



**Anusandhan Trust**

**Institutional Ethics Committee**

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**INSTITUTIONAL ETHICS COMMITTEE**

**STANDARD OPERATING PROCEDURES  
(SOPs)**

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# Standard Operating Procedures

## Institutional ethics committee (IEC) of Anusandhan Trust (AT)

### 1. Objective of Standard Operating Procedures

The objective of this Standard Operating Procedures of the Institutional ethics committee (IEC) of Anusandhan Trust (AT) is to maintain effective functioning of the AT-IEC and to ensure quality and consistent ethical review of all the submitted projects and ongoing approved projects in accordance with the ICMR ethical guidelines for biomedical research on human subjects, 2017.

### 2. Roles and Responsibilities of Institutional Ethics Committee

**a.** The basic responsibility of IEC is to ensure the protection of the dignity, rights, safety and wellbeing of individuals and groups connected with the project under review. This includes participants, researchers, the institution (Anusandhan Trust and its centres) and the research community.

**b.** The IEC must ensure that universal ethical values and international scientific standards, as well as applicable Indian regulatory standards and guidelines, are followed while keeping in mind local community values and customs.

**c.** The IEC is entrusted with the initial review of projects prior to their initiation, and also has a continuing responsibility to regularly monitor the approved project to ensure ethical compliance during the conduct of the project.

**d.** The IEC is responsible for scientific and ethical review of projects. Although the IEC may obtain documentation from a prior scientific review, they must determine that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy. The IEC can raise scientific queries besides ethical ones as both good science and ethics are important to ensure the quality of research and participant protection.

**e.** The IEC members and/or their designates are encouraged to make field visits to ongoing projects to monitor fieldwork and may do so to acquaint themselves with how the fieldwork is being conducted, and to monitor the conduct of the study.

**f.** The IEC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations. This would be facilitated by the secretariat with support from the Anusandhan Trust.

**g.** The IEC should assist in the capacity building of project teams under the Anusandhan Trust on a regular basis.

**h.** The IEC may request that the conduct of same/similar research by different investigators from the same institution is harmonized. 'Me too' research (replicative) should not be encouraged and submission of the same research proposal to different funding agencies simultaneously would be discouraged.

**The projects** which are under the purview of the IEC are:

**a.** All formal research projects which are directly implemented by the AT institutions. This includes independent projects, funded research projects as well as formal research which is nested within a larger programme.

**b.** Social action projects are projects undertaken by institutions for well-being of communities and those who are marginalised. There will be no certification of social action projects by IEC. The social action projects will be reviewed, and inputs will be provided as there are ethical issues even in social action projects. The inputs will be provided through a formal ethics review, it would be different from a research project review and the format and frameworks will continue to be adapted to the needs of action projects.

**c.** All PhD research which is conducted under the supervision/guidance of key staff within the Anusandhan Trust involving research projects or sites under the trust or with the formal support of the institution.

**d.** Data gathering which is to plan an intervention (Formative research) or for routine programme monitoring (user- information records, surveillance, facility records, site reports)

**e.** The internal members of the institutions will provide oversight to the projects undertaken by students at the institutions as a part of their fieldwork. The members can approach and seek advice from the other members of the IEC if required.

**f.** External projects: The projects of other organizations and independent researchers can be reviewed by IEC depending on workload and a case to case basis.

- Any external institution seeking review of their project should be a non-government organization or an international organization (voluntary); pharma and profit-making entities to be excluded.
- The AT- IEC should not accept projects for review from investigators affiliated to institutions that have their IECs unless there is an MoU between the institution and AT towards this review providing access for oversight purposes, and only when there is a clear rationale for this.
- The external applicant must agree to get monitored for their project.
- The external applicant must agree to pay a one-time application fee for review, and where applicable annual review fees as well. The waiver of this fee can be considered by IEC from a case to case basis on the request of an external applicant.
- If field visits are required for the monitoring of the project, the travel expenditure any other relevant costs should be borne by an external applicant seeking review.

### **3. Composition**

- a.** The IEC should be multi-disciplinary and multi-sectoral.
- b.** There should be adequate representation of age and gender.
- c.** The IEC should comprise external as well as internal members with at least two representatives from the institution. External members, who are not directly associated with trust and its institutions, should be in a majority.
- d.** The IEC should be competent and independent in its functioning. Thus, heads of the institutions of trust should not be a part of IEC.
- e.** The external membership of the IEC should include members who have a background in, medicine/public health, law/philosophy/ethics and social sciences. There should be at least one external member who represents the interests of the lay public/ community.
- f.** The number of members in IEC should preferably be between seven and 15 and a minimum of five members should be present to meet the quorum requirements.
- g.** Members of IEC are selected in their 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.
- h.** 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 a 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 documented.
- i.** The IEC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members.

### **4. Terms of Reference for IEC members**

- a.** AT- IEC is an independent body which is constituted by Anusandhan Trust. The members of the committee are selected and appointed by the trust. If a member leaves the Committee during its tenure, the trust will endeavour to fill this gap, in consultation with the remaining committee members within three months.
- b.** The appointment letter issued to all members should specify the TORs. The letter issued by the trust should include, at the minimum, the following:
  - Role and responsibility of the member in the committee
  - Duration of appointment
  - Conditions of appointment
- c.** 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. One-third of IEC members should be changed regularly.

- d.** IEC members should be given a reasonable honorarium for attendance at the meeting by trust
- e.** 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 preparing for these meetings.
- f.** 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 strive to communicate to the Secretary the review report and connected papers available in respect of the submitted projects.
- g.** 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.

### **Requirements for IEC members**

Every IEC member should

- Provide a recent signed CV
- Either be trained on ethics of research at the time of induction into the IEC, or must undergo training and submit training certificates within 6 months of appointment
- Be willing to undergo training or update their skills/knowledge during their tenure as an IEC member;
- Be aware of relevant guidelines and regulations;
- Read, understand, accept and follow the conflict of interest policy of the IEC and declare it, if applicable, at the appropriate time;
- Subject to statutory exceptions, the IEC members will maintain confidentiality with regard to the identifiable research information to which they have access as a part of their work on the IEC and will sign a statement or agreement to that effect.
- Any member having a pecuniary or another 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.
- Be willing to place her/his full name, profession and affiliation to the EC in the public domain; and
- Be committed and understanding to the need for research and for imparting protection to research participants in research.

**h.** Members may resign their positions by submitting a letter of resignation to the Chairperson. The Chairperson may resign by submitting a letter of resignation to the member Secretary who will forward it to IEC members, and the trustees (AT).

**i.** Objection about the 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.

## 5. Specific Roles and responsibilities of IEC members

- a. All members of the IEC are required to undertake the review of submitted projects, participate in the meetings, monitoring of the ongoing projects and acquire training in research methodology and ethics.
- b. 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.
- c. All IEC members should participate in the annual evaluation of the committee and should cooperate with the member secretary in the finalization of the annual report.
- d. Members are appointed to the IEC for a particular role. They cannot substitute for the role of any other member who is absent from a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications. For example, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson

### *Chairperson and co-chairperson*

- a. The chairperson and co-chairperson (optional position) 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.
- b. 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, the co-chairperson or an interim chairperson appointed for the specific meeting from among the external members will preside over the meeting. The Interim Acting Chairperson will have all the powers of the Chairperson for that meeting.

### **Role and responsibilities of the chairperson**

The chairperson's responsibility is to

- Conduct IEC meetings, ensure active participation of all members and be accountable for the independent and efficient functioning of the committee
- Ratify minutes of the previous meetings
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, IEC members, conflicts of interest issues and requests for use of IEC data, etc.
- Communicate with the Trust on IEC related issues on behalf of the IEC.

### *Secretariat*

- a. The internal members will constitute the IEC Secretariat. One of the internal members will be appointed as the Member Secretary of the IEC. A co-member secretary might also be appointed from among the internal members (optional)

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

**c.** 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.

### **Role and responsibilities of the secretariat**

The Secretariat responsibility is to:

- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
- Schedule IEC meetings, prepare the agenda and minutes
- Organize IEC documentation, communication and archiving
- Ensure training of IEC secretariat and IEC members, as well as IEC registration and accreditation as required.
- Ensure SOPs are updated as and when required
- Ensure adherence of IEC functioning to the SOPs
- Prepare for and respond to audits and inspections
- Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for IEC review.
- Assess the need for expedited review/ exemption from Review or full review
- Issue certificates to the project team after obtaining approval from the committee members.
- Compilation of the annual report of IEC with full cooperation and feedback from IEC members.

## **6. Training**

**a.** Members should be trained in human research protection, IEC functions and SOPs, and should be conversant with ethical guidelines, and relevant regulations of the country. IEC members should undergo initial and continuing training. All training should be documented.

**b.** The IEC members shall endeavour to train researchers on matters related to research ethics, procedures for submission before IEC etc.

**c.** Any change in the relevant guidelines or regulatory requirements should be brought to the attention of all IEC members by the secretariat.

## **7. Protocol Submission and Review Process**

**a.** 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.



**b.** 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 the scientific review committee (also known as the Program Development Committee (PDC)). The primary objective of the scientific review committee is to look into the scientific rigour of the project. 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

**c.** 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.

**d.** All the proposals that are to be discussed in the meeting shall be received by the Secretariat at least 12 days before the meeting and circulated to the members of the IEC at least 1 week before the meeting.

**e.** Ethics review of projects should be linked to the following stages of projects:

- At stage I- Before submitting the project to a funder. It is good practice to submit the project at this stage. However, considering the time constraints it is not always possible to submit a project at this stage.
- At stage II- Finalisation of methodology and before data collection
- At stage III- After completing fieldwork
- Stage IV- Before publishing the report

**f.** For certain projects, where specified by the IEC at the time of approval, the project may be reviewed more frequently. Project teams can also seek consultation with IEC at any other stage in the research in the interim period.

**g.** The coordinators of the Trust's centres can use their 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 decide that whether a project can be discussed through e- consultation activities like email, teleconference, skype conference calls or if a formal meeting is required.

**h.** If the work on the project has commenced before stage II 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.

**i.** The Member Secretary/Secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review, and full committee review.

## Types of review

- **Exemption of review:** Projects with less than minimal risk where there are no linked identifiers, for example, research conducted on data available in the public domain for systematic reviews or meta-analysis
- **Expedited review:** Proposals that pose no more than minimal risk, and those during emergencies and disasters may undergo expedited review.
- **Full committee review:** All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review.

**j.** An applicant cannot decide that her/his project falls in the exempted, expedited or full review category. All projects must be submitted to the IEC. The decision on the type of review required rests with the IEC and will be decided on a case-to-case basis. The applicant can approach the IEC with appropriate justification for the project to be considered as exempt, expedited or if a waiver of consent is requested.

**k.** The IEC may adopt a system for pre-meeting peer review by subject experts and obtain clarifications from the researchers before the meeting to save time and make the review more efficient during the full committee meeting.

**l.** The IEC may have a system of appointing primary and secondary reviewers. The Member Secretary should identify the primary reviewer for reviewing the scientific content and the ethical aspects of the project. During a full review meeting, the primary and second reviewers can brief the members about the project.

**m.** Projects should be taken up item-wise, as given in the agenda. The time allotted for the meeting should be reasonable to allow ample discussion on each agenda item.

**n.** The comments of an independent consultant (if applicable) could be presented by the Member Secretary or subject experts could be invited to offer their views, but they should not participate in the decision-making process. However, her/his opinion must be documented.

**o.** The applicant may be called in to present or provide clarifications on the project that has been submitted for review but should not be present at the time of decision making.

**p.** If an IEC member submits a project as an Investigator (PI) or associated as a consultant or in any other way significantly involved in the project 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. This should be documented in minutes and the quorum rechecked.

## 8. Decision making

**a.** A meeting will be considered valid only if the quorum is fulfilled. This should be maintained throughout the meeting and at the time of decision making.

### Quorum requirements

- A minimum of five members present in the meeting room.
- The quorum should include both medical, non-medical or technical or/and non-technical members.
- Minimum one non-affiliated member should be part of the quorum.
- Preferably the lay/community person should be part of the quorum.

**b.** To evolve or attain consensus of views of the members the IEC would promote extensive discussion among members.

**c.** All members of the EC (including the Chairperson and the Member Secretary) present in the room have the right to vote/express their decision and should exercise this right.

**d.** The decisions in the IEC will be taken by arriving at a consensus. But in the event of the members not being able to reach a consensus, the decision will be taken based on the majority of those present and voting. If an IEC member dissents on a decision or has serious reservations, these should be recorded.

**e.** The IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the benefit-risk assessment

**f.** The applicant should have an opportunity to reply/clarify to IEC comments or to discuss or present her/his stand. In case s/he has strong reservations with respect to the IEC decision, s/he can also approach the head of the Anusandhan Trust (Managing Trustee) who serves as an appellate for IEC matters.

**g.** The Member Secretary (assisted by the Secretariat) should record the discussions and prepare the minutes which should be circulated to all the members for comments before final approval by the Chairperson/Vice-Chairperson/designated member of the committee.

**h.** Project team has 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 implemented.

### Approval categories for the projects reviewed

IEC can give one of the following decisions after reviewing the submitted project:

- **Approved** – with or without suggestions or comments;
- **Revision with minor modifications/amendments** – approval is given after examination by the Member Secretary or expedited review, as the case may be;
- **Revision with major modifications for resubmission** – this will be placed before the full committee for reconsideration for approval; or

- **Not approved (or termination/revoking of permission if applicable)** – clearly defined reasons must be given for not approving/terminating/revoking of permission.

## **9. Communicating decision**

- a.** Minutes will be prepared by the Secretary (and/or co-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.
- b.** The Member Secretary and/or co-secretary will communicate the decision of the IEC in writing to the applicant within 2 weeks of the IEC meeting.
- c.** Any decision suggesting changes in the proposal would contain the information on specific changes suggested and clear reasons for the same.
- d.** Negative decision/disapproval should always be supported by clearly defined reasons.

## **10. Certification**

- a.** The Secretary will issue a certificate of approval if the project has been granted straight approval or approval with comments.
- b.** In case the project has been asked for revisions (minor or major modifications) 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.
- c.** 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.

## **11. Ongoing monitoring of approved projects**

All approved projects must submit application forms at stages of post data collection and before publication. Additionally, depending on the risk involved and duration of the project, the progress of the proposal may be monitored annually or at shorter intervals (quarterly, half-yearly) as per the IEC decision. The update must include the following items as relevant:

- Date of the start of the project
- 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
- Decisions regarding authorship for publications resulting from the study (whether in print or published)

- Any ethical issue that arose during the project and how it was resolved.

## **12. Adverse events reporting and follow up**

- All submitted projects need to define the anticipated risks and the criteria for assessing their seriousness.
- Project team has the responsibility to bring to the notice of the IEC any serious and unexpected adverse events and remedial steps are taken to tackle them as well as any new information that may influence the conduct of the project, 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.
- The Chairperson may convene a meeting of the IEC to decide on the future course of action and required remedies

## **13. Research involving vulnerable population**

Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so.

### **Principles of research among vulnerable populations**

- Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.
- If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.
- Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.
- In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.
- Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.
- If vulnerable populations are to be included in research, all stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.

### **Obligation/Duties of Ethics Committee Members**

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| <ul style="list-style-type: none"> <li>• During review, determine whether the prospective participants for a particular research are vulnerable.</li> <li>• Examine whether inclusion/exclusion of the vulnerable population is justified.</li> <li>• Ensure that COI do not increase harm or lessen benefits to the participants.</li> </ul> |
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- Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible.
- Suggest additional safeguards, such as more frequent review and monitoring, including site visits.
- Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations.
- IEC members have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. Committee should ensure that these exceptions are as minimal as possible and are clearly spelt out in the Informed Consent.
- ICMR Guidelines, 2017 can be referred for handling proposals involving vulnerable populations.

### **Consideration issues and protection of specific vulnerable groups**

#### **1. Children: Before undertaking research in children the investigator must ensure following points:**

- a. Children will not be involved in research that could be carried out equally well with adults;
- b. A parent or legal guardian of each child has given proxy consent;
- c. The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.;
- d. Research should be conducted in settings in which the child and parent can obtain adequate Medical and psychological support;
- e. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;
- f. The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;
- g. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions;
- h. The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.

**2. Pregnant or nursing women:** Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation.

As a general rule, pregnant or nursing women should not be participants of any research except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.

The justification of participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from intervention.

Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast-feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.

**3. Research related to termination of pregnancy:** Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

**5. Research related to pre-natal diagnostic techniques:** In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

#### **14. Access to information, documentation and reporting**

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

- The names and short biodata of all IEC members
- The Standard Operating Procedures (SOP) of the IEC
- All forms prescribed by the IEC
- Annual calendar of meetings of the IEC

#### **15. Documentation and dissemination of ethics review**

**a.** The minutes of all meetings of the IEC will be prepared by the Member Secretary and/or co-secretary, and they 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 an email confirmation from all external members. Minutes of IEC meetings, consultations and ethics review reports will be available to the institution through their internal members.

**b.** All other documents and communications relating to the functions of the IEC are to be dated, filed and preserved. 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 the application, decision and follow up;
- Agenda of all IEC meetings;

- Minutes of all IEC meetings with the 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.

**c.** All records will be maintained for at least 3 years in the form of electronic or hard copies after the completion of the project. All the physical documents of the IEC will be stored in a locked filing cabinet in the Secretariat.

**d.** The Member-Secretary must hand over full custody of such records to her/his successor and the handing over must be documented.

**e.** The annual report of the IEC is a public document that will be available to anyone on request and may be disseminated in print or online

**f.** As IEC reports are public, they will not contain any information that identifies individuals, to maintain the confidentiality of discussions.

## **16. Auditing of the IEC**

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