
 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 1 of 22

REVISION HISTORY			
Rev No.	Review Date	Description of Change	Date of Next Review
0		Original	August 2012
1	February 2012	Change of Format	February 2013
2	February 2015	Change of Format	February 2016
3	November 2015	Change of Format	November 2016
4	July 2017	Change of Format	July 2018
5	December 2018	Change of Format	December 2019
6	July 2019	Change of Format	July 2020
7	December 2020	Change of Format	December 2021
8	January 2024	Change of Format	January 2025

Reviewed by:	MARIA TERESA B. ABOLA, MD Deputy Executive Director for Education Training and Research Services	Approved by:	JOEL M. ABANILLA, MD Executive Director
--------------	---	--------------	---

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001	
		POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title		Revision Number: 8
	IERB STRUCTURE AND COMPOSITON		Page: 2 of 22

Appointment of Institutional Ethics Review Board (IERB) Members

1.1 Appointment of Institutional Ethics Review Board (IERB) Members

1.1.1 Purpose


To describe the appointment procedures of the members of the Philippine Heart Center-IERB and to identify the roles and responsibilities of IERB officers and members.

1.1.2 Scope

While the IERB remains under the authority of the Executive Director, it has to maintain its independence and develop its competence related to decision making as defined in international and national guidelines. The membership SOPs cover the nomination and appointment procedures of IERB members and officers.

1.1.3 Responsibility

- | | | |
|----------------------------------|---|--|
| Executive Director | - | sign the appointment of the Members, |
| Deputy Executive Director | - | recommends to the executive director appointment letter of members. |
| IERB Chair | - | selects possible members of the IERB and recommends to the Deputy Executive Director for Education Training and Research Services after due consultation with the current members of the IERB. |
| IERB Member | - | reads, understands and respects the policies and procedures set by the IERB of the Philippine Heart Center |
| Alternate Member | - | attends meeting and actively participates in the review of research |
| Designated Member | - | acts as topic expert to guide the Board during the discussion of the protocol. |
| | - | evaluates the protocol for review and accomplish the assessment form. |
| | - | summarizes the comments of IERB members providing scientific and ethical comments. |

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 3 of 22

Independent

Consultant

- provides expert review of study protocols which require scientific or medical expertise not represented in the current composition of the board or those which the board has ascertained to require additional expert review.


1.1.4 Process Flow/Steps

NO.	ACTIVITY	PERSONS/RESPONSIBLE	TIMELINE
1	Define the composition of the membership of the IERB	Chair, Board Secretary, IERB members	To be done 60 days before expiry of the appointment
2	Open the nomination of new IERB members from IERB itself, hospital management, department chairs, section heads and submit names of potential members to the IERB members for screening	IERB Members, Hospital Management, Department Chairs, Section Heads	
3	Recommend and submit the list of potential members to the Executive Director thru Deputy Executive Director	Chair	
4	Obtain approval of appointment of IERB members and officers	Executive Director thru Deputy Executive Director	
5	Ensure completion of membership documents like Confidentiality agreement and Conflict of Interest	New Member, Secretariat	
6	Organize and complete the documents in the Membership Files	Secretariat	
7	Quorum Requirements	Chair, Board Secretary	
8	Dissolving the IERB	Executive Director	
9	Incentives	IERB Board	

1.1.5 Detailed Instructions

1.1.5.1 Define the composition of the membership of the IERB


- The Chair shall discuss the qualifications of additional/new members with the existing members of the IERB.
- The IERB shall be composed of at least 9 deciding members.

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 4 of 22

- B1. The members include seven (7) members whose primary concerns are in medical science, one (1) member whose primary concerns are in non-medical / non-scientific areas, and one (1) member from outside the PHC.
- B2. The IERB membership is multidisciplinary. The IERB members have diverse background and experience to foster a comprehensive and efficient review of research activities commonly conducted by its own affiliated and non-affiliated researchers.
- B3. Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. It is recommended that the IERB should include a person who will represent the interest and concerns of the community.
- B4. Professional qualifications prefer to include physician, pharmacist, nurse, social scientist, lawyer, statistician, paramedic and/or lay person specifically conversant with or grounded on ethical value studies.
- B5. The IERB has adequate representation of men and women members in order to promote gender sensitivity in its review procedures.
- B6. The IERB has representatives from both the older and younger generations.
- B7. During review meetings, the IERB adheres to quorum requirements as defined in international and national guidelines for IERB that review health research.
- B8. When reviewing clinical trials involving children or pediatric patients, a pediatrician or child development specialist is present during its board meeting.

1.5.1.2 Open the nomination of new IERB members from IERB itself, hospital management, department chairs, section heads and submit names of potential members to the IERB members for screening

- A. The Deputy Executive Director for Education, Training and Research Services (ETRS) shall announce the open nomination process for the IERB to hospital management, department chairs, and section heads.
- B. Any hospital staff may submit the name of their nominees to the Chair for deliberation, with their corresponding Curriculum Vitae.
- C. IERB members shall be selected based on their good moral character and personal capacities, their scientific expertise and knowledge of ethical principles,

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 5 of 22


as well as their willingness to volunteer their time and effort to perform their functions in the IERB.

- D. Members shall have prior training in research ethics, research methodology, and Good Clinical Practice or should be willing to undergo continuing training during their membership.
- E. During the IERB meeting the Chair shall present the credentials of the person being nominated.
- F. IERB Members shall discuss and decide by consensus on the final list of nominees to be submitted to the Executive Director thru Deputy Executive Director of Education Training and Research Services (ETRS)
- G. Conflict of interest issues of nominees shall also be discussed.

1.1.5.3 Recommend and submit the list of potential members to the Executive Director thru Deputy Executive Director of ETRS

A. Selecting Members

- A.1 The Executive Director thru Deputy Executive Director of ETRS shall review the list of nominees and decide on the appointment to be made.
- A.2. The appointment letter shall include conditions of appointment, term of office, and honorarium (if any), as follows:
 - A.2.1 Members are appointed for a period of three (3) years and renewable for several consecutive terms depending on their performance.
 - A.2.2 Willingness to make public his/her full name, profession, and affiliation as an IERB member.
 - A.2.3 Members disclose all financial accountability related to their work in the IERB that may record and publicly disclose its financial records upon request.
 - A.2.4 Members sign the Confidentiality and Conflict of Interest Agreements. The agreement covers all applications, meeting deliberations, information on research participants and related matters.
- A.3. It shall contain an attachment about the responsibilities of an IERB member, as follows:

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 6 of 22

A.3.1 Serve as Designated Reviewers for research protocol documents within their area of expertise, and as General Reviewers for all researches discussed at convened meetings of the IERB

A.3.2 Submit on time (within 7 calendar days) to the Secretariat the completed Protocol and ICF Assessment forms when they are Designated Reviewers

A.3.3 Perform post-approval review procedures of protocol-related documents within 7 calendar days.

A.3.4 Update CV and training record every time appointment is renewed

A.3.5 Conform at all times with the legal and ethical principles accepted by the IERB

A.3.6 Attend basic and continuing education on Research Ethics at least once a year

A.3.7 Perform other tasks requested by the Chair.

A.4 Appointment of Non-Medical/Non-Scientific Member of the IERB shall contain an attachment of their responsibilities as follows:

A.4.1 Focus on the human subject/participant concern.


A.4.1 Review the informed consent process and the informed consent forms to ensure adequate the proper application of international and national principles and guidelines.

A.5 The IERB shall adopt some mechanism to enable participation of new members with fresh outlook and approaches, but it shall also strive to ensure continuity, as well as the development and maintenance of expertise.

B. Selecting Officers - The Chair and Board Secretary are nominated by the members of the IERB. They are highly-respected individuals within or outside the institution, fully capable of managing the IERB and ensuring fairness and impartiality in dealing with matters brought to the IERB. They shall have the following qualifications:

B1.1 Good personal characteristics and reputation

B1.2 Have training on Basic Research Ethics, GCP in Research and advanced courses on Research Ethics in the past 3 years

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 7 of 22

B1.3 Have been a member of an Ethics Review Committee for **at least three (3) years.**

1.1.5.4 Obtain approval of appointment of IERB members and officers


- A. The Executive Director thru Deputy Executive Director for Education Training and Research Services of the **PHC** shall be responsible for approval and appointment the IERB Officers with due consideration to the IERB recommendations.
- B. The Executive Director thru Deputy Executive Director for Education Training and Research Services shall issue an appointment letter that identifies the IERB member
- C. The appointment letter shall include an attachment of the responsibilities of the IERB Officers as follows:

Responsibilities of the Chair


The Executive Director thru the Deputy Executive Director for Education Training and Research Services shall select and appoint for three (3) years IERB Chair based on experience and expertise from among current and former IERB members.

The responsibilities of the Chair include the following:

1. Preside the meetings and liaise directly with the Executive Director of the Philippine Heart Center thru the Deputy Executive Director for Education Training and Research Services and invite independent consultants to provide special expertise to the IERB on proposed research protocol.
2. Provide leadership to the IERB in ensuring the rights and welfare of human subjects participating in research.
3. Conduct convened meetings, review and approve the minutes documenting IERB discussions and findings thru the Board Secretary.
4. Lead discussions with principal investigators to resolve controversial and/or procedural matters relating to research approval and conduct.
5. Complete the Conflict of Interest/Disclosure Form and disclosing any potential conflicts prior to IERB review of the research for which a conflict may exist.
6. Manage conflict of interest by ensuring that IERB members with conflict of interest are not present for review of research for which a conflict may exist.

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 8 of 22

7. Maintain confidentiality of IERB-related information in accordance with the terms and conditions of the Confidentiality Agreement.
8. Administer Board decisions and maintain the independence of the IERB.
9. Sign correspondence communicating and documenting IERB decisions.
10. Sign decision recommendation by designated reviewer for trainees and other PI to review protocols with minor modifications and with amendment based on their field of expertise.
11. Review, approve and sign the recommendations made by the TRC representative on the review of minor modifications made by the fellow/resident after full board review.
12. Participate in the development of meeting agenda, policies, procedures, and educational efforts to support the human research protection program.
13. Maintain a current knowledge of and assuring compliance with relevant regulations, laws, and policies related to the protection of human subjects.
14. Consult yearly with the secretariat/staff regarding IERB issues.
15. Assist investigation and review of alleged noncompliance with human subjects protection requirements.
16. Ensure that all IERB members receive orientation and undergo basic Research Ethics Training immediately after their appointment, and continuing education thereafter
17. Obtain administrative and logistics support for the sustained operations of the IERB
18. Approve the agenda and preside over IERB review meetings (If Chair has COI relative to the protocol for deliberation s/he designates the Vice-Chair or any Member to preside over the meeting).
19. Selects suitable (somebody with related expertise) member/independent consultant to be the designated reviewer of a protocol whether by full board or expedited review, and ensures that aforementioned member does not have conflict of interest.
20. Manage complaints from study participants, authorities or the general public
21. Designate a member or group of members to investigate in cases of complaints or report of major non-compliance ensures that the IERB is perceived as fair and impartial, and complies with institutional, national and international standards

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 9 of 22

22. Represent the IERB in various local, national and international meetings and conferences.
23. Review the Annual Budget and the Project Procurement Management Plan (PPMP) and approved by the Deputy Executive Director of Education Training and Research Services.
24. Ensure adherence to quality standards to maintain the accreditation status.

The Vice-Chair shall:

The Vice-Chairman can be appointed by the Chair for three (3) years and selected based on experience and expertise from among current and former IERB members. The Vice-Chairman can be re-appointed but not more than three (3) consecutive terms. Have a replacement until the completion of the normal term if he/she resigns or be disqualified.

The responsibilities include:


1. Support the role and responsibilities of the Chair and assume duties as delegated by the Chair.
2. Responsible to chair the meetings in the absence of the Chair.

Responsibilities of the Board Secretary

The Board Secretary shall be appointed by the Chair for three (3) years. He/She may be re-appointed but not more than three (3) consecutive terms. If he/she resigns or be disqualified, the Board Secretary may be replaced until the completion of the normal term.

The responsibilities of the Board Secretary include the following:

1. Fill out Conflict of Interest Screening/Disclosure Form and disclosing any potential conflicts prior to IERB review of the research for which a conflict may exist.
2. Maintain confidentiality of IERB-related information in accordance with the terms and conditions of the IERB Member Confidentiality Agreement.
3. Maintain a current knowledge of and assure compliance with relevant regulations, laws, and policies related to the protection of human subjects.
4. Monitors the activities of the IERB office.

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 10 of 22


5. Orients the secretariat and ensure having continues training on office management.
6. Takes minutes of the meeting.
7. Record and review accurately all minutes of the meeting of the IERB.
8. Supervise the Secretariat related to good IERB office management.
9. Ensure that the members completely fill out necessary forms used for the review of protocol or protocol related submissions.
10. Supervise the Secretariat in the preparation of the meeting agenda and notice of meeting.
11. Supervise the Secretariat in the preparation of the annual report of the IERB to be submitted to the Executive Director thru Deputy Executive Director for Education Training and Research Services of PHC, DOH, PHREB and other bodies.
12. Ensure good IERB documentation and archiving.
13. Ensures overall IERB compliance with good clinical practice.
14. Ensure good financial management of IERB resources.

Secretariat

The Secretariat can be appointed by the Executive Director thru the Deputy Executive Director for Education Training and Research Services shall be supervised by the Board Secretary. The Secretariat is composed of the Executive Secretary and the Assistant Secretary who are employees of the Hospital.

The Secretariat shall have the following functions:

1. Maintain a list of all its members including alternate members with their current CVs and signed confidentiality agreements.
2. Maintain a list of independent consultants.
3. Organize an effective and efficient tracking procedure for each proposal received.
4. Prepare, maintain and distribute study files to the IERB members.
5. Organize IERB meetings.
6. Prepare and maintain meeting agenda and minutes given by the Board Secretary.

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 11 of 22


7. Maintain and archive the IERB's documents.
8. Communicate with the IERB members and principal investigators.
9. Arrange training for the IERB Members and Secretariat.
10. Organize, prepare, review, revise and distribute the Policy/SOP to Executive Director and Deputy Executive Director for Education Training and Research Services.
11. Provide the necessary administrative support for IERB related activities to the Chair of the Board (e.g. communicating a decision to the principal investigator).
12. Provide updates on relevant and contemporary issues related to ethics in health research as well as relevant contemporary literature to the Board members

Member or Alternate Member

The member or alternate member shall be appointed by the Executive Director thru the Deputy Executive Director for Education Training and Research Services or upon the recommendation of IERB members and chairman based on experience and expertise. A Technical Review Committee (TRC) representative shall be recommended by the Chair to the Executive Director thru the Deputy Executive Director of Education Training and Research Services as a member of the IERB with voting capacity.

The IERB or alternate members shall have the following functions:

1. Attend IERB meetings and actively participate in the review of research, unless arrangements have been made for the alternate's attendance.
2. Complete initial training in human subjects protection for IERB members with continuing education every three (3) years and attend yearly updates on research ethics.
3. Provide timely written comments on research undergoing IERB review.
4. Review, discuss and consider research proposals submitted for evaluation.
5. Monitor serious adverse event reports and recommend appropriate action/s.
6. Review the progress reports and monitor ongoing studies as appropriate.
7. Evaluate final reports and outcomes.
8. Maintain confidentiality of IERB-related information in accordance with the

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 12 of 22

terms and conditions of the IERB Member Confidentiality Agreement.


9. Fill out Conflict of Interest Form and disclosing any potential conflicts prior to IERB review of the research for which a conflict may exist.
10. Participate in continuing education activities on biomedical ethics and biomedical research.
11. Maintain a current knowledge of and assure compliance with relevant regulations, laws, and policies related to the protection of human subjects.
12. Participate in the discussion of issues affecting the human research protection program and contribute to policy development, as appropriate.
13. Review and approve research by expedited procedures, when designated by the Chair.

Appointment of Additional Member

1. The Chair shall recommend a possible member to the Executive Director thru the Deputy Executive Director for Education Training and Research Services.
2. The IERB member shall signs a confidentiality agreement at the start of the term.
3. The IERB member shall disclose in writing any interest or involvement (financial, professional or otherwise) in a project or proposal under consideration.

1.1.5.5 Ensure completion of membership documents like Confidentiality agreement and Conflict of Interest

- A. After the approval of the appointment, newly appointed members/officers shall complete all documents in their Membership File.
- B. Upon the acceptance of their appointment, and before assuming their responsibilities as members/officers, they shall sign and date the TOR of the appointment letter indicating their willingness to assume their responsibilities
- C. The Secretariat shall provide duplicate copies of the Confidentiality and Conflict of Interest Agreement form (**FM-E-IRB-2019-006 Rev. 04**) to newly appointed members of the PHC-IERB, one copy for the member and the other for the Membership File. For each protocol that they review, they shall disclose their COI

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 13 of 22

(any interest or involvement such as financial, professional or otherwise in a research proposal under review).

D. The IERB Member/Secretariat shall follow the instruction:

D.1 The IERB member requests for a copy of the document in behalf of a non-member requesting for a copy of the document.

D.2 The IERB Member/Secretariat signs the confidentiality/conflict of interest agreement form.

D.3 The Chair approves the request.

D.4 The Secretariat prepares a copy of the requested documents.

D.5 The Secretariat encodes the request in the Log of requested IERB's Document form.

D.6 The Secretariat files the log of request for copies of document form and log of requested IERB's document form.

D.7 The requestor receives the requested documents.

E. All IERB Members, Secretariat, independent consultants, guests shall sign the Confidentiality/Conflict of Interest Agreement Form and filed.

F. Confidentiality of study protocols, IERB documents and other correspondence shall be mandatory.

G. If non-members of the IERB need copies of any document, it shall be the responsibility of the IERB member/secretariat to request a copy on behalf of the non-members to maintain confidentiality of documents.

H. The types of documents to be reviewed by IERB members shall include:

H.1 Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)


H.2 The IERB documents (Policies, Procedures, Forms, meeting minutes, recommendations and decisions).

H.3 The correspondence (from experts, auditors/surveyors, study participants, etc)

I. Copies of documents, including draft and sequential versions, shall be considered confidential and shall not be permitted to be brought out except when a document is needed for day-to-day operations.

I.1 Only IERB members shall be allowed to ask for copies of documents.

I.2 Only the Secretariat shall be allowed to make such copies.

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 14 of 22

I.3 The Secretariat may ask help from IERB members, but is responsible for maintaining confidentiality of all documents.

J. A Log of Requested Document shall be kept by the Secretariat.

J.1 The log includes: the name and signature of the individual receiving the copy (name of recipient); the initial of the Secretariat who made the copy; the number of copies made and the date that the copies were made.

J.2 Copies of documents requested by non-members of the IERB (including the Secretariat) is only given after the permission from the Chair of the IERB and the person requesting for the document signs a confidentiality agreement form.

J.3 Copies made for non-members of the IERB is be recorded in both the Log of Request for Copies of Document Form (FM-E-IRB-2019-037 Rev. 03) and the log of Copies of Requested IERB's Document Form (FM-E-IRB-2019-036 Rev. 03).

J.4 The Log of Requested IERB's Document Form is stored with the original documents.

J.5 A Log of Requested IERB's Document Form is maintained.


K. The appointee shall submit an updated, signed and dated curriculum vitae, and the completed Training Record including photocopies of relevant training certificates.

Resignation, Disqualification, and Replacement of Members

1. Any member may resign their positions by submitting a letter of resignation to the Chair and endorsed to the Executive Director thru Deputy Executive Director for Education Training and Research Services.
2. Any member may be separated from the committee by disqualification for valid reasons as determined by majority vote of the committee members.
3. Members who have resigned or have been disqualified may be replaced by following the nomination and appointment procedures previously stated.
4. The terms of replacement shall be limited to the remaining term of the member that he/she has replaced.

1.1.5.6 Organize and complete the documents in the Membership Files

- A. The Membership Files shall contain the following:

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 15 of 22

A.1 Appointment letter signed and dated by the appointee

A.2 Updated curriculum vitae that is signed and dated by the member

A.2.1 The CV is updated every time the appointment is renewed.

A.2.2. Training Record and photocopy of Training Certificates of relevant trainings

A.2.3 Confidentiality and Disclosure of Conflict of Interest Agreement signed and dated by the member.

B. The Secretariat shall create one membership file for each member, and file the following documents in each member's file.

B.1 Letter of Appointment

B.2 Curriculum Vitae

B.3 Training Records

B.4 Confidentiality and Disclosure of Conflict of Interest Agreement

1.1.5.7 Quorum Requirements

A. A minimum of 5 of the members shall be present at a meeting in order to issue a valid advice and/or decision.

B. Professional qualifications of the quorum requirements shall consist of at least one member whose primary area of expertise is medical, one non-scientific/non-medical, and one independent of the institution/research site.


1.1.5.8 Dissolving the IERB

A. At any point in time, should the Philippine Heart Center cease to exist, the IERB shall automatically be dissolved.


B. The IERB shall also be dissolved at any time by the Executive Director of the Philippine Heart Center following written notification to each of the members.

C. In case of dissolution of the IERB all active protocols shall be endorsed to another accredited IERB.

1.1.5.9 Incentives

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 16 of 22

- A. The IERB members shall receive honorarium to be declared and approved by the Executive Director.

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 17 of 22

Appointment of Independent Consultant

1.2 Appointment of Independent Consultants

1.2.1 Purpose

To describe the procedures for the appointment of Institutional Ethics Review Board (IERB) Consultants

1.2.2 Scope


This SOP describes the procedures for engaging the services of a professional/expert as a consultant to the Philippine Heart Center IERB. If the Chair of the Philippine Heart Center IERB determines that a study involves procedure(s) that are not within the area of competence or expertise of any of the IERB members, the Chair may invite individuals with expertise in special areas to assist in the review of protocols that require such expertise in addition to those available within the IERB.

1.2.3 Responsibility

Upon the advice or recommendation of the Secretariat or any IERB member, the Chair may recommend appointment of the independent consultants.

1.2.4 Process Flow/Steps

NO.	ACTIVITY	PERSONS/ RESPONSIBLE	TIMELINE
1	Assess the need for Independent Consultants and seek approval for contracting their services	IERB Chair, Board Secretary, IERB members	To be done every quarter
2	Recruit and appoint an Independent Consultant	Chair, Secretariat	To be completed within 30 days
3	Organize and complete the documents in the Independent Consultant Files	Secretariat	

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 18 of 22

1.2.5 Detailed Instructions

1.2.5.1 Assess the need for independent consultants and seek approval for contracting their services


- A. Considering the nature of the protocol for review, the Chair with the Members shall identify the expertise needed that the IERB membership may not have. Including protocols that needs an additional expert not present in the existing independent consultants' roster.
- B. The Chair shall submit the names of independent consultants to the Executive Director thru Deputy Executive Director for Education Training and Research Services to request for corresponding honorarium.

1.2.5.2 Recruit and appoint an independent consultant

- A. Once the Chair decides to invite an Independent Consultant, the Secretariat shall prepare the letter of invitation that includes the following:
 - A.1 Terms of Reference (TOR) - duration of consultancy, general overview of deliverables
 - A.2 Honorarium
 - A.3 Request for a copy of the consultant's curriculum vitae (CV)
- B. The Secretariat sends the letter to the independent consultant after it is signed by the Chair together with the duplicate copies of the Confidentiality and Conflict of Interest Agreement form for the consultant's signature.
- C. The Secretariat asks the independent consultant to sign and date his acceptance of the TOR of the appointment.
- D. The Secretariat collects the signed and dated Confidentiality and Conflict of Interest Agreement, and the signed and dated updated CV using the prescribed format.

1.2.5.3 Organize and complete the documents in the Independent Consultant Files


- A. The Independent Consultant Files shall contain the following:
 - A.1 IERB Letter of invitation signed and dated by the Chair
 - A.2 Updated curriculum vitae that is signed and dated by the Independent Consultant
 - A.3 The CV is updated every time the appointment is renewed.

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 19 of 22

A.4 Training Record and photocopy of Training Certificates of relevant trainings

A.5 Confidentiality and Disclosure of Conflict of Interest Agreement signed and dated by the Independent Consultant.

B. The Secretariat creates one file for each independent consultant.

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 20 of 22

Training of IERB Members, Alternate Members and Secretariat Staff

1.3 Training of IERB Members, Alternate Members and Secretariat Staff

1.3.1 Purpose

To describe Institutional Ethics Review Board (IERB) procedures to ensure initial and continuing training of IERB members, Alternate members and Secretariat staff

1.3.2 Scope

The IERB recognizes the importance of training and continuing professional development. This SOP describes the training requirements of IERB members and Secretariat staff from initial training to continuing education to maintain and update IERB competence in the review of different types of protocols.

1.3.3 Responsibility


It is the responsibility of the IERB officers, members and staff to have themselves educated and trained regularly.

It is the responsibility of the Chair along with the Secretariat to assess the training needs and prepare a training plan for all members, Independent Consultants, and Secretariat staff.

Secretariat keeps track of the training records of all members, Independent Consultants, and secretariat staff in accordance with the training plan.

1.3.4 Process Flow/Steps

NO.	ACTIVITY	PERSONS/ RESPONSIBLE	TIMELINE
1	Require basic research ethics training for all members and secretariat staff	Chair	Needs assessment to be done at the beginning of the year
2	Provide opportunities for continuing education for board members, alternate members and secretariat staff through	Chair, Secretariat	


 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 21 of 22

	participation in meetings, conferences and training courses		
3	Track member and secretariat staff participation initial and continuing ethics training and file the documents in the Membership File	Secretariat	

1.3.5.1 Detailed instructions

1.3.5.1 Require Basic Research Ethics Training for all members and secretariat staff

- A. All IERB members shall be required to have basic research ethics training that shall consist of research ethics principles, GCP, SOPs, etc.
IERB members shall maintain competence by ensuring that they have updated knowledge of the following:
 - A.1 IERB Structure and Composition
 - A.2 Good Clinical Practice (GCP)
 - A.3 Declaration of Helsinki
 - A.4 CIOMS
 - A.5 Ethical Guidelines
 - A.6 Relevant laws and regulations
 - A.7 Relevant developments in science, health and safety, etc.
 - A.8 International meetings and conferences
- B. Upon appointment, a new member or staff shall undergo orientation, individually or as a group, to cover the following:
 - B.1 Member's/Secretariat Staff's responsibilities
 - B.2 Confidentiality and Conflict of Interest Agreement
 - B.3 IERB review process and use of Protocol and ICF Assessment forms;
 - B.4 IERB SOPs.
- C. The Chair and Board Secretary shall ensure that initial research ethics training is provided to all new members.

 <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p>	Document Type	Document Code: POL-E-IRB-001
	POLICY/STANDARD OPERATING PROCEDURE	Effective Date: January 2024
	Document Title	Revision Number: 8
	IERB STRUCTURE AND COMPOSITON	Page: 22 of 22

1.3.5.2 Provide opportunities for continuing education for board members, alternate members, and secretariat through participation in meetings, conferences and training courses

- A. The Chair shall provide training opportunities to members/secretariat staff through participation in local and national research ethics seminars, conferences and workshops, and allocating funds for this purpose.
- B. The Chair and Secretariat shall plan the training activities for individual IERB members based on their training needs.
- C. The Chair and Secretariat shall track and facilitate attendance of IERB members, alternate members and secretariat of specific training activities needed to ensure that each one gets training at least once a year.
- D. The IERB Members who participate in research ethics training course or seminar-workshops either through personal or through IERB efforts/funding shall be encouraged to:
 - D.1 Share information with other members during IERB meetings; and
 - D.2 Distribute photocopies/e-copies of relevant materials to the other members.

1.3.5.3 Track member and secretariat staff participation in initial and continuing ethics training and file the documents in the Membership File

- A. For in-house training, the secretariat shall prepare attendance sheets with relevant information about the topic, duration, date and venue. He/she shall ask member-attendees to sign the attendance sheet and keep a photocopy of the attendance in the membership files, if Training Certificate is not given.
- B. All IERB Members, alternate members and Secretariat Staff shall 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 Secretariat Staff for filing.
- C. Secretariat shall update the Training Record of individual Member and Secretariat Staff to reflect their attendance in training activities every time a photocopy of Training Certificate is submitted for filing.