1. **Purpose**

The purpose of this section is to inform the Ethics committee personnel and members why training is necessary and how the members should seek to occasionally attend training or workshop programs to up-date themselves on the progress of technology, information and ethics.

New IEC members are required to undergo a training program on joining the Committee. It is the responsibility of the IEC Secretariat to give copy of the SOPs of the IEC, ICMR guidelines to the IEC members for reference and use.

2. **Scope:**

The SOP applies to all personnel of the IEC.

3. **Responsibility:**

It is the responsibility of the IEC members to have them educated and trained periodically.

4. **Flow chart:**

Sl.No.	Activity	Responsibility
1	Topics for training ↓	IEC members / staff
2	How to get trained ↓	IEC members / staff
3	Keeping the training record	IEC members /staff

5. **Detailed instructions:**

5.1 Topics for training: Ethics committee members should have knowledge of Good Clinical Practice (GCP) including Schedule Y, Declaration of Helsinki and other International guidelines like CIOMS, WHO Ethical Issues:

- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- E6 Good Clinical Practice: Consolidated Guidance, April 1996.
- WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011
- Forum for Ethical Review Committees in Asia and the Western Pacifica SOPs 2006
- New Drugs and Clinical Trial rules, 2019

An interchange of ideas, information and experiences with overseas institutions and organizations related to research ethics will be attempted. Efforts would be made to collect

information on overseas trends and to attend international specialist meetings organized for the exchange of experience and information.

5.2 How to get trained

- IEC conducts formal training to all the members on the recent amendments and guidelines

5.3 Keeping the training records

- Fill in the form to record the training/workshop/conference activities in chronological order.
- Make a copy of the form.
- Keep the original form (Attendance list) as records with signed and dated.
- Give the copy to the administrative staff to keep in the IEC member training record file.

6. Glossary:

Conference: A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.

Meeting: Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.

Workshop: A group of people engaged in study or work on a creative project or subject

7. References:

- ✓ International Conference on Harmonization of technical requirements for pharmaceuticals for human use(ICH)-2016
- ✓ Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
- ✓ WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013
- ✓ Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- ✓ Standard and operational guidance for ethics review of health related research with human participants-2011
- ✓ New Drugs and Clinical Trial Rules, 2019

ANNEXURE: 01 **AF/IEC/01/04/V-8.0**

Training Record Form

Name:

Department Name / Affiliation:

Staff / Membership since: Status:

Education Background:

Professional Qualification

1. Legal expert
2. Basic science Scientist
3. Basic medical scientist
4. Clinician
5. Social worker
6. Lay person
7. Any other Work Experience

Sl.No	Courses/ Workshops/ Conferences/Meetings attended	Organized by	Venue	Dates	Source of Funding
1					
2					