Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

Title: Training Personnel and Ethics Committee Members

SOP Code: 04/V1.2 Dated : 8th November 2024 Page Nos: 42 to 45

4.1. 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 update themselves on the progress of technology, information, and ethics.

ICMR-National Institute for Research in Reproductive and Child Health recognizes the importance of periodic training (at least once in 3 years) and continuing professional development. For the Secretarial staff it will provide training for EC office management including EC surveyor training. Therefore the institution will make arrangements for the training of the IEC personnel/secretariat and members through Institutional budget funds.

The IEC members who have obtained any fresh training in bioethics will surmise the new developments in the area of bioethics and regulations to the IEC members prior to or at the end of the EC meeting. Rules and regulations laid down by the CDSCO/DCGI will also be circulated to the IEC members and discussions may be encouraged.

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/stem cell research guidelines, etc. to the IEC members for reference and use.

4.2. Scope

The SOP applies to all personnel of the IEC.

4.3. Responsibility

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

4.4. Flow chart

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

4.5. Detailed instructions

4.5.1 Topics for Training

Ethics committee members should maintain competence by ensuring currency of their knowledge of:

1. Good Clinical Practice (GCP) including New Drugs and Clinical Trials Rules 2019
2. Any changes in regulations

3. Declaration of Helsinki and other International guidelines like CIOMS, WHO
4. Training in Standard operating procedures for members and secretariat staff.
5. Ethical Issues
    i. Risk-Benefit Assessment
    ii. Vulnerability Evaluation
    iii. Informed Consent/ Assent Assessment
6. Guidelines
    a. WHO's Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011
    b. Helsinki Declaration of Helsinki 7th version 2013
    c. ICH GCP Guidelines E6 (R1) 1996, (R2) 2016
    d. CIOMS International Guidelines for Health-related Research Involving Humans, 2016
    e. WHO's Ethical standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R&D, 2020
    f. SIDCER FERCAP – TOR and SOP for survey 2020
    g. SIDCER FERCAP – Online Survey Guidelines 2021
    h. US revised Common Rules effective January, 2019
    i. Indian GCP 2001
    j. National guidelines for Stem Cell Research, ICMR, 2017
    k. National Ethical Guidelines for Bio-medical Research involving Children, ICMR, 2017
    l. National Ethical Guidelines for Biomedical Health Research involving Human Participants, ICMR , 2017
    m. National guidelines for Ethics committees reviewing biomedical & health research during COVID-19 pandemic (ICMR, 2020)
    n. ICMR Guidelines for Good Clinical Laboratory Practices, 2021
    o. National Guidelines for Gene Therapy Product Development and Clinical Trials, 2019
    p. Establishment of a Network of Biorepositories in India, 2021

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.

4.5.2 How Ethics Secretariat Staff Can Get Trained

1. Get information about training courses, workshops, conferences, etc. which are periodically announced on websites, bulletin boards, and various media channels.
2. Select the ones you need.
3. Take approval from the EC Chairperson /Member Secretary and Director
4. Register to attend.
5. Keep the receipt.
6. Get reimbursed for the training expense as approved by the Director, ICMR-NIRRCH as per rules.

4.6. ANNEX

Annex 1 Document History

ANNEX 1 **AF/01/04/V1.2**

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.0	20th March 2013	First approved copy
Dr. Beena Joshi	Version 1.1	1st May 2019	Document History added
Dr. Vikrant Bhor	Version 1.2	8th November 2024	All bullets are numbered. Modifications done in the following points: 4.1 Training period reduced to every 3 years 4.5.1 Topics for training are added 4.5.2 Training for Ethics Secretariat staff is added