

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)

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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-maleficence 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.cdsc.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 <input type="checkbox"/>	Central <input type="checkbox"/>	State <input type="checkbox"/>	Institutional <input type="checkbox"/>
	b) Private <input type="checkbox"/>			
2. International	a) Government <input type="checkbox"/>	Private <input type="checkbox"/>		UN Agencies <input type="checkbox"/>
3. Industry	a) National <input type="checkbox"/>	Multinational <input type="checkbox"/>		
4. Contact address of sponsor				
5. Budget				

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



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 <input type="checkbox"/>	Children <input type="checkbox"/>	Elderly <input type="checkbox"/>
Fetus <input type="checkbox"/>	Illiterate <input type="checkbox"/>	Handicapped <input type="checkbox"/>
Terminally ill <input type="checkbox"/>	Seriously ill <input type="checkbox"/>	Mentally Challenged <input type="checkbox"/>
Economically & socially backward <input type="checkbox"/>	Any other <input type="checkbox"/>	

vii. Special group subjects Yes No

(Tick the appropriate boxes)

Captives <input type="checkbox"/>	Institutionalized <input type="checkbox"/>	Employees <input type="checkbox"/>
Students <input type="checkbox"/>	Nurses / Dependent <input type="checkbox"/>	Armed Forces <input type="checkbox"/>
Any other <input type="checkbox"/>	Staff <input type="checkbox"/>	

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 abortions. 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



<p>a. Sample will be sent abroad because (Tick appropriate box)</p> <p>Facility not available in India <input type="checkbox"/></p> <p>Facility in India inaccessible <input type="checkbox"/></p> <p>Facility available but not being accessed <input type="checkbox"/></p> <p>If so, reasons</p> <p>b. Has necessary clearance been obtained Yes <input type="checkbox"/> No <input type="checkbox"/></p>															
<p>8. Consent * Written <input type="checkbox"/> Oral <input type="checkbox"/> Audio-Visual <input type="checkbox"/></p>															
<p>i. Patient Information Sheet attached: (Tick the included elements) Yes <input type="checkbox"/> No <input type="checkbox"/></p>															
Understandable language	<input type="checkbox"/>	Alternatives to participation	<input type="checkbox"/>												
Statement that study involves research	<input type="checkbox"/>	Confidentiality of records	<input type="checkbox"/>												
Sponsor of study	<input type="checkbox"/>	Contact information	<input type="checkbox"/>												
Purpose and procedures	<input type="checkbox"/>	Statement that consent is voluntary	<input type="checkbox"/>												
Risks & discomforts	<input type="checkbox"/>	Right to withdraw	<input type="checkbox"/>												
Benefits	<input type="checkbox"/>	Consent for future use of material biological	<input type="checkbox"/>												
Compensation for participation	<input type="checkbox"/>	Benefits if any on future commercialization e.g. Genetic basis for drug development	<input type="checkbox"/>												
<p><input type="checkbox"/> Compensation for study related injury <input type="checkbox"/></p> <p><input type="checkbox"/> Translation of information sheet in local language <input type="checkbox"/></p>															
<p>ii. If healthy volunteers will be included, information sheet for them attached Yes <input type="checkbox"/> No <input type="checkbox"/></p>															
iii. Consent form in English	<input type="checkbox"/>	Hindi	<input type="checkbox"/>												
iv. Who will obtain consent (PI/Co-PI)	<input type="checkbox"/>	Nurse / Cousellor	<input type="checkbox"/>												
Research Staff	<input type="checkbox"/>	Any other	<input type="checkbox"/>												
<p>* If written consent is not obtained, giver reasons:</p>															
<p>9. Will any advertising be done for recruitment of Subjects? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>(Posters, flyers, brochure, websites – if so attach a copy)</p>															
<p>10. Risks & benefits</p>															
<p>i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country? Yes <input type="checkbox"/> No <input type="checkbox"/></p>															
<p>ii. Is there physical / social / psychological risk / discomfort? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>if yes, Minimal or no risk <input type="checkbox"/></p> <p>More than minimum risk <input type="checkbox"/></p> <p>High risk <input type="checkbox"/></p>															
<p>iii. Is there benefit</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 30%;"></td> <td style="width: 30%;">a) to the subject?</td> <td style="width: 20%;">Yes <input type="checkbox"/></td> <td style="width: 20%;">No <input type="checkbox"/></td> </tr> <tr> <td></td> <td></td> <td>Direct <input type="checkbox"/></td> <td>Indirect <input type="checkbox"/></td> </tr> <tr> <td></td> <td>b) to the society?</td> <td>Yes <input type="checkbox"/></td> <td>No <input type="checkbox"/></td> </tr> </table>					a) to the subject?	Yes <input type="checkbox"/>	No <input type="checkbox"/>			Direct <input type="checkbox"/>	Indirect <input type="checkbox"/>		b) to the society?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	a) to the subject?	Yes <input type="checkbox"/>	No <input type="checkbox"/>												
		Direct <input type="checkbox"/>	Indirect <input type="checkbox"/>												
	b) to the society?	Yes <input type="checkbox"/>	No <input type="checkbox"/>												
<p>11. Data monitoring</p>															
<p>i. Is there a data & safety monitoring committee/Board (DSMB)? Yes <input type="checkbox"/> No <input type="checkbox"/></p>															
<p>ii. Is there a plan for reporting of adverse events? Yes <input type="checkbox"/> No <input type="checkbox"/></p>															



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? Yes No

If yes, by

Sponsor Investigator

Insurance Company Any other

13. Do you have conflict of interest? Yes No

(Financial / Non financial)

If yes, specify

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:		Date:
(Signature Required)		



**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 nor 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, उ०प्र०, 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 उद्देश्य:-
अध्ययन की प्रक्रियाएं:-
अध्ययन से जोखिम:-
अध्ययन से लाभ:-
सम्भावित जटिलताएं:-
क्षतिपूर्ति:-
गोपनीयता:-
प्रतिभागी के अधिकार:-
अध्ययन में भागीदारी के विकल्प:-

भाग-2

1. मेरी पुष्टि है कि मैंने 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 मैं बिना कोई कारण बताए किसी भी समय अपनी चिकित्सीय देखभाल या कानूनी अधिकारों पर प्रभाव पड़े बिना हट जाने के लिए स्वतंत्र हूँ।
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 स्वार्थी अभिलेखों को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी, भले ही मैं इस परीक्षण से हट ही क्यों न जाऊँ। तथापि मैंने समझ लिया है कि तृतीय पक्ष



को दी गई या प्रकाशित की गई किसी जानकारी में मेरी पहचान को उजागर नहीं किया जाएगा।

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

सहभागी के हस्ताक्षर या अगूठे 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 में आने वाली भाषा में, 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/ Attended	Meeting	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)

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

Signature

Name

Designation

Seal

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
<i>Chairman</i>	1. Prof. S.P.S. Gaur, Retd. Director, CDRI, Lucknow	For a max. period of 3 years
<i>Senior Clinician of the University</i>	2. Prof. A.A. Sonkar, Head, Department of Surgery (Gen.), KGMU, U.P., Lucknow	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
<i>Senior Clinician outside of the University</i>	5. Dr. Vimal Kumar Paliwal, Department of Neurology, SGPGIMS, Rai Bareilly 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
<i>Basic Scientist of the University</i>	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
<i>Chairman & Legal Expert</i>	10. Hon'ble Justice Vishnu Sahai (Retd.)	For a max. period of 3 years
<i>Basic Scientist outside of the University</i>	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
<i>Lay Person</i>	12. Sri Ram Niwas Jain, A-2, Sindhu Nagar, Kanpur Road, Lucknow-226003	For a max. period of 3 years
<i>Social Scientist/Philosopher/Ethicist/Theologian</i>	13. Dr. Manju Agrawal, Director, Amity Institute of Behavioral & Allied Sciences, Amity University Campus, Lucknow	For a max. period of 3 years
<i>Member-Secretary</i>	14. Prof. R.K. Garg, Faculty Incharge, Research Cell, KGMU UP, Lucknow	Ex-Officio



ANNEXURE: 17-RV-1/2019 (SOP-IEC-KGMU)

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
<input type="checkbox"/> 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 <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment
Are site facilities appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment
Is the recent version of Informed Consent Document (ICD) after IEC approval used? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment
Whether appropriate vernacular consent has been taken from all patients? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment
Any other findings noted about the ICDs? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment
Is recent IEC approved version of protocol used? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment
Have the eligibility, inclusion exclusion criteria been adhered to? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment
Any adverse events found? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment



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



Are storage of data and investigating products locked? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment
How well are the participants protected? <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Not good	Comment
Any other remarks <input type="checkbox"/> Yes <input type="checkbox"/> 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., Lucknow	
	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	 28/09/19
Senior Clinician outside of the University	5. Dr. Vimal Kumar Paliwal, Department of Neurology, SGPGIMS, Rai Bareilly 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	 12/10/2019
Chairman & Legal Expert	10. Hon'ble Justice Vishnu Sahai (Retd.)	 11/10/2019
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	

