 <p><b>FERCI</b></p>	<p><b><u>FERCI MODEL SOPs</u></b></p> <p><b><u>Training and Assessment of Ethics Committee</u></b></p> <p><b><u>Members</u></b></p>	<p><b><u>SOP 21/V1:</u></b></p> <p><b><u>Effective Date: aa/bb/cccc</u></b></p>
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**Title: Training and Assessment of Ethics Committee Members**

**SOP Code: SOP 21/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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## **1. Purpose**

The purpose of this SOP is to describe requirements and methodology for training and performance assessment of the Institutional Ethics Committee (IEC) members and the Secretariat.

## **2. Scope**

The SOP applies to all the IEC members and the Secretariat.

## **3. Responsibility**

It is the responsibility of the IEC Chairperson with the assistance of Member Secretary to ensure that there is adequate initial and continued training of the IEC members and the Secretariat. The Chairperson is responsible for assessment of all IEC members and complete a self-assessment exercise at prescribed intervals.

## **4. Detailed instructions**


### ***4.1. Topics for training***

IEC members should have knowledge of the following:

- ✓ Relevant research ethics and regulatory guidelines
- ✓ Roles and Responsibilities of IEC members
- ✓ Review of protocol and related documents, including concepts of Risk Benefit assessment, Equity in recruitment, Autonomy, Confidentiality and Privacy
- ✓ Recent Developments in relevant health science specialities
- ✓ SOPs of the IEC

Secretariat should have knowledge and relevant skills for conducting the following activities:

- ✓ Competency in working on Microsoft word, Excel, IEC office software
- ✓ Maintenance of IEC Database
- ✓ Communication skills- written and verbal
- ✓ Knowledge about the SOPs


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#### ***4.2. Training of new IEC Members***

- Every time a new committee is constituted, the members must undergo initial training on ethics in clinical research and good clinical research and SOPs. One training every year at the minimum should be provided.
- An individual selected as a new member of the IEC will be required to attend two meetings as an ‘Observer’ before being inducted as a member of the IEC. Member Secretary or an IEC member will provide an introductory training to the new member. The new IEC members would be encouraged to undergo online EC training programme too.
- The IEC Member Secretary, member, Chairperson will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.
- The IEC will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the IEC Members to the Institutional faculty members.
- The IEC may sponsor or reimburse the expenses of an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program (if applicable).

#### ***4.3. Training of the Secretariat***

The IEC Member Secretary along with other members will train the Secretariat on SOPs. There will be initial training and at least one training session per year on SOPs. The competency of staff in computers and communication skills will be evaluated and ensured initially at the time of appointment by the Member Secretary and Chairperson.

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#### **4.4. Assessment of IEC members**

- The IEC members' performance should be evaluated once a year using an assessment form (AX 01/SOP 21/V1) by the Chairperson.
- The Chairperson should do self-assessment once a year

#### **4.5. Maintenance of training records of the IEC Members and the Administrative Staff**

The Secretariat should maintain copies of the certificates of all training workshops and conferences in research ethics attended by the individual IEC members. The copies will be filed in the individual members' files. The records regarding training copies of the Secretariat will also be maintained in their respective files.


### **5. Annexures**

Annexure 1 AX 01/SOP 21/V1- Self Assessment Form for ECMember Secretary/ Member

#### ***Annexure 1: AX 01/SOP 21/V1***

##### ***Assessment Form for Ethics Committee Members***

1. Current tenure
2. Terms served
3. Training received
4. Type of training received
5. No of meetings attended
6. No of projects reviewed per meeting as primary reviewer
7. No of projects reviewed per meeting as secondary reviewer
8. Participation in SAE report review process- yes/no
9. Participation in site monitoring visits - yes/no

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10. Number and type of continuing training workshops organised for IEC members (applicable to Member Secretary)
11. Number and type of continuing training workshops organised for staff of the IEC secretariat (applicable to Member Secretary)
12. Any other significant contribution to the field of research ethics
13. Remarks by the Chairperson on the self-assessment

***Annexure 2: AX 02/SOP 21/V1  
Self Assessment Form for IEC Chairperson***

1. Current tenure-
2. Terms served -
3. Training received -
4. Type of training received -
5. No. of meetings held in current year -
6. No of meetings attended-
7. Whether quorum requirement fulfilment ensured as per schedule Y in IEC meetings
8. Whether considerations related to conflict of interest considered
9. Any significant contribution to the field of research ethics
10. Any other comments \_\_\_\_\_

**6. Flow Chart**

No.	Activity	Responsibility
1	Ensuring Training of IEC members	IEC Member Secretary/ Chairperson
2	Training of Secretariat	IEC Member Secretary/ Members
3	Assessment of performance of members	IEC Chairperson
4	Assessment of performance of Chairperson	IEC Chairperson (self evaluation)