



## **FERCI MODEL SOPs**

**SOP**

### **Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC**

**Effective Date:**  
**aa/bb/cccc**

### **Title: Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC**

**SOP Code: SOP 02/V1**

**Effective Date:** aa/bb/cccc

*[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]*

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**Table of Contents:**

<b>No.</b>	<b>Contents</b>	<b>Page No.</b>
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Detailed Instructions	2
5	Reference to other applicable SOPs	14
6	Annexures	14
7	Flowchart	21



	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p><b>Effective Date: aa/bb/cccc</b></p>
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## 1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the terms of reference (TOR), which provide the framework for constitution, selection, roles and responsibilities of the Institutional Ethics Committee (IEC) and procedures for maintaining confidentiality of all activities and documents.

## 2. Scope

This SOP applies to the constitution of the IEC, selection, roles and responsibilities of members of the IEC and maintenance of confidentiality of all activities and documents.

## 3. Responsibility


The selection of Chairperson, Member Secretary and IEC members will be done by the Head of the Institution. It is the responsibility of all the IEC members and the Secretariat to read, understand, follow and respect this SOP.

## 4. Detailed Instructions


### 4.1 Composition of the Institutional Ethics Committee

The IEC will be established by the **Head of the Institution (HOI)**. The Chairperson and IEC members can suggest names of potential members but the final decision will remain with the Head of the Institute.

- Its hierarchical position in the organisation and authority under which it is established will be clearly indicated (*AX 02/SOP 02/V1*)
- The IEC will be multidisciplinary and multi-sectoral in composition.
- The IEC will be composed of at least 7 members upto a maximum of 15 (as per current CDSCO requirements).

	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p><b>Effective Date: aa/bb/cccc</b></p>
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- The members will
  - ✓ include a combination of medical and non-medical, scientific and non-scientific persons including lay persons to represent the different points of view.
  - ✓ have differing backgrounds to promote complete and adequate review of research.
  - ✓ Have the required qualifications as prescribed by applicable regulations and guidelines from time to time
  - ✓ Have the expertise, time and commitment to perform all functions
- The IEC will have representation that is varied in terms of gender, age and social background to safeguard the interests and welfare of all sections of the community / society’.
- The committee should include at least one member whose primary area of expertise is in a non-scientific area, a clinician and at least one member who is independent of the institution/ research site.
- The IEC may invite member(s) of specific patient groups or other special interest groups for an IEC meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement (*AX 05/SOP 02/V1*) and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of ‘Guest/ Observer’ and will not have right to vote. (See SOP 05/V1)
- The Composition shall be as follows:
  - ✓ Chairperson (non -affiliated to the institution)
  - ✓ Co-Chairperson (non-affiliated to the institution, optional)
  - ✓ One Member Secretary (institutional)
  - ✓ One Joint Member Secretary (institutional, optional)
  - ✓ One or more persons from basic medical science (preferably a pharmacologist, especially if overseeing drug, device, vaccine, biologics etc. research)

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- ✓ One or more clinicians from various institutes
- ✓ One legal expert
- ✓ One social scientist/ representative of non-governmental agency
- ✓ One philosopher, ethicist or theologian
- ✓ One or more lay person from community

#### ***4.2 Criteria for selection of members of IEC***

##### ***Chairperson***


- From outside the institution.
- A person with high standing in society
- have at the minimum 1-3 years experience of serving on an ethics committee

##### ***Co-Chairperson (if applicable)***

- From outside the institution (preferably).
- have at the minimum 1-3 years experience of serving on an ethics committee

##### ***Member-Secretary (and Joint Member-Secretary, if applicable)***

- Will be a staff member of the institution.
- Preferably be a medical professional for institutions doing biomedical research. For institutions doing social research, the MS may be a social scientist.
- Should have a state medical council recognised postgraduate degree
- Should have domain speciality experience, clinical research and ethics knowledge, personal interest and capacity, good communication skills

	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p><b>Effective Date: aa/bb/cccc</b></p>
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### ***Members***


- Members will be selected in their personal capacities based on their qualification, experience in domain field, interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC. They should not have any known record of professional misconduct.
- Medical scientists and clinicians should have post graduate qualifications.
- Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests (See SOP 03/V1).

### ***4.3 Agreement regarding Maintenance of Confidentiality***

- It is the responsibility of each IEC member, reviewing research project or attending IEC meetings, to read, understand, accept and sign the agreement contained in the confidentiality Form (*AX 03A/SOP 02/V1*).
- The staff of the secretariat will sign confidentiality agreement which should be filed with the IEC. (*AX 03B/SOP 02/V1*)
- The Secretariat will obtain the signature of the IEC Chairperson on the Confidentiality form
- The secretariat will provide IEC member a photocopy of the Confidentiality Form for their records (duly signed and dated by them and IEC Chairperson) and acknowledge the receipt of agreement with their signature.
- The Secretariat will keep the original copies of the signed Agreements in the IEC office in the file entitled 'Confidentiality Agreement file for members and photocopies of the agreement in the individual members files.

### ***4.4 Tenure of Membership***

- The tenure of IEC will be for a continuous period of 2 years (*this can be 3 or 4 years depending upon institutional policy*) from the date of appointment.

	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p><b>Effective Date: aa/bb/cccc</b></p>
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#### ***4.5 Appointment of New Members***

- a) The IEC members will be appointed by the HOI.
- b) New members will be appointed under the following circumstances:
  1. When a regular member completes his/ her tenure.
  2. If a regular member resigns before the tenure is completed.
  3. If a regular member ceases to be a member for any reason including death or disqualification.
  4. To fulfill the membership requirements as stated in this SOP
- c) New members will be identified by the Chairperson according to the membership requirement (i.e. as per the composition specified in Section 4.1 of this SOP) and provided the potential member fulfils the conditions of appointment) after discussion by the IEC. The names of new members to be appointed may be suggested by the IEC members and the Chairperson to the HOI. The final decision regarding appointment of members will be taken by the HOI.

#### ***4.6 Conditions to be fulfilled by a member after appointment***

Members to be appointed on the IEC will need to fulfill the following conditions:

- Members must submit
  - ✓ a recent signed CV
  - ✓ Preferably, if available training certificates in Ethics and/ or GCP [if not available at time of induction as member in the IEC, the member must submit these within *6months (as per institutional policy)* of appointment].
- Members must be willing to
  - ✓ publicize his/her full name, profession and affiliation.


	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p><b>Effective Date: aa/bb/cccc</b></p>
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- ✓ sign the Confidentiality Agreement (as per Annexure 3A/SOP 02/V1) and maintain confidentiality regarding meetings, deliberations, research proposals, information on research participants and related matters.
- ✓ read, understand, accept and follow the Conflict of interest policy and sign the Conflict of interest agreement/form (See SOP 03/V1).


#### ***4.7 Resignation and Disqualification of Members.***

- Resignation: An IEC member may resign from membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson.
- Disqualification for conduct unsuitable of an IEC member: A member may be disqualified from continuance should IEC determine by a three-fourth majority specifically called for the purpose that the member's conduct has been inappropriate of an IEC member.
  - (i) The process will be initiated if IEC Chairperson or Member-secretary receives a communication in writing (provided by IEC member or a member of the public) alleging misconduct by a member.
  - (ii) The Chairperson will satisfy himself/ herself that a prima facie case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of IEC could be questioned, the Chairperson may suspend the membership of the concerned IEC member till final decision is taken by IEC. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an IEC member and will not perform any duties of IEC member.
  - (iii) The Chairperson may call for a meeting of the IEC specifically to discuss this issue or the matter will be taken up for discussion. The meeting convened will follow the usual rules.
  - (iv) of quorum. The allegation will be discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.



	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p><b>Effective Date: aa/bb/cccc</b></p>
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- (v) The member would stand disqualified, if members present approve of disqualification by voting (voting by 2/3<sup>rd</sup> of majority of members present in the meeting and voting). The Chairperson will convey the disqualification to the concerned member through a written communication.
- Disqualification for not attending IEC meetings: A member may be disqualified from IEC membership if the member fails to attend more than 3 regular consecutive IEC meetings without prior intimation. The process conducted will be as follows:
    - (i) The Member Secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the IEC without prior intimation to the IEC.
    - (ii) The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next regular IEC meeting.
    - (iii) A written communication will be sent to the concerned IEC member informing him/ her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case. Alternately, the concerned IEC member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson
    - (iv) The matter will be discussed and reviewed at the IEC meeting. The concerned member will be provided adequate opportunity to represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.
  - The Chairperson or Member-Secretary will inform the IEC members about the cessation of membership by a confidential written communication to other members of IEC or at the next meeting of IEC.


	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p><b>Effective Date: aa/bb/cccc</b></p>
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#### ***4.8 Training of the IEC Members in Research Ethics***

- An individual selected as a new member of the IEC will be required to attend one meeting as an ‘Observer’ before being inducted as a member of the IEC.
- Member Secretary or an IEC member will provide introductory training in Research Ethics, GCP and SOPs to the new member.
- A newly inducted member should submit certificate of training in 6 months.
- All members including Chairperson and Member Secretary will be encouraged to receive continued training by participating in a workshop, conference and/ or re-training program related to research ethics, as a delegate, faculty, facilitator, etc.
- The IEC will conduct workshops on ethics in clinical research, GCP and SOPs from time to time to impart training and update the IEC Members and Institutional faculty members.
- The IEC may nominate *and / or sponsor the expenses of (as applicable)* an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program etc.

#### ***4.9 Hierarchy***

- There will be one Chairperson, one Member Secretary and one Joint Member Secretary (wherever applicable) may be appointed amongst the members.
- The Chairperson will head the committee.
- The Member Secretary and the Joint Member Secretary (whenever applicable) will be the guardian of all documents and funds in the possession of the committee.
- Other IEC members will be regular committee members with equal ranking.

	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p><b>Effective Date: aa/bb/cccc</b></p>
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#### ***4.10a Functions of Chairperson***


- The Chairperson will be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to the review of research proposals.
- The Chairperson will preside over all elections as well as administrative and financial matters pertinent to the committee's functions. The Chairperson will represent the IEC at various meetings and forums.
- The Chairperson will sign documents and communications related to IEC functioning.
- The Chairperson will delegate his/ her responsibilities to the Co-Chairperson in accordance with IEC SOPs.
- In case of anticipated absence of both Chairperson and Co-Chairperson at a planned meeting, the Chairperson will nominate a committee member as Acting Chairperson or the members present may elect the chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

#### ***4.10b Functions of Co- Chairperson***

- To act as Chair in the absence of Chairperson and to perform all functions of Chairperson.

#### ***4.11 Functions of the Member secretary***

- Receive research proposals
- Organize an effective and efficient tracking procedure for each proposal received.
- Prepare, maintain and distribute of study files.
- Schedule and organize IEC meetings
- Prepare and maintain meeting agenda and minutes.
- Maintain IEC documentation and to archive them.
- Sign documents and communications related to IEC functioning.

	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p><b>Effective Date: aa/bb/cccc</b></p>
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- Communicate with the IEC members and applicants/ investigators.
- Notify the Principal Investigator regarding IEC decisions related to the submitted research proposal.
- Arrange for training of personnel and IEC members.
- Organize the preparations, review, revision and distribution of SOPs and guidelines.
- Provide necessary administrative support for IEC related activities to the Chairperson.
- Provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
- Receive ethics committee review processing fees and issue official receipts for the same.
- Delegate various responsibilities to appropriate and authorized individuals
- Ensure adherence of IEC functioning as per SOPs
- Prepare for audits and inspections
- Prepare and make available for scrutiny by auditors/ inspectors annual reports/ annual financial statements of the IEC.

***4.12 Functions of the Joint/ Associate/ Alternate Member Secretary*** (whenever appointed)

The Joint Member Secretary will perform the same functions of Member Secretary in his/her absence.

***4.13 Functions of IEC members***


- Attend IEC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- Review, discuss and consider research Proposals submitted for evaluation.

	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p><b>Effective Date: aa/bb/cccc</b></p>
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- Monitor Serious Adverse Event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate.
- Do onsite visits wherever needed
- Evaluate final reports and outcomes.
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- Declare any conflict of interest in writing to the Chairperson, if any, at each meeting.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
- Provide an updated CV when requested for by the IEC secretariat
- Carry out the work delegated by Chairperson, Member-secretary and Jt. Member-secretary
- Assist Chairperson, Member-secretary and Jt. Member-secretary in carrying out IEC work as per SOPs
- Be updated on relevant laws and regulations

#### ***4.14 Secretariat***

- The Secretariat will be composed of the scientific officer/s, the administrative Officer/s and other administrative supporting staff.
- The Secretariat will support the Member Secretary and Joint Member Secretary (if applicable) in all their functions
- All the staff of the Secretariat will sign confidentiality agreement which should be filed with the IEC. (AX 03-B/SOP 02/V1)
- The working rules for the Secretariat are stated in (AX 01/SOP 02/V1)

	<p><u><b>FERCI MODEL SOPs</b></u></p> <p><u><b>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</b></u></p>	<p><u><b>SOP 02/V1</b></u></p> <p>Effective Date: aa/bb/cccc</p>
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#### ***4.15 Types of projects reviewed by IEC***


The IEC will review scientific and ethical aspects of all types of research studies involving human participants; sponsored by pharmaceutical companies, sponsored by Government of India / NGOs, studies in collaborations with international organisations/universities, all dissertation projects (postgraduate students :MD, MS, MCh, DM, Mch, DNB, PhD, MSc, MPTh, MOTh, Nursing, dental and any other course run by Institution as applicable), research projects of undergraduate students carried out under guidance of teachers (e.g. Indian Council for Medical research studentship or any other) and investigator initiated research studies which are self funded / funded by institutional funding bodies.

#### ***4.16 Quorum Requirements***

- The full board meeting will be held as scheduled provided there is quorum.
- For the IEC meeting, a quorum will consist of at least 5 members for regulatory clinical trials with the following representation: one basic medical scientist (preferably one pharmacologist), one clinician, one legal expert, one social scientist/representatives of non-governmental voluntary agency/Philosopher/ethicist/theologian or a similar person, one Lay person from the community, **apart from** Member Secretary and Chairperson as mandated by Schedule Y.
- Without satisfying this condition, any decision taken by the committee shall remain null and void.
- In absence of the Chairperson, Co-Chairperson will chair the meeting.

#### ***4.17 Honorarium to the Members***

Reimbursement of travelling expense and /or reasonable honorarium for attending the IEC meetings may be given to the IEC members.

	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p><b>Effective Date: aa/bb/cccc</b></p>
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#### ***4.18 Preparing an annual activity report of the IEC for submission to the Head of the Institute***

The Member Secretary will make a yearly activity report for submission to the Head of the Institute which will include the following elements:

- a. Number and dates of the IEC meetings of full board
- b. Number of SAE subcommittee and any other subcommittee, as applicable )  
Number and type of proposals (Pharma/ Government sponsored/ Dissertations/ investigator initiated) reviewed in a year, status of each study proposal whether completed / ongoing / terminated
- c. Number of approvals for full board review/ expedited review with decisions
- d. Brief details about workshops, training programmes and other activities undertaken by the IEC and those attended by IEC members
- e. Any other matter

#### ***5. Reference to other applicable SOPs***

***SOP 03/V1 - Conflict of Interest Policy for Institutional Ethics Committee***

***SOP 08/V1 - Agenda Preparation, Meeting Procedures and Recording of Minutes***


#### **6. Annexures**

Annexure 1 *AX 01/SOP 02/V1* - IEC Administrative Staff: Working rules

Annexure 2 *AX 02/SOP 02/V1* - Organizational Chart of the Institution

Annexure 3A *AX 03 A/SOP 02/V1* - Confidentiality Agreement Form for IEC members

Annexure 3B *AX 03B/SOP 02/V1* – Confidentiality Agreement Form for Staff of the Secretariat

	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p><b>Effective Date: aa/bb/cccc</b></p>
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*Annexure 1: AX 01/SOP 02/V1*

***The IEC Administrative Staff: Working Rules***

- There will be administrative officer / assistant /s and attendant/s /helper/s who will help the IEC Chairperson and Member-Secretary in executing functions of the IEC. Additional staff may be appointed and duties assigned; as and when deemed necessary by the IEC. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile and qualifications, office timing, salary structure and number of leaves may be recommended by IEC members and discussed during regular IEC meeting and will be recorded in minutes.
- The administrative staff will report to the Chairperson and/or Member Secretary.
- The administrative staff will be appointed by the IEC chairperson and Member secretary with the help of members by conducting formal interviews


***Duties of Administrative officer/ assistant***

- Correspondence with IEC members and external experts
- Correspondence with the investigators
- Preparing agenda and minutes of the IEC meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving and maintaining the study files, SOPs, all correspondences
- Maintaining electronic database of the IEC records

***Duties of the attendant/s /helper/s***

- Assisting the secretariat in arranging the IEC meetings
- Dispatching sets of study documents to IEC members and external experts



	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC</u></b></p>	<p><b><u>SOP 02/V1</u></b></p> <p>Effective Date: aa/bb/cccc</p>
--	--	--

- Receiving the study related documents from and dispatching the IEC letters to the investigators
- Filing study related documents
- Archiving and maintaining the study files
- Assisting the Secretariat during the meetings

***Annexure 2: AX 02/SOP 02/V1***

*(Organizational flow Chart to be made by individual IEC to indicate Authority under which it is established and its hierarchy position in the organisation)*

***Annexure 3A: AX 03A /SOP 02/V1***

***Confidentiality Agreement Form for IEC Members***

In recognition of the fact, that I, \_\_\_\_\_

\_\_\_\_\_ (Member's name, his/her position on IEC and affiliation) herein referred to as the "undersigned", have been appointed as a member of the 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.

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.

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 and the undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behavior to carry out its mandate.



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This agreement encompasses any information deemed Confidential provided to the Undersigned in conjunction with the duties as a member of the IEC. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC. The undersigned agrees to hold all confidential 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.

I, \_\_\_\_\_ (name of the IEC member) have read and accept the aforementioned conditions as explained in this Agreement.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Chairperson's Signature

\_\_\_\_\_  
Date

*[The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to the Undersigned.]*

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date



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***Annexure 3B: AX 03-B/SOP 02/V1***

***Confidentiality Agreement Form for Staff of the Secretariat***

I, \_\_\_\_\_

(*Staff's name and designation*) herein referred to as the "undersigned", have been appointed as a staff of the IEC office. This agreement encompasses any information deemed confidential provided to the Undersigned in conjunction with the duties as a staff of the IEC. All confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The undersigned hereby agrees not to disclose or utilize, directly or indirectly all confidential information known to him or her during his tenure of service.

I, \_\_\_\_\_ (name of the IEC office staff) have read and I accept the conditions as explained in this Agreement.

\_\_\_\_\_

Signature

Date

\_\_\_\_\_

Chairperson's Signature

Date

*[The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to the Undersigned.]*



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**Constitution of Institutional Ethics  
Committee (IEC), Selection, Roles and  
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**7. Flow Chart**

<b>No.</b>	<b>Activity</b>	<b>Responsibility</b>
1	Composition of the Institutional Ethics Committee	Head of the Institute
2	Selection and appointment of Chairperson	Head of the Institute
3	Appointment of new members	Head of the Institute
4	Conditions of appointment	IEC Members and Secretariat
5.	Initiation of the process of appointment	Secretariat
6.	Tenure of Membership	Chairperson, IEC Members and Secretariat
7.	Resignation and disqualification of members	IEC Members and Secretariat
8.	Quorum requirements	IEC Members and Secretariat