

**Guidelines for preparing Standard Operating Procedures (SOP) for
Institutional Ethics Committee for Human Research**

1. Objective:

The objective of this SOP is 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 of ICMR.

2. Role of IEC

IEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The IEC will take care 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 the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and 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 appropriate well documented procedures for example annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

The mandate of the IECs will be to review all research projects involving human subjects to be conducted at the Institute, irrespective of the funding agency. The role of IEC can be modified according to the requirement of each Institute

3. Composition of IEC

IECs should be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of an IEC.

The number of persons in an ethical committee should be kept fairly small (7-9 members). It is generally accepted that a minimum of five persons is required to compose a quorum. There is no specific recommendation for a widely acceptable maximum number of persons but it should be kept in mind that too large a Committee will make it difficult in reaching consensus opinions. 12-15 is the maximum recommended number.

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The Chairperson of the Committee should preferably be from outside the Institution and not head of the same Institution to maintain the independence of the Committee. The Member Secretary who generally belongs to the same Institution should conduct the business of the Committee. Other members should be a mix of medical / non-medical scientific and non-scientific persons including lay public to reflect the differed viewpoints.

The composition may be as follows :-

1. Chairperson
2. 1-2 basic medical scientists.
3. 1-2 clinicians from various Institutes
4. One legal expert or retired judge
5. One social scientist / representative of non-governmental voluntary agency
6. One philosopher / ethicist / theologian
7. One lay person from the community
8. Member-Secretary

The ethical committee at any institution can have as its members, individuals from other institutions or communities if required. There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. The membership of IEC will include Epidemiologist(s), Sociologist(s), Lawyer(s), Theologian, Statistician(s), Clinician(s), Basic scientists, Pharmacist(s)/Clinical Pharmacologist(s) etc They should be appointed by the Head of the Institute based on their competencies and integrity, and could be drawn from any public or private Institute from anywhere in the country.

IEC should be constituted in the following pattern :

- i) A Chairperson
- ii) A Deputy Chairman if need be,
- iii) A Member Secretary,
- iv) 5-15 members from different Departments / Specialties / disciplines or areas etc.

4. Authority under which IEC is constituted:

The Institutional Head constitutes the IEC.

5. Membership requirements:

- a. The duration of appointment is initially for a period of 2-3 years

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- b. At the end of 2-3 years, as the case may be, the committee is reconstituted, and 50% of the members will be replaced by a defined procedure.
- c. A member can be replaced in the event of death or long-term nonavailability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- d. A member can tender resignation from the committee with proper reasons to do so.
- e. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
- f. Conflict of interest should be declared by members of the IEC

6. Quorum requirements:

The minimum of 5 members are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals.

7. Offices

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority.

8. Independent consultants

IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. 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 are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IEC .

9. Application Procedures:

- a. All proposals should be submitted in the prescribed application form, the details of which are given under Documentation
- b. All relevant documents should be enclosed with application form
- c. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be forwarded by the Head of the Departments / Institution to the ethics committee.
- d. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.

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- e. The decision 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 or before the next meeting.
- f. Prescribed fee if any, should be remitted along with the application.

10. Documentation:

For a thorough and complete review, all research proposals should be submitted with the following documents :

1. Name of the applicant with designation
2. Name of the Institute/ Hospital / Field area where research will be conducted.
3. Approval of the Head of the Department / Institution
4. Protocol of the proposed research
5. Ethical issues in the study and plans to address these issues.
6. Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow - up cards, etc.
7. Informed consent process, including patient information sheet and informed consent form in local language(s).
8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available.
9. Curriculum vitae of all the investigators with relevant publications in last five years.
10. Any regulatory clearances required.
11. Source of funding and financial requirements for the project.
12. Other financial issues including those related to insurance
13. An agreement to report only Serious Adverse Events (SAE) to IEC.
14. Statement of conflicts of interest, if any.
15. Agreement to comply with the relevant national and applicable international guidelines.
16. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions(e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
17. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
18. Any other information relevant to the study

11. Review procedures:

- a. The meeting of the IEC should be held on scheduled intervals as prescribed and additional meetings may be held as and when the proposals are received for review.

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- b. The proposals will be sent to members at least 2 weeks in advance.
- c. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.
- d. Researchers will be invited to offer clarifications if need be.
- e. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.
- f. The decisions will be minuted and Chairperson's approval taken in writing.

12. Element of review

- a. Scientific design and conduct of the study.
- b. Approval of appropriate scientific review committees.
- c. Examination of predictable risks/harms.
- d. Examination of potential benefits.
- e. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.
- f. Management of research related injuries, adverse events.
- g. Compensation provisions.
- h. Justification for placebo in control arm, if any.
- i. Availability of products after the study, if applicable.
- j. Patient information sheet and informed consent form in local language.
- k. Protection of privacy and confidentiality.
- l. Involvement of the community, wherever necessary.
- m. Plans for data analysis and reporting
- n. Adherence to all regulatory requirements and applicable guidelines
- o. Competence of investigators, research and supporting staff
- p. Facilities and infrastructure of study sites
- q. Criteria for withdrawal of patients, suspending or terminating the study

13. Expedited review

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review should be specified.

14. Decision-making

- a. Members will discuss the various issues before arriving at a consensus decision.
- b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
- c. Decisions will be made only in meetings where quorum is complete.
- d. Only members can make the decision. The expert consultants will only offer their opinions.

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- e. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
- g. Modified proposals may be reviewed by an expedited review through identified members.
- h. Procedures for appeal by the researchers should be clearly defined.

15. Communicating the decision

- a. Decision will be communicated by the Member Secretary in writing.
- b. Suggestions for modifications, if any, should be sent by IEC.
- c. Reasons for rejection should be informed to the researchers.
- d. The schedule / plan of ongoing review by the IEC should be communicated to the PI.

16. Follow up procedures

- a. Reports should be submitted at prescribed intervals for review.
- b. Final report should be submitted at the end of study.
- c. All SAEs and the interventions undertaken should be intimated.
- d. Protocol deviation, if any, should be informed with adequate justifications.
- e. Any amendment to the protocol should be resubmitted for renewed approval.
- f. Any new information related to the study should be communicated.
- g. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
- h. Change of investigators / sites should be informed.

17. Record keeping and Archiving

- a. Curriculum Vitae (CV) of all members of IEC.
- b. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
- c. Minutes of all meetings duly signed by the Chairperson.
- d. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
- e. Copy of all correspondence with members, researchers and other regulatory bodies.
- f. Final report of the approved projects.
- g. All documents should be archived for prescribed period.

18. Updating IEC members

- a. All relevant new guidelines should be brought to the attention of the members.
- b. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.