



**IHEC – MGMCRI SOPs
Training and Assessment of Ethics Committee
Members**



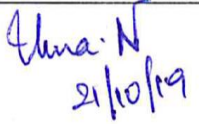

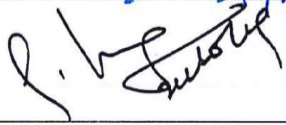
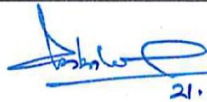

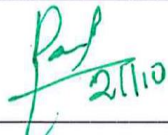
**SOP Code: SOP 21/V2
Effective from 21/10/2019**

Title: Training and Assessment of Institutional Human Ethics Committee Members

SOP Code: SOP 21/V2

Effective Date: 21-10-2019

SOP Constitution and Approval

Prepared by:	Signature and Date:
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Reviewed by:	Signature and Date:
Dr. Ananthakrishnan. N, IHEC Member	 21/10/19
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Dr. Adithan C, Dean Research, SBV	 21/10/19
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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 Human Ethics Committee (IHEC) members and the Secretariat of IHEC, MGMCRI.

2. Scope

The SOP applies to all the members and the Secretariat of IHEC, MGMCRI.

3. Responsibility

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

4. Detailed instructions

4.1. Topics for training

IHEC members should have knowledge of the following:

- ✓ Relevant research ethics and regulatory guidelines
- ✓ Roles and Responsibilities of IHEC 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 IHEC

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

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

4.2. Training of new IHEC 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 IHEC will be required to attend two meetings as an ‘Observer’ before being inducted as a member of the IHEC. Member Secretary or an IHEC member will provide an introductory training to the new member.



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The new IHEC members would be encouraged to undergo online EC training programme too.

- The IHEC Member Secretary/Additional 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 IHEC will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the IHEC Members to the Institutional faculty members
- The IHEC may sponsor or reimburse the expenses of an IHEC member or prospective members for attending conference, continuing education session workshop and / or training program.

4.3. Training of the Secretariat

IHEC Member Secretary/Additional 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/Additional Member Secretary and Chairperson.

4.4. Assessment of IHEC members

- IHEC members' performance should be evaluated once a year using an assessment form (AX01/SOP 21/V2) by Chairperson.
- Chairperson should do self-assessment once a year

4.5. Maintenance of training records of the IHEC 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 IHEC 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: AX01/ SOP 21/V2- Self Assessment Form for IHEC Member Secretary/ Member/
Additional Member Secretary

Annexure 2: AX02/ SOP 21/V2- Self Assessment Form for IHEC Chairperson



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Annexure 1: AX01/SOP 21/V2

Assessment Form for Institutional Human Ethics Committee Member Secretary / 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
10. Number and type of continuing training workshops organized for IHEC members (applicable to Member Secretary)
11. Number and type of continuing training workshops organized for staff of the IHEC 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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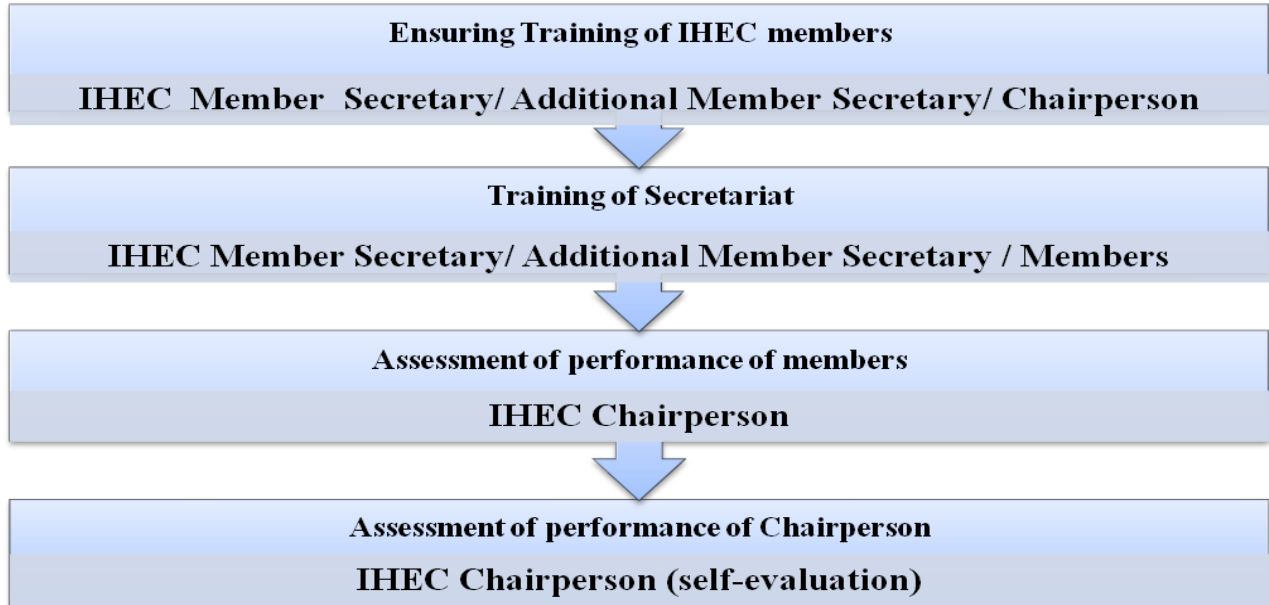
Annexure 2: AX02/SOP 21/V2

Assessment Form for Institute Human Ethics Committee 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 fulfillment ensured as per schedule Y in IHEC 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



7. References

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: <http://www.ferci.org/sops/>*