

# INSTITUTE OF ECONOMIC GROWTH, UNIVESITY OF DELHI ENCLAVE, NORTH CAMPUS, DELHI-110007

# TERMS OF REFERENCES (TORs) FOR IEG ETHICS COMMITTEE

The Ethics Committee of IEG is established to formalize and specify Institute's commitment to the promotion of high scientific and ethical standards in biomedical, social and behavioral science research for health and wellbeing involving human participants. The ethics committee rules are consistent with the guidelines of Indian Council of Medical Research (ICMR), WHO, AMA and University Grants Commission (UGC) etc. The Committee is responsible for evaluating and certifying the suitability of conducting research involving humans and suggesting precautionary measures, if necessary. The committee is entrusted with the initial review of research proposals prior to their initiation, and also have a continuing responsibility to regularly monitor the approved research to ensure ethical compliance during the conduct of research.

# **Composition of the Committee**

Sr.	Designation	Qualifications	Proposed Member
No.			
1.	Chairperson	Ph.D.	Prof. Mausumi Das
		(Non-affiliated to IEG)	
2.	Member (Internal)	Ph.D.	Prof. Indrani Gupta
3.	Member (Internal)	Ph.D.	Prof. Saudamini Das
4.	Member (Internal)	Ph.D.	Prof. Purnamita Dasgupta
5.	Member (Internal)	Ph.D.	Dr. Sushil Kumar Sen Academic Programmes Officer
6.	Legal Expert (External)	Ph.D. (Law) (Non-affiliated to IEG)	Dr. Parikshet Sirohi
7.	Civil Society representative/Medical Practitioner	MBBS (Non-affiliated to IEG)	Dr. Arun Kumar
8.	Member-Secretary (Internal)	Ph.D.	Dr. William Joe

Date of formation of the Committee: May 6, 2024

Tenure: Three years

CVs available at: Academic Section

# ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS \*

# Membership

Criteria for selection of members:

- Members are selected in their personal capacities, based on their interest, commitment and availability, ethical and/or scientific knowledge and expertise, experience in the domain field and profile.
- Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests.
- All members should maintain absolute confidentiality of all discussions during the meeting
- Conflict of interest should be declared by members of the IEG Ethics Committee
- The tenure/period of IEG Ethics Committee members will be for 3 years or till further orders.
- The Director will not serve as member or ex-officio member.

# **Quorum requirements for IEG Ethics Committee meetings**

A minimum of five members including the Chairperson and member- secretary/Convener are required to compose a quorum.

#### Procedure for submission of research project for review

- Copies of the study proposal containing a cover letter, Participant Information Sheet (English and vernacular languages, as maybe applicable) and Consent forms (English and vernacular languages, as maybe applicable), study tools such as questionnaires, any other requisite documents, along with filled in and completed <u>application form</u>, duly signed and dated by the investigator(s) must be submitted to the IEG Ethics Committee.
  - The IEG Principal Investigator has to submit the application to the Member Secretary/Convener of the IEG Ethics Committee in the prescribed format along with study protocol and other study related documents necessary for review of the IEG Ethics Committee.

## \*Based on ICMR (2017) Guidelines

- Application can be submitted to the Member-Secretary/Convener of the IEG Ethics Committee on any working day.
- All the proposals and documents must be submitted ordinarily at least **three weeks** in

advance before starting of the work by email to the Member-Secretary of the IEG Ethics Committee.

The application would include the following (vide Application Form):

- Name, Designation and contact details of Principal Investigator, if the applicant is faculty (Professors/Associate Professors/Assistant Professors). For Post-doctoral fellow, Research scholar or students, the name, Designation and contact details of their supervisor should also be additionally mentioned.
- Title of the project and Name and contact details of Sponsor
- Research Objectives, Study Design, Materials and Methods of Data and Sample Collection. Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge.
- Subject recruitment procedures or proposed methods / advertisement / notices
- Inclusion and exclusion criteria for entry of subjects in the study.
- Precise description of methodology of the proposed research, including details of invasive procedures if any.
- The details of statistical analysis of the study.
- Procedure for seeking and obtaining informed consent with sample of interest information sheet and informed consent forms in English and the local language(s). Translation and back translation certificates (if applicable).
- Safety of proposed intervention (if any) including results of relevant laboratory and animal research.
- For research carrying more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity should be included.
- Case Record Form / Proforma / Questionnaire
- Proposed compensation for participation and reimbursement of incidental expenses/ serious adverse events occurring during the study participation.
- Plans for storage and maintenance of all data collected during the study period.
- Plans for publication of results, while maintaining the privacy and confidentiality of the study participants.
- A statement on probable ethical issues and steps taken to tackle the same.
- Activity plan / Timeline.
- Amendments to protocol (if any)
- Signature by the Principal investigator. If the applicant is Research Associate, Post-doctoral fellow, Research scholar or students, additional signature of the supervisor.
- All other relevant documents related to the study protocol including regulatory clearances and insurance documents as applicable.
- Details of Funding agency / Sponsors and fund allocation for the proposed work.
- Insurance policy of the study (if applicable).
- Undertaking by the Principal Investigator
- Memorandum of Understanding (MOU) between collaborative institutions (if applicable)
- Ethics Committee clearance of other centers (if applicable)

- Recent curriculum vitae of the investigators indicating qualification and experience.
- Any additional document(s), as required by IEG Ethics Committee

# Procedure for initial scrutiny of proposals

- Every proposal will be collected and compiled by the IEG Ethics Committee (Academic Section).
- An office staff/ member nominated by the Member Secretary/Convener/Director will verify the proposals for completeness.
- In case of incomplete data, the investigators will be informed by the office after consulting the Member-Secretary/Convener to make the necessary corrections and to resubmit.

### **Procedure for convening and conducting IEG Ethics Committee meetings**

- Meetings will be planned in accordance with the need of the workload (as and when application is received for consideration by the Ethics Committee) & the Member Secretary/Convener in consultation with chairman may convene the IEG Ethics Committee meeting.
- Members will be given not less than 10 days' time in advance to review study proposals and the relevant documents.
- Minutes of the IEG Ethics Committee meetings, all the proceedings and deliberation will be documented.
- Signatures of the Chairperson, the Member Secretary & members will be obtained on the minutes of the meeting.
- Applicant or investigator may be invited to present the proposal or elaborate on specific issues.
- Independent experts may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement.

## Procedure for reviewing the research proposals

- Every proposal will be sent not less than 10 days before the meeting to all members of IEG Ethics Committee. They will evaluate them on ethical issues, scientific content, and technical excellence of the proposed research before it is taken up for IEG Ethics Committee review meeting.
- All the members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality, and justice issue.
- Generally, the IEG Ethics Committee review will be done through formal meetings but if required IEG Ethics Committee can also decide through electronic circulation of proposal.
- Expert opinion of additional members would be obtained if necessary. Every proposal will be collected and compiled by the IEG Ethics Committee office (Academic Section).
- The Ethics Committee will decide on the status of the application in one week and

the Member-Secretary and Chairperson will issue a certificate to the Principal Investigator.