

	Institutional Ethics Committee Title: Training and Assessment of Ethics Committee Members	SOP 21/V1 Effective from September 2019 Valid till September 2022
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21.1. 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.

21.2. Scope

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

21.3. 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 a complete self-assessment exercise at prescribed intervals.

21.4. Detailed instructions

21.4.1. 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

21.4.2. 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 Practice Guidelines and SOPs, unless they are not already trained. Refresher training will be provided at least once in every year.

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- Member Secretary or an IEC member will provide an introductory training to the new members. They would be encouraged to undergo EC training programme too within six months of joining as members.
- The Chairperson, IEC Member Secretary, and members 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 Practice Guidelines from time to time to impart training to the IEC Members and the Institutional faculty members.
- The IEC may sponsor or reimburse the expenses of IEC members or prospective members for attending conference, continuing education session workshop and/ or training program (if applicable).

21.4.3. 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.

21.4.4. Assessment of IEC members

- The IEC members' performance should be evaluated once a year using an assessment form by the Chairperson.
- The Chairperson should undergo self-assessment once a year

21.4.5. 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. Copies of the records regarding training of the Secretariat will also be maintained in their respective files.

5. Annexures

Annexure 1: AXO1/SOP 21/V1- Self Assessment Form for IEC Member Secretary/ Member

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

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Annexure 1: AX 01/SOP 21/V1

Self Assessment Form for Ethics Committee secretary/ Member

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
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

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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 was ensured when required as per New Drugs and Clinical Trials Rules (19.3.2019) in IEC meetings
8. Whether issues related to conflict of interest considered
9. Whether any other issues of serious consequences addressed
10. Any significant contribution to the field of research ethics
11. Any other comments.

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21.6. 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)