Standard Operating Procedures

of

Ethics Committee

of

King George's Medical University U.P. Lucknow

DCGI Registration No.: ECR/262/Inst/UP/2013

Sixth Edition

Modified Version – Sept 2014

1. Preamble:

King George's Medical College converted into a Medical University has a long history of excellence in research. Faculty of KING GEORGE'S Medical University U.P. has contributed to some leading innovations and discoveries which have lead to improvement in art and science of medicine. In keeping with advances in research and developments in realm of medical ethics, and to provide impetus to research, it was decided to expand the Ethics Committee in keeping with ICMR norms. Hence the following expanded Ethics Committee was formed as structured below:

Structure	**Time Period**
Chairperson (Preferably from outside the University and not the KGMUUP, Vice Chancellor or Dean or other office bearer)	3 Years
Two Basic Medical Scientist of the University and one Basic Medical Scientist from a reputed Institution **(Member)**	3 years
Two Senior Clinicians from various departments of the University **(Member)**	3 Years
One Legal Expert or retired Judge **(Member)**	3 years
One Social Scientist/ Representative of NGO **(Member)**	3 years
One Philosopher/ Ethicist/ Theologian **(Member)**	3 years
One Lay person **(Member)**	3 years
One Member Secretary from the University	Ex-officio

Prof. Mahendra Bhandari, Vice Chancellor, King George's Medical University addressing the 1st meeting of expanded Ethics Committee said that the main work of Ethics Committee is to protect the interest of the patient and to ensure that no harm in done. He said that that the Ethics Committee should facilitate and promote working of researchers. Ethics Committee has a major role for giving impetus to research so that all conflicts of interest must be shared by appropriate declaration.

2. Expansion of Ethics Committee:

2. A. Institutional Ethics Committee

2.A.1. The Ethics Committee of King George's Medical College was expanded vide Notice No. 01/R.Cell dated 22.09.2003 as under in accordance with ICMR norms and G.C.P. Guidelines:

1.	Chairperson	Prof. Devika Nag 24, New Berry Road, Lucknow	Chairperson	For a period of 2 years
2.	Senior Clinicians of the University	Prof. C. G. Agarwal, Head, Department of Medicine, CSMMUUP, Lucknow	Member	For a period of 2 years or till the retirement whichever is earlier.
3.	Basic Medical Scientist of the University	Prof. Nisha Mishra, Head, Department of Pharmacology, CSMMUUP, Lucknow	Member	For a period of 2 years or till the retirement whichever is earlier.
4.	Basic Medical Scientist of the University	Dr. Abbas Ali Mahdi, Assoc. Prof., Deptt. of Bio-chemistry, CSMMUUP, Lucknow	Member	For a period of 2 years
5.	Legal Expert	Mr. Sudhir Chandra Verma, Lokayukt, 14-B, Mal Avenue, Lal Bahadur Shastri Road, Lucknow	Member	For a period of 2 years
6.	Social Scientist/ Representative of NGO	Dr. (Mrs.) Indu Sahai, Deptt. of Anthropology, Lucknow University, Lucknow	Member	For a period of 2 years
7.	Philosopher/ Ethicist/ Theologian	Mr. Srikrishna Singhal, Deptt. of Astrology, Lucknow University, Lucknow	Member	For a period of 2 years
8.	Member Secretary	Faculty Incharge, Research Cell, Prof. Shally Awasthi	Member-Secretary	Ex-Officio

2.A.2. In partial modification in the notice No. 01/R.Cell dated 22.09.2003 the names of Dr. R. C. Srimal, Former Director, ITRC, Lucknow and Prof. Ashok Chandra, Deptt. of Medicine CSMMUUP, Lucknow were included as members of CSMMUUP-Ethics Committee vide notice No. 03/R.Cell Dated 13.11.2003 and notice No. 01/R.Cell-04 dated 07.04.2004, respectively for a period of 2 years each.

2.A.3. The name of Prof. A. K. Agarwal, Ex-Head, Department of Psychiatry, KGMC was included as members of CSMMUUP-Ethics Committee vide notice No. 03/R.Cell Dated 11.07.2005 for a period of 2 years.

2.A.4. In super session to previous notice No. 01/R.Cell-03, dated 22.09.2003, 03/R.Cell dated 13.11.2003, 02/R.Cell-04 dated 07.04.2004 and 03/R.Cell-05 dated 11.07.2005, the Institutional Ethics Committee was reconstituted as under in accordance with ICMR norms & GCP guidelines with effect from 21.09.2005 for a period of 3 years:

Structure	***Name***	***Tenure***
Chairperson	Prof. Devika Nag 24, New Berry Road, Lucknow	For a period of 3 years
Senior Clinicians of the University	1. Prof. C. G. Agarwal, Head, Department of Medicine, CSMMUUP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
	2. Prof. Ashok Chandra, Department of Medicine, CSMMUUP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
	3. Prof. A. K. Tripathi, Department of Medicine, CSMMUUP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
	4. Prof Sandeep Kumar Department of surgery (Gen), CSMMUUP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
Basic Medical Scientist of the University	1. Prof. Nisha Mishra, Head, Department of Pharmacology, CSMMUUP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
	2. Prof. Sunita Tewari, Department of Physiology, CSMMUUP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
Legal Expert	Hon. Justice Sudhir Chandra Verma, Lokayukt, 14-B, Mal Avenue, Lal Bahadur Shastri Road, Lucknow	For a period of 3 years
Social Scientist/ Representative of NGO	Prof. (Mrs.) Indu Sahai, Deptt. of Anthropology, Lucknow University, Lucknow	For a period of 3 years
Philosopher/ Ethicist/ Theologian	Prof. Srikrishna Singhal, Deptt. of Astrology, Lucknow University, Lucknow	For a period of 3 years
Basic Medical Scientist outside the University	Dr. R. C. Srimal, Ex-Director, ITRC, Lucknow	For a period of 3 years
Senior Clinicians	Prof. A. K. Agarwal Ex-Head, Department of Psychiatry,	For a period of 3 years

	CSMMUUP, Lucknow	
Member Secretary	Prof. Shally Awasthi Faculty In-charge, Research Cell,	Ex-Officio

2.A.5. The name of ***Dr. J. S. Srivastava***, *MBBS, MD (Psychiatry) DM (Clinical Pharmacology), MHSc (Bio-ethics),* Scientist-F, Deputy Director, Clinical & Experimental Medicine, Central Drug Research Institute, Lucknow was included as member of Institutional Ethics Committee with immediate effect upto 21st September 2008 vide notice No. 01/R.Cell-06 Dated 12.05.2006.

2.A.6 The Institutional Ethics Committee was reconstituted by the Hon'ble Vice Chancellor in accordance with ICMR norms and GCP guidelines w.e.f. 21st September 2008 for a period of 3 years vide notice No. 001/R.Cell-08 Dated 11.09.2008.

2.A.7 The name of Prof. A. K. Saxena, Department of Pharmacology, CSMMU UP was removed from the list of members of Institutional Ethics Committee vide notice No. 05/R.Cell-08 Dated 10.10.2008.

2.A.8 The name of Hon. Justice Shailendra Saxena was included as member of Institutional Ethics Committee with immediate effect upto 20th September 2011 vide notice No. 07/R.Cell-08 Dated 14.11.2008.

2.A.9 In partial modification to the notice no. 001/R.Cell 08 dated 10-09-08, **Dr. Madhu Pathak** was included as member of the Institutional Ethics Committee as **"Lay Person"** upto 20th September 2011 in place of Mrs. Sneh Lata Pushkar.

Institutional Ethics Committee Members (21st September 2008 to 20th September 2011):

Structure	***Name***	***Tenure***
Chairperson	Prof. U. C. Chaturvedi, Former Head, Deptt. of Microbiology	For a period of 3 years
Senior Clinicians of the University	1. Prof. Virendra Atam, Department of Medicine, CSMMU UP	For a period of 3 years or till superannuation whichever is earlier
	2. Prof. R. K. Garg, Department of Neurology, CSMMU UP	For a period of 3 years or till superannuation whichever is earlier
	3. Dr. Divya Mehrotra, Department of Oral & Max. Surgery, CSMMU UP	For a period of 3 years or till superannuation whichever is earlier

	4. Dr. Saumyendra Vikram Singh, Department of Prosthodontics, CSMMU UP	For a period of 3 years or till superannuation whichever is earlier
	5. Dr. Mohd. Parvez Department of Anesthesiology, CSMMU UP	For a period of 3 years or till superannuation whichever is earlier
Basic Medical Scientist of the University	1. Prof. Neena Srivastava, Deptt. of Physiology, CSMMU UP	For a period of 3 years or till superannuation whichever is earlier
	2. Prof. Abbas Ali Mahdi, Deptt. of Bio-chemistry, CSMMU UP	For a period of 3 years or till superannuation whichever is earlier
Legal Expert	1. Hon. Justice Karuna Kant Mishra	For a period of 3 years
	2. Hon. Justice Shailendra Saxena	upto 20th September 2011
Social Scientist/ Representative of NGO	Dr. Neelam Singh, Chief Functionary, Vatsalya, C-377, Indira Nagar, Lucknow	For a period of 3 years
Philosopher/ Ethicist/ Theologian	Dr. J. S. Srivastava, Scientist-F, Deputy Director, Clinical & Experimental Medicine, CDRI, Lucknow	For a period of 3 years
Basic Medical Scientist outside the University	Dr. C. L. Khetrapal, Ex-Vice Chancellor, Allahabad University Director, CBMR, SGPGIMS, Lucknow	For a period of 3 years
Senior Clinicians	Prof. Indu Wakhlu Ex-Head, Department of Pediatrics, CSMMU UP	For a period of 3 years
Lay person	Dr. (Mrs.) Madhu Pathak, B-739, Sector C, Opposite – SBI, Mahanagar, Lucknow	upto 20th September 2011
Member Secretary	Prof. Shally Awasthi Faculty In-charge, Research Cell,	Ex-Officio

2.A.10. The Institutional Ethics Committee was reconstituted by the Hon'ble Vice Chancellor in accordance with ICMR norms and GCP guidelines w.e.f. 21st September 20011 for a period of 3 years **vide notice no. 1557/R.Cell-11 dated 26-09-2011:**

Institutional Ethics Committee Members (21st September 2011 to 20th September 2014):

Structure	***Name***	***Tenure***
Chairperson	***Prof. P. K. Seth,*** Chief Executive Officer, Biotech Park, Lucknow	For a period of 3 years
Senior Clinicians of the University	1. ***Prof. A. K. Tripathi,*** Head, Department of Clinical Haematology, KGMU UP	For a period of 3 years or till superannuation whichever is earlier
	2. ***Prof. R. K. Dixit,*** Department of Pharmacology, KGMU UP	For a period of 3 years or till superannuation whichever is earlier

	3. ***Prof. A. A. Sonkar,*** Department of Surgery (Gen), KGMU UP	For a period of 3 years or till superannuation whichever is earlier
	4. ***Dr. R. A. S. Kushwaha,*** Department of Pulmonary Medicine, KGMU UP	For a period of 3 years or till superannuation whichever is earlier
	5. ***Dr. Avinash Agarwal,*** Department of Medicine, KGMU UP	For a period of 3 years or till superannuation whichever is earlier
	6. ***Dr. Amit Nagar,*** Department of Orthodontics, KGMU UP	For a period of 3 years or till superannuation whichever is earlier
Basic Medical Scientist of the University	1. ***Prof. Amita Jain,*** Department of Microbiology, KGMU UP	For a period of 3 years or till superannuation whichever is earlier
	2. ***Dr. Punita Manik,*** Deptt. of Anatomy, KGMU UP	For a period of 3 years or till superannuation whichever is earlier
Legal Expert	***Hon. Justice Vishnu Sahai*** (Retd.)	For a period of 3 years
Social Scientist/ Representative of NGO	***Sri C. K. Rastogi*** Hari Om Seva Sansthan, Lucknow	For a period of 3 years
Philosopher/ Ethicist/ Theologian	***Dr. J.S. Srivastava,*** Deputy Director, Clinical & Experimental Medicine, Central Drug Research Institute, Lucknow	For a period of 3 years
Basic Medical Scientist outside the University	**Dr. Madhu Dikshit,** Head, Division of Pharmacology, C.D.R.I., Lucknow	For a period of 3 years
Senior Clinicians	***Prof. Ramesh Chandra,*** Former Principal, King George's Medical College, Lucknow	For a period of 3 years
Lay person	***Dr. Gopal Chaturvedi,*** Chairman, Bhasha Sansthan, U.P., Lucknow	For a period of 3 years
Member Secretary	***Prof. Shally Awasthi*** Faculty In-charge, Research Cell,	Ex-Officio

2.A.11. In partial modification, to notice no. 1557/R.Cell-2011 dated 26-09-2011, Dr. J.S. Srivastava was included as member of the Institutional Ethics Committee as "Philosopher/ Ethicist/ Theologian" in place of Dr. S.K. Goel.

2.A.12. In partial modification and in continuation to notice no. 1557/R.Cell-2011 dated 26-09-2011, the name of Prof. Ramesh Chandra was included as member of the Institutional Ethics Committee as "Senior Clinician" in place of Prof. A. M. Kar.

2.A.13. As Member Secretary of Institutional Ethics Committee is an ex-officio post Hon'ble Vice Chancellor has nominated Prof. R. K. Garg, Faculty Incharge, Research Cell as the Member Secretary of Institutional Ethics Committee of King George's Medical University, UP, Lucknow in place of Prof. Shally Awasthi, Former Faculty Incharge, Research Cell w.e.f. 12th June 2014.

2.B.1. Current Institutional Ethics Committee

The Institutional Ethics Committee has been reconstituted by the Hon'ble Vice Chancellor in accordance with ICMR norms and GCP guidelines w.e.f. 21st September 20014 for a period of 3 years **vide notice no. 1/R.Cell-14 dated 26.08.2014 and revised vide notice no. 02/Ethics/R.Cell-15 dated 11.08.2015:**

Structure	Name	Tenure
Chairperson	***Prof. P.K. Misra,*** Former Principal, K.G's Medical College, Lucknow.	For a period of 3 years
Senior Clinicians of the University	1. ***Prof. V.S. Narain,*** Department of Cardiology, KGMU, UP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
	2. ***Prof. Shally Awasthi,*** Department of Paediatrics, KGMU, UP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
	3. ***Prof. Anupam Mishra,*** Department of E.N.T, KGMU, UP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
	4. ***Prof. Rajesh Verma,*** Department of Neurology, KGMU, UP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
	5. ***Dr. Balendra Pratap Singh*** Department of Prosthodontics, KGMU, UP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
	6. ***Dr. Mayank Singh,*** Department of Prosthodontics, KGMU, UP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
Senior Clinicians/Basic Scientists outside of the University	1. ***Dr. S.P.S. Gaur,*** Ex-Chief Scientist, Division of Clinical & Experimental Medicine, C.D.R.I., Lucknow	For a period of 3 years
	2. ***Dr. Surjit Bhattacharya,*** Sr. Consultant, Plastic Surgeon Sahara Hospital, Lucknow	For a period of 3 years
Basic Medical Scientist of the University	1. ***Prof. Amita Jain,*** Department of Microbiology, KGMU, UP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
	2. ***Prof. Rajendra Nath,*** Department of Pharmacology KGMU, UP, Lucknow	Till the end the term of committee or till superannuation whichever is earlier

Legal Expert	***Hon. Justice Vishnu Sahai (Retd.)***	For a period of 3 years
Lay Person	***Dr. S. K. Singhal,*** Centre of Human Excellence, Institute of Vedic Sciences, Lucknow	For a period of 3 years
Social Activist/Legal Expert	***Nawab Jafar Mir Abdullah*** Sheesh Mahal, Durga Devi Marg, Lucknow	For a period of 3 years
Member Secretary	***Prof. R.K. Garg,*** Faculty In-charge, Research Cell, KGMU, UP, Lucknow	Ex-Officio

The current "ADR Sub-Committee" consists of following members**:**

Structure	**Name**	**Tenure**
Chairperson	***Dr. S.P.S. Gaur,*** Ex-Chief Scientist, Division of Clinical & Experimental Medicine, C.D.R.I., Lucknow	For a period of 3 years
Senior Clinicians of the University	1. ***Prof. Rajesh Verma,*** Department of Neurology, KGMU, UP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
	2. ***Dr. Balendra Pratap Singh*** Department of Prosthodontics, KGMU, UP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
Basic Medical Scientist of the University	1. ***Prof. Amita Jain,*** Department of Microbiology, KGMU, UP, Lucknow	For a period of 3 years or till superannuation whichever is earlier
	2. ***Prof. Rajendra Nath,*** Department of Pharmacology KGMU, UP, Lucknow	Till the end the term of committee or till superannuation whichever is earlier
Legal Expert	***Hon. Justice Vishnu Sahai (Retd.)***	For a period of 3 years
Lay Person	***Dr. S. K. Singhal,*** Centre of Human Excellence, Institute of Vedic Sciences, Lucknow	For a period of 3 years
Social Activist/Legal Expert	***Nawab Jafar Mir Abdullah*** Sheesh Mahal, Durga Devi Marg, Lucknow	For a period of 3 years
Member Secretary	***Prof. R.K. Garg,*** Faculty In-charge, Research Cell, KGMU, UP, Lucknow	Ex-Officio

3. Standard Operating Procedures

3.A. Decisions of First Ethics Committee Meeting regarding Standard Operating Procedures:

The first meeting of Institution Ethics Committee was held on 18th October 2003 in which the committee decided on the following aspects which have been incorporated in the standard operating procedures of Ethics Committee:

3.A.1. Frequency of meetings:

It was decided that the Ethics Committee will meet about once in 3 months.

3.A.2. Quorum requirement:

It was decided that the quorum would consist of a minimum of 5 persons at any time, including the chairperson and secretary.

3.A.3. Independent consultants:

The committee agreed to establish the process of calling/consulting independent consultants to provide special expertise who can belong to legal, ethical, methodology, disease, community, patients, and special interest groups on case-to-case basis.

3.A.4. Elements of review:

It was decided that review should be based on scientific design and conduct of study; ensure care and protection of research participants; protect research participant's confidentiality; have community considerations and have informed consent process both in English and local language, that is Hindi **(Annexure –1)**.

3.A.5. Presentation by researchers:

It was decided that in special case provision can be made for presentation by researchers. For "review/clarify" of disallowed projects personal presentation is also acceptable and will be reviewed by a subcommittee, if constituted by the Chair.

3.A.6. Expedited Review:

It was decided that expedited review can be done by circulation and there must be an immediate response (7 days). Time factor for review process must be kept to a minimum. Whether the review be done by all or few

members will depend on the subject and at the discretion of the Chairperson. 1-2 members of committee along with Chairperson can be called for expedited review. All expedited reviews would be ratified at the next meeting of the EC.

3.A.7. Waiver:

The Chairperson will decide about the waiver if needed. All projects done in the institution should come to ethical committee which will then decide whether it is a "non-research work" and therefore eligible for waiver. Standardized waiver form will be used by researcher at the time of submission of proposal. **(Annexure – 2)**

3.A.8. Suggested decisions made by committee:

For all new proposals reviewed the committee will come to one of the following decisions:

- Approval as submitted
- Withheld approval contingent upon specific revisions- Chair alone will approve the revisions.
- Tabled for substantive change- Full EC will approve changes.
- Disapproval

It was decided that if a proposal has been disapproved then the person could resubmit it for review to the committee.

3.A.9. Decision process:

All the proposals will be approved by consensus (i.e. agreement among all members); and in case of disagreement decision will be based on voting by members and be approved if majority votes in favour of proposal.

3.A.10. Communicating decision:

- *Process of communicating*: Minutes documented by the Secretary will be distributed in form of hardcopy to each member. Each member has to give his/her comments /suggestions within a stipulated time frame of 7 days in writing.

- It was decided that suggestions/comments on minutes by each member will be incorporated in the final copy as such or following discussions.

- Chairperson will sign the final minutes.

- Communication to researchers will be done by secretary's signature.

- It was decided that a brief CV of all members will be maintained at the institutional office. The C.V. will to contain the following: Name; Address; Professional qualification; Area of expertise; Current affiliation if any**.**

3.A.11. Follow-up:

Approved projects will be followed for

- Adverse Drug Reaction Report: Adverse drug reactions if any during the course of the project will be reported.
- Annual progress report will be reported in a standardized format. **(Annexure–3)**

3.A.12. Distribution of review work:

New Proposal:

Review proposals have to come to full committee. Full proposals must have an executive summary in a standardized format. **(Annexure-4)**

Revised Proposal:

In case of minor amendments the investigator will state what changes have been made. This will be subject to approval by the Chair. If there are major modifications the Chair may place the proposal before full committee for approval.

3.A.13. Depending on the specialized area of the proposal, the Chair may direct the secretary to obtain review by an expert prior to consideration for ethical approval by the EC. The reviewer has to give comments in writing on scientific merit and feasibility to assist in the decision of the EC. Chairperson

will identify the name of the external reviewer. Members of EC can suggest names of external reviewers to the Chair for approval.

3.A.14. Special cases:

It was decided

- That in case if any member is unable to attend the meeting, he/she can send his/her written comments in absentia.
- To adjourn meeting in absence of Chairperson / Secretary
- No documenter needed amongst ethical committee members.

3.A.15. The committee was in favour of a standard format for submission of proposals.

- Protocol must have all necessary sections to give a complete and holistic picture and be send in a particular fixed format
- In case legal advice is needed, the secretary will flag relevant sections in proposal.
- Executive Summary. Each proposal must be accompanied by an executive summary in a specified format laid down.

3.A.16. The sponsors will now have to submit a fee of Rs. 35,000/- at the time of submission of any new drug trial for review of Institutional Ethics Committee and Rs. 5,000/- for review of modifications through a Demand Draft in favour of "Vice Chancellor, KGMU".

3.B. Decisions of Second Ethics Committee regarding Standard Operating Procedures:

The second meeting of Institution Ethics Committee was held on 13th December 2003 in which the committee decided on the following aspects which has been incorporated in the standard operating procedures of Ethics Committee:

3.B.1. The ethics committee will not under usual circumstances take up more than 15 new proposals for clearance in one sitting. To avoid inconvenience to researchers, additional meeting/s can be called by the Chair within a fortnight.

3.B.2. The ethics committee will not under usual circumstances take up proposals not listed in the agenda for review under "Other matters" with permission of the Chair.

3.B.3. Member secretary will give a time line for response to the proponents for modifications recommended by the committee in new/modified proposals. She will ensure with reasonable certainly within the stipulated time that the proponents have received communications from the committee. Non-adherence to time line will result in dropping of the proposal from the agenda.

3.B.4. Members will sign to confirm their participation in all meetings including the past and current one.

3.C. Decisions of Third Ethics Committee regarding Standard Operating Procedures:

The third meeting of Institution Ethics Committee was held on 31st January 2004 in which the committee decided on the following aspects which has been incorporated in the standard operating procedures of Ethics Committee:

3.C.1 It was pointed out that certain funding agencies require ethical approval in special formats. Member secretary can issue the same and inform the ethics committee about it.

3.D. Decisions of Fifth Ethics Committee regarding Standard Operating Procedures:

The fifth meeting of Institution Ethics Committee was held on 24th April, 2004 in which the committee decided on the following aspects which has been incorporated in the standard operating procedures of Ethics Committee:

3.D.1. It was decided that since most members of the ethics committee are competent scientists, some of national and international eminence, the committee will also review the proposals for adequacy of research methodology along with the ethical review. This reinforced 3.A.4.

3.D.2. It is recommended that current Institutional Mechanisms will be followed for review of research work done for theses purpose. Research works will not be considered for post -hoc ethical clearance ordinarily.

3.E. Decisions of Sixth Ethics Committee Meeting regarding Standard Operating Procedures:

The sixth meeting of Institution Ethics Committee was held on 10th July 2004 in which the committee decided on the following aspects which has been incorporated in the standard operating procedures of Ethics Committee:

3.E.1. For extra-mural funding through industry, the sponsor must sign a memorandum of understanding (MOU) with the university clearly stating the budget approved for the project, benefits provided to the subjects, investigators and university for participation in the study, intellectual property rights of the research findings as well as publications and dissemination policy including the use of name of investigators and/or university. It is recommended that 25% of total budget (less the cost of equipment) be provided as institutional overheads. **(Annexure 5 & 6)**

3.E.2. Ethics committee will only consider proposals submitted with a budget with justifications. Research cell has to include this as essential requirement in its checklist for accepting proposal submissions.

3.E.3. Funding for projects cleared by the ethics committee can only be received in the name of "Vice Chancellor, King George Medical University". This information has to be circulated to all faculty members.

3.E.4. Ethics Committee is not responsible for any rights claimed by the patients or investigators and they are not liable to be contacted. This information has to be circulated to all faculty members as well as written along with letters of approval. Investigators of projects approved by the ethics committee, since inception, have to be informed accordingly.

3.E.5. Investigators have to sign an undertaking stating they are responsible to ensure safely and best available care of patients enrolled for the duration of the research project. Format of MOU can be requested from SGPGI for reference and a standard format be prepared for CSMMUUP. This information has to be circulated to all faculty members.

3.E.6. Chairperson should be sent all communications received in the name of ethics committee along with full proposals. Executive summary of all proposals should be all other members. For technical review, full proposal, either new submission or modification/addition to an approved proposal, should be send to at least one competent member of the ethics committee. This member must provide comments in writing, along with his/her signature, at the time of the meeting. If the member cannot attend the meeting, the comments can be sent in advance and taken in absentia.

3.E.7. Legal and non-medical aspects of proposal, either new submission or modification/addition to an approved proposal, should similarly be sent to competent member/s of the ethics committee. Concerned member/s must provide comments in writing, along with his/her signature, at the time of the meeting. If the member cannot attend the meeting, the comments can be sent in advance and taken in absentia.

3.F. Decisions of Eighth Ethics Committee Meeting regarding Standard Operating Procedures:

The eighth meeting of Institution Ethics Committee was held on 6th November 2004 in which the committee decided on the following aspects which has been incorporated in the standard operating procedures of Ethics Committee:

3.F.1. Modification in checklist for submission of new proposal for ethical review in KGMUUP is approved **(Annexure –7).**

3.F.2. It was decided that for Industry sponsored projects:

- There is a need to pay stamp duty of Rs. 100/- for Indemnity bond.
- MOU will be a part of this bond
- Tripartite agreement is needed
- Indian agents can sign on behalf of foreign sponsor
- Vice Chancellor is the only fit person as an arbitrator in case of dispute.

3.G. Decisions of Twelfth Ethics Committee Meeting regarding Standard Operating Procedures:

The twelfth meeting of Institution Ethics Committee was held on 23rd July 2005 in which the committee decided on the following aspects which has been incorporated in the standard operating procedures of Ethics Committee:

3.G.1. For independent research work the Principal Investigator/Investigator has to act independently and no honourarium/salary is expected to be paid/ received. The Ethical Committee is of the opinion that payment of remuneration in the form of honourarium should be totally prohibited. However collateral, miscellaneous and contingency could be included in grants.

3.G.2. The grant received by the Principal investigator should come in a consolidated form and not in form of grant for individual patient recruitment.

3.H. Decisions of Thirteen Ethics Committee Meeting regarding Standard Operating Procedures:

3.H.1. The members of Ethics Committee will maintain confidentiality with regards deliberations during the meeting. The final and approved minutes will only be made public.

3.H.2. Members of Ethics committee will declare conflict of interest with proponent and/or projects at the initiation of meeting. They will not be part of deliberations on projects submitted by self, siblings, spouse, children, parents and first degree relatives. In case they abstain from participation for other reasons they have to agree with the decisions of the Ethics Committee.

3.H.3 When there are more than 3 ADR reports for review from a particular project, the Principal Investigator has to submit a composite summary indicating types and frequency of ADR and their place of occurrence.

3.I. Decisions of Nineteenth Ethics Committee Meeting regarding Standard Operating Procedures – 23rd Sept 2006

3.I.1 Validity of Ethical approval for a study is for one year only. If the study has not been initiated within the time frame, the approval automatically gets cancelled.

3.J. Decisions of Twenty Eighth Ethics Committee Meeting regarding Standard Operating Procedures - *29th March 2008*

3.J.1 If legal expert is not available then drug trials will not be reviewed in the Ethics Committee Meeting.

3.J.2 No multicentric studies involving drug trial will be undertaken for expedited review. A circular to all faculty members must be send to this effect

3.K. Decisions of Thirtieth Ethics Committee Meeting regarding Standard Operating Procedures – 2nd August 2008

3.K.1 Clinical trial insurance must be made mandatory in future trials sponsored by Pharmaceutical Companies. This has to be circulated to all departments.

3.K.2 In acute psychosis use of placebo as one arm will not be permissible.

3.K.3 Consent from Guardian or next friend must also be obtained in acute psychotic patients. Hence "double" consent is mandatory

3.L. Decisions of Fourteenth Ethics Committee Meeting regarding Standard Operating Procedures – 17th May 2013

3.L.1 An ADR sub-committee has been formed from among members of existing Institutional Ethics Committee under the chairperson ship of Prof. Ramesh Chandra, the committee consist of Hon. Just. Sri Vishnu Sahai, Prof. R. K. Dixit and Prof. R.A.S. Kushwaha. It will be convened by Prof. S. Awasthi, Member Secretary of the Ethics Committee, whenever local ADR occurs. The sub-committee will report to the Chairperson of Institutional Ethics Committee vide this office notice no. 01/R.Cell-13 dated 14-06-2013.

3.L.2 Legal document of death is a government death certificate.

3.L.3 Documents informing about death have to be countersigned by District Magistrate.

3.L.4 Principal Investigator to certify the causal relation of death on his/her letter head

3.M. Decisions of Fifteenth Ethics Committee Meeting regarding Standard Operating Procedures – 20th July 2013

3.M.1 A fees of Rs. 25000/- (Rs. Twenty Five Thousand) will be charged for the ethical review of drug trials sponsored by pharmaceutical companies and alike with effect from 19th July 2013. The sponsors will have to submit a fee of Rs.

25000/- (Rs. Twenty Five Thousand) through a Demand Draft in favour of "Vice Chancellor, KGMU" at the time of submission of any new drug trial for review of Institutional Ethics Committee of KGMU, prospectively, vide letter no. 4890/R.Cell-13 dated 19-07-2013.

3.M.2 Fees for the ethical review of drug trials sponsored by pharmaceutical companies and alike has been revised w.e.f 31st July 2015, the sponsors will now have to submit a fee of Rs. 35,000/- at the time of submission of any new drug trial for review of Institutional Ethics Committee and Rs. 5,000/- for review of modifications through a Demand Draft in favour of “Vice Chancellor, KGMU”.

ANNEXURE - 1

Standard Format Informed Consent Form in English & Hindi

Title of Project:

Investigators (Name & Affiliation):

Collaborators (if any):

Potential funding agency:

Patient/Parent/Guardian Consent

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

Patient/Parent/Guardian Consent

I have had the study explained to me and have read the contents of this form/had the contents of this form read to me. I have been given the opportunity to ask question and have them answered to my satisfaction.

I am willing for my child to be enrolled in the study

Name of subject:

Signature of Patient/Parent/Guardian:

Name of Patient/Parent/Guardian:

Date:

Relationship to 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:

ANNEXURE - 2

THE INSTITUTIONAL ETHICS COMMITTEE
King George's Medical University U.P., Lucknow

Human Subjects Review Waiver Form

Protocol/Project Title:

Principal Investigator (s):

Determination: KGMUUP-Ethics Committee review is NOT required for this project, because:

I. Activity is not research. Activity is a disease control activity with no research component.

A. Epidemiologic/endemic disease control activity, data collected are directly relevant to disease control needs.

B. Surveillance activity, data used for disease control program or policy purposes.

C. Demonstration project which may or may not include evaluation.

OR

II. Activity is not research NOT involving identifiable human subjects.

All of the following are required:

A. No contact with human subjects is/was involved for this subject…….....and...…..…....

B. Data or specimens are/were collected for another purpose ...…….....and...…..…....

C. No extra data/specimens are/were collected for this purpose……..and...…….....

D. Identifying information was (or will be) either not obtained or was (or will be) removed before analysis so that data cannot be linked or re-linked with identifiable human subjects.

OR

III. Activity is research involving collection/analysis of data about units other than individual persons.

Additional Comments:

However, Ethics Committee review is not required in this instance research, proper consideration must be given to:

1. the risks to the subjects,
2. the anticipated benefits to the subjects and others,
3. the importance of the knowledge that may be reasonably be expected to result,
4. the informed consent process to be employed,
5. the provisions to protect the privacy of subjects, and
6. any appropriate additional safeguards for vulnerable populations.

OTHER COMMENTS:

Signed:_____ _____

KGMU UP Ethics Committee Chairperson Date

ANNEXURE – 3

Standard Format for Annual Progress Report

(up to 5 pages)

1. Title of Project:
2. Investigators (Name & Affiliation):
3. Collaborators (if any):
4. Potential Funding Agency:
5. Hypothesis and Objectives:
6. Progress against activities planned:
7. If planned activities did not occur, provide explanation:
8. Preliminary observations / results, if any:
9. Obstacles:
10. Future plans for upcoming quarter:
11. Comments, if any:

ANNEXURE – 4

Standard Format for Executive Summary

to be submitted for Ethical Approval

(up to 5 pages)

1. Title of Project:
2. Investigators (Name & Affiliation):
3. Collaborators (if any):
4. Potential Funding Agency:
5. Background and Brief Review of Literature with references:
6. Hypothesis and Objectives:
7. Study design and methods:
8. Intervention:
9. Setting:
10. Inclusion and exclusion criteria:
11. Sample size for primary outcomes:
12. Data Management and Analysis:
13. Ethical clearances:
14. Time Line:

ANNEXURE – 5

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.

5.

Responsibilities of KGMU UP

1.

2.

3.

4.

5.

Responsibilities of Second Party

1.

2.

3.

4.

5.

Responsibilities of Third Party

1.

2.

3.

4.

5.

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.

5.

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/-***

INDEMNITY AGREEMENT

The indemnity agreement is between KING GEORGE'S Medical University U.P., Lucknow, U.P., India (hereinafter KGMU UP) through Principal Investigator and _____ _____ the authorized Signatory of Second party

(Name of the second party/sponsor)

(hereinafter SPONSOR)

whereas KGMUUP engages in medical research that involves experimental and investigational products, drugs devices or therapy and

whereas SPONSOR owns or has right to such experimental or investigational products, drugs devices specifically as it relates to this agreement, products devices, drugs shall mean the following:

1.
2.
3.
4.
5.

Whereas KGMUUP and SPONSOR have agreed that KGMUUP will use SPONSOR's experimental and investigational products, devices, drugs for research purposes.

Now therefore, the parties agree as follows:

1. ***Undesirable side effects, injuries, illness or reactions:***
   The SPONSOR agrees to indemnify, protect, defend and hold harmless KGMUUP, its officers, employees against cost or expenses associated with the diagnosis and treatment of undesirable side effects, injuries, illness or reactions that arise specifically from SPONSOR's products, devices, drugs.

2. ***Loss, Damage or Liability:***

The SPONSOR agreed to indemnify, protect, defend and hold harmless KGMUUP, its officers, employees from any loss, damage or liability they may suffer or incur as a result of claims or demands made against them that arise specifically from research involving SPONSOR's products, devices, drugs.

3. ***Insurance:***

The SPONSOR agrees to maintain inforce at its sole cost and expense with reputable insurance companies, Insurance of a type and in amounts equal to atleast _____ per occurrence combined

(specify the amount of money)

single limit and _____ annual

(specify the amount of money)

aggregate. KGMUUP shall have the right to request the appropriate certificates of insurance from SPONSOR for purposes of ascertaining the sufficiency of coverage.

4. ***Attorneys and legal coverage:***

The SPONSOR agrees to provide, at its own expense, attorneys to defend against any claims made or action filed against KGMUUP its officers, employees. The SPONSOR also agrees to pay any settlement amounts or judgments levied against KGMUUP or any losses or expenses incurred by KGMUUP resulting from such claims or action.

5. ***Cooperation of parties***

KGMUUP (Principal Investigator) agrees to notify promptly, SPONSOR in writing when any undesirable side effect, injury, illness or reaction arises from research involving SPONSOR's products, devices, drugs. KGMUUP agrees to cooperate with SPONSOR in defending any claim or action covered by this agreement. The SPONSOR agrees to consult on a regular basis with KGMUUP regarding the defense or settlement of any claim or action. Neither party will compromise or settle any claim or action without prior written consent of the other party.

6. ***Other***

This indemnity agreement does not displace, supercede or in any way limit any other agreements between the parties.

Signed for and on behalf of KGMUUP

Name_____

Signature_____

Seal_____

Date_____

Signed for and on behalf of SPONSOR

Name_____

Signature_____

Seal_____

Date_____

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

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

Check List for submitting Research Proposals for clearance of Ethical Committee

PART I

1. Title of the Project : _____

   _____

2. Investigator's Name & Department : _____

3. Source of Funding : _____

4. Check List:

S. No.	***Particulars***		***Yes***	***No***	***If No (Give Reason)***
a.	Executive Summary (Proposal/Modification)				
b.	New Proposal or Modification				
c.	Informed consent form	(a) English			
		(b) Hindi			
d.	Budget				
e.	Memorandum of Understanding (Industry Sponsored Projects)				
f.	Indemnity Agreement (Industry Sponsored Projects)				

5. Whether the project involves

   5.1. Clinical trial with new drug(s) device(s) approved by DCGI Yes/No

   5.2. Clinical trial with existing drug(s) device(s) approved by DCGI Yes/No

   5.3. Clinical trial with traditional medicines from Ayurvedic/ Unani/ Homeopathy/ Tribal systems Yes/No

   5.4. None of the above

   CAUTION NO DRUG/DVICE IS TO BE USED UNLESS APPROVED BY DRUG CONTROLLER OF INDIA

If answer to 5.1. is yes, kindly furnish evidence of experimental and clinical safety of the drug (Use separate sheets)

6. If the human material to be collected is human tissue specify the tissue (_____ _____)

6.1. It will be obtained by Operation/Biopsy/ Abortion /Autopsy Other (Specify _____ _____)

6.2. Whether the procedure required to obtain the tissue is otherwise indicated for the management of the patient Yes/No

6.3. Whether the project involves normal human tissue Yes/No

If answer to 6.2 is yes please explain the full procedure and justify collection and use of material (Use separate sheets)

6.4. Will it be collected in amounts in excess of which would otherwise be collected for the management of patient Yes/No

If answer to 6.4 is yes then specify the excess amount

…….ml at a time

…….ml total

6.4. (a) Will it be collected by extraperipheral venous puncture which would otherwise be required for the management of the patient Yes/No

If answer to 6.4.(a) is yes then specify the total number of peripheral venous punctures (_____)

6.4. (b) Will it be collected by a method which would otherwise not be required for the management of the patient? Yes/No

If answer to 6.4.(b) is yes then specify the method (_____)

7. Any other human material (Specify_____) If answer to 7 is yes then answer 7.1. and 7.2. below

7.1. Specify the method of collection (_____ _____)

7.2. Specify the amount to be collected (_____)

PART II

(DECLARATION BY THE PRINCIPAL INVESTIGATOR)

I hereby declare that:

1. Voluntary written consent of the human subject will be obtained.

2. In case of children and mentally handicapped subjects-voluntary written informed consent of the parents/guardians will be obtained.

3. The probable risk involved in the project will be explained in full details to the subjects/parents/guardians.

4. Subjects/parents/guardians will be at liberty to opt out of the project at any time.

5. I will terminate the experiment at any stage, if I have probable cause to believe, in the exercise of the good faith, skill and careful judgement required for me that continuation of the experiment is likely to result in injury, disability of death to the experimental subject.

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

Deptt._____

PART III

(DECLARATION BY THE PRINCIPAL INVESTIGATOR/HEAD OF THE DEPTT.)

1. Is The Department/University ready to undertake the responsibility of the human subjects in case of injury? Yes/No
   If yes, then will it include
   - Transportation charges Yes/No
   - Hospitalization charges Yes/No
2. Do you think that the experiments are so designed that they would yield meaningful results that could not be obtained by the other method? Yes/No
3. Do you think that the animal experiments carried put support the need for clinical experimentation? Yes/No
4. Do you think that the experiments would be conducted in a manner to avoid all unnecessary physical and mental suffering and injury? Yes/No
5. Do you think the experiments have been planned in a manner so that the degree of risk to be taken would never exceed that determined by the humanitarian importance of the problem to be solved by the experiment? Yes/No
6. Do you think that proper preparations would be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, Disability or death; Yes/No
7. Do you think that safeguards have been taken to see that the experimentation would be conducted only by scientifically qualified persons who possess the requisite competence, experience and qualities to carry out the research? Yes/No

(Signature of Principal Investigator) ***(Signature of Head of the Deptt.)***

Date of Receiving_____ ***(Signature)***
On behalf of Research Cell