Title: Training Personnel and Ethics Committee Members

SOP Code : SOP/04/V1.0

Effective date : 20/03/2013

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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.

National Institute for Research in Reproductive Health recognizes the importance of training and continuing professional development, therefore the institution will make arrangement towards training of the IEC personnel/secretariat and members through Institutional budget funds .

The IEC members if have attained 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.

2. Scope

The SOP applies to all personnel of the IEC.

3. Responsibility

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

4. Flow chart

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 maintain competence by ensuring currency of their 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 , 2006
  - E6 Good Clinical Practice: Consolidated Guidance, April 1996, ICH –GCP
  - 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 Pacificac SOPs 2006
  - Stem Cell guidelines
  - Relevant laws and Regulations
  - International Issues/cases of Ethical concerns
  - Developments in relevant science, technical and environmental, health and safety aspectsClinical Audit procedures or Monitoring practices.

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

- Get information about training courses, workshops, conferences, etc. which are periodically announced on websites, bulletin boards and various media channels.
- Select the ones you need.
- Take approval from the IEC and the Director
- Register to attend.
- Keep the receipt.
- Reimburse the training expense as approved by the Director NIRRH as per rules.

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 as your record.
- Give the copy to the administrative staff to keep in the IEC member training record file.
- Keep the copy of the documents received at the time of training (soft and hard copy) for referral purpose by the other IEC members at the Ethics Committee office.

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

i. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
ii. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996
iii. Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

8. ANNEX

Annex 1 Training Record Form

ANNEX 1 **AF/EC/01/04/V1.0**

Training Record Form

First name: Last name:

Department Name / Affiliation

Staff / Membership since: Status:

Education Background:

Professional Qualification

1. Legal expert
2. Basic Scientist
3. Clinician
4. Public health Expert
5. Social Scientist
6. Community member/Lay person
7. Any other

Work Experience:

S.N	Courses/ Workshops/ Conferences/Meetingsattended	Organized by:	Venue	Duration with dates	Source of Funding
1					
2					
3					
4					
5					
6					
7					
8					
9					