PHILIPPINE HEART CENTER **INSTITUTIONAL ETHICS REVIEW BOARD**	Document Type **POLICY/STANDARD OPERATING PROCEDURE**	Document Code: POL-E-IRB-005
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	Document Title **WRITING AND REVISING OF STANDARD OPERATING PROCEDURE**	Revision Number: 6
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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	December 2018	Change of Format	December 2019
4	July 2019	Change of Format	July 2020
5	December 2020	Change of Format	December 2021
6	January 2024	Change of Format	January 2025

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Writing SOPs

5.1 Writing SOPs

5.1.1 Purpose

To describe the procedure for writing and SOPs used by the Institutional Ethics Review Board (IERB).

5.1.2 Scope

The SOP provides instruction on how the new IERB SOPs are prepared.

5.1.3 Responsibilities

Chair	- organizes an SOP Team to formulate the SOPs of the IERB. - convenes an IERB meeting to review and finalize draft SOPs and submits the final draft to the Executive Director thru Deputy Executive Director for Education Training and Research Services for final approval.
SOP Team Member	- an ad hoc committee composed of designated IERB members and invited resource person responsible for drafting new SOPs and revising existing SOPs when necessary. The team follows existing institutional procedures when drafting SOPs in consultation with the Secretariat and Chair. The team submits the draft SOPs to the Chair.
Secretariat	- keeps all versions of SOPs and ensures that all IERB members and have access to current versions of SOPs to guide them in the performance of their functions.

5.1.4 Process Flow for Writing New SOPs

NO.	ACTIVITY	PERSON RESPONSIBLE
1	Organize an SOP Team	Chair
2	Identify reference templates with corresponding layout	Secretariat
3	Draft new SOPs and submit to Chair	SOP Team
4	Review and finalize new SOP in an IERB meeting	Chair, IERB Members
5	Submit the new SOPs to the Hospital	Chair

	Director/Deputy Executive Director for Education Training and Research Services	
6	Approve and sign new SOPs	Director/Deputy Executive Director for Education Training and Research Services
7	Distribute approved SOPs and keep copies in the IERB files	Secretariat

5.1.5 Detailed Instructions

5.1.5.1 Organize an SOP Team

A. The Chair assigns members to be part of the SOP Team, and invites resource person as needed.

Note: The Chair may organize SOP Team workshops to facilitate the drafting of SOPs.

B. The SOP Team receives an orientation from the Chair regarding its duties and responsibilities.

5.1.5.2 Identify reference templates with corresponding layout

A. The Secretariat identifies reference templates with corresponding layout from SOPs of other IERBs to guide the SOP team in drafting new SOPs.

B. The SOP Team uses the following format:

B.1 Document History

1. The SOP Document Revision History Template (FM-E-IRB-2019-053 Rev. 05) describes the different versions of the document by version no., version date, description of main changes and date of next review. This is attached to the Master List of PHC-IERB's Standard Operating Procedures (FM-E-IRB-2019-059 Rev. 04)
2. The SOP uses a header with the following elements:
    - 2.1 Institutional seal or logo
    - 2.2 Name of institution
    - 2.3 Name of Office
    - 2.4 Document Type
    - 2.5 Document Title
    - 2.6 Document Code
    - 2.7 Effectivity date
    - 2.8 Page number

B.2 SOP Number

1. Each SOP shall be given a number and a title that is self-explanatory and is easily understood.

B.3 Title

B.4 Purpose of the SOP

B.5 Scope which identifies the extend of coverage of the SOP and its limitations

B.6 Responsibility identifies the persons assigned to perform specific tasks during SOP implementation

B.7 Process Flow/Steps

B.8 Detailed Instructions which elaborates the steps outlined in the process flow

B.9 Appendices (Standard forms and checklists to be used)

B.10 References

B.11 List of Acronyms and terminologies

5.1.5.3 Draft new SOPs and submit to the Chair.

A. The SOP team drafts new SOPs that contain details under the following main topics:

1. Introduction – contains a statement of ethical principles that will guide the IERB and historical background)
2. Structure and Composition of the IERB – describes the composition of IERB membership with specific review functions
3. Initial Review Procedures – describe types of review and initial review procedures
4. Monitoring Procedures – describe how the IERB monitor implementation of approved protocols
5. Management of Meetings, Documentation and Archiving–describe administrative procedures that support the review functions
6. Writing and Revising SOPs – describes how to draft and revise SOPs

B. The SOP Team submits completed SOP draft to the Chair.

5.1.5.4 Review and finalize new SOPs in an IERB meeting and

A. The SOP Team Leader presents the draft SOPs during an IERB meeting for the members to discuss and finalize the draft.

5.1.5.5 Submit to the Executive Director thru Deputy Executive Director for Education Training and Research Services

A. The Chair submits the approved draft to the Executive Director thru Deputy Executive

Director for Education Training and Research Services for approval.

5.1.5.6 Approve and sign new SOPs

A. The Executive Director/Deputy Executive Director for Education Training and Research Services reviews and approves the SOPs by signing in the designated section.

Note: The approved SOPs shall be implemented after approval by the Executive Director thru Deputy Executive Director for Education Training and Research Services

5.1.5.7 Distribute approved SOPs and keep copies in the IERB files.

A. The Secretariat distributes the new IERB SOPs to all IERB Members and Staff and files the original copy in the IERB storage cabinet.

Note: The SOP Manual with downloadable forms shall be uploaded on the Hospital website for the use of and guidance of researchers.

Revising SOPs

5.2 Revising SOPs

5.2.1 Purpose

To describe the procedure for revising SOPs used by the Institutional Ethics Review Board (IERB).

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5.2.2 Scope

This SOP provides instructions to IERB Member on how to revise existing SOPs.

5.2.3 Responsibility

Chair - appoints an SOP Team, an ad hoc committee composed of designated IERB members and invited resource persons.

IERB members - suggests revisions in existing SOPs

SOP Team - responsible for revising relevant parts of existing SOPs. The team follows existing institutional procedures when drafting or editing SOPs and consults the Secretariat and Chair about revisions. The team submits the revised sections to the Chair.

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Secretariat - responsible for keeping all versions of SOPs and ensures that all IERB members and have access to current versions of SOPs to guide them in the performance of their functions.

5.2.4 Process Flow/ Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Propose to revise an SOP	IERB Members
2	Revise existing SOPs	SOP Team
3	Review & discuss SOP revision in full board meeting IERB Members	IERB Members
4	Approve SOP revision	Executive Director, Deputy Executive Director, ETRS
5	File and distribute revised SOP	Secretariat
6	Retrieve and archive copies of superseded SOP	Secretariat

5.2.5 Detailed Instructions

5.2.5.1 Propose to revise an SOP

A. Any member of the board proposes for the revision of the any SOPs.

Note: 1. SOPs shall be reviewed at least every year and may be revised, as necessary by the IERB members.

2. A revision shall be substantial enough to warrant major changes. Major changes are those that have a substantial effect on procedures, definitions, requirements, and similar considerations. Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures.

3. When an SOP section does not cover what it should, or it does not follow new regulations, a revision may become necessary.

5.2.5.2 Revise existing SOPs

A. The Chair appoints the SOP team or an IERB Member designated by the Chair to draft the revision,

B. The SOP team prepares the draft of revisions.

5.2.5.3 Review & discuss SOP revision in full board meeting

A. The Chair convenes a full board meeting to discuss the revisions and finalize the draft.

B. The SOP team member presents the revised SOP to the IERB for deliberation during a full board meeting.

5.2.5.4 Approve SOP revision

A. The Chair submits the final version of the revised SOP to the Executive Director thru Deputy Executive Director Education Training Research Services for final approval.

B. The Executive Director thru Deputy Executive Director Education Training Research Services approves the revised SOP by signing on the appropriate SOP section.

Note: The approved version of revised SOPs shall be implemented from the date of approval by the Executive Director thru Deputy Executive Director Education Training Research Services.

5.2.5.5 File and distribute revised SOP

A. Upon approval, the Secretariat distributes the printed copy of the revised SOPs to the IERB members and staff and retrieves the extra copies of superseded SOP for disposal.

B. The Secretariat changes the electronic copy of the SOP published in the IERB's website with the newly revised version.

C. The Secretariat maintains an updated IERB SOP Manual in the office.

D. The Secretariat retains the original signed copy of the revised SOP in the SOP Masterfile.

E. The Secretariat transfers the original copy of the superseded copy is transferred to the archive after the updating of the SOP Document History.

5.2.5.6 Retrieve and archive original copy of superseded SOP

A. The Secretariat archives the superseded version of the SOP as part of the historical file maintained by the IERB.

B. The Secretariat stamp on the cover page of the superseded SOPs with the date of archiving,

Note: All printed copies of the superseded SOP in circulation shall be retrieved and disposed by shredding