

Philippine Children's Medical Center Institutional Research – Ethics Committee (IR-EC) SOP 6.0 Training of IR-EC Members, Independent Consultants and Staff

Effective Date: JUN 2 5 2021

PCMC IR-EC SOP 6.0: Training of IR-EC Members, Independent Consultants and Staff

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
Authored by:	SOP Team / PCMC IR-EC Members
Effective Date:	
Prepared by:	Rachelle Angeli R. Niñalga, MD Mandelle (M. Niñalga, MD)
Endorsed by:	Mary Ann C. Bunyi, MD
Approved by:	Julius A. Lecciones, MD, PhD, DPA, CESO III Acieu an
Approval Date:	

PCMC IR-EC address: Quezon Ave. corner Agham Road, Quezon City, Philippines Contact number: (02) 8588-9900 Loc. 356 ; Fax Number: (02) 8924-0840

E-mail address: irec@pcmc.gov.ph



Philippine Children's Medical Center Institutional Research – Ethics Committee (IR-EC)

SOP 6.0 Training of IR-EC Members, Independent Consultants and Staff

Effective Date: JUN 2 5 2021

6.0 TRAINING OF IR-EC MEMBERS, INDEPENDENT CONSULTANTS AND STAFF

6.1 Policy Statement

The IR-EC Members, Independent Consultants and Staff shall have basic research ethics and good clinical practice training.

6.2 Purpose of the Activity

To ensure that all the IR-EC Members, Independent Consultants and Staff are provided with the necessary research ethics training to improve their participation during review.

6.3 Scope

This SOP includes the procedures for the training of the IR-EC Members that begins from requiring Basic Research Ethics Training (BRET) for all Members and Staff and ends with keeping track of Member and Staff participation in the initial and continuing ethics training and filing the documents in the Membership File.

6.4 Process Flow/Steps for the Training of the IR-EC Members, Independent Consultants and Staff

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Requiring Basic Research Ethics Training (BRET) for all Members and Staff	Chair
2	Providing opportunities for continuing education for the Members and Staff through participation in meetings, conferences and training courses	Chair, Secretariat
3	Keeping track of Member and Staff participation in the initial and continuing ethics training and filing the documents in the Membership File	Members, Secretariat

6.5 Detailed Instructions

6.5.1 Requiring Basic Research Ethics Training (BRET) for all the Members and Staff

6.5.1.1 All IR-EC Members shall be required to have Basic Research Ethics Training (BRET) that shall consist of research ethics principles, GCP, SOPs, etc. Upon appointment, a new member or staff shall undergo orientation, individually or as a group, to cover the following:



Philippine Children's Medical Center Institutional Research – Ethics Committee (IR-EC)

SOP 6.0 Training of IR-EC Members, Independent Consultants and Staff

Effective Date: JUN 25 2021

- a. Member's/Staff's responsibilities
- b. Confidentiality and Conflict of Interest Agreement;
- c. IR-EC review process and use of Protocol and ICF Assessment Forms
- d. IR-EC SOP
- **6.5.1.2** The IR-EC Chair and Secretariat shall ensure that initial research ethics training is provided to all new members.

6.5.2 Providing opportunities for continuing education for the Members and Staff through participation in meetings, conferences and training courses

- **6.5.2.1** The IR-EC Chair shall provide training opportunities to the Members and Staff through participation in local and national research ethics seminars, conferences and workshops, and allocating funds for this purpose.
- **6.5.2.2** The IR-EC Chair and Secretariat shall plan the training activities for individual IR-EC Members based on their training needs.
- **6.5.2.3** The IR-EC Chair and Secretariat shall track and facilitate attendance of IR-EC Members and Staff of specific training activities needed to ensure that each one gets training at least once a year.
- **6.5.2.4** The IR-EC Members who shall participate in research ethics training course or seminar-workshops either through personal or through IR-EC efforts/funding are encouraged to:
 - a. Share information with other members during IR-EC meetings
 - b. Distribute photocopies/e- electronic copies of relevant materials to the other members

6.5.3 Keeping track of Member and Staff participation in the initial and continuing ethics training and file filing the documents in the Membership File

- 6.5.3.1 For in-house training, the IR-EC Secretariat shall prepare attendance sheets with relevant information about the topic, duration, date and venue. They shall ask member-attendees to sign the attendance sheet and keep a photocopy of the attendance in the Membership Files, if a Training Certificate is not issued.
- **6.5.3.2** All IR-EC Members and Secretariat Staff should regularly update their Training Record. They shall submit proof of attendance in relevant training or continuing professional education sessions conducted outside of the institution (e.g. certificates of training) to the IR-EC Staff for filing.
- **6.5.3.3** The Secretariat shall update the Training Record (Form 6.1) of each IR-EC Member and Staff to reflect their attendance in training activities every time a photocopy of Training Certificate is submitted for filing. The Secretariat shall also update the CV of each IR-EC Member and Staff to reflect attendance of in training activities.



Philippine Children's Medical Center Institutional Research – Ethics Committee (IR-EC) SOP 6.0 Training of IR-EC Members, Independent Consultants and Staff

Effective Date: JUN 2 5 2021

6.6 Forms

Form 6.1 V.1.0 Training Record IR-EC Member

6.7 Glossary