

SOP 5 Training of IRB Members and Staff

1. Purpose

To describe the PELI-IRB procedures regarding initial and continuing training of IRB members and staff

2. Scope

The PELI-IRB recognizes the importance of training and continuing professional development. This SOP describes the training requirements of PELI IRB members, Independent consultants, Technical Reviewer and staff from initial training to continuing education to maintain and ensure competence in the review of different types of protocols.

3. Responsibility

It is the responsibility of the PELI IRB members, Independent consultants, Technical Reviewer and staff to have themselves educated and trained regularly. The Staff Secretary under the supervision of Member-secretary shall keep track of the training needs of all members and prepares a training plan for approval of both the board and Managing-Director.

4. Process Flow/Steps

| STEP | ACTIVITY | RESPONSIBILITY |
|------|---|-----------------------|
| 1 | Chair officially requests initial training to Managing Director | Chair/Staff Secretary |
| 2 | Ensure that all members undergo initial basic training | Chair/Staff Secretary |
| 3 | Keep track of training needs of IRB members and staff and plan for continuing education | Chair/Staff Secretary |
| 4 | Watch out for training opportunities and attend as needed | IRB Member/Staff |
| | | Secretary |
| 5 | Keep training records of the IRB members and staff | Staff Secretary |

5. Detailed Instructions

Step 1 Chair shall officially request initial training; which Managing Director approves.

Step 2 Chair and Staff Secretary should ensure that all members, consultants, committee and staff undergo initial (basic) training. It is the role of all members, consultants, committee and staff to be subjected with proper training as indicated in the following table.

| Initial (Basic) Training | | | | | |
|--------------------------|--|---|--|--|--|
| | IRB Members | Technical Reviewer | Independent Consultants | Staff Secretary and Member- Secretary | |
| • | Good Clinical Practice Training Health Research Ethics training | Research Methodology Training | • Good Clinical Practice Training • Health Research Ethics training | • Good Clinical Practice Training • Health Research Ethics training | |
| • | In-House PELI- IRB SOP and Assessment forms Training | • In-House PELI- IRB SOP and Assessment forms Training | • In-House PELI-IRB SOP and Assessment forms Training | In-House PELI-IRB SOP and Assessment Forms Training Documentation and Archiving | |

Step 3 Staff and Member Secretary shall keep track of training needs of the board, independent consultant, technical review committee and staff. They shall include this in annual budget plan. IRB members should maintain competence by ensuring that they have updated knowledge of the following:

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- CIOMS
- Ethical guidelines
- Relevant laws and regulations
- Relevant developments in science, health, and safety, etc.
- International meetings and conferences

Step 4 Staff, members and officers shall check for training opportunities needed and shall attend the said training once it has been approved by the managing director

Step 5 Staff secretary shall keep training records of the IRB members, consultants and staff under the supervision of the member-secretary. Prepare attendance sheets of in-house training with relevant information about the topic, duration, date and venue. Ask member attendees to sign the attendance sheet and keep a copy in the membership files.

Update the CV and Training Record (**Form 1.3**) of individual member/staff to reflect attendance of training activities at least every 2 years.