2.3. Training Personnel and IRB Members

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2.3. Training Personnel and IRB Members

1. Purpose

The purpose of this section is to inform the IRB 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.

EPHI recognizes the importance of training and continuing professional development, therefore the institution will allocate an annual budget for specific training and study visits for IRB personnel and members. New IRB members are required to undergo a training program prior to joining the Committee.

2. Scope

The SOP applies to all personnel and members of the IRB.

3. Responsibility

It is the responsibility of the institute, chairperson and IRB members to have themselves educated, to arrange/ train periodically.

4. Flow chart

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

5. Detailed instructions

5.1. Topics for training

IRB members should maintain competence by ensuring currency of their knowledge of:

- Good Research Practice
- Good laboratory practice (GLP)
- Good Clinical Practice (GCP)
- Data management

- Declaration of Helsinki
- Ethical Issues
- Relevant laws, national and international guidelines, manual and SOP's
- Developments in relevant science, technical and environmental, health and safety aspects
- Relevant requirements of health, safety and environmental laws and regulations and related documents
- Audit procedures
- And other relevant topics

An interchange of ideas, information and experiences with overseas institutions and organizations related to research ethics is also being carried out. International cooperation is also necessary to discuss ways of tackling harmful information distribution and joint efforts to tackle such distribution patterns. Efforts are being 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, meeting etc. which are periodically announced on websites, bulletin boards and various channels.
- Select the ones you need.
- Finalize administrative and financial issues
- Register and attend.
- Settle the finance according to EPHI regulation

5.3. Keeping the training records

- Submit the copy of training certificate to SERO
- Fill in the form EPHI-IRB AF 01-005/02.0 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 IRB 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

1. World Health Organization, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, 2011.
2. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Guidance for Good Clinical Practice (ICH GCP) E6(R2), 2016.

8. Annex

Annex 1: Training Record Form
(EPHI-IRB AF 01-005/02.0)

First name:	Last name:
Staff / Membership since:	Status:
Education Background:	
Work Experience:	

Training Experience:

#	Courses / Workshops / Conferences / Meetings Attended	Organized by:	Where?	Duration	Source of Funding
1					
2					
3					
4					
5					
6					
7					
8					
9					