

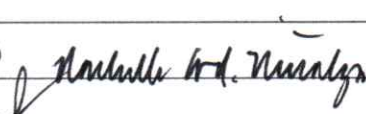
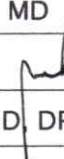
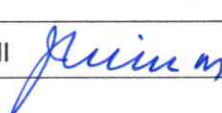


Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 4.0 Appointment of IR-EC Members**

Effective Date:  
**JUN 25 2021**

## PCMC IR-EC SOP 4.0: Appointment of the IR-EC Members

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Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
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## **4.0 APPOINTMENT OF THE IR-EC MEMBERS**

### **4.1 Policy Statement**

The IR-EC shall have a chair, a vice-chair, and a committee secretary who shall be selected and designated from among the regular members.

The PCMC Executive Director shall be responsible for the formal appointment of the Members and Officers of the IR-EC through a Memorandum Order after endorsement from the Deputy Executive Director for Education, Training and Research Services.

### **4.2 Purpose of the Activity**

To ensure that the IR-EC membership has the authority to function as the research ethics committee of the institution and will carry out their duties and responsibilities in order to have proper and smooth operations through appropriate supervision.

### **4.3 Scope**

This SOP includes the procedures in outlining the appointment of the IR-EC Members that begins from the approval of the new Members and Officers of the PCMC IR-EC and ends with the organizing and completing the documents in the Membership Files.

### **4.4 Process Flow/Steps for the Appointment of the IR-EC Members**

<b>NO.</b>	<b>ACTIVITY</b>	<b>PERSON/S RESPONSIBLE</b>
1	Approval of the new members and Officers of the PCMC IR-EC	Executive Director
2	Completion of membership documents	IR-EC Members, Secretariat
3	Organizing and completing the documents in the Membership Files	Secretariat

### **4.5 Detailed Instructions**

#### **4.5.1 Approval of the new Members and Officers of the PCMC IR-EC**

**4.5.1.1** The Executive Director shall be responsible for appointing the IR-EC Members and Officers with due consideration of the IR-EC recommendations.

**4.5.1.2** The Executive Director shall issue an Appointment Letter/Memorandum that identifies the IR-EC Members.



Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 4.0 Appointment of IR-EC Members**

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- 4.5.1.2.1** The Appointment Letter/Memorandum of the IR-EC Members shall include the term of office, scope of work, conditions of appointment, and honorarium as follows:
- a. Members are appointed for a period of one (1) year
  - b. Their appointments may be renewed by the Appointing Authority for up to six (6) consecutive terms at the discretion of the Executive Director depending on their performance
  - c. Members shall sign the Confidentiality and Conflict of Interest Declaration (Form 4.3). The agreement shall cover all applications, meeting deliberations, information on research participants and related matters. The confidentiality agreement shall protect the privacy and confidentiality of all parties whose information may be disclosed to the IR-EC in the course of its work.
- 4.5.1.2.2** The Appointment Letter/Memorandum shall include an attachment describing the responsibilities of an IR-EC Member, as follows:
- a. Make himself/herself familiar with the IR-EC SOP
  - b. Serve as Primary Reviewer for research protocol documents within his/her area of expertise
  - c. Serve as General Reviewer for all protocols discussed during full board meetings of the
  - d. Submit on time (within 7 working days of the full board meeting) to the Secretariat the completed Protocol and ICF Assessment Forms when he/she is designated as Primary Reviewer
  - e. Conduct Expedited Review of protocols assigned by the Chair, on behalf of the IR-EC, and submit the Assessment Forms on time (within 7 working days of receipt of assignment)
  - f. Perform post-approval review procedures of protocol-related documents within 7 working days
  - g. Update CV and training record (Form 4.2) with signature and date upon initial appointment then at least once every three years if reappointed
  - h. Willing to make public his/her full name, profession, and affiliation as an IR-EC member
  - i. Disclose any financial, professional or personal interest or involvement in a project or proposal under consideration, which is in conflict with his/her function as a reviewer



Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 4.0 Appointment of IR-EC Members**

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- j. Attend basic and continuing education on Research Ethics at least once a year
  - k. Obtain Good Clinical Practice (GCP) training certification which shall remain valid for three (3) years;
  - l. Maintain confidentiality of documents and deliberations during IR-EC meetings
  - m. Conform at all times with the legal and ethical principles accepted by the IR-EC
  - n. Perform other tasks requested by the IR-EC Chair on behalf of the IR-EC
- 4.5.1.2.3** The appointment of Non-Medical/Non-Scientific/Lay Member of the IR-EC shall contain an attachment describing his/her responsibilities as follows: The Non-Medical/No-Scientific/Lay Member of the IR-EC shall focus on the human subject/participant concerns, review the informed consent process as well as the informed consent forms to ensure the proper application of international and national principles and guidelines.
- 4.5.1.2.4** Alternate Member shall be appointed who is tasked to attend an IR-EC meeting to substitute for the Regular Member. During the specified meeting, the Alternate Member shall have the same roles and responsibilities as the Regular IR-EC Member he/she is substituting for.
- 4.5.1.2.5** The Executive Director shall issue an Appointment Letter/Memorandum that identifies the IR-EC Officers
- 4.5.1.2.6** The Appointment Letter/Memorandum of the IR-EC Officers shall include the term of office, scope of work, conditions of appointment, and honorarium as follows:
- a. Officers are appointed for a one (1) year term
  - b. They may be re-appointed but not for more than six (6) consecutive terms
- 4.5.1.2.7** The Appointment Letter/Memorandum shall include an attachment describing the responsibilities of the IR-EC Officers.
- 4.5.1.2.8 Responsibilities of the IR-EC Chair**
- The responsibilities of the Chair shall include the following
- a. Ensure that all IR-EC Members receive orientation and undergo basic Research Ethics Training immediately after their appointment, and continuing education thereafter
  - b. Obtain administrative and logistical support for the sustained operations of the IR-EC
  - c. Approve the agenda and preside over IR-EC full board review meetings



Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
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- d. Decide which protocols may be expedited
- e. Select suitable (somebody with related expertise) Member/ Independent Consultant to be the Primary Reviewer of a research protocol whether by Full Board Review or Expedited Review ensure that chosen reviewer does not have any conflict of interest.
- f. Ensure that a final decision on all research protocols reviewed is rendered
- g. Approve communication of IR-EC decisions to research proponents
- h. Manage complaints and queries from study participants, authorities or the general public
- i. Investigate, or designate Member/s to investigate, cases of complaints or reports of major non-compliance
- j. Ensure that the IR-EC is perceived as fair and impartial, and complies with institutional, national and international standards
- k. Represent the IR-EC interests within the hospital administration:
- l. Represent the IR-EC in various local, national and international meetings and conferences.
- m. Prepare the annual Work Financial Plan (WFP) and the Project Procurement Management Plan (PPMP) for endorsement by the Deputy Executive Director for Education, Training and Research Services and for approval by the Executive Director
- n. Ensure adherence to quality standards to maintain the accreditation status
- o. Supervise the IR-EC Secretariat in the preparation of the meeting agenda, meeting minutes and good office management

**4.5.1.2.9 Responsibilities of the IR-EC Vice Chair**

The responsibilities of the Vice Chair shall include the following:

- a. Preside over the IR-EC meetings in the absence of the Chair or if the Chair has a conflict of interest e in relation to the proposal to be deliberated
- b. Assist the Chair to ensure overall IR-EC compliance with good clinical practice
- c. Represent the Chair and the PCMC IR-EC in institutional, national and international meetings when the Chair is not available



Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
**SOP 4.0 Appointment of IR-EC Members**

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- d. Perform other duties as designated by the Chair or on behalf of the IR-EC

**4.5.1.2.10 Responsibilities of the Member-Secretary**

The responsibilities of the Member-Secretary shall include the following:

- a. Record and prepare the minutes during the IR-EC meeting
- b. Assist the Chair to ensure proper IR-EC documentation and archiving
- c. Perform other duties as designated by the Chair or on behalf of the IR-EC

**4.5.1.3 IR-EC Secretariat**

**4.5.1.3.1** The PCMC IR-EC Secretariat is composed of the administrative support staff who are employees of PCMC and appointed by the Executive Director.

**4.5.1.3.2** The Secretariat shall have the following functions:

- a. Collect the Assessment Forms submitted by the Primary Reviewers before the full board review meeting
- b. Ensure that the Members completely fill out necessary forms used for the review of protocols or submitted protocol-related documents
- c. Organize an effective and efficient tracking procedure for each research protocol package received
- d. Organize IR-EC meetings regularly
- e. Prepare and maintain meeting agenda and meeting minutes
- f. Maintain proper IR-EC documentation and archiving procedures
- g. Communicate with the IR-EC Members and Research Proponents and Investigators
- h. Arrange training for personnel and IR-EC Members, Independent Consultants and Secretariat
- i. Prepare, maintain and distribute study files and IR-EC documents
- j. Organize the preparation, review, revision and distribution of SOP and guidelines
- k. Provide the necessary administrative support to the Chair for IR-EC-related activities
- l. Provide updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the IR-EC members
- m. Maintain a library of relevant resource materials and references
- n. Relay and disseminate incoming and outgoing communication to and from IR-EC



Philippine Children's Medical Center  
Institutional Research – Ethics Committee (IR-EC)  
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**4.5.2 Completion of membership documents**

- 4.5.2.1** After the approval of the appointment, the newly appointed Members and Officers shall complete all documents in their Membership File.
- 4.5.2.2** Upon acceptance of their appointment, and before assuming their responsibilities as IR-EC Members and Officers, they shall sign and date the Terms of Reference (TOR) of the appointment letter indicating their willingness to assume their responsibilities.
- 4.5.2.3** The Secretariat shall provide duplicate copies of the Confidentiality and Conflict of Interest Declaration Form (Form No. 4.3) to the newly appointed Members for signature. One copy shall be given to the Member and the other copy is kept for the Membership File. For each protocol to be reviewed, they must disclose their COI (any interest or involvement such as financial, professional or otherwise in a research proposal under review).
- 4.5.2.4** The appointee shall also be required to submit an updated, signed and dated curriculum vitae and completed Training Record including photocopies of relevant training certificates.
- 4.5.2.5** The Secretariat shall likewise be expected to sign a similar document.
- 4.5.2.6 Resignation, Disqualification, and Replacement of Members**
  - 4.5.2.6.1** Members may resign their positions by submitting a letter of resignation to the Chair and endorsed by the Deputy Executive Director for Education, Training and Research Services to the Hospital Executive Director for approval.
  - 4.5.2.6.2** Members may be removed from the IR-EC by disqualification for valid reasons as determined by majority vote of the IR-EC Members. These may include frequent absences without valid reason, breach of confidentiality, violation of ethical principles, acts inimical to the interests of the IR-EC, etc.
  - 4.5.2.6.3** Members who have resigned or have been disqualified shall be replaced by following the nomination and appointment procedures previously stated.
  - 4.5.2.6.4** In the event that the IR-EC Chair's position is vacated, the Vice Chair shall become the Acting Chair until a new Chair is appointed.
  - 4.5.2.6.5** Vacated positions shall be filled upon appointment by the Executive Director through the recommendation of the IR-EC Chair and Members.
  - 4.5.2.6.6** The terms of replacement shall be limited to the remaining term of the Member that he/she has replaced.



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**4.5.3 Organizing and completing the documents in the Membership Files**

**4.5.3.1** The IR-EC Secretariat shall create one membership file for each member and file the following documents in each member's file.

- a. Letter of Appointment duly signed and dated by the appointee
- b. Updated Curriculum Vitae duly signed and dated by the Member
- c. Training Records and photocopy of Training Certificates of relevant research ethics trainings
- d. Confidentiality and Disclosure of Conflict of Interest Agreement Form duly signed and dated by the Member.

**4.6 Forms**

Form 4.1 V.3.0 Letter of Appointment of IR-EC Member

Form 4.2 V.3.0 Curriculum Vitae

Form 4.3 V.1.0 Confidentiality and Conflict of Interest Declaration

**4.7 Glossary**