing).

Amendments to the MOU:

Amendments if any, before the expiry of this MOU shall be made in writing by the authorized representatives of KGMU UP and _____ _____ (third party) after mutual agreement.

Resolution of Dispute:

Any dispute or difference between the collaboration parties shall be amicably resolved by

either through mutual consultation or arbitration. The Vice Chancellor, KING GEORGE'S Medical University U.P. will be the arbitrator and the decision of the arbitrator shall be final.

Jurisdiction and Courts:

The MOU shall be governed by Laws of India and the parties agree to be subject to jurisdiction of competent courts at Lucknow i.e. High Court and Subordinate courts at Lucknow in addition to other places in India only.

Seal of the Parties:

In witness thereof Parties hereto have signed this MOU on the day, month and year mentioned herein before.

Parties:

(1) Signed and delivered for
and behalf of KGMU UP (First Party)

Signature
Name
Designation
Seal

(2) Signed and delivered for
and behalf of (Second Party)

Signature
Name
Designation
Seal

(3) Signed and delivered for
and behalf of (Third)
Signature
Name
Designation
Seal

Note: ***This is to be written on Stamp of Rs. 100/-***

KING GEORGE'S MEDICAL UNIVERSITY, UP, LUCKNOW

LIST OF MEMBERS OF CURRENT ETHICS COMMITTEE (2017-2020)

Structure	Name	Tenure
Chairman	**1.** Prof. S.P.S. Gaur, Retd. Director, CDRI, Lucknow	For a max. period of 3 years
Senior Clinician of the University	**2.** Prof. A.A. Sonkar, Head, Department of Surgery (Gen.), KGMU, U.P., Luckow	For a max. period of 3 years
	3. Prof. Anoop Kumar Verma, Head, Department of Forensic Medicine, KGMU, U.P., Lucknow	For a max. period of 3 years
	4. Prof. Rajeev Garg, Department of Respiratory Medicine, KGMU, U.P., Lucknow	For a max. period of 3 years
Senior Clinician outside of the University	**5.** Dr. Vimal Kumar Paliwal, Department of Neurology, SGPGIMS, Rai Barely Road, Lucknow	For a max. period of 3 years
	6. Dr. Surajit Bhattacharya, Sr. Consultant Plastic Surgeon, Sahara Hospital, Lucknow	For a max. period of 3 years
Basic Scientist of the University	**7.** Prof. Amita Jain, Department of Microbiology, KGMU, U.P., Lucknow	For a max. period of 3 years
	8. Prof. Rajendra Nath, Department of Pharmacology, KGMU, U.P., Lucknow	For a max. period of 3 years
	9. Dr. Preeti Agarwal, Department of Pathology, KGMU UP, Lucknow	For a max. period of 3 years
Chairman & Legal Expert	**10.** Hon'ble Justice Vishnu Sahai (Retd.)	For a max. period of 3 years
Basic Scientist outside of the University	**11.** Dr. Smriti Bhadoria, Toxicology & Experimental Medicine, CSIR-Central Drug Research Institute, BS-10/1, Sector 10, Jankipuram extension, Lucknow	For a max. period of 3 years
Lay Person	**12.** Sri Ram Niwas Jain, A-2, Sindhu Nagar, Kanpur Road, Lucknow-226003	For a max. period of 3 years
Social Scientist/ Philosopher/Ethicist/ Theologian	**13.** Dr. Manju Agrawal, Director, Amity Institute of Behavioral & Allied Sciences, Amity University Campus, Lucknow	For a max. period of 3 years
Member-Secretary	**14.** Prof. R.K. Garg, Faculty Incharge, Research Cell, KGMU UP, Lucknow	Ex-Officio

Site Monitoring Visit Report

(Please tick the box corresponding to the answer)

IEC Project NO.	Date of Visit
Study Title:	
Principal Investigator and Department	
Type of Study Investigator initiated Pharma Thesis	
☐ Government agency Others _____	

Date of IEC approval:

Date of Initiation of the study

Duration of study:

Reason for monitoring: Routine For-cause (state reason/s)
Protocol Violations/Deviations
SAE reporting
Recruitment rate
Other _____

Last monitoring done. If any,
Yes Date of last monitoring .....
No

Project Status
1. Ongoing
2. Completed
3. Recruitment Completed
4. Follow-up, extension study
5. Suspended
6. Terminated

In case of the response to the above question is option 5 or 6. Kindly provide reason/s

_____

_____

Recruitment Status:
Total patients to be recruited _____
Screened: _____
Screen failure: _____
Enrolled _____
Withdrawn: _____ Reason _____

_____

Discontinued _____ Reason _____

_____

Completed: _____
Active: _____

Are the present study team members as per the list approved by the IEC ☐ Yes ☐ No	Comment
Are site facilities appropriate? ☐ Yes ☐ No	Comment
Is the recent version of Informed Consent Document (ICD) after IEC approval used? ☐ Yes ☐ No	Comment
Whether appropriate vernacular consent has been taken from all patients" ☐ Yes ☐ No	Comment
Any other finding s noted about the ICDs? ☐ Yes ☐ No	Comment
Is recent IEC approved version of protocol used? ☐ Yes ☐ No	Comment
Have the eligibility, inclusion exclusion criteria been adhere to? ☐ Yes ☐ No	Comment
Any adverse events found? ☐ Yes ☐ No	Comment

Any SAEs found? ☐ Yes ☐ No	Comment
Were the SAEs informed to IEC within timelines specified by CDSCO? ☐ Yes ☐ No	Comment
No. of details reported: ☐ Deaths unrelated to participation in the trial: ☐ Deaths related to participation in the trial: Any other non-death study related injury	_____ _____ ☐ Yes ☐ No ☐ NA Comments (if any) _____ _____
Compensation paid for study related injury or death	☐ Yes ☐ No ☐ NA Comment (if any)
Are there any protocol non-compliance deviations / violations? ☐ Yes ☐ No	Comment
Have the protocol non-compliance deviations/violations been informed to IEC? ☐ Yes ☐ No	Comment
Are all Case Record Forms up to date? ☐ Yes ☐ No	Comment

Are storage of data and investigating products locked? ☐ Yes ☐ No	Comment
How well are the participants protected? ☐ Good ☐ Fair ☐ Not good	Comment
Any other remarks ☐ Yes ☐ No	Give details
Duration of visit: _____ hours	Starting from finish
Name of the study team member/s present Signature _____	Date
Name of IEC members and representatives who attended monitoring visit:	
Completed by Signature: _____	Date

Final Decision at the IEC meeting held on _____

_____

_____

_____

_____

Signature of Chairperson, IEC
with date

Monitoring of Audiovisual recoding of AV consent Process

1. Facility where informed consent process should be carried out – (well lit, free from noise, privacy ensured):

   - Yes _____ No _____
   - Remarks:

   _____

2. The consent is taken in language the participant/LAR understands best and is literate in,

   - Yes _____ No _____
   - Remarks:

   _____

3. Introduction of each person (person conducting the informed consent discussion participant / legally acceptable representative (LAR)/impartial witness) involved during informed consent process and information about necessity for audiovisual recording.

   - Yes _____ No _____
   - Remarks:

   _____

4. Information to the participant/LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules.

   - Yes _____ No _____
   - Remarks:

   _____

5. Information to the participant/LAR and impartial witness (As applicable) that the confidentiality of information and privacy of participants is assured.

   - Yes _____ No _____
   - Remarks:

   _____

6. Information to the participant / LAR and impartial witness (as applicable) that the recording may be shown to government agencies o members from the IEC.

   - Yes _____ No _____
   - Remarks:

   _____

7. Explanation or narration by the person conducting the informed consent discussion.

- Yes _____ No _____
- Remarks:

_____

8. Question asked by the potential participant / LAR are answered satisfactorily.

- Yes _____ No _____
- Remarks:

_____

9. Allowing ample time and opportunity to read/understand the information in the informed consent document or discuss the same with family members.

- Yes _____ No _____
- Remarks:

_____

10. Reading out by the participant / LAR (or having read out by impartial witness) the statements mentioned in Informed Consent and stating whether participant agrees or not for each statement.

- Yes _____ No _____
- Remarks:

_____

11. Documentation of signatures of all those involved in the Informed Consent Process.

- Yes _____ No _____
- Remarks:

_____

12. Clarity and completeness of AV recording

- Yes _____ No _____
- Remarks:

_____

13. Storage of recording in password protected laptop / desktop computer and/or hard drive and labelled CD with access allowed only to the principal investigator and designated members of the study team.

- Yes _____ No _____
- Remarks:

_____

SOP Reviewed by

Structure	Name	Signature
Chairman	1. Prof. S.P.S. Gaur, Retd. Director, CDRI, Lucknow	
Senior Clinician of the University	2. Prof. A.A. Sonkar, Head, Department of Surgery (Gen.), KGMU, U.P., Luckow	
	3. Prof. Anoop Kumar Verma, Head, Department of Forensic Medicine, KGMU, U.P., Lucknow	25.9.19
	4. Prof. Rajeev Garg, Department of Respiratory Medicine, KGMU, U.P., Lucknow	25/09/19
Senior Clinician outside of the University	5. Dr. Vimal Kumar Paliwal, Department of Neurology, SGPGIMS, Rai Barely Road, Lucknow	30/9/19.
	6. Dr. Surajit Bhattacharya, Sr. Consultant Plastic Surgeon, Sahara Hospital, Lucknow	30.09.2019
Basic Scientist of the University	7. Prof. Amita Jain, Department of Microbiology, KGMU, U.P., Lucknow	25.9.19
	8. Prof. Rajendra Nath, Department of Pharmacology, KGMU, U.P., Lucknow	25-09-19
	9. Dr. Preeti Agarwal, Department of Pathology, KGMU UP, Lucknow	30/9/2019
Chairman & Legal Expert	10. Hon'ble Justice Vishnu Sahai (Retd.)	1/10/2019
Basic Scientist outside of the University	11. Dr. Smriti Bhadoria, Toxicology & Experimental Medicine, CSIR-Central Drug Research Institute, BS-10/1, Sector 10, Jankipuram extension, Lucknow	25/9/19
Lay Person	12. Sri Ram Niwas Jain, A-2, Sindhu Nagar, Kanpur Road, Lucknow-226003	
Social Scientist/ Philosopher/Ethicist/ Theologian	13. Dr. Manju Agrawal, Director, Amity Institute of Behavioral & Allied Sciences, Amity University Campus, Lucknow	30/9/19
Member-Secretary	14. Prof. R.K. Garg, Faculty Incharge, Research Cell, KGMU UP, Lucknow	

DEPARTMENT OF NEUROLOGY

King George Medical University Uttar Pradesh,
Gandhi Memorial and Associated Hospitals,
Lucknow - 226 003 India

Ref. No. 125/Neuro/20

Date. 26/05/2020

G. M. & ASSOCIATED HOSPITALS S.No. 15070 Date. 27-5-20 LUCKNOW.

सेवा में,

इंचार्ज,
ट्रॉमा सेन्टर
के0जी0एम0यू0यू0पी0, लखनऊ।

महोदय,

न्यूरोलाजी विभाग की SOP (Acute Stroke Management) इस पत्र के साथ संलग्न किया जा रहा है। कृपया इसे ट्रॉमा सेन्टर के सम्बन्धित विभागों को सूचित करें।

संलग्नकः उपरोक्तानुसार।

भवदीय,

(आर0के0गर्ग)
विभागाध्यक्ष, न्यूरोलाजी विभाग
के0जी0एम0यू0यू0पी0, लखनऊ।

प्रतिलिपि निम्नलिखित को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषितः–

1–चिकित्सा अधीक्षक, गांधी स्मारक एवं सम्बद्ध चिकित्सालय, लखनऊ।
2–विभागाध्यक्ष, मेडिसिन विभाग, के0जी0एम0यू0यू0पी0, लखनऊ।
3– माननीय कुलपति जी के निजी सचिव को।

Email. Circular to all faculties of medicine/pediatrics/ENT/Ophthal. – CMS/MS – HOD, medicine/CW, Neuro Surg/I/c Trauma Centre, Faculty I/c area for N/A

SOP: MANAGEMENT OF ACUTE STROKE IN CoVID-19 PANDEMIC

PATEINT RECEIVED IN "CHILD PSYCHIATRY (SCREENING AREA)" AND SHIFTED TO HOLDING AREA IN "GERIATRIC MENTAL HEALTH DEPARTMENT" (Tier-1)

↓

PRELIMINARY ASSESSMENT AND MANAGEMENT OF STROKE PATIENT BY EMO TEAM IN HOLDING AREA

↓

- **PEFORM A-B-C** (AIRWAY/BREATHING/CIRCULATION)
- **CHECK VITALS/ASSESMENT OF GCS**
- **CAPILLARY BLOOD SUGAR FOR HYPOGLYCEMIA**
- **PROPPED UP OR LATERAL RECUMBENT POSITION**
- **DECONGESTANT THERAPY FOR RAISED ICP AS REQUIRED**
- **CoVID-19 TESTING AS PER EXISTING PROTOCOL**

MANAGEMENT AS PER THE APPENDIX ATTACHED ALONG WITH

↓

PATIENT REFFERED TO "TRAUMA CENTRE HOLDING AREA " (EMERGENCY MEDICINE DEPARTMENT)(Tier-2)

- REASSESS (VITALS/GCS)
- **URGENT CT BRAIN (PLAIN)**
- **COVID TESTING IF NOT DONE EARLIER AS PER PROTOCOL**
- ABG(ARTERIAL BLOOD GAS ANALYSIS)
- CBC/KFT/LFT/ELECTROLYTES/RBS
- PT/INR/VIRAL MARKER

MANAGEMENT AS PER THE APPENDIX ATTACHED ALONGWITH

CoVID STATUS

POSITIVE | **NEGATIVE**

↓

REFFERED TO IDH

REFERENCE TO* MEDICINE DEPARTMENT FOR ADMISSION IF

- *GCS≤8*
- *ICU OR VENTILATORY SUPPORT NEEDED*
- *METABOLIC DERANGEMENT*
- *SEPTICEMIA*
- *RENAL DYSFUNCTION*
- *DKA/HONK*
- *CARDIAC FAILURE*

↓

***DONOT SHIFT PATIENT, ONLY SEND REFFERENCE TO NEUROLOGY DEPARTMENT IF ADVICE ON MANAGEMENT NEEDED**

REFERENCE TO "NEUROLOGY DEPARTMENT FOR ADMISSION IF

- **GCS> 8**
- **NO ICU OR VENTILATORY SUPPORT NEEDED**
- **STROKE ELIGIBLE FOR THROMBOLYSIS (WINDOW PERIOD-<4.5 HR FROM LAST SEEN NORMAL)**
- **STROKE IN YOUNG(<40 YEARS)**
- **RECURRENT STROKE**
- IF NO COMORBIDITIES PRESENT, MENTIONED IN **REFFERENCE TO MEDICINCE**

** DONOT SHIFT PATIENT, ONLY SEND REFFERENCE OR CALL NEUROLOGY EMERGENCY TELEPHONICALLY IMMEDIATELY FOR MANAGEMENT ADVICE. SENIOR RESIDENT ON DUTY CAN BE CONTACTED ON 8887147300 / 8887019141

APPENDIX: PLAN OF TREATMENT AND MANAGEMENT AT DIFFERENT LEVELS

1. LINE OF MANAGEMENT IN HOLDING AREA AT "GERIATRIC MENTAL HEALTH CENTRE" (1ST TIER)

1. IMMEDIATE IV ACCESS WITH FLUID
2. MANAGE A-B-C (AIRWAY-BREATHING-CIRCULATION)
3. LATERAL DECUBITUS
4. SUPPLEMENTAL OXYGEN TO MAINTAIN SPO2 >94%
5. CATHETERISATION IF REQUIRED
6. REFFER TO TRAUMA CENTRE

2. LINE OF MANAGEMENT IN "TRAUMA CENTRE HOLDING AREA"(EMERGENCY MEDICINE DEPARTMENT) (2ND TIER)

- RE-ASSESS
- AFTER URGENT CT BRAIN

1. SPECIFIC MANAGEMENT (TO BE INITIATED AS PER CT BRAIN FINDING)

Ischemic stroke

1. ANTIPLATELET and STATIN THERAPY [1]
2. BP LOWERING REQUIRED IF >220/120 mm/Hg REDUCE 15% OF BASE LINE IN 24 HR
3. If plan for thrombolysis TARGET BP<185/100

Hemorrhagic Stroke

1. Lower BP < 140/90

IV Antihypertensives for urgent lowering:

1. Inj Labetalol- 20 mg iv stat over 2 mins followed by 40 mg every 10 mins for max 300 mg /day
2. Inj Lasix 40 mg iv stat/ AS REQUIRED

General management :

1. Elevation of head 30 ^{0} with preferable left lateral decubitus
2. Oxygen supplementation FOR SP02 >94%
3. Manage Hyperglycemia With Insulin To Maintain Blood Sugar Below 180 mg/dl
4. Manage hyperthermia with cold sponging or paracetamol infusions
5. For raised ICT – inj mannitol[2]/inj Lasix /Acetazolamide[4]/3% hypertonic NaCl [5]
6. Fluid therapy as per daily maintenance if patient not taking orally
7. Anti epileptics to be given if seizures occurs (as per seizure protocol)
8. ORAL ANTIHYPERTENSIVES FOR MAINTAINANCE OF BP[3]

DOSES:

1. TAB ECOSPRIN 150 mg 1 tab OD HS/TAB ATORVA 40 mg 1 tab OD HS
2. INJ MANNITOL – 1-1.5 gm/kg iv stat f/b 0.25-1.25 gm /kg every 6 hrly (ideally repeat ABG daily)
3. Tab Amlodipine /Tab Telmisartan (dose to be adjusted to maintain bp <140/90 mg.
4. Tab Acetazolamide - 250 mg tds
5. INJ 3% NaCl – 3-5ml/Kg loading over 2 hour f/b 2ml/kg every 6 hrs (to be used under strict monitoring)

NEUROSURGERY OPINION IF :

1. CEREBELLAR BLEED
2. OBSTRUCTIVE HYDROCEPHALUS
3. IV EXTENSION
4. MID LINE SHIFT WITH DETORIATING GCS
5. LARGE MCA STROKE AT PRESENTATION (with mid line shift)

** DONOT SHIFT PATIENT, ONLY SEND REFFERENCE OR CALL NEUROLOGY EMERGENCY TELEPHONICALLY IMMEDIATELY FOR MANAGEMENT ADVICE. SENIOR RESIDENT ON DUTY CAN BE CONTACTED ON 8887147300 / 8887019141

King George's Medical University, U.P., Lucknow
Office of the Research Cell

Prof. Shally Awasthi
Faculty Incharge

No.: 1005/R. Cell-2021
Date: 05/1/2021

To,

All the Faculty,
All the Departments,
King George's Medical University, U.P.,
Lucknow

Subject: "Standard Operating Procedure for Research projects procurement/payment"

Sir/Madam,

Please find attached the **"Standard Operating Procedure for Research projects procurement/payment"** approved by the Hon'ble Vice Chancellor to streamline and fastrack financial dealings within research projects.

Thanking you,

Yours Sincerely

(Shally Awasthi)
Faculty Incharge

No.: 1006 **of dated**

Copy forwarded to the following for favour of information and necessary action:

1. The Pro- Vice Chancellor, K.G.M.U., U. P., Lucknow
2. The Finance Officer, K.G.M.U., U. P., Lucknow
3. The Finance & Accounts Officer, K.G.M.U., U. P., Lucknow
4. PS to Hon'ble Vice Chancellor

(Shally Awasthi)
Faculty Incharge

Standard Operating Procedure for Research projects procurement/payment

To streamline and fastrack financial dealings within research projects, the following Standard Operating Procedure will be implemented.

1. Principal Investigator must maintain a parallel ledger for each of their Research Projects for recording head wise details of funds received and expenditure incurred/paid. The ledger should be countersigned by the concerned HOD.

2. Comparison of research cell accounts will be done by the account cell with the project ledger maintained by the PI from time to time on test check basis. For this, project ledger from PI shall be called for on random basis to the research cell by the faculty Incharge.

3. All appointments, including those made for 89 days, must have prior approval of Hon'ble Vice Chancellor.

4. Every salary bill must be accompanied with a note mentioning the details of salary including any change in salary or salary drawn from previous month, with reason/s for the same. PI shall, besides other requirements, include in the salary bill the following details,:
   a. Name of the personnel.
   b. Designation
   c. Date of appointment
   d. Date of joining (new joining to be highlighted)
   e. No of days present
   f. Salary due.

   For all new joining, appointment letter and joining letter shall also be put up before the Finance Officer for verification (by the PI).

5. For clinical trials, where salary/wages have not been fixed by the funding agencies, it must be ensured that at least minimum wages as per Government fixations should be paid to the personnel engaged for research projects.To

Shally 28/12/20

Vice Chancellor
King George's Medical University U P
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the extent possible, departmental staff should be engaged for clinical trial works and they can be given honorarium after deduction of TDS at source.

6. A separate committee is being formed for approval of purchases received from Principal Investigators for procurement of items related to their Research Projects. The constitution of the committee is as follows:
   i. Nominee of Hon'ble Vice Chancellor
   ii. Principal Investigator of related Research Project

   or

   Mentor/Supervisor in case of SRF/JRF/Research Associates/Women Scientists/Young Scientists/PDF/Student Research Projects etc.
   iii. Faculty Incharge, Research Cell
7. After the approval of the above committee the approved purchase proposals will be approved by the following:

   In the case of FCRA accounts:
   i. For proposals upto Rs.20,000 by F & A O and FO.
   ii. For proposals between Rs.20,001 to Rs.50,000 by F & AO, FO and Pro VC.
   iii. For proposals above Rs.50,000 by F & AO, FO and Hon'ble VC

   In the case of other accounts:
   i. For proposals upto Rs.20,000 by F & A O.
   ii. For proposals between Rs.20,001 to Rs.50,000 by F & AO, FO and Pro VC.
   iii. For proposals above Rs.50,000 by F & AO, FO and Hon'ble VC

8. For approval of payment of Bills same procedure as given in 7. above shall be followed.

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King George's Medical University U P
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9. All the GEM purchases related to research projects will be done from Department's GEM ID and payment will be done from Research Accounts after following due procedures for purchase.

10. GEM purchase proposals must be submitted atleast seven working days before the expiry from cart of GEM portal. GEM files should be marked in bold with signature:

S.No.		Date	Name	Signature
a	Submission to Research Cell			
b	Submission to FO Office			
c	Submission to Pro VC Office			
d	Submission to Hon'ble VC office			

11. For adjustment of advance only the authorized/valid expenditures should be accepted. When 75% of the advance is utilized, based on the declaration from the PI, second advance can be issued. However, the third advance shall be issued only when the first advance is fully adjusted.

12. In Foreign payments GST liabilities must be deducted from the Project funds while doing the payments.

13. From the next financial year i.e. 2021-22, sub head wise detailed columnar project ledger should be used by the research Cell.

14. All utilization certificates, whether mandated by the funding agency or not, should be verified by the Chartered Accountant.

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Vice Chancellor
King George's Medical University U P
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Format of Note to be attached with salary bills

This is to certify that Research Project entitled ".....(title of the project)....." sponsored by .....(Name of sponsor)..... has been sanctioned vide ..... (attach Sanction letter)

Mr/Ms. ..... has been appointed in the above project on the post of .....vide Order No. ..... dated ..... (attach appointment letter) for a period of ..... w.e.f date..... to date ..... His/Her current salary is Rs. ..... per month.

Attached is his/her bill for the month of ..... There is no change in the salary from previous month/the change in salary from previous month is because of the following Reason:

.....

.....

Signature of Principal Investigator

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Vice Chancellor
King George's Medical University U P
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Format of Note to be attached with purchase approvals

This is to certify that Research Project entitled ".....(title of the project)....." sponsored by .....(Name of sponsor)..... has been sanctioned vide ..... (attach Sanction letter)

The funding agency has sanctioned an amount of Rs. ..... in the budget for purchase of.....(Name of item to be purchased)..... (attach sanction copy). Rs. ..... is available in project funds for purchase of item.

The item is available/not available on GEM.

For approval of purchase of above item we are attaching the documents for purchase through GEM portal/Quotation basis/Tender/Proprietary basis.

Signature of Principal Investigator

Shally 28/12/20

किंग जार्ज चिकित्सा विश्वविद्यालय,

अधीक्षक कार्यालय

गाँधी स्मारक एवं सम्बद्ध चिकित्सालय,
उत्तर प्रदेश, लखनऊ-२२६००३

पत्र संख्या-....8280...../, दिनांक-25./03./2021,

अति-आवश्यक

सेवा में,

1. **समस्त विभागाध्यक्ष (क्लीनिकल)**
2. **समस्त विभागाध्यक्ष (दंत संकाय),**
3. **मुख्य चिकित्सा अधीक्षक (ट्रामा सेन्टर)**

किंग जार्ज चिकित्सा विश्वविद्यालय, उ0प्र0, लखनऊ।

महोदय/महोदया,

अवगत कराना है कि चिकित्सालय के कार्यकारणी-परिषद की बैठक दिनांक 10.03.2021 को अपरान्ह 2:00 बजे मा0 कुलपति महोदय की अध्यक्षता में आहूत हुई थी। बैठक में चिकित्सा विश्वविद्यालय के विभिन्न महत्वपूर्ण बिन्दुओं के साथ-साथ, अधोहस्ताक्षरी कार्यालय के पत्र संख्या-6550 दिनांक 09.03.2021 द्वारा, विपन्न/लावारिस रोगियों को प्राप्त होने वाली निःशुल्क चिकित्सा सुविधाएं क्रियान्वित किये जाने से सम्बन्धित Standard Operating Procedure (SOP) for Vippan Category को Agenda No-15, Any other Item No.9 के अन्तर्गत सम्मिलित किया गया, जिस पर कार्य परिषद द्वारा अनुमोदन प्रदान किया गया है। (छायाप्रति संलग्न)

अतएव विपन्न/लावारिस रोगियों को प्राप्त होने वाली निःशुल्क चिकित्सा सुविधाएं क्रियान्वित किये जाने से सम्बन्धित Standard Operating Procedure (SOP) for Vippan Category इस पत्र के साथ संलग्न कर इस अनुरोध के साथ प्रेषित है कृपया विभाग में भर्ती होने वाले विपन्न/लावारिस रोगियों के निःशुल्क उपचार हेतु SOP में दिये गये निर्देशों का अनुपालन सुनिश्चित करने की कृपा करें, जिससे इस श्रेणी के रोगियों के निःशुल्क उपचार में किसी प्रकार की असुविधा न हो।

नोटः- विपन्न श्रेणी का लाभ प्राप्त करने वाले रोगियों से विपन्न होने का शपथ-पत्र भी अवश्य लें, जिससे किसी प्रकार की अनियमितता न हो।

भवदीय

संलग्नक-उपरोक्तानुसार

चिकित्सा अधीक्षक
गांधी स्मारक एवं सम्बद्ध चिकित्सालय,
के0जी0एम0यू0, लखनऊ।

पृष्ठाकंन संख्या...8281.....उक्त दिनांक

प्रतिलिपि- निम्नलिखित को सूचनार्थ एवं अग्रिम आवश्यक कार्यवाही हेतु प्रेषितः-

1. मुख्य चिकित्सा अधीक्षक, गांधी स्मारक एवं सम्बद्ध चिकित्सालय, के0जी0एम0यू0, उ0प्र0, लखनऊ।
2. उप-चिकित्सा अधीक्षक, गांधी स्मारक एवं सम्बद्ध चिकित्सालय, के0जी0एम0यू0, उ0प्र0, लखनऊ।
3. जन-सम्पर्क अधिकारी (मुख्य पटल), गांधी स्मारक एवं सम्बद्ध चिकित्सालय, के0जी0एम0यू0, उ0प्र0, लखनऊ।
4. निजी सचिव को, मा0 कुलपति महोदय जी के अवलोकनार्थ।
5. सम्बन्धित कर्मचारीगण।

चिकित्सा अधीक्षक
गांधी स्मारक एवं सम्बद्ध चिकित्सालय,
के0जी0एम0यू0, लखनऊ।

STANDARD OPERATING PROCEDURE (SOP) FOR VIPPAN CATEGORY

1- For 'Unclaimed Patients' (Lawaris) admitted in KGMU, treatment of up to Rs 10,000 / - and above should be made at per with 'Vipann Scheme'. While recruiting an unclaimed patient, it is necessary to put Copy of Police Information/FIR/Complaint done by the police and unclaimed patient should be considered as the person who has the benefit of no any relative or friend.

2- The benefits of this 'Vipann Scheme' will be given to those patients who are not eligible for the other public welfare schemes operated by the government (BPL Card Holder, Antyoday Rashan Card Holder, Ayushman Card., Govt. employees etc.) or unable to present their card.

3- Such patients should be identified and verified by the two doctors of the concerned department and an affidavit will be taken on time for the patient to be fortified and not benefited from other schemes, after which the completed form of the patient will be verified by the concerned department head will be sent to Chief Medical Superintendent and Medical Superintendent Office.

4- The 'Vipann Form' up to Rs 10,000 / - can be obtained on approval by the Chief Medical Superintendent / Medical Superintendent, upon verification by two faculty members and the Head of Department.

5- 'Vipann Form' of more than Rs. 10,000 / - can be obtained after two faculty members and HOD respectively, after verification by the department, counter signed from the designated committee. The members of this committee will be the Medical Superintendent, Chief Medical Superintendent, Finance Officer, the Registrar and the Hon'be Vice Chancellor.

6- Whatever amount will be mentioned in the 'Vipann Form', that is, the various diseases / surgeries/implants/ should be equivalent according to 'Ayushman Scheme'.

7- Capping would also be more appropriate as per "Ayushman Yojana". In the first case of the 'Vipann Category' of a patient, the money can be re-routed in special circumstances. Such as the need for a Ventilator/ICU etc. Testing and verification of the form will be required to be done by the concerned committee.

8- If the amount sanctioned under the Vipann Category is exhausted and there is a need for some other amount for the treatment, then it will be necessary to first provide the utilization certificate of the amount approved earlier.

AGENDA NO – 15 ANY OTHER ITEM NO. 9

चिकित्सा अधीक्षक, गांधी स्मारक एवं सम्बद्ध चिकित्सालय, के पत्र संख्या- 6550 दिनांक 09.03.2021 द्वारा निम्नवत् प्रकरण पर Standard Operating Procedure (SOP) for Vippan Category संलग्न करते हुए चिकित्सा विश्वविद्यालय की माननीय कार्य-परिषद् के समक्ष अनुमोदनार्थ प्रस्तुत करने की अपेक्षा की गई है ।

"विपन्न/लावारिस रोगियों को प्राप्त होने वाली निःशुल्क चिकित्सीय सुविधायें, क्रियान्वित किये जाने के सम्बन्ध में ।"

सन्दर्भ: चिकित्सा अधीक्षक, गांधी स्मारक एवं सम्बद्ध चिकित्सालय, के पत्र संख्या- 6227 दिनांक 06.03.2021 ।

RESOLUTION :-

कार्य-परिषद् द्वारा प्रस्ताव पर अनुमोदन प्रदान किया गया ।

कुलसचिव
किंग जॉर्ज चिकित्सा विश्वविद्यालय, उत्तर प्रदेश
लखनऊ ।

Vice Chancellor
King George's Medical University U.P
LUCKNOW

संख्या-67/2020/4051/71-2-20-के0जी0एम0यू0-49/2017

प्रेषक,

आनन्द कुमार
विशेष सचिव,
उ0प्र0 शासन।

सेवा में,

कुलसचिव,
किंग जार्ज चिकित्सा विश्वविद्यालय, उ0प्र0,
लखनऊ।

चिकित्सा शिक्षा अनुभाग-2 लखनऊ : दिनांक 12 नवम्बर, 2020

विषय:- वित्तीय वर्ष 2020-21 में के0जी0एम0यू0 में बी0पी0एल0/अन्त्योदय कार्ड धारकों, लावारिस/विपन्न मरीजों को निःशुल्क चिकित्सा सुविधा उपलब्ध कराये जाने हेतु धनराशि की स्वीकृति।

महोदय,

उपर्युक्त विषयक वित्त अधिकारी, किंग जार्ज चिकित्सा विश्वविद्यालय, उ0प्र0, लखनऊ के पत्रांक-2774/वित्त एवं लेखा/2020, दिनांक 19-10-2020 के क्रम में सम्यक विचारोपरांत मुझे यह कहने का निदेश हुआ है कि वित्तीय वर्ष 2020-21 में (के0जी0एम0यू0 में बी0पी0एल0/अन्त्योदय कार्ड धारकों, लावारिस/विपन्न मरीजों को निःशुल्क चिकित्सा सुविधा उपलब्ध कराये जाने के लिए राजस्व पक्ष में 20-सहायता अनुदान-सामान्य (गैर वेतन) मद में प्राविधानित धनराशि रू0 400.00 लाख के सापेक्ष रू0 100.00/- (रूपया सौ लाख मात्र) की धनराशि अवमुक्त किये जाने की श्री राज्यपाल सहर्ष स्वीकृति प्रदान करते हैं।) — बिन्दु संख्या (1)

2- उक्त धनराशि की स्वीकृति इस शर्त सहित प्रदान की जा रही है कि 20-सहायता अनुदान-सामन्य (गैर वेतन) से स्वीकृत धनराशि का आहरण, आवश्यकतानुसार एवं व्यय, नियमानुसार किया जायेगा तथा इस योजना से आच्छादित मरीजों को सर्वप्रथम (आयुष्मान भारत योजना से लाभान्वित कराया जायेगा एवं सम्भव न होने पर) इस मद का उपयोग किया जायेगा। बिन्दु संख्या (2)

3- धनराशि उसी मद में खर्च की जायेगी जिसके लिये इसकी स्वीकृति दी जा रही है। अन्य मद में खर्च वित्तीय अनियमितता मानी जायेगी। स्वीकृत धनराशि का व्यय विवरण निर्धारित प्रारूप पर शासन को उपलब्ध कराया जायेगा। वित्त विभाग के कार्यालय ज्ञाप संख्या 1/2020/बी0-1-149-दस/2020-231/2020, दिनांक 24.03.2020, शासनादेश संख्या 4/2020/बी0-1-192/दस-2020-231/2020, दिनांक 07.04.2020 एवं शासनादेश संख्या 10/2020/बी0-1-564/दस-2020-231/2020, दिनांक 29.09.2020 में उल्लिखित दिशा निर्देशों का पूर्ण अनुपालन किया जायेगा।

4- प्रश्नगत स्वीकृत धनराशि का उपयोग निर्धारित मदों में सुसंगत नियमों के अधीन किया जायेगा तथा धनराशि का आहरण वास्तवित आवश्यकता के आधार पर सुनिश्चित किया जाएगा एवं धनराशि के उपयोग की स्थिति से यथासमय अवगत कराया जायगा। धनराशि आहरित कर बैंक/पोस्ट ऑफिस/पी0एल0ए0 में नही रखी जायेगी।

GA
19.11.2020

5- स्वीकृत धनराशि का व्यय सुसंगत वित्तीय नियमों के अनुसार जारी किये जाने का दायित्व विश्वविद्यालय के कुलसचिव/वित्त अधिकारी का होगा। धनराशि को कोषागार से वित्त अधिकारी, के0जी0एम0यू0, लखनऊ द्वारा आहरित किया जायेगा तथा बिलों पर महानिदेशक, चिकित्सा शिक्षा एवं प्रशिक्षण, उ0प्र0 के प्रतिहस्ताक्षर प्राप्त किया जायेगा।

6- इस संबंध में होने वाला व्यय **वित्तीय वर्ष 2020-21 के अनुदान संख्या-31-चिकित्सा विभाग (चिकित्सा शिक्षा एवं प्रशिक्षण) के लेखाशीर्षक "2210-चिकित्सा तथा लोक स्वास्थ्य-05-चिकित्सा शिक्षा-प्रशिक्षण तथा अनुसंधान-105-एलोपैथी-03-शिक्षा-0367-किंग जार्ज चिकित्सा विश्वविद्यालय, उ0प्र0 में बी0पी0एल0/अन्त्योदय काई धारकों, लावारिस/विपन्न मरीजों को निःशुल्क चिकित्सा सुविधा-20-सहायता अनुदान-सामान्य (गैर वेतन)" के नामे डाला जायेगा।**

7- यह आदेश वित्त विभाग के कार्यालय ज्ञाप संख्या 1/2020/बी0-1-149-दस/2020-231/2020, दिनांक 24.03.2020 द्वारा प्रशासकीय विभाग को प्रतिनिहित किये गये अधिकारों के अधीन निर्गत किये जा रहे हैं।

भवदीय,

(आनन्द कुमार)
विशेष सचिव।

संख्या-बी0/405/(1)/71-2-20-तद्दिनांक

प्रतिलिपि निम्नलिखित को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषितः-

1. महालेखाकार (लेखा एवं हकदारी) प्रथम/द्वितीय, उ0प्र0, इलाहाबाद।
2. महालेखाकार (सिविल आडिट) प्रथम/द्वितीय, उ0प्र0, इलाहाबाद।
3. कोषाधिकारी, लखनऊ।
4. वित्त अधिकारी, के0जी0एम0यू0, लखनऊ।
5. महानिदेशक, चिकित्सा शिक्षा एवं प्रशिक्षण, उ0प्र0 लखनऊ।
6. वित्त (व्यय नियंत्रण) अनुभाग-3/नियोजन अनुभाग-4/वित्त (आय-व्ययक) अनुभाग-2
7. स्थानीय निधि लेखा परीक्षा विभाग, उ0प्र0
8. प्रभारी अधिकारी, एन0आई0सी0, छठा तल, योजना भवन ।
9. गार्ड फाइल।

आज्ञा से,

(प्रेमशंकर तिवारी)
अनु सचिव।

New Mangal G.O. Print

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

Uttar Pradesh, Lucknow-226003

Ref. No. - covid Ic/001 2084 22/4/21 Date: 21/04/2021

SOP FOR ADMISSION TO DIFFERENT COVID WARDS

- Any call will be forwarded to Corona control room of KGMU.
- Corona control room will contact different wards/ICU for availiability of beds.
- Receiving area of RALC will co-rdinate & help CCR.
- It will be responsibility of CCR to get the patient admitted.
- In case No beds are available CCR will infrom the patient regarding non availiability of beds in KGMU.
- All Isolation/Private wards/ICU will update their bed status to CCR every hour.
- No false information should be passed to CCR.
- In case bed is available approval should be given immediately by Incharge of wards/ICU.

E-Mail to All HOD/Faculty

Prof V. Atam
Incharge, Covid KGMU

Prof Sandeep Tiwari
Co-Incharge, Covid KGMU

Copy to:-

1. I/c CCR
2. DMS Covid Hospital (RALC)
3. MS Covid Hospital (RALC)
4. Faculty I/c TDH.
5. Faculty I/c Gandhi ward
6. Faculty I/c Surgical ward I & II
7. CMS/MS GMAH.
8. PS to Honourable Vice chancellor Sir

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

Uttar Pradesh, Lucknow-226003

Ref. No. - covid Ic/001 2084 22/4/21 Date: 21/04/2021

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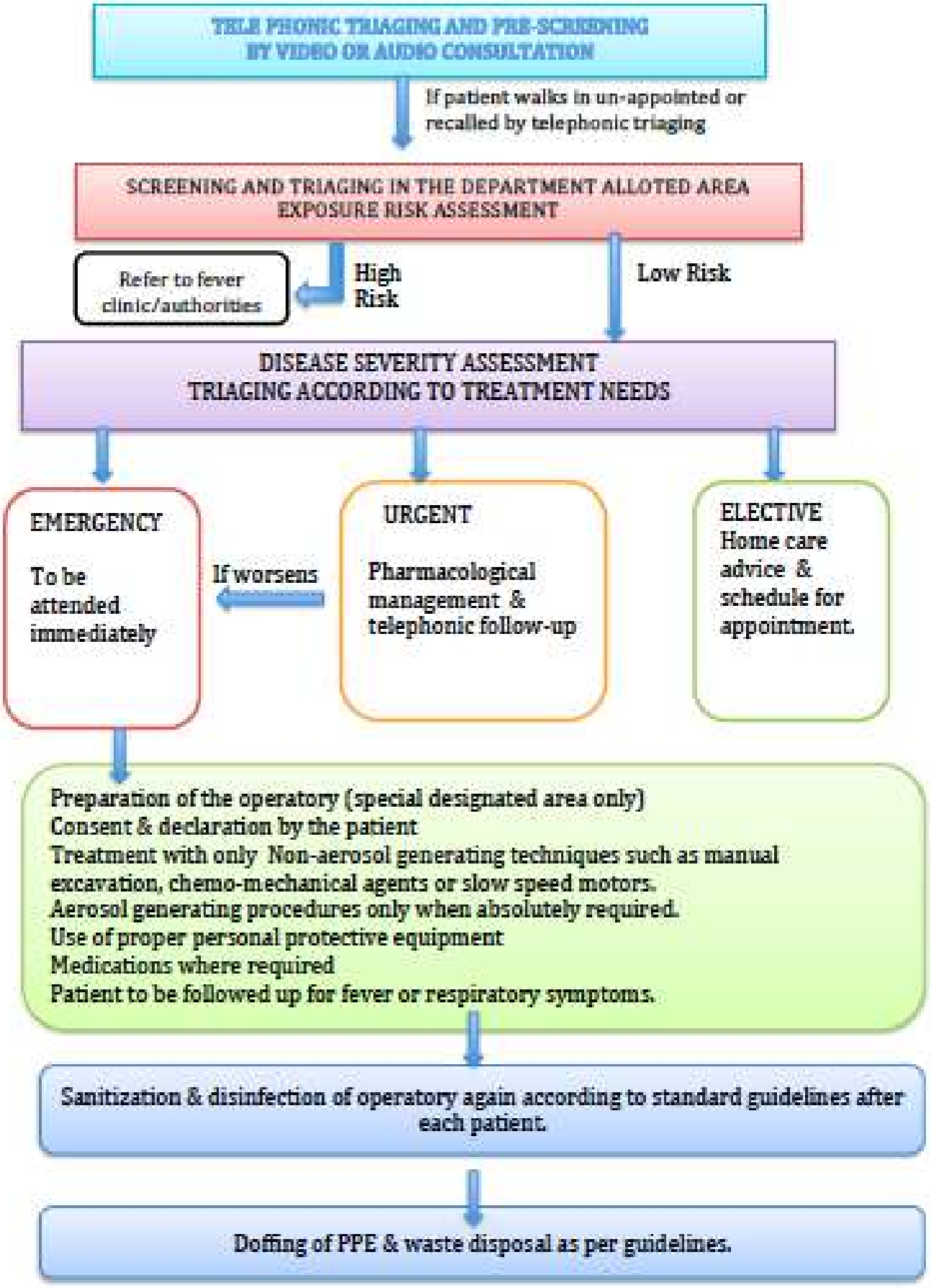
OVER-VIEW OF THE COVID SOP CONSERVATIVE DENTISTRY & ENDODONTICS



KING GEORGE'S MEDICAL UNIVERSITY

Uttar Pradesh, Lucknow- 226003, India

DEPARTMENT OF PATHOLOGY

Ph.: 0522-2257580

Ref: 2124 Date: 29.4.2021

सेवा में,

चिकित्सा अधीक्षक
गाँधी स्मारक चिकित्सालय
के0जी0एम0यू0 लखनऊ

विषयः— रक्त नमूना संग्रह करने हेतु दिशा निर्देश।

महोदय,

अवगत हो कि विगत कई सप्ताह से प्रायः देखा जा रहा है कि विभिन्न वार्डो से आने वाले पैथालॉजी फार्म के साथ भेजे जाने वाले रक्त नमूने गलत वायल/बिना UHID/Admission/Zero bills के RALC Pathology Lab में भेजे जा रहे है ऐसी अवस्था में पैथालॉजी परीक्षण करना सम्भव नहीं होता एवम् ऐसे रक्त नमूने रिजेक्ट कर दिये जाते है।

अतः रक्त नमूना कलेक्शन हेतु एक SOP for Pathology sample Collection इस पत्र के साथ संलग्न किया जा रहा है। कृप्या उक्त SOP को आप अपने स्तर से समस्त Covid Wards RALC एवम् Main Campus में नर्सिंग स्टेशन पर चस्पा करवाने का कष्ट करें जिससे कि रक्त नमूना RALC Lab में भेजते वक्त त्रुटि होने की सम्भावना ना हों।

धन्यवाद।

भवदीय

विभागाध्यक्ष पैथालॉजी विभाग

संलग्नः— उपरोक्त / यथाअनुसार

प्रतिलिपिः—

1. मुख्य चिकित्सा अधीक्षक, जी.एम. एण्ड ए.एच., के.जी.एम.यू. लखनऊ।
2. मुख्य चिकित्सा अधीक्षक, RALC कोविड हास्पिटल, के.जी.एम.यू. लखनऊ।
3. चिकित्सा अधीक्षक, गाँधी वार्ड, कोविड हास्पिटल, के.जी.एम.यू. लखनऊ।

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Standard Operating Procedure for Pathology Specimen Collection
COVID-19 Pathology Lab, RALC, KGMU.

BLOOD GAS		
ABG	Heparin/Syringe or Vial	2ml
BIOCHEMISTRY		
ALBUMIN	Plain Vail (Red/Yellow)	2ml
ALKALINE PHOSPHATASE	Plain Vail (Red/Yellow)	2ml
AMYLASE	Plain Vail (Red/Yellow)	2ml
BILIRUBIN (TOTAL AND DIRECT)	Plain Vail (Red/Yellow)	2ml
Ca++	Plain Vail (Red/Yellow)	2ml
CALCIUM TOTAL	Plain Vail (Red/Yellow)	2ml
CHOLESTEROL TOTAL	Plain Vail (Red/Yellow)	2ml
CK-MB SL	Plain Vail (Red/Yellow)	2ml
CREATININE	Plain Vail (Red/Yellow)	2ml
CRP	Plain Vail (Red/Yellow)	2ml
ELECTROLYTE	Plain Vail (Red/Yellow)	2ml
FERRITIN	Plain Vail (Red/Yellow)	2ml
GLUCOSE - F	Fluoride Vail (Grey Tube)	2 OR 3ml Upto the Mark
GLUCOSE (R)	Fluoride Vail (Grey Tube)	2 OR 3ml Upto the Mark
GLUCOSE (PP)	Fluoride Vail (Grey Tube)	2 OR 3ml Upto the Mark
K	Plain Vail (Red/Yellow)	2ml
KIDNEY PANEL	Plain Vail (Red/Yellow)	2ml
LDH	Plain Vail (Red/Yellow)	2ml
LIPASE	Plain Vail (Red/Yellow)	2ml
LIPID PROFILE	Plain Vail (Red/Yellow)	2ml
LIVER FUNCTION TEST	Plain Vail (Red/Yellow)	2ml
MAGNESIUM, SERUM	Plain Vail (Red/Yellow)	2ml
NT- ProBNP	Plain Vail (Red/Yellow)	2ml
PHOSPHORUS, SERUM	Plain Vail (Red/Yellow)	2ml
PROCALCITONIN (PCT)	Plain Vail (Red/Yellow)	2ml
SODIUM	Plain Vail (Red/Yellow)	2ml
TOTAL PROTEIN	Plain Vail (Red/Yellow)	2ml
TRIGLYCERIDE	Plain Vail (Red/Yellow)	2ml
TROPONIN - I	Plain Vail (Red/Yellow)	2ml
UREA	Plain Vail (Red/Yellow)	2ml
URIC ACID	Plain Vail (Red/Yellow)	2ml
URINE EXAM		
URINE EXAMINATION ROUTINE	Urine Container	15ml
COAGULATION		
APTT	Sodium Citrate Vial (Sky Blue Tube)	2ml
D-DIMMER	Sodium Citrate Vial (Sky Blue Tube)	2ml
FDP	Sodium Citrate Vial (Sky Blue Tube)	2ml
FIBRINOGEN	Sodium Citrate Vial (Sky Blue Tube)	2ml
P-TIME (PROTHROMBIN TIME)	Sodium Citrate Vial (Sky Blue Tube)	2ml
BODY FLUID		
CSF	Plain Vail	2ml
HAEMATOLOGY		
ABSOLUTE EOSINOPHIL COUNT	EDTA Vail (Purple Tube)	2 OR 3ml Upto the Mark
ABSOLUTE NEUTROPHIL COUNT	EDTA Vail (Purple Tube)	2 OR 3ml Upto the Mark
BLOOD GROUP AND RH FACTOR	EDTA Vail (Purple Tube)	2 OR 3ml Upto the Mark

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CBC	EDTA Vail (Purple Tube)	2 OR 3ml Upto the Mark
CBC 5 part	EDTA Vail (Purple Tube)	2 OR 3ml Upto the Mark
ESR (Wintrobe)	EDTA Vail (Purple Tube)	2 OR 3ml Upto the Mark
ESR (WG)	Sodium Citrate Vial (Black Tube)	Upto the Mark
GBP	EDTA Vail (Purple Tube)	2 OR 3ml Upto the Mark
PCV	EDTA Vail (Purple Tube)	2 OR 3ml Upto the Mark
PLATELET COUNT	EDTA Vail (Purple Tube)	2 OR 3ml Upto the Mark
RETICULOCYTE COUNT	EDTA Vail (Purple Tube)	2 OR 3ml Upto the Mark
TLC	EDTA Vail (Purple Tube)	2 OR 3ml Upto the Mark
HORMONE & IMMUNOLOGY ASSAY		
T3	Plain Vail (Red/Yellow)	2ml
T4	Plain Vail (Red/Yellow)	2ml
THYROID PROFILE	Plain Vail (Red/Yellow)	2ml
TSH	Plain Vail (Red/Yellow)	2ml
HbA1c	EDTA Vail (Purple Tube)	2 OR 3ml Upto the Mark
IMMUNOLOGY		
IL-6	Sodium Citrate Vial (Sky Blue Tube) / Plain Vial (Red/Yellow)	3ml
SEROLOGY		
HBSAG	Plain Vail (Red/Yellow)	2ml
HCV	Plain Vail (Red/Yellow)	2ml
VM	Plain Vail (Red/Yellow)	2ml

Note:

1) Please send Sample with Patho Form with UHID, Admission ID and Zero Bill.
2) All vials must be prelabled with indicated quantity of blood.
3) For more than 5 Test of Biochemistry / Serology vials must be contain 5ml blood.
4) All samples with pathoform to be sent to RALC Lab ground floor by ward staff.
5) ABG Sample and pathoform to be sent to ABG Lab, RALC Campus, with zero bills
6) Hard copy of Pathology test reports cannot be provided in any case except ABG reports.
7) All soft copy reports can be extracted/downloaded from E-hospital Software in your ward through online

(Dr.Wahid Ali)
Faculty Incharge
Covid-19 Pathology Lab,
RALC,KGMU, Lucknow

Prof. Wahid Ali
Professor (Additional) Chemical Path.
Department of Pathology
King George's Medical University
Lucknow, U.P., India

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LT. GEN. (DR.) BIPIN PURI
PVSM, VSM (RETD.)
VICE CHANCELLOR
लेफ्टिनेंट जनरल (डॉ०) बिपिन पुरी
पी०वी०एस०एम०, वी०एस०एम० (सेवानिवृत्त)
कुलपति

KING GEORGE'S MEDICAL UNIVERSITY
U.P., LUCKNOW
किंग जार्ज चिकित्सा विश्वविद्यालय, उ०प्र०
लखनऊ

Ref. No.: KGMU/VC/154/2021 **Date: October 06, 2021**

CIRCULAR

In partial modification to previous circular no. KGMU/VC/69/2021, Dated: June 11, 2021, **The revised SOPs of CPR** training at KGMU is being circulated for information and compliance:

SOPs for CPR training in KGMU
Patron – Hon'ble Vice Chancellor KGMU
Co-Patron- Pro-Vice Chancellor, KGMU
Dean-Academics, KGMU

A. Guidelines - As per American Heart Association with AHA certification and course material (03 courses)

- **Hands Only CPR**
- **BLS** – Basic Life Support
- **ACLS** – Advanced Cardiac Life Support

Organizing Chairman	**Prof GP Singh,** Head, Department of Anesthesiology
Course Director	**Prof Rajni Gupta,** Department of Anesthesiology
Course Joint Director	**Prof Mohd. Parvez Khan,** Department of Anesthesiology
Target Audience	• Faculty • Residents • Undergraduates • Interns • Nursing • Paramedics
Course Nomenclature	Main Course, Refresher Course and Instructor Course
Frequency	As decided by Course Director
Fee Structure (Book Manual and certificate)	**KGMU** — **Doctors/Nurses/Paramedics/Instructor** BLS Provider: Rs 1500 (e-book) Rs. 2000 (Hand Book) ACLS Provider: Rs 3500 (e-book) Rs. 4000 (Hand Book) BLS Instructor: Rs 5000 (e-book) Rs. 6000 (Hand Book) ACLS Instructor: Rs 7000 (e-book) Rs. 8000 (Hand Book) **Non KGMU** — **Doctors/Nurses/Paramedics/Instructor** BLS Provider: Rs 2000 (e-book) Rs. 2500 (Hand Book) ACLS Provider: Rs 4000 (e-book) Rs. 4500 (Hand Book) BLS Instructor: Rs 6000 (e-book) Rs. 7000 (Hand Book) ACLS Instructor: Rs 8000 (e-book) Rs. 9000 (Hand Book)
Instructor Manual	BLS – 60-100; ACLS – 50
Seats per course	BLS – 60-100; ACLS – 50
Faculty renumeration	Rs 2500/course
Centre	Kalam Centre KGMU/Skill Center
Account	Indian Bank KGMU
Course Co-Ordinator(s)	All AHA Instructors
Financial Signatory(s)	Course Director, Finance and Account Officer, KGMU
Auditing Authority	Madhur Jain and Co.

B. Guidelines - As per American Heart Association with KGMU e-Certificate and AHA algorithms (03 courses)

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कुलपति

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किंग जार्ज चिकित्सा विश्वविद्यालय, उ०प्र०
लखनऊ

Fee Structure (Book Manual and certificate)	**KGMU**	**Doctors**	**Nurses/ Paramedics**
	BLS	Rs 200	Rs 100
	ACLS	Rs 400	Rs 200
	Non KGMU	**Doctors / Nurses/ Paramedics**	
	BLS	Rs 500	
	ACLS	Rs 1000	
Seats per course	BLS – 60-100; ACLS – 50		
Faculty renumeration	Rs 2000/course		
Centre	Kalam Centre KGMU/Skill Center		
Account	Indian Bank KGMU		
Course Co-Ordinator(s)	All AHA Instructors		
Financial Signatory(s)	Course Director, Finance & Account Officer KGMU and HOD, Anaesthesiology		
Auditing Authority	Madhur Jain and Co.		

C. Guidelines - Indian Resuscitation Council (IRC) - Indian Society of Anaesthesiologists – CPR INDIA (03 courses)

- **COLS** - Compression-Only Life Support
- **BCLS** - Basic Cardiopulmonary Life Support
- **CCLS** - Comprehensive Cardiopulmonary Life Support

Course Director	**Prof GP Singh,** Head, Department of Anesthesiology		
Course Convenor	**Prof Monika Kohli,** Department of Anesthesiology		
Course Co-Ordinator(s)	**Dr Satish,** Department of Anesthesiology **Dr Ravi Prakash,** Department of Anesthesiology		
Target Audience	• Faculty • Residents • Undergraduates* *Free for all Students	• Interns • Nursing* • Paramedics*	
Course Nomenclature	Main Course, Refresher Course and Instructor Course		
Frequency	As decided by Course Director		
Fee Structure (Book Manual and certificate)	**KGMU**	**Doctors**	**Nurses/ Paramedics**
	BLS	Rs 750	Rs 500
	ACLS	Rs 1500	Rs 1000
	Non KGMU	**Doctors**	**Nurses/ Paramedics**
	BLS	Rs 1250	Rs 750
	ACLS	Rs 2000	Rs 1500
Seats per course	40-50		
Faculty renumeration	Rs 2000/course		
Centre	Institute of Skills, AB Vajpayee Scientific Convention Centre Lucknow (First Floor)		
Account	Indian Bank KGMU		
Financial Signatory(s)	Course Director, IoS Director AND Finance Officer KGMU		
Auditing Authority	Madhur Jain and Co.		

(Lt. Gen. (Dr.) Bipin Puri)
Vice Chancellor

Distribution:

1) All Faculty Members, KGMU, Lucknow.
2) Registrar, KGMU, Lucknow.
3) Finance Officer, KGMU, Lucknow.
4) Circular Book.

LT. GEN. (DR.) BIPIN PURI
PVSM, VSM (RETD.)
VICE CHANCELLOR
लेफ्टिनेंट जनरल (डॉ०) बिपिन पुरी
पी०वी०एस०एम०, वी०एस०एम० (सेवानिवृत्त)
कुलपति

KING GEORGE'S MEDICAL UNIVERSITY
U.P., LUCKNOW
किंग जार्ज चिकित्सा विश्वविद्यालय, उ०प्र०
लखनऊ

Ref. No.: KGMU/VC/89/2021 **Date: July 09, 2021**

CIRCULAR

To ensure the immediate action for day to day activities related to the various hostels in the University, the Provost of all hostels are being entrusted with restricted financial powers so that day to day general issue can be resolved in time. The following directives are being issued related to the use of hostels fund by Provost/Dean Student Welfare for information and compliance:

1. Civil Work i.e. (white washing of room, plumbing related work, minor repairs) etc. can be done with the upper capping of Rs. 20,000/- per month.
2. Electric work i.e. (fan repair, AC repair (if not under AMC) Sockets, bulbs, tube lights repair of electric equipment) with the capping of Rs. 5000/- per month.
3. Student welfare activities with capping of Rs. 5000/- per month.
4. Horticulture and Aesthetics activities with capping of Rs. 5000/- per month.
5. All expenditure has to be approved by at least two authorized signatories out of which one has to be the Provost of Hostel.
6. Monthly expenditure under above heads should be sent to Chief Provost for information.
7. For any kind of expenditure, the office of the provost will maintain a Cash Book & Stock Book which need to be quarterly reviewed by Chief Provost.
8. Any other expenditure apart from above heads will require to be approved by Vice Chancellor.

(Lt. Gen. (Dr.) Bipin Puri)
Vic Chancellor

Distribution:

1. Chief Provost, KGMU, Lucknow.
2. Provosts of all Hostels, KGMU, Lucknow.
3. Dean Student Welfare, KGMU, Lucknow.
4. Chief Proctor, KGMU, Lucknow.
5. Registrar, KGMU, Lucknow.
6. Finance Officer, KGMU, Lucknow.
7. Circular Book.

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पी०वी०एस०एम०, वी०एस०एम० (सेवानिवृत्त)
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KING GEORGE'S MEDICAL UNIVERSITY
U.P., LUCKNOW
किंग जार्ज चिकित्सा विश्वविद्यालय, उ०प्र०
लखनऊ

Ref. No.: KGMU/VC/ 116 /2021 **Date: July 29, 2021**

CIRCULAR

The following SOPs regarding CMC and repair/maintenance of Medical Equipments is hereby circulated for information & strict compliance: -

(A) SOPs for CAMC of Medical Equipments:-

Step 1 – Purchase order of the medical equipment stating warranty period and CMC conditions.
Step 2– Proposal from OEM or their authorized service partner as per CMC terms and conditions mentioned in purchase order (CMC cannot be more than 5% inclusive GST of equipment cost as per Govt of UP directives with a maximum of 5% escalation every year)
Step 3 – Document mentioning about the items/work covered under CAMC and the items/work not covered under CAMC.
Step 4 – Preventive maintenance reports of each quarter (at least 04 reports) of last CMC or warranty year.
Step 5 – Final comments of Head of Department.
Step 6 – All documents mentioned in Step 1 to 5 should be collected and sent to Common Equipment Cell for allocating Unique Equipment ID and then the CEC will forward the proposal to Finance Office for needful.

(B) SOPs for repair/maintenance of Medical Equipments for faults not covered under warranty/CMC (forwarding proposal through CEC):-

Step 1 – Purchase order of the medical equipment stating warranty period and CAMC conditions.
Step 2 – Service Report of the OEM engineer clearly mentioning the fault and reason for escape of warranty or CAMC terms and conditions.
Step 3 – Comments of Bio Medical Engineer on the service report. The damaged/non-functional accessories should be made available to BME for collection and record entry and only then new spares will be issued.
Step 4 – Proposal from OEM or their authorized service partner for repair with proper recent price justification of a Govt/Semi private/PSU.
Step 5 – Final comments of Head of Department.
Step 6 – All documents mentioned in Step 1 to 5 should be collected and sent to Common Equipment Cell for allocating Unique Equipment ID and then the CEC will forward the proposal to Finance Office for needful.

(Lt. Gen. (Dr.) Bipin Puri)
Vice Chancellor

Distribution: -

1- All Head of the Departments, KGMU, Lucknow.
2- Faculty Incharge, Common Equipment Cell, KGMU, Lucknow.
3- All CMS/MS/DMS, KGMU, Lucknow.
4- Registrar, KGMU, Lucknow.
5- Finance Officer, KGMU, Lucknow.
6- Executive Engineer (Electrical)/Assistant Engineer (Mechanical), KGMU, Lucknow.
7- Circular Book.

LT. GEN. (DR.) BIPIN PURI
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VICE CHANCELLOR
लेफ्टिनेंट जनरल (डॉ०) बिपिन पुरी
पी०वी०एस०एम०, वी०एस०एम० (सेवानिवृत्त)
कुलपति

KING GEORGE'S MEDICAL UNIVERSITY
U.P., LUCKNOW
किंग जार्ज चिकित्सा विश्वविद्यालय, उ०प्र०
लखनऊ

Ref: No: KGMU/VC/181 /2021, **Dated: November 18, 2021**

CIRCULAR

As per the earlier circular no vc/kgmu/163/2021, dated: 22 Oct-2021 online leave submission is mandatory for all facuty members.

It has been observed that there are few issues are causing confusion among faulty members and officials regarding online leave submission and execution of the online leave portal.

In view of above, the following SOP is being circulated for perusal and strict compliance.

1. Faculty applying for leave will log on to the Leave Module on Manav Sampada portal with their User ID Password. The leave shall be sent to the immediate reporting officer-Head of the Department/Incharge.
2. After that, the Head of the Department/In-charge will forward the concerned Leave to the Registrar with his login ID and password. The approval/rejection of casual leave and restricted holiday shall be by the respective head of the department/In-charge. Except for the first time, where the casual leave and restricted holiday have to be forwarded to the Registrar for the entry of leave balance if not filled.
3. The Registrar will forward it to the concerned section through his login id and password.
4. After leave balance entry, the leave request shall come back again to the Registrar.
5. The Registrar will send the leave to the concerned officer (Pro-Vice Chancellor / Vice Chancellor/ Head of the department/In-charge) with his login ID and password for action.
6. All faculty while applying online leave have to upload an attachment that indicates the name of the person taking care of clinical/administrative/teaching/work/duties in his/her absence. Faculty can use the previous hard copy leave perform for the same.
7. Also, All HODs while applying for leave to select reporting officer as Registrar, KGMU, Lucknow **(EHRMS ID of Registrar - 1388893)** for smooth maintenance of leave balance.
8. The leave which are not forwarded through the proper channel will not be entertained.

(Lt. Gen.(Dr.) Bipin Puri)
Vice Chancellor

Distribution

1- All faculty Members, KGMU, Lko.
2- Registrar, KGMU, Lko.
3- Finance Officer KGMU, Lko
4- Circular Book.

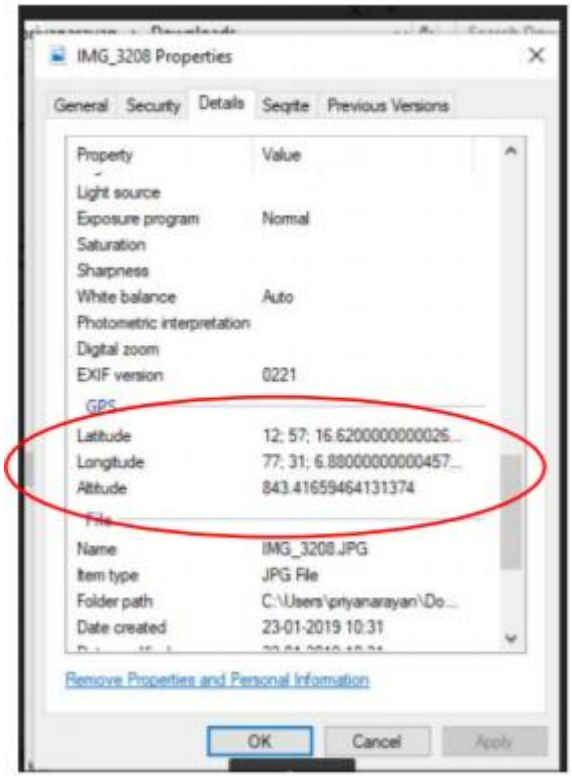
Standard Operating Procedure (SOP) For Data Validation and Verification of Manual of Health Sciences for Universities as on 18.12.2020

General Guidelines for HEIs

- The NAAC Portal supports only 5MB data for each metric. If the HEI's data exceeds 5MB, please host the supporting documents in the HEI's website and provide the link of the same in the template and/or in the HEI-DVV clarification Space
- Please provide the supporting documents during the SSR submission to facilitate speedy DVV clarification process.
- It is mandatory to respond to all the DVV clarification raised in extended profile and metrics with in stipulated time. If the data is large, ensure to fill the data template. During DVV clarification, the DVV will seek for sample selective documents for validation
- Data should not be hosted in google drive and third-party websites. The data should be either in the NAACs portal or in the HEI website
- The data that are hosted in the HEI's website should not be changed after the submission of link to the NAAC. Such incidences will be viewed seriously as misappropriation of data and may lead to actions against the HEI.
- The instruction while providing links should ensure that the links work properly and are operational. The institution also should give the links as appropriate to the metric and not general links whose landing page is the HEI's home page.
- Content of the Supporting document s in regional languages should be translated in English and should be duly signed by the head of the institution. The translated copy should be uploaded along with the regional language document.
- Geotagging: Kindly follow the steps to obtain a Geo-tagged photo

    1) In setting of your digital camera, set the location on
    2) If you are taking photos in a smart phone, then set the location on
    3) Take pictures after setting the location on.
    4) Download the pictures in a computer system and examine the properties. In properties, click on the details tab, scroll down to see GPS: you will see

something like the picture provided below, the value entries in Latitude and longitude will determine the location in which the photo was taken.



- It is possible that both Extended Profile and some Quantitative Metrics (QnM) seek responses that require similar data/documents. In such cases, it is adequate to present data/documents in Extended Profile. That is, if the data/documents sought are given in response to Extended Profile they need not be resubmitted under those specific Quantitative Metrics (QnM).

- Whenever both Extended Profile and some Quantitative Metrics (QnM) seek similar responses make sure that data/documents provided for those Quantitative Metrics (QnM) match with the corresponding data/documents given in the Extended Profile.

EXTENDED PROFILE

STANDARD OPERATING PROCEDURE (SOP)

Metric No.	Metric Details	Documents requirements	Specific Instructions to HEIs	Not to be considered
1.1	Number of all Programmes offered by the Institution during the last five years	Include all the programs that were/are operational during the years of the accreditation	Programs are a range of learning experiences offered to students in a formal manner over a period of one-to-five years leading to certificates/ diplomas/ degrees. Examples: BSC Nursing, MBBS, etc. All possible formal degree Programmes are identified by UGC	Short term program which do not award degree OR P.G. Diploma are not to be considered
2.1	Number of students year wise during the last five years	• Include all the students on campus in all the semester year-wise	• Ensure to fill in the template completely	Avoid adding of students of ODD and even semesters in a year
2.2	Number of **graduated students year-wise during the last five years**	• The final year student s of different program in the years of assessment period should be considered here		
3.1	Number of full time teachers year wise during the last five years	• This is a year wise metric. Consider the teachers working in the institution year-wise (Repeat counting in	A teacher employed for at least 90 per cent of the normal or statutory number of hours of work for a full-time	

		different years allowed) • Random list of fulltime teachers may be asked by DVV during verification.	teacher over a complete academic year is classified as a full-time teacher.	
3.2	Number of sanctioned posts year wise during the last five years	• Official letter of sanction of post from the statutory body or Government • Official letter from the Board of Management or Syndicate clearly mentioning the sanction of posts	• Include State/Central Government sanction post • Include Management sanctioned post	
4.1	Total Expenditure excluding salary year-wise during the last five years (INR in Lakhs)	• Extract of expenditure duly audited and certified by the finance officer and Head of the institution • Audited state of income and expenditure highlighting the salary component	--	

Metric wise Standard Operating Procedure (SOP)

Metric No.	Metric Details	Documents requirements	Specific Instructions to HEIs	Not to be considered
1.1.2	***Percentage of Programmes where syllabus revision was carried out during the last five years***	• Approved Minutes of relevant Academic Council/BOS meetings highlighting the specific agenda item regarding the metric from the competent authority: (university/autonomous bodies) • Details of the revised Curricula/Syllabi of the programmes during the last five years • Syllabus prior and post revision of the courses.	• Change of scheme is considered as "change of syllabus". Content change / introduction of electives or renaming the course cannot be considered as "change of syllabus" • If the number of courses in a given programme changed greater than or equal to 20 % then it can be considered as the "change in syllabus" • If a programme is revised three times during last five years, it should be counted only once.	• Renaming / minor changes in the course content cannot be considered

			• The programs mentioned in the IIQA and SSR and the SRA should match. • Kindly read the definition of programs in the manual • Programs which are revised more than once in five years should be counted only once.	
1.2.1	***Percentage of Programmes in which Choice-Based Credit System (CBCS)/Elective course system has been implemented, wherever provision was made by the Regulatory Bodies (Data for the preceding academic year).***	• Minutes of relevant Academic Council/BOS meetings highlighting the relevant. • University letter stating implementation of CBCS by the institution • Structure of the program clearly indicating courses, credits/Electives as approved by the competent board.	• Either CBCS or Elective or both can be considered • If CBCS, course structure along with credit details to be given. • If elective, list of elective offered for the program to be given • If both, CBCS details alone is sufficient.	

1.2.2	***Percentage of new Degree Programmes, Fellowships and Diplomas introduced by the University across all Faculties during the last five years (certificate programmes are not to be included)***	• Minutes of relevant Academic Council/BoS meetings Clearing approving the introduction of new Degree Programmes, Fellowships and Diplomas claimed in the SSR	• The introduction of the program should be with-in the assessment period.	
1.2.3	***Percentage of interdisciplinary courses under the Programmes offered by the University during the last five years***	• Minutes of relevant Academic Council/BoS meetings Clearly approving the interdisciplinary Courses with specifications of departments involved	• The introduction of the course should be with-in the assessment period • The courses should be interdisciplinary in nature	
1.3.2	***Number of value-added courses offered during the last five years that impart transferable and life skills***	• Brochure or /Course content of Value added courses	• Courses of varying durations (of at least 16 contact hours), that are optional, and offered outside the curriculum that add value and helping them students in getting placed • No repeat count	• Avoid courses opted by student/students not offered by the institution • Courses, that are optional, and offered outside the curriculum are considered

			of courses offered each year	
1.3.3	***Percentage of students who successfully completed the value-added courses during the last five years***	• List of enrolled students in such courses	• Course Completion Certificate of 5 % of random selected specific student list will be sought by DVV during DVV clarification process. • If the institutions do not comply with the DVV's clarification, the claim of the institution will reduced pro rata.	
1.4.1	***Mechanism is in place for obtaining structured feedback on curricula/syllabi from various stakeholders*** **1. Students** **2. Teachers** **3. Employers** **4. Alumni** **5. Professionals**	• Stakeholder feedback analysis report. • Sample filled in Structured Feedback to be provided by the institution for each category claimed in SSR	• The feedback concerned with curriculum development only can be considered • Only filled –in feedback report will be considered • In case of selecting C, B, or A provide three filled forms	• Feedback not related to design and review of syllabus will not be considered

			from each criteria	
1.4.2	***Feedback process of the Institution may be classified as:*** **Options(***Opt any one that is applicable)***:** A. Feedback collected, analysed and action taken on feedback and such documents are made available on the institutional website B. Feedback collected, analysed and action has C. been taken D. Feedback collected and analysed E. Feedback collected F. Feedback not obtained/coll	• Stakeholder feedback report. • Action taken report of the Institution on feedback report as minuted by the Governing Council, Syndicate, Board of Management.	• In case of option A, only those links which leads directly to the concerned web page hosting action taken report will be considered • Un available websites will not be considered. • In case of option B,C and D reports of the same shall be provided • Hosting the report on 3rd party website will not be considered • General web-link to homepage of the HEI shall not be considered	• Feedback not related to design and review of syllabus will not be considered

	ected			
2.1.1	***Due consideration is given to equity and inclusiveness by providing reservation of seats to all categories during the admission process***	• Copy of letter issued by state govt. or and Central Government Indicating the reserved categories to be considered as per the state rule (in English) • Final admission list published by the HEI • Admission extract submitted to the state OBC, SC and ST cell every year. • Initial reservation of seats for admission.	• Include only those reserved categories as specified by State/central Government orders for admission. • Only those seats filled against the quota should be counted here. • Number of admitted cannot go more than the number allocated. • For minority institutions and other private institutions where reservations are not applicable, consider the total admitted students as reserved.	
2.1.2	***Student Demand Ratio, applicable to programmes where***	• Document relating to Sanction of intake • Extract of No. of	• Sanctioned admission strength in	

	State/Central Common Entrance Tests are not conducted	application received in each program • The details certified by the Controller of Examination or Registrar evaluation clearly mentioning the programs that are not covered under CET and the number of applications received for the same	each program Vs No. of Application received for each program	
2.1.3	***Student enrolment pattern and student profile demonstrate national/international spread of enrolled students from other states and countries***	• Copy of the domicile certificate/passport from respective states / countries • Previous degree/ Matriculation / HSC certificate from other state or country	• In case of large data, the DVV will seek for the above mentioned documents for specific list of students during DVV clarification.	
2.2.1	***The Institution assesses the learning levels of the students after admission and organises special programmes for advanced learners and slow performers*** 1. Adopts measurable criteria to identify slow performers.	• Methodology and Criteria for the assessment of Learning levels Details of special programmes • Details of outcome measures • Proforma created to identify slow performers/advanced learners • Consolidated report to	The supporting document should clearly elicit the following: • Methodology and Criteria for the assessment of Learning levels Details of special programmes	

	2. Adopts measurable criteria to identify advanced learners 3. Organizes special programmes for slow performers and advanced learners 4. Follows protocols to measure students' achievement	Dean academics /Dean student's welfare on special programs for advanced learners and slow learners	• Details of outcome measures	
2.2.2	***Student - Fulltime teacher ratio (data for the preceding academic year)***	• This is an automatic metric. Both values used in the formula is obtained from extended profile	• A teacher employed for at least 90 per cent of the normal or statutory number of hours of work for a full-time teacher over a complete academic year is classified as a full-time teacher.	Avoid inclusion of part-time / Ad-hoc / visiting faculty
2.3.2	***Has provision for the use of Clinical Skills Laboratory and Simulation Based Learning*** 1. Has Basic Clinical Skills Training Models and	• Proof of Establishment of Clinical Skill Laboratories • Proof of patient simulators for simulation-based training • Report on training programmes in Clinical skill lab/simulator Centre	Provide supporting documents mentioned as according to the choice of the institution among A,B,C,D	

	Trainers for clinical skills in the relevant disciplines. 2. Has advanced patient simulators for simulation-based training 3. Has structured programs for training and assessment of students in Clinical Skills Lab / Simulation centre 4. Conducts training programs for the faculty in the use of clinical skills lab and simulation methods of teaching-learning	• Details of training programs conducted and details of participants. • Geotagged Photos of the *Clinical Skills Laboratory*		
2.3.4	***Student :Mentor Ratio (preceding academic year)***	• Copy of circular pertaining the details of mentor and their allotted mentees • Approved Mentor list as announced by the HEI • Allotment order of mentor	• Only full-time teachers can be considered as mentors. • Mentors in preceding year	

		to mentee • In addition, issues raised and resolved in the mentor system has to be attached mentor-wise • Approved Mentor list as announced by the HEI Allotment order of mentor to mentee • Log Book of mentor	alone to be considered and this metric is for preceding year only.	
2.4.1	***Average percentage of fulltime teachers against sanctioned posts during the last five years***	• Sanction letters indicating number of posts (including Management sanctioned posts) by competent authority (in English/translated in English) • This is automatic metric and the values are derived from the extended profile	• Appointment letter of selected faculty will be asked during DVV clarification stage • All full-time teachers with at least 90% prescribed workload should be counted as full-time teachers	
2.4.2	**Average percentage of fulltime teachers with Ph.D./D.Sc./D.Lit./DM/M Ch/DNB in Super Specialities /other PG degrees (like MD/ MS/ MDS etc.,) in Health**	• Copies of Guide-ship letters or authorization of research guide provide by the **Regulatory Councils / Universities**	• These guide-ship awarded before the assessment period can be considered here • Repeat count of the guides in each year is allowed	

	Sciences for recognition as Ph.D guides as per the eligibility criteria stipulated by the Regulatory Councils / Universities. Last five years data to be entered		• If the data is large, details selected (about 5%)faculty will be asked during DVV clarification stage if the data is large	
2.4.3	***Average Teaching experience of fulltime teachers in number of years (preceding academic year)***	• Experience certificate of full time teacher	• Experience certificate/ appointment order of selected faculty will be asked during DVV clarification stage if the data is large • Cumulative teaching experience is considered (Past and Present)	
2.4.4	***Average percentage of teachers trained for development and delivery of e-contents / e-courses / video lectures / demonstrations during the last 5 years***	• Certificate of completion of training for development of *and delivery of e-contents / e-courses / video lectures / demonstrations* • Web-link to the contents delivered by the faculty hosted in the HEI's	• Training completion certificate of selected faculty (about 5%) will be asked during DVV clarification stage	

		website • List of e-contents / e courses / video lectures / demonstrations developed		
2.4.5	***Average Percentage of fulltime teachers who received awards and recognitions for excellence in teaching, student mentoring, scholarships, professional achievements and academic leadership at State, National, International levels from Government / Government-recognized agencies / registered professional associations / academies during the last five years***	• e-Copies of award **/Recognitions** letters (scanned or soft copy) for achievements • Awards **/Recognitions** claimed without certificates will not be considered	• Only State, National and International level from Government, recognised bodies only should be considered • The date of award **/Recognitions** should fall with-in the assessment period • One Full-time teacher to be counted once for a year irrespective of number of awards or recognition in the same year.	• Award that are local in nature need to be avoided. • Intra and inter university / institution awards **/Recognitions** to be avoided • Participation / presentation certificates – during paper presentation etc needs to be avoided
2.5.1	***Average number of days from the date of last semester-end/ year- end examination to the***	• Reports from Controller of Exam (COE) office/ Annual reports mentioning the relevant details. • Notified exam date and	In case of semester system, take the average days of two semesters in a year	

	date of declaration of results during the last five years	result declaration date year – wise / semester wise		
2.5.2	***Average percentage of student complaints/ grievances about including evaluation against the total number of students appeared in the examinations during the last five years***	• Certificate from Registrar / Controller of examination / Data on student grievances from the office of the Registrar (Evaluation) • Minutes of the grievance cell / relevant body • List of students applied for revaluation certified by Registrar / Controller of Examinations	• Grievance is based on number of students and not number of subjects. One student to be counted once only in a year • Grievances including re-valuation to be considered	
2.5.3	***Evaluation-related Grievance Redressal mechanism followed by the Institution:*** The University adopts the following for the redressal of evaluation-related grievances. **Options (***Opt any one which is applicable to you)***:** 1. Double	• Provide links to the examination procedure and re-evaluation procedure developed by the institution and duly hosted in the institution's website • Report of the Controller of Examination/ registrar evaluation regarding the *Grievance Redressal mechanism followed by the Institution*	• The examination procedure and re-evaluation procure are expected to be hosted in the institution's website.	

	valuation/Multiple valuation with appeal process for retotaling/revaluation and access to answer script 2. Double Valuation/Multiple valuation with appeal process for revaluation only 3. Double Valuation/Multiple valuation with appeal process for retotaling only 4. Single valuation and appeal process for revaluation 5. *Grievance Redressal mechanism does not exist*			
2.5.5	***Status of automation of Examination division using Examination Management System (EMS) along with approved online***	• Snap shot of EMS used by the institution • Copies of the purchase order of the software/AMC of the software • The present status of automation., Invoice of		

	Examination Manual	the software, & screenshots of software • Annual report of examination including present status of automation as approved by BOM / Syndicate / Governing Council		
2.6.2	***Incremental performance in Pass percentage of final year students in the last five years***	• Reports from Controller of Exam (COE) office/ Registrar evaluation mentioning the relevant details.	• Consider only pass of final year examination thus qualifying the degree program	
2.7.1	***Online student satisfaction survey regarding teaching learning process.***	Details to be provided during SSR submission only		
3.1.2	***The Institution provides seed money to its teachers for research***	• Sanction letter of seed money to the faculty is mandatory • Budget and expenditure statements signed by the Finance Officer indicating seed money provided and utilized.	• In case of large data, the DVV will ask for valid document for specific list of teachers • Only formal research project seed money will be considered	• Grants for other than research projects need to be avoided • Sponsorship to conferences / seminars etc. to be avoided
3.1.3	***Average Percentage of teachers awarded national/ international***	• E-copies of the award letters of the teachers. • Fellowship award letter from the	• Documents for all awards are compulsory • The fellowship is	

	fellowship/ Financial support for advanced studies/collaborative research / conference participation in Indian and Overseas Institutions during the last five years	funding agency	for advanced studies only • Financial grants to attend conference and short-term visits will be considered here	
3.1.4	***Number of JRFs, SRFs, Post Doctoral Fellows, Research Associates and other research fellows in the university enrolled during the last five years***	• E copies of fellowship award letters • Registration and guide / mentor allocation by the institution	• E copies of fellowship award letters is mandatory	
3.1.5	***University has the following facilities**** 1. Central Research Laboratory / Central Research Facility 2. Animal House/ Medicinal plant garden / Museum 3. Media laboratory/Business Lab/e-resource Studios	• videos and geo-tagged photographs	Photos/videos shall be hosted in the institution's website and links may be shared in the SSR	

	4. Research/Statistical Databases/Health Informatics 5. Clinical Trial Centre			
3.1.6	***Percentage of departments with recognition by ICMR-CAR, DST-FIST, DBT, MCI, DCI, PCI, AICTE, AYUSH, NACO, WHO, NIH etc. and other similar recognitions by national and international agencies, (****excluding mandatory recognitions by Regulatory Councils for UG / PG programmes)* ***(Data for the last 5 years)***	• e-copies of departmental recognition award letters • Details of the departments offering academic programmes certified by the head of the Institution /University	• The running grant should be valid for the **assessment period** • Data will not be considered without documentations prescribed • *Examples: WHO collaborating Centre, AYUSH & AICTE Centre for Excellence, MCI Regional / Nodal Centre for Medical*	

			Education etc.,	
3.2.1	***Grants for research projects / clinical trials sponsored by non-government sources such as industry, corporate houses, international bodies, endowments, professional associations, endowment-Chairs etc., in the Institution during the last five years***	• E-copies of the grant award letters for research projects sponsored by non-government sources • Funds received from Mother Trust and Sister Institutions will not be considered.	• Sanction letter of grants by the funding agency is mandatory to support the claim, and the source of funding should be from non-government organisations. The duration of the grant period should align with the assessment period. • Funding grants for projects from the management etc. will not be admitted here • Research endowment funds can be considered here. • Data will not be considered without documentations prescribed	• Grants given by their own trust / sister institutions not to be included

3.2.2	***Grants for research projects/clinical research project sponsored by the government funding agencies during the last five years***	• E-copies of the grant award letters for research projects sponsored by government sources. .	Sanction letter of grants by the funding agency is mandatory to support the claim, and the source of funding should be from government organisations. The duration of the grant period should align with the assessment period.	• Grants for Equipments / software / skill development centres will not be considered
3.2.3	***Ratio of research projects/clinical trials per teacher funded by government/industries and non-government agencies during the last five years***	• Supporting document/s from Funding Agencies • List of research projects and funding details (Data Template) • Copy of the letter indicating sanction of research project funded by govt./non-govt agency and industry including details of name of teacher and amount in INR • Consultancy from Hospital will not be	• This metric is about the number of projects, **hence the number of projects in 3.2.1, 3.2.2. and 3.5.2 put together should result in 3.2.3**	• Non-government agency does not include own institution/trust/sister institutions

		considered		
3.3.3	***Number of awards / recognitions received for innovation / discoveries by the Institution/teachers/ research scholars/students from recognized bodies during the last five years***	• E-Copies of award letters (scanned or soft copy) for innovations with details of awardee and awarding agency • This metric specifically emphasise awards for innovations • Patents are not considered here.	• Awards for innovation only to be considered here. • This should not include patents • The claims without certificate or award letter will not be considered	• Participation / presentation certificates in workshops / conferences etc to be avoided
3.3.4	***Number of start-ups incubated on campus during the last five years***	• E copy of sanction order of the University for the Start Ups on campus. • Registration letter and contact details of the promoters	• Supporting document in favour of start-ups with company registration details, and incubation details mentioning the facilities extended by the institution to the company should be provided.	
3.4.1	***The Institution has a stated Code of Ethics for research, the implementation of which is ensured by the following:***	• Institutional code of Ethics document • Course content of research ethics and details of members of ethical	These information are expected to be hosted in the HEI's website vide public access and the link to be	

	Option 1. ***Research methodology with course on research ethics*** 2. ***Ethics committee*** 3. ***Plagiarism check*** 4. ***Committee on Publication guideline***	committee • Copy of software procurement for plagiarism check • Details of committee on publication guidelines • Proceedings of the meeting on relevant committees	shared during Submission of SSR	
3.4.2	***The Institution provides incentives for teachers who receive state, national or international recognitions/awards*** ***Option*** ***1. Career Advancement*** ***2. Salary increment*** ***3. Recognition by Institutional website notification*** ***4.Commendation***	• Policy on Career advancement for the awardees • Policy on salary increment for the awardees • Snapshots of recognition of notification in the HEI's website • Copy of commendation certificate and receipt of cash award • Incentive details (link to the appropriate details on the Institutional website)	The institution to provide documents as per the choice of A/B/C/D in the SSR	

	certificate with cash award			

3.4.3	***Number of Patents/ Copyrights published/awarded/technology-transferred during the last five years***	• E- copies of the letters of award/ publication of patent/copyright/ *technology-transferred*
		  • Certified e- copies of the letters of awards/publications (Consolidated statement by the head of the Institution).
		  • Technology transfer document
			• Only awarded / published patents should be considered.
			• Patents/copyright / *technology-transferred* awarded should be supported with a letter of award and the unique patent number which can be cross-verified.
			• The award / publication of patent/copyright / *technology-transferred* should be with-in the assessment period	

3.4.4	***Average number of Ph.D/ DM/ M Ch/ PG Degree in the respective disciplines awarded per recognized PG teacher* of the Institution during***	• PhD*/ DM/ M Ch/ PG Degree* Award letters of students • Web page for research in the Institutional website.	• Number of PhD*/ DM/ M Ch/ PG* awarded (not-ongoing) under every eligible research guide working as faculty in the	

	the last five years		institution should be considered. • The recognised guides should be authenticated with guide-ship letters awarded by the University. • If the data is large, details of guide-ship letter/award details for selected faculty will be asked during DVV clarification process	
3.4.5	***Average Number of research papers per teacher in the approved list of Journals in Scopus / Web of Science/ PubMed during the last five calendar years***	• This metric inputs will be verified by INFLIBNET • Web-link provided by institution in the template which redirects to the journal webpage published in UGC notified list • This metric will be verified by INFLIBNET	• Only *Journals notified on UGC website / PubMed / Scopus / Web of Science* approved Journals will be considered. • In the template paste the link of UGC approved list of journals. • Digital Object Identifier (DOI) number to be pasted in the	

			templet • In case of research papers published in deleted list of UGC until 2nd may 2018, the details in the link column may please mentioned as: the Sl.No. of the journal – Deleted list • In case of publications in journals indexed in PubMed / *Scopus / Web of Science please provide the links*	
3.4.6	***Average Number of research papers per teacher in the approved list of Journals notified in UGC-CARE list during the last five calendar years***	• This metric input will be verified by INFLIBNET	• Publications without ISBN number will not be considered • If the data is large, specific sample publications will be sough bye DVV (about 5%) during DVV clarification	
3.4.7	***Total Number of***	• This metric input will	• **Publications not**	

	books/ chapters in edited volumes and papers in National/International conference-proceedings published per teacher and indexed in Scopus/ Web of Science / PubMed UGC-CARE list during the last five calendar years	be verified by INFLIBNET	**included in UGC-CARE list will not be considered.** • If the data is large, specific sample publications will be sought by INFLIBNET (about 5%) during DVV process	
3.4.8	***Bibliometrics of the publications during the last five calendar years based on average Citation Index in Scopus/ Web of Science***	• This metric input will be verified by INFLIBNET		
3.4.9	**Provide Scopus/ Web of Science – h-index of the Institution for the last 5 calendar years.**	• This metric input will be verified by INFLIBNET		
3.5.2	***Revenue generated from advisory / R&D consultancy and***	• Audited statements of accounts indicating the	• Amount generated	

	service consultancy projects (exclude Patients consultancy) including Clinical trials Industries during the last five years	revenue generated through consultancy. • CA certified copy/Finance Officer Certified copy attested by head of the institute	through **R&D projects, advisory and service consultancy** work alone has to be considered here. • **R & D projects and Instrumentation service projects executed by the faculty and technical staff are allowable for consideration**	
3.6.1	***Extension* and outreach activities* such as community Health Education, Community health camps, Tele-conferences, Tele-Medicine consultancy etc., are conducted in collaboration with***	• Photographs / preferably geo tagged photographs or any supporting document in relevance • Detailed program report for each extension and outreach program should be made available, with specific mention of number of students and	• Can be supplemented with Newspaper reports of events.	

	industry, Government and non- Government Organizations engaging NSS/NCC/Red cross/YRC, Institutional clubs etc., during the last five years ****check glossary for definition***	collaborating agency participated		
3.6.2	***Average percentage of students participating in extension and outreach activities beyond the curricular requirement as stated at 3.6.1***	• Detailed program report for each extension and outreach program should be made available, with specific mention of number of students and collaborating agency participated and Photographs or any supporting document in relevance		
3.7.1	***Average Number of Collaborative activities for***	• Copies of collaboration /related documents with	• The Collaboration should be valid for	

	research, faculty exchange, student exchange/ Industry-internship etc.., per year	details of nature of collaboration and activities year-wise	the assessment period. • The collaboration activities of research/faculty exchange or/and student exchange should be facilitated through the mentioned collaboration only.	
3.7.2	***Presence of functional MoUs with Institutions/ industries in India and abroad for academic, clinical training/ internship, on-the-job training, project work, student / faculty exchange, collaborative research programmes etc., during the last five years***	• E-copies of the functional MoU's with institution/ industry/ corporate house, Indicating the start date and completion date	• The MoU should be functional during the assessment period • If the MoU is for three years viz 2011-2013, it shall be counted only once.	
4.1.4	***Average percentage of expenditure incurred, excluding salary, for infrastructure***	•Provide the consolidated fund allocation towards infrastructure development and augmentation facilities	•This metric is supposed to be looked at with the perspective of	•Avoid recurring expenditure on laboratory and acquisition of books and journals

	development and augmentation during the last five years	duly certified by Finance Officer •Highlight the relevant items in the balance sheet	**infrastructure development and augmentation** •In case of privately funded University the document should be certified by Chartered Accountant also.	
4.2.3	***Availability of infrastructure for community-based learning*** **Institution has:** 1. Attached Satellite Primary Health Centres 2. Attached Rural Health Centres available for training of students 3. Attached Urban Health Centre for training of students 4. Residential	• Geotagged photos of health centers • Government Order on allotment/assignment of PHC to the institution • Documents of resident facility	• Supporting document to be provided as per the claim made	

	facility for students / trainees at the above peripheral health centres / hospitals			
4.2.4	**Is the Teaching Hospital / Clinical Laboratory accredited by any National Accrediting Agency?** A. NABH accreditation B. NABL accreditation C. International accreditation like JCI., D. ISO certification of departments /Institution E. GLP/GCLP accreditation.	• Provide certificates of accreditation	• As per the claim of the institution in SSR, appropriate certificate from the National Accrediting Agency to be provide failing which the claim will not be accepted.	
4.3.3	***Does the Institution have an e-Library with membership/subscription for the following:***	• E-copy of subscription letter/member ship letter or related document with the mention of year to be submitted	• Scan copy of books claimed as e-books cannot be accepted. • In the absence of appropriate	

	Options 1. e – journals / e-books consortia 2. e - ShodhSindhu 3. Shodhganga 4. SWAYAM Discipline-specific Databases		subscription letter, the claims will not be considered	
4.3.4	***Average annual expenditure for purchase of books and journals*** (including e-resources) ***during the last five years***	• provide consolidated extract of expenditure for purchase of books and journals during the last five years duly attested by Finance Officer • Audited Statement highlighting the expenditure for purchase of books and journal library resources • Proceedings of Library Committee meetings for allocation of fund and utilization of fund	• In case of privately funded University the document should be certified by Chartered Accountant also. • Give links or upload document of e-content developed	
4.3.5	***E-content resources used by teachers /Students :*** 1. NMEICT/NPTEL	• Give links or upload document of e-content both used and developed. • Supporting documents from the hosting	• Both the content used / developed by the teachers of the institution need be considered	Informal e-content will not be accepted

	2. other MOOCs platforms 3. SWAYAM 4. Institutional LMS 5. e-PG-Pathshala	agency for the e-content developed by the teachers need to be given • Give links e-content repository used by the teachers / ***Students***		
4.4.1	**Percentage of classrooms, seminar halls and demonstration rooms linked with internet /Wi-Fi enabled ICT facilities (data for the preceding academic year)**	• Geo-tagged photos • Consolidated list duly certified by the Head of the institution.		
4.4.3	***Available bandwidth of internet connection in the Institution (Leased line)*** Opt any one: A. ≥1 GBPS B. 500 MBPS - 1 GBPS C. 250 MBPS - 500 MBPS D. 50 MBPS - 250 MBPS E. <50 MBPS	• Bills for any one month of the last completed academic year indicating internet connection plan, speed and bandwidth • Annual subscription bill • If donated, letter from the donor		• Snapshot/Screenshot of speed test for WIFI/internet facility not be considered

4.5.1	***Average percentage of expenditure incurred on maintenance of physical facilities and academic support facilities excluding salary component during the last five years***	• Provide balance sheet highlighting the items of expenditure incurred on maintenance of physical facilities and academic support facilities duly certified by Finance Officer. • Provide budget extract incurred on maintenance of physical facilities and academic support facilities duly certified by Finance Officer.	• The emphasis of this metric is in the maintenance of physical and academic support facilities • In case of privately funded University the document should be certified by Chartered Accountant also.	
5.1.1	***Average percentage of students benefited by scholarships /free-ships / fee-waivers by Government / Non-Governmental agencies / Institution during the last five years***	• Upload sanction letter of scholarship. • Consolidated document in favor of free ships and number of beneficiaries duly signed by the Head of the institution	• Both Government/ non-government Scholarships are considered here • For large data, the DVV will ask documents for specific list of students in specific schemes during DVV clarification.	

			Hence please ensure to provide the list of students in the template.	
5.1.2	***Institution implements a variety of capability enhancement and other skill development schemes*** 1. Soft skills development 2. Language and communication skill development 3. Yoga and wellness 4. Analytical skill development 5. Human value development 6. Personality and professional development 7. Employability skill development	• Detailed report of the Capacity enhancement programs and other skill development schemes		

5.1.3	***Average percentage of students undergone guidance for competitive examinations and career advancement offered by the Institution during the last five years***	• Copy of circular/brochure of such programs • Year-wise list of students attending each of these schemes signed by competent authority • Institutional website. Web-link to particular program/scheme mentioned in the metric • List of students (Certified by the Head of the Institution) benefited by guidance for competitive examinations and career advancement offered by the Institution during the last five years	• "Students benefited" refers to students enrolled / attending the said programs	
5.1.5	***The Institution has a transparent mechanism for timely redressal of student grievances/ prevention of sexual harassment and prevention of ragging*** *a. Adoption of guidelines of*	• Minutes of the meetings of student redressal committee, prevention of sexual harassment committee and Anti Ragging committee. (the names of the complainant shall be masked) • Circular/web-link/ committee report justifying the objective of the metric	• Report of incident management of grievances from the concerned cell is essential. • The mechanism of redressal should be available as document and preferably hosted in the HEI's Website. The link	

	Regulatory bodies *b. Presence of the committee and mechanism of receiving student grievances (online/ offline)* *c. Periodic meetings of the committee with minutes* b) *d. Record of action taken*		of the same shall be provided to validate the same.	
5.2.1	***Average percentage of students qualifying in state/ national/ international level examinations during the last five years (eg: NET/SLET/GATE/ GMAT/GPAT/CAT/ GRE/TOEFL/ PLAB/ USMLE /AYUSH/Civil Services/Defense /UPSC/ State government examinations/PG-NEET/*** AIIMSPGET, JIPMER Entrance Test, PGIMER	• Pass Certificates of the examination	• In absence of certificate, the claim will not be considered. • In case of large data, certificates of specific list of students will be sought during DVV clarification	

	Entrance Test etc.,)			
5.2.2	***Average percentage of placement /self-employed professional services of outgoing students during the last five years***	• Annual reports of Placement Cell. • Self-attested list of students placed / self-employed	• In case of large data, documents of specific list of students will be sought during DVV clarification • In case of ***self-*** employed professional services registration with MCI / any other Professional Bodies and documents for randomly selected students should be provided as sought by DVV.	
5.2.3	***Percentage of the graduates in the preceding academic year, who have had progression to higher education.***	• Upload supporting data for student/alumni in prescribed format. • Any proof of admission to higher education	• The details of selected students progressing to higher education will be asked by DVV during DVV clarification. The	

			validating document for the same to be provided then.	
5.3.1	***Number of awards/medals for outstanding performance in sports/cultural activities at state/regional/national/international events (award for a team event should be counted as one) during the last five years***	• e-copies of award letters and certificates.	• Only State/nation or international achievements will be considered. • Inter collegiate competitions will not be considered here.	• Participation/appreciation certificates at the regional/local /institutional levels should be avoided
5.3.3	***Average Number of sports and cultural activities / events/ competitions organised in the Institution per year***	• Report of the events/along with photographs appropriately dated and captioned year-wise. • Copy of circular/brochure indicating such kind of activities	• Events cannot be split into activities • Only the activities organised by the institution need to be considered	
5.4.2	**Provide the areas of contribution by the Alumni Association / chapters during the**	• Annual audited statements of accounts. Extract of Audited statements of highlighting		

	last five years 1. Financial / kind 2. Donation of books /Journals/ volumes 3. Students placement 4. Student exchanges 5. Institutional endowments	Alumni Association contribution duly certified by the Finance Officer and Head of the Institutions		
6.2.3	***The University has implemented e-governance in the following areas of operation*** 1. Planning and Development 2. Administration (including Hospital Administration & Medical Records) 3. Finance and Accounts 4. Student	• Institutional budget statements allocated for the heads of E-governance implementation ERP Document • Screen shots of user interfaces of each module Annual e-governance report approved by Governing Council/ Board of Management/ Syndicate Policy document • e-Governance related document		

	Admission and Support 5. Examination			
6.3.2	***Average percentage of teachers provided with financial support to attend conferences/ workshops and towards membership fee of professional bodies during the last five years***	• Policy document on providing financial support to teachers • E-copy of letter/s indicating financial assistance to teachers and list of teachers receiving financial support year-wise under each head. • Audited statement of account highlighting the financial support to teachers to attend conferences/workshops and towards membership fee for professional bodies. • List of teachers provided membership fee for professional bodies during the last five years	• If the data is large, the DVV will seek for document of specific list of teachers during DVV clarification	
6.3.3	***Average number of professional development / administrative training***	• Detailed program report for each program should be made available Reports of the Human Resource Development Centres	• The program should be minimum of one day duration	

	programmes organized by the University for teaching and non-teaching/technical staff during the last five years	(UGC ASC or other relevant centres). • Reports of Academic Staff College or similar centres Verification of schedules of training programs • Copy of circular/ brochure/report of training program self conducted program may also be considered • lists of participants with signature who attended the above programmes year-wise during the last 5 years as a proof of attendance (Data template)		
6.3.4	***Average percentage of teachers undergoing Faculty Development Programmes (FDP) including online programmes (Orientation/ Induction Programmes, Refresher Course, Short Term Course etc.) during the last***	• Annual reports of the AQAR submitted to NAAC • E-copy of the certificate of the program attended by teacher • Days limits of program/course as prescribed by UGC/AICTE or Preferably Minimum one day programme conducted by recognised	• One teacher attending one or more professional development Program in a year to be counted as one only. • The DVV will ask for certificates of specific faculty during DVV process as a part of validation	

	five years	body/academic institution • Courses with 30 or more contact hours are considered		
6.4.2	***Funds/Grants received from government/non-government bodies/ philanthropists during the last five years (excluding scholarships and research grants covered under Criterion III)***	• Annual audited statements of accounts • Copy of letter indicating the grants/funds received by respective agency as stated in metric • Provide the budget extract of audited statement towards Grants received from non-government bodies, individuals, philanthropist duly certified by chartered accountant and/or Finance Officer		• Avoid duplication • Funds from own institutions/own trust and sister institutions not to be considered
6.5.2	***Quality assurance initiatives of the Institution include:*** 1. Academic and Administrative Audit (AAA) and initiation of follow-up	• Report of AAA • Details of Conferences Workshops with thrust on quality education • Details of the Collaborative initiations (with or without MOU) • Report of orientation	• These documents are expected to be hosted in the website of the HEI for public access	

	action 2. Conferences, Seminars, Workshops on quality 3. Collaborative quality initiatives with other Institution(s) 4. Orientation programmes on quality issues for teachers and students 5. Participation in NIRF process 6. Any other quality audit by recognized State, National or International agencies (ISO, NABH, NABL Certification, NBA, any other)	programs for teachers and students • NIRF details • Any other relevant document • Certificate of the quality audit		
7.1.2	***The Institution has facilities for alternate sources of energy and energy conservation measures***	• Geo tagged photos • Installation receipts	• The documents to be provided as per the options chosen by the institution	

	1. Solar energy 2. Biogas plant 3. Wheeling to the Grid 4. Sensor-based energy conservation 5. Use of LED bulbs/ power efficient equipment			
7.1.4	***Water conservation facilities available in the Institution:*** 1. Rain water harvesting 2. Borewell /Open well recharge 3. Construction of tanks and bunds 4. Waste water recycling 5. Maintenance of water bodies and distribution system in the campus	• Geo tagged photos • Installation or maintenance reports	• The documents to be provided as per the options chosen by the institution	
7.1.5	***Green campus***	• Geotagged photo Code of		

	initiatives include: 1. Restricted entry of automobiles 2. Battery-powered vehicles 3. Pedestrian-friendly pathways 4. Ban on the use of Plastics 5. Landscaping with trees and plants	conduct or visitor instruction displayed in the institution • Geo tagged photos of the facilities as the claim of the institution		
7.1.6	***Quality audits on environment and energy regularly undertaken by the Institution and any awards received for such green campus initiatives:*** • Green audit • Energy audit • Environment audit • Clean and green campus recognitions / awards • Beyond the campus	• Audit reports of the institution related to the metric (as per Annexure-1)	• The audit has to be performed by recognised agencies	

	environmental promotion activities			
7.1.7	***The Institution has disabled-friendly, barrier free environment*** • Built environment with ramps/lifts for easy access to classrooms. • Disabled-friendly washrooms • Signage including tactile path, lights, display boards and signposts • Assistive technology and facilities for persons with disabilities (*Divyangjan*) accessible website, screen-reading software, mechanized equipment • Provision for enquiry and	• Geo tagged photos of the facilities as per the claim of the institution		

	information : Human assistance, reader, scribe, soft copies of reading material, screen reading			
7.1.10	***The Institution has a prescribed code of conduct for students, teachers, administrators and other staff and conducts periodic programmes in this regard.*** 1. The Code of Conduct is displayed on the website 2. There is a committee to monitor adherence to the Code of Conduct 3. Institution organizes professional ethics	• Weblink of the code of conduct • Details of the monitoring committee of the code of conduct • Details of Programs on professional ethics and awareness programs	These documents are expected to be hosted in the website of the HEI for public access	

	programmes for students, 4. teachers, administrators and other staff 5. Annual awareness programmes on Code of Conduct are organized			