

**STANDARD OPERATING PROCEDURES
FOR
INSTITUTIONAL ETHICS COMMITTEE OF
ANUSANDHAN TRUST**

Centres: CEHAT and SATHI

November, 2015

Version: 1

Table of Contents

A. Objectives.....	1
B. Composition	1
B.1.1 Roles and responsibilities.....	2
B.1.2 Time allocation to the IEC.....	2
B.2.1 Appointment, replacement and tenure of members	3
B.2.2 Resignation, Disqualification, Replacement of Members.....	3
B.2.3 Dissolving of the IEC.....	3
B.3 Chairperson	4
B.4 Secretariat	4
B.5 Confidentiality and conflict of interest.....	5
B.6 Training.....	5
C. Review Process	5
C.1.1 Schedule	6
C.1.2 Extraordinary meeting	6
C.1.3 Interim / emergency review.....	6
C.2 Quorum	6
C.3 Stages of review	6
C.4 Protocol Submission Process.....	7
C.5 Reviewing applications	8
C.6.1 Decision Making.....	8
C.6.2 Communicating decision	9
C.6.3 Reversing positive decision.....	10
C.6.4 Certification.....	10
D.1 Ongoing Monitoring of Research for its ethical conduct	10
D.2 Adverse events reporting and follow up	11
D.3 Access to information, documentation and reporting	11
D.4 Documentation and dissemination of ethics review	12
E. Auditing of the IEC	12

A. The objectives of the IEC are as follows:

1. To protect the dignity, rights, safety and wellbeing of individuals and groups connected with the project under review. This includes participants, researchers, the institution and the research community.
2. To provide objective and timely ethics review for research by institution keeping in mind the provision of accepted ethical guidelines (see annexure 1 for list of guidelines) and the local context.
3. To undertake monitoring of research by a system of ongoing review.
4. To conduct or facilitate the training of staff and researchers regarding ethics in research on regular basis.

For the purpose of this SOP, research which is under the purview of the IEC is defined as follows:

- All formal research projects which are directly implemented by the institution. This includes projects which are independent, funded research projects as well as formal research which is nested within a larger programme.
- All PhD research which is conducted under the supervision/guidance or with the formal support of institution.
- Informal data gathering which is for the purpose of planning an intervention (interviews with a few relevant individuals, mapping) or for routine programme monitoring (user-information records, surveillance, facility records, site reports)
- Student research undertaken as a part of a short-internship and dissertation.

IEC should be informed about all the research projects and then members can decide that whether project needs a formal meeting or can be responded over email.

The projects of other organizations can be reviewed by IEC depending on work load and from case to case basis (refer to terms of reference).

B. Composition

1. The IEC will comprise external as well as internal members with at least two representatives from institution. External members, who are not directly associated with institution, should be in a majority.

2. The IEC will comprise a minimum of five members: three external and two internal members.
3. The tenure of the IEC member is for three years, with each member permitted to serve on the IEC for a maximum of two consecutive terms.
4. The external membership of the IEC should include members who have a background in, medicine/public health, law/philosophy/ethics and social science. Committee will engage or reach out to a lawyer if required for inputs. There should be at least one external member who represents the interests of the lay public.
5. Members are selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment to invest the necessary time and effort for the IEC's work. Members are accountable to deliver on their commitment.
6. As and when required, the IEC is authorized to invite subject experts, representatives of patient groups such as HIV or genetic disorders, or community or interest groups to offer their views on specific proposals under ethics review by the IEC or for creating common understanding of the IEC members on an issue. Such invited non-members do not participate in the final decision-making in the IEC, but the views expressed by them shall be tabled, considered and recorded.

B.1.1 Roles and responsibilities

1. All members of the IEC are required to undertake the review of research proposals, participate in the meetings, monitoring of the ongoing research and acquire training in research methodology and ethics.
2. All members are required to read all protocols sent to them and participate in the discussion during the meeting for their ethics review to ensure that they conform to the guidelines used by the IEC.
3. Members should deliver on their commitments in a timely manner.
4. All IEC members should participate in annual evaluation of committee and should cooperate with member secretary in finalization of annual report.

B.1.2 Time allocation to the IEC

1. IEC members will commit to spending a minimum of 4 days a year on meetings for ethics review. They will spend an equivalent number of days to prepare for these meetings.

2. All members are expected to allocate time for the meeting as per the agreed annual calendar of the meeting. If for some unavoidable reasons a member is not able to attend the meeting, she/he should inform the Member Secretary at the earliest. However, the member should hand over to the Secretary the review report and connected papers available in respect of the proposals allocated for review.

3. IEC members must seek a prior leave of absence from the Chairperson in case of anticipated inability to attend.

4. If an IEC member is unable to attend three successive meetings, the IEC, may, in discussion with the member, consider whether a replacement is necessary.

B.2.1 Appointment, replacement and tenure of members

1. The trustees of institution are authorized to select the members of the IEC, based on the recommendations of the sitting IEC.

2. All IEC Members and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters

B.2.2 Resignation, Disqualification, Replacement of Members

1. Members may resign their positions by submitting a letter of resignation to the Chairperson.

2. The Chairperson may resign by submitting a letter of resignation to the member Secretary who will forward to IEC members.

3. Objection about conduct of any member can be tabled as a representation to other members. Such a member may also be disqualified from continuance if there is unanimous agreement within the rest of the IEC. Such a decision will be communicated to the Anusandhan Trust management

4. If a member leaves the Committee during its tenure, the IEC will endeavor to fill this gap, in consultation with the remaining members within three months.

B.2.3 Dissolving of the IEC

1. At any point in time, when institution ceases to exist, the IEC is automatically dissolved.

2. At any point of time, when institution withdraws its affiliation, the IEC is automatically dissolved.

B.3 Chairperson and Co-Chairperson

1. The chairperson and co- chairperson will be appointed by the IEC from among the external members. The chairperson and co-chair would be subject to change yearly among external members.

2. Normally, the chairperson _chairs the meetings of the IEC. If, however, for some unforeseen reason the Chairperson is unable to attend the meeting or the post is vacant, co- chairperson will preside over the meeting.

3. The chairperson's responsibilities are to oversee the conduct of the meeting, approve the minutes, finalize and sign the IEC annual report and other official documents pertaining to the committee.

B.4 Secretariat

1. The internal members will constitute the IEC Secretariat. At least two members of the Secretariat should be present for IEC meetings.

2. One of the internal members will be appointed as the Member Secretary of the IEC.

3. The Member Secretary reports to the committee on all matters related to the IEC, including obtaining updates of the research proposals reviewed by the IEC and proactively informing members about review schedules.

4. The Member Secretary will be the sole correspondent between the IEC and researchers who are applying for IEC review of projects. Member Secretary will inform and invite the researchers to the IEC meeting.

5. The Secretariat will organize programmes for the staff of the institutions on research ethics.

6. The Secretariat will inform all staff, at the time of recruitment, of the Ethical Guidelines for Social Science Research in Health, prepared by the National Committee for Ethics in Social Science Research in Health, as also other guidelines and this document on research ethics review.

7. The Secretariat will provide the website details of both documents and also make printed copies available.

8. The Member Secretary will prepare the meeting agenda, scrutinize the applications and distribute the IEC applications to the members.

9. The Member Secretary will keep institution informed of the IEC deliberations and co-ordinate any actions/ discussions if required.

10. The Member Secretary will prepare minutes and circulate them after obtaining the approval of the Chairperson/ Co-chairperson.

11. The Member Secretary will issue certificates to the research team whose projects have been reviewed after obtain approval from the committee members.

12. The Secretariat will be responsible for the final compilation of the annual report of IEC with full cooperation and feedback from IEC members.

B.5 Confidentiality and conflict of interest

1. Subject to statutory exceptions, the IEC members will maintain confidentiality with regard to the identifiable research information to which they have access to as a part of their work on the IEC, and will sign a statement or agreement to that effect.

2. Any member having a pecuniary or other conflict of interest will declare it in writing to the Chairperson at the time of appointment to the IEC as and when the conflict of interest arises.

3. If an IEC member submits a project proposal as an Investigator (PI) or associated as a consultant or in any other way significantly involved in a research proposal submitted to IEC, the member should declare her/his conflict of interest to the Chair. He/she will not participate in the review and withdraw from the meeting when this proposal is discussed and decided upon in the IEC meeting.

B.6 Training

1. The IEC or its designated representatives shall endeavor to train researchers on matters related to research ethics, procedures for submission before IEC etc.

C. Review Process

All projects designed to involve interaction with individuals or communities must be reviewed by the IEC. All research activities should be informed to the committee.

C.1.1 Schedule

1. An annual calendar of the meetings of the IEC will be announced in advance. The IEC will meet in normal circumstances at an interval of three months. Additional meetings may be scheduled, if required.
2. The ethics review of the proposals will be strictly done in the formal meetings of the IEC. This does not preclude the IEC from appointing sub-committees for undertaking ethics review of some proposals or for expedited review or for emergency review or for other purposes; but the decision of such review or work of the sub-committee shall be reported in the next full meeting of the IEC. (See Section C.1.2 and Section C.1.3)
3. The Secretariat will schedule all meetings in consultation with IEC members.
4. The Secretariat shall inform all members about the date and venue of the meeting, the agenda and provide copies of the protocols for review sufficiently in advance of the meeting.

C.1.2 Extraordinary meeting

1. The coordinators of institution's centres can use his/her discretion to request an urgent meeting, for short-term projects or for work that is in the organization's interest that must begin at short notice. In such a scenario, IEC members can take a decision that whether project can be discussed through e-consultation activities like email, teleconference, skype conference calls or if a formal meeting is required.

C.2 Quorum

1. At least three members (including two external members) constitute quorum for an IEC meeting.
2. This quorum will be satisfied when members (three) will be present in person.
3. If there is a disagreement between two external members satisfying quorum, then it is the chairperson's responsibility to conduct a discussion till a consensus is reached.

C.3 Stages of review

1. Ethics review of research projects should be linked to stages of projects:

- a. At the beginning of the project, following the finalization of the methodology & tools, before commencement of data collection, post data collection and prior to publishing the research report. .
 - b. Every 12 months following the initial review or on a case to case basis.
 - c. For certain projects, where specified by the IEC, the project may be reviewed every six months.
2. Project teams can also seek consultation with IEC at any other stage in the research in the interim period.
 3. If the work has commenced before phase I of the review, the IEC will give the feedback but will not certify it, and the project report should state that the IEC has not certified the project. There will be no retrospective review of projects by IEC.
 4. The outcome of the research will be reviewed by the IEC provided that its comments will be incorporated in the final report.

C.4 Protocol Submission Process

1. It is the responsibility of the IEC secretariat to receive record, distribute for review and get the submission packages approved by the IEC, as well as to deliver the review results to the protocol applicants.
2. All projects must be reviewed and approved by the scientific review committee prior to application for ethics review. The comments of the scientific committee must be enclosed with the application. There can be a possibility of conflict or difference in opinion between IEC and PDC. In such a scenario, chairpersons of both the committees can communicate with each other through a joint meeting, and involve other members of the IEC and PDC when needed.
3. The Member Secretary / Secretariat should not assign a proposal for ethics review unless the application form is completely and adequately filled up and the enclosures are in order.
4. All the proposals that are to be discussed in the meeting shall be received by the Secretariat at least three weeks prior to the meeting and circulated to the members of the IEC at least two weeks prior to the meeting. The Member Secretary may give each member responsibility to undertake rigorous review of a few proposals as primary or secondary reviewer.

5. Researchers have the responsibility to bring to the notice of the IEC any proposed amendment to the protocol in the originally approved protocol with proper justification. Such amendments must be reviewed by the IEC before it is finalized and the research is implemented.

C.5 Reviewing applications

1. The IEC members will scrutinize applications for ethical issues, identify inadequacies and problems (if any), formulate proposals for changes needed (if any) to make proposed research ethical and make presentation on the proposals in the IEC meeting for all members to deliberate.

2. If a member is unable to attend the meeting for unavoidable reasons, s/he should send comments by email.

3. Usually, the IEC should deliberate on the project under review in the absence of the researcher involved. However, the researcher will be asked to remain present for clarification of doubts or to obtain additional information. The researcher may also be called to summarize and present their project. The collective queries of the IEC members will be raised by the Chairperson/Co-Chairperson on behalf of the committee.

4. The sub-committee undertaking interim review can provide approval or request minor modifications to proposals prior to approval by IEC in next formal meeting.

5. For any major revision required, or in case a decision is reached to disapprove the proposal, the proposal should be tabled to the next full committee meeting. The IEC members undertaking the emergency/interim review may call for meeting of the full IEC.

C.6.1 Decision Making

1. In order to evolve or attain consensus of views of the members the IEC would promote extensive discussion among members.

2. The decisions in the IEC will be taken by arriving at consensus. But in the event of the members not being able to reach a consensus, the decision will be taken on the basis of the majority of those present and voting. Internal members will participate in discussions but their opinions shall not determine the decision.

3. If an IEC member dissents on a decision or has serious reservations, these should be recorded.

4. Approval categories used by the IEC for the proposals reviewed:

I. Study can begin;

(a) -Full approval: Granted when the Committee has no questions about the application. But the members may, however, make comments about this approval or recommendations for future submissions. Such comments will be included in the approval letter itself.

(b) Conditional approval: Granted when the Committee approves an application with conditions that the committee recommends but require a response to those conditions. Conditional approval can also be given if a PI is asked to submit a finalized version of a questionnaire or letters of support from others including Institute's departments cooperating in the research and that is complied with. Once the PI responds to the conditions, an approval letter is sent out by the Member Secretary by the authority vested in her/him by the committee.

(c) Resubmission: Committee does not approve the study without additional information and review. This is resorted to when serious concerns are raised about the risk/benefit ratio or other issues of participants' protection, and the members agree that additional information, justification, or changes are needed before approval can be reconsidered. The PI must respond to this request in writing and then the IEC reviews the revised proposal in the next meeting. If the revised proposal meets the requirements, it is granted contingent, conditional, or straight approval at the time of the second review. However, the proposal may be returned again for further required revisions if the committee decides so. A proposal can be resubmitted a maximum of three times.

(d).Rejection: The rejection can be based on several considerations. It may be because the IEC disapproves the study in principle. It may deny approval because members' concerns for the protection of the participants have not been satisfactorily addressed even after the revision. The denial letter should provide adequate information on the grounds for the denial.

C.6.2 Communicating decision

1. Minutes will be prepared by the Secretary and circulated to all IEC members within a week. All members should give their comments within 2 weeks before final approval by chairperson/co- chairperson.

2. The Member Secretary will communicate decision of the IEC in writing to the applicant within 3 weeks of the IEC meeting.

3. Any decision suggesting changes in the proposal would contain the information on specific changes suggested and clear reasons for the same.

4. Negative decision/disapproval should always be supported by clearly defined reasons.

C.6.3 Reversing a decision

1. The IEC may decide to reverse its approval on a study in the event of receiving information that may adversely affect the benefit /risk ratio and call for an extra-ordinary meeting.

C.6.4 Certification

1. The Secretary will issue a certificate of approval if the study has been granted straight approval or approval with comments. (See section C.6.1)

2. In case the study has been granted conditional approval, the Member Secretary will review the response of the applicant and communicate his/her views about the completeness of the response to the IEC. The response will also be forwarded to the IEC. If the response is found satisfactory on approval by three members then a certificate of approval will be issued by the Member Secretary.

3. In case the study has been asked for resubmission, the revised application will be reviewed by IEC members. On the instruction of the Chairperson, the Member Secretary may issue a certificate of approval to the applicant.

4. For all other categories of approval and denial of approval, no certificate of approval will be issued prior to a full-review and decision of IEC.

5. Certification of the protocol: After the approval is granted by the IEC, in addition to sending the approval letter to the PI, the Member Secretary certifies the protocol and a copy of the same is preserved in the Secretariat.

6. In case the Member Secretary has abstained from the review and/or declared a conflict of interest, the certificate will be issued by the internal member who maintained minutes for that period of the meeting following the same procedure as described above.

D.1 Ongoing Monitoring of Research for its ethical conduct

1. IEC members are encouraged to make field visits to monitor fieldwork, and may do so in order to acquaint themselves with how the fieldwork is being conducted, and to monitor the conduct of the study.

2. When potential risks have been clearly highlighted at the time of the approval of a project, the IEC may appoint a team of standing subcommittee whom the research team can approach for guidance on ethical issues during the course of the research.

3. All approved studies must submit annual updates to the IEC from the date of approval. (See section C.3) The update must include the following items as relevant:

- Date of the start of the study
- Status of the project (whether still to start, ongoing, suspended, terminated or any other)
- Details of the work completed so far
- Reasons for suspension, termination
- Any adverse events which have or have not been reported to the IEC
- Any deviations from the protocol which have or have not been reported to the study
- Decisions regarding authorship for publications resulting from the study (whether in print or published)
- Any ethical issue that arose during the study and how it was resolved.
- All publications must be attached as annexure to the report.

D.2 Adverse events reporting and follow up

1. All research proposals need to define the anticipated risks and the criteria for assessing their seriousness.

2. Researchers have the responsibility to bring to the notice of the IEC any serious and unexpected adverse events and remedial steps taken to tackle them as well as any new information that may influence the conduct of the study, including the need to amend the protocol and the informed consent form. These adverse events should be reported to members within 2 (working) days to the IEC secretariat in prescribed format.

3. The Chairperson may convene a full meeting of the IEC or appoint a sub-committee to decide on the future course of action and required remedies

D.3 Access to information, documentation and reporting

The institution should assist in making the following records of the IEC available in public domain:

- a. The names and the curriculum vitae of all IEC members
- b. The Standard Operating Procedures (SOP) of the IEC
- c. All Forms prescribed by the IEC
- d. Annual calendar of meetings of the IEC

D.4 Documentation and dissemination of ethics review

1. The minutes of all meetings of the IEC will be prepared by the Member Secretary and will send it to all members of the IEC for their comments. The Member Secretary will incorporate all revisions/comments received from the members. These minutes are considered final after receiving email confirmation from all external members. Minutes of IEC meetings, consultations and ethics review reports will be available to institution through their internal members.

2. All other documents and communications relating to the functions of the IEC are to be dated, filed and preserved according to written procedures. Strict confidentiality is to be maintained during access and retrieval procedures. These documents include:

- Copies of protocols submitted for review;
- All correspondence with IEC members and investigators regarding application, decision and follow up;
- Agenda of all IEC meetings;
- Minutes of all IEC meetings with signature of the Chairperson;
- Copies of decisions communicated to the applicants;
- Record of all interim decisions, meetings and interactions involving the IEC
- Final protocol of the study including microfilms, CDs and video recordings.
- All records will be maintained for at least 3 years in the form of electronic or hard copies after the completion of the project, if it is not possible to maintain the same permanently.
- All the physical documents of the IEC will be stored in a locked filing cabinet in the Secretariat.
- The Member-Secretary must hand over full custody of such records to her/his successor and the handing over must be documented.
- The annual report of the IEC is a public document which will be available to anyone on request and may be disseminated in print or online
- As IEC reports are public, they will not contain any information that identifies individuals, in order to maintain the confidentiality of discussions.

E. Auditing of the IEC

There will be an annual self-evaluation by the IEC. Feedback will be sought from the PIs whose projects were reviewed in that year. The report of this evaluation will be included in the annual report of the IEC.