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|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | | Revision Number: 9 |
| | | Page: 1 of 27 |
| Document Title | DOCUMENTATION AND ARCHIVING | |

| REVISION HISTORY | | | |
|------------------|---------------|-----------------------|---------------------|
| Rev No. | Review Date | Description of Change | Date of Next Review |
| 0 | | Original | August 2012 |
| 1 | March 2012 | Change of Format | March 2013 |
| 2 | May 2014 | Change of Format | May 2015 |
| 3 | April 2015 | Change of Format | April 2016 |
| 4 | November 2015 | Change of Format | November 2016 |
| 5 | July 2017 | Change of Format | July 2018 |
| 6 | December 2018 | Change of Format | December 2019 |
| 7 | July 2019 | Change of Format | July 2020 |
| 8 | December 2020 | Change of Format | December 2021 |
| 9 | January 2024 | Change of Format | January 2025 |
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| Reviewed by: | MARIA TERESA B. ABOLA, MD Deputy Executive Director for Education Training and Research Services | Approved by: | JOEL M. ABANILLA, MD Executive Director |
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|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 2 of 27 |

Preparing the IERB Preparation of Meeting Agenda

4.1 Preparing the IERB Preparation of Meeting Agenda

4.1.1 Purpose

To describe the procedures involved in agenda preparation before the conduct of the full board meeting of the Institutional Ethics Review Board (IERB).

4.1.2 Scope

This SOP provides instructions related to the preparation of meeting agenda before a full board meeting.

4.1.3 Responsibility

Chair - reviews and approves the agenda sent to him/her by the Secretariat.

Board Secretary - Supervise the Secretariat and reviews the prepared agenda.

Secretariat - prepares the agenda for the IERB meeting.


4.1.4 Process Flow/Steps

| NO. | ACTIVITY | PERSON/S RESPONSIBLE | TIMELINE |
|-----|---|------------------------------|----------|
| 1 | Prepare and finalize the Meeting Agenda | Secretariat, Board Secretary | 7 days |
| 2 | Make arrangements for the meeting | Secretariat | |
| 3 | Email Notice of Meeting | Secretariat | 1-5 days |
| 4 | File a copy of the agenda after the meeting | Secretariat | |

4.1.2 Detailed Instructions

4.1.2.1 Prepare and Finalize the Meeting Agenda

- A. One week before the scheduled meeting date, the Secretariat checks the submissions since the last full board meeting and prepares a list of items for

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 3 of 27 |

review during the next full board meeting.

B. The Secretariat uses the Meeting Agenda template **(FM-E-IRB-2019-050 Rev. 07)**

to classify the items for review.

C. The Secretariat forwards the draft meeting agenda to the Board Secretary to review and finalize.

D. The Board Secretary reviews the draft meeting agenda and makes changes, if needed.

E. The Secretariat presents the draft agenda to the Chair for approval and comments and it becomes the provisional meeting agenda.

F. The Chair presents the provisional meeting agenda at the beginning of the full board meeting and IERB members are given the chance to suggest additional items to finalize the meeting agenda.

4.1.2.2 Make arrangements for the meeting

A. The Secretariat contacts IERB members to check who will be available to attend the meeting to ensure quorum.

B. The Secretariat makes the necessary arrangements:

B.1. for reservation of meeting room on the scheduled meeting date and time.

B.2 for snacks of meeting attendees.

C. The Secretariat prepares relevant documents to be distributed to IERB Members who confirmed to attend the meeting.


4.1.2.3 Distribute Notice of Meeting

A. The Secretariat emails the Notice of Meeting (with the provisional meeting agenda) together with the relevant documents for review during the meeting to IERB Members within 1-5 days prior to meeting date.

4.1.2.4 File the meeting agenda

A. Secretariat takes note of changes in the provisional meeting agenda after this is presented for approval to the IERB. If there are no changes, the provisional meeting agenda becomes the final meeting agenda.

B. Secretariat files a copy of the provisional meeting agenda in a folder of Meeting Agenda for the year.

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 4 of 27 |

Conduct of a Full Board Meeting

4.2 Conduct of a Full Board Meeting

4.2.1 Purpose

To describe the procedures of Institutional Ethics Review Board (IERB) when it conducts a full board meeting to review protocol submissions

4.2.2 Scope

This SOP describes the various steps the IERB follows to review various types of protocol submissions, the types of decision and action taken as well as necessary documentation to record its proceedings.

4.2.3 Responsibility


Chair

- determines quorum - has to be reviewed thoroughly
- presides the IERB full board meeting
- sees to it that preliminary requirements related to the declaration of conflict of interest and confidentiality agreement and other related matters are complied with
- introduces the members of IERB to the PI
- Moderates discussion by identifying common findings and dissenting opinion, reconcile contradicting views, integrate and summarize findings
- calls on the designated reviewer to present the findings and recommendations
- directs the discussion for a consensus decision
- ensures that the documentation is accurate and covers all significant points

IERB

Scientific Member

- thoroughly reviews the scientific study protocols before the meeting
- makes observations, comments during the meeting, gives recommendations/decision.


| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | | Document Title |
| | DOCUMENTATION AND ARCHIVING | Page: 5 of 27 |

IERB Non-Scientific Member - Thoroughly reviews the non-scientific study protocols parts before the meeting makes observations, comments during the meeting, gives recommendations/decision. after the presentation of the protocol.

Principal Investigator - presents the protocol or study during the board meeting
summarizes the findings after the discussion

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.

Secretariat - Manages the document submission, prepares protocol documents to the board members and refers the protocol for full board meeting for discussion and decision
- prepares the ethical review decision using the consensus form (FM-E-IRB-2019-017 Rev. 06 IERB's Decision) to be signed by all members present
- transmits the ethical review decision or results to the Principal Investigator within one (1) to five (5) days for digital copy and within ten (10) working days for physical copy.
- Keeps copies of the documents in the protocol files and updates the protocol entry in the IERB database.
- creates a specific protocol file, prepares copies for distribution to the IERB members before the meeting

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 6 of 27 |


4.2.4 Process Flow/ Steps

| NO. | ACTIVITY | PERSONS/ RESPONSIBLE |
|-----|--|--------------------------------------|
| 1 | Call the Meeting to order | Chair |
| 2 | Determine Quorum | Board Secretary |
| 3 | Approve or modify the agenda | IERB Members |
| 4 | Declare Conflict of Interest | IERB Members |
| 5 | Approve the Minutes of the previous Full Board Meeting and discuss business arising from the Minutes | IERB Members |
| 6 | Discuss and decide on protocols for initial review | Designated Reviewer, IERB Members |
| 7 | Decide on protocol document resubmission with major modification | Designated Reviewer, IERB Members |
| 8 | Discuss and decide on major Protocol Amendments | Designated Reviewer, IERB Members |
| 9 | Discuss and decide on Progress Reports for full board review | Designated Reviewer, IERB Members |
| 10 | Approve Final Reports | Designated Reviewer, IERB Members |
| 11 | Report Onsite SAEs for appropriate action | Designated Reviewer, IERB Members |
| 12 | Discuss Protocol Deviation/ Violation Reports for appropriate action | Designated Reviewer, IERB Members |
| 13 | Report Expedited Review results | Chair/Secretariat |
| 14 | Report on protocols exempted from review | Chair/Secretariat |
| 15 | Report protocol reviewed and approved of the SJREB | Chair/Secretariat |
| 16 | Report/ Discuss other matters for full board action/ information | Chair, IERB Members, Board Secretary |
| 17 | Formally close the Full Board Meeting | Chair |

4.2.5 Detailed Instructions

4.2.5.1 Call the Meeting to order

- A. The Chair declares the formal opening of the Meeting at the appointed time and place once majority of the members are present.

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 7 of 27 |

4.2.5.2 Determine Quorum

A. The Board Secretary, or in his/her absence the Secretariat checks and reports if the quorum requirements are met to enable the meeting to start. IERB Quorum requirements should comply with national and international requirements and as defined in these SOPs.

Note: 1. Quorum shall be maintained throughout the duration of the meeting when members are required to vote to arrive at a decision.

2. The following shall be met to constitute quorum in a full board meeting of IERB:

A.1 50%+ 1 of panel membership but not less than 5

A.2 presence of medical/ scientific and non-medical/non-scientific members

A.3 presence of non-affiliated member

4.2.5.3 Approve or modify the agenda

A. The Chair asks the Members to examine and approve the items in the Meeting Agenda.

B. IERB members may suggest additional items for discussion and the meeting agenda may be modified to include additional items for discussion.

4.2.5.4 Declare Conflict of Interest

A. The Chair asks the IERB members to declare their conflict of interest related to any protocols to be discussed.


B. The IERB members check the agenda and declare their COI related to any protocol to be reviewed.

Note: 1. They shall be asked to leave the room during the discussion of such protocols, unless they are asked to reply to questions for clarification.

2. Quorum shall be maintained when members tin COI leave the room. They return to the room after discussion of their protocol.

4.2.5.5 Approve the Minutes of the previous Full Board Meeting and discuss business arising from the Minutes

A. The Secretariat sends the Minutes of the previous meeting to all members before the meeting for comments.

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 8 of 27 |

B. The Chair asks the members to approve the Minutes of the last meeting and ask the members to voice out their comments, if any.

C. The Chair also asks the members to comment about issues arising from the Minutes

D. The Board Secretary records the discussion of the current meeting.

4.2.5.6 Discuss and decide on protocols for initial review

The list of protocols for initial review are discussed according to the following procedures:

A. The Board Secretary determines the presence of quorum.

B. The designated medical reviewer summarizes the protocol to enable the members to understand it.

C. The designated medical reviewer uses the assessment form to comment on the technical and ethical issues in the protocol and makes recommendations about clarification, modification or approval. He/she also comments on the qualifications of the researchers and the sites.

D. The Chair opens the protocol for discussion of IERB members taking note of additional and contradictory comments.

E. The PI is called to enter the room to answer questions and clarify certain protocol related matters, after which, he/she is asked to leave the room.

F. The Designated Reviewer summarizes the points raised and notes different views among members that should be resolved. The Chair asks the members for consensus based on the decision points in the SOPs.

F.1 Approve (no further revision of the documents is required)

F.2 Minor Modification


F.2.1 When the decision is for minor modification the resubmitted protocol will go to expedited review.

F.3 Major Modification

F.3.1 When the decision is for major modification due to scientific and ethical issues, the resubmitted protocol will go to full board review.

F.4 Disapprove

G. The Non Medical/Non Scientific Reviewer presents his/her assessment of the Participants Information and Informed Consent Form (FM-E-IRB-2019-044 Rev.07). The comments should take note of the discrepancies between the protocol and the information sheet, the correct consent or assent is enclosed, and provisions for proper signatures in the form. The Chair asks the members for consensus based on the following decision points:

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 9 of 27 |

G.1 Approve

G.2 Minor modification

G.2.1 When the decision is for minor modification the resubmitted consent/assent form will go to expedited review.

G.3 Major modification

G.3.1 When the decision is for major modification due to scientific and ethical issues, the resubmitted consent/assent will go to full board review.

G.3.2 When the decision is for major modification but not due to scientific and ethical issues, the resubmitted consent/assent will go to expedited review at the level of the Chair/Reviewer.

G.4 Disapprove

H. The Board Secretary takes note of consensus results, records them and includes them in the Minutes of the meeting.

I. Once the protocol documents are approved, the IERB agrees on the frequency of continuing review.

4.2.5.7 Decide on protocol document resubmission with Major Modification

A. The Secretariat includes in the Meeting Agenda resubmissions required for Major Modification for full board discussion.

B. The Designated Reviewers check if the researchers complied with the IERB requirements and recommend appropriate decision. The IERB members conduct consensus to approve the resubmission.

4.2.5.8 Discuss and decide on Major Protocol Amendments

A. The Board Secretary screens amendments to determine Major Protocol Amendments that require full board review to ensure inclusion in the Meeting Agenda.


B. The Designated Reviewers review the amendment and present their assessment in full board meeting.

C. The IERB members conduct consensus to approve the Major Amendment.

4.2.5.9 Discuss and decide on Progress Reports for full board review

A. The Secretariat/Board Secretary screens Progress Reports that require full board review to ensure inclusion in the Meeting Agenda.

B. The Designated Reviewers review Progress Reports and present their assessment in full board meeting.

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 10 of 27 |

C. The IERB members conduct consensus to approve the Progress Reports.

4.2.5.10 Approve Final Reports

- A. The Secretariat submits a list of Final Reports to full board review and includes them in the Meeting Agenda.
- B. The Designated Reviewers review Final Reports and presents their assessment to full board.
- C. The IERB members vote to approve the Final Reports

4.2.5.11 Report Onsite SAEs for appropriate action

- A. The Secretariat prepares a list of Onsite SAEs/SUSARs and submits them for appropriate action in the full board meeting.
- B. The Designated IERB Reviewer reviews the Onsite SAE/SUSAR Reports and present their assessment and recommendation for appropriate action in the full board.
- C. The IERB members conduct consensus to take corresponding action on the Onsite SAE/ SUSAR Reports.

4.2.5.12 Discuss Protocol Deviation/ Violation/Non-Compliance Reports for appropriate action


- A. The Secretariat includes all Protocol Deviations/Violation/Non-Compliance Reports in the Meeting Agenda.
- B. The Designated Reviewers review the Reports and present their assessment and recommendation for appropriate action in the full board meeting.
- C. The IERB members conduct consensus to take corresponding action on the Protocol Deviation/Violation/Non-Compliance Reports.

4.2.5.13 Report Expedited Review results

- A. The Secretariat prepares a list of all Expedited Review results approved by the Chair and submits them inform the IERB members in the full board meeting.
- B. The Chair reports in a full board meeting.
- C, IERB Members may comment on the Report

4.2.5.14 Report on protocols exempted from review

- A. The Secretariat prepares a list of all exempted from review approved by designated

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 11 of 27 |

reviewer and by the Chair.

B. The Chair reports in the full board meeting.

4.2.5.15 Report on protocol reviewed and approved of the SJREB

A. The Secretariat prepares a list of all protocols reviewed and approved of the SJREB.

B. The Chair reports in the full board meeting.


4.2.5.16 Report/ Discuss other matters for full board action/information

A. The Chair/Board Secretary or any IERB Members may suggest items or other matters for the information or discussion by board.

B. The Chair/Board Secretary or any IERB Members may report queries and complaints that may need board discussion for appropriate action.

4.2.5.17 Formally close the Full Board Meeting

A. The Chair formally closes the full board meeting after determination that all the Meeting Agenda items have been discussed.

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 12 of 27 |

Preparation of the Minutes of Meeting

4.3 Preparation of the Minutes of Meeting

4.3.1 Purpose

To describe procedures for the preparation and approval of the minutes of the Institutional Ethics Review Board (IERB) full board meeting

4.3.2 Scope

This SOP provides instructions related to the preparation of the IRB full board meeting minutes and its approval by the IERB members.

4.3.3 Responsibility

Chair - signs the minutes of the meeting.


Board Member Secretary - documents and signs the conduct of the full board meeting, including the issues discussed, the decisions and recommendations made in accordance with the items in the meeting agenda.

IERB Member - attends the meeting and approves agenda and minutes of the meeting.

Secretariat - prepares the agenda for the IERB meeting

4.3.4 Process Flow/Steps

| NO. | ACTIVITY | PERSON/S RESPONSIBLE | TIMELINE |
|-----|--|----------------------|----------|
| 1 | Prepare of Minutes of Meeting template | Secretariat | 1-4 days |
| 2 | Preparation/Correction/ Finalization of minutes of the meeting | Board Secretary | 7 days |
| 3 | Approve minutes of the meeting | IERB Members | |
| 4 | File Minutes of the Meeting | Secretariat | |

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 13 of 27 |


4.3.5 Detailed Instructions

4.3.5.1 Prepare of Minutes of the Meeting template

- A. The Secretariat fills out the basic information about each protocol submission for review of the Minutes of the meeting template (FM-E-IRB-2019-033 Rev. 07) with identifying information (Protocol number, title, PI, sponsor, etc.) before the meeting date.
- B. The Secretariat uses this prepared template to document the proceedings during the full board meeting.

4.3.5.2 Preparation/Correction/Finalization of minutes of the meeting

- A. As the IERB meeting proceeds, the Board Secretary takes minutes of the meeting on real time according to the prescribed format and projects this on the multimedia screen to enable the IERB Members to closely follow the proceedings, and to facilitate the recapitulation of discussion points by the Chair/ Presiding Officer.
- B. The IERB makes decisions and recommendations in a collective nature thru consensus. No attribution to specific IERB member is stated in the minutes.
- C. The minutes of the meeting includes the following items
 - C.1 Date and venue of the meeting
 - C.2 Member attendance
 - C.3 Attendance of Researchers/PI, Independent Consultant and guest or observer, if any
 - C.4 Presiding Officer
 - C.5 Time when the meeting was called to order
 - C.6 Status of quorum at the start of the meeting and before every decision making
 - C.7 Discussion of items based on the order in meeting agenda
 - C.8 Members who declared COI and the protocol concerned
 - C.9 Summary of technical and ethical discussion points and recommendations
 - C.10 IERB decision and consensus results according to decision categories, abstention and consensus for disapproval with reasons given.
 - C.10.1 If the review decision (for initial and continuing reviews) is “approved”, the frequency of submission of progress report is determined.
 - C.10.2 If the review decision is disapproved, the reasons for the disapproval are stated.

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 14 of 27 |

C.10.3 If the review decision (for initial and continuing reviews) is “for modification”, the items to be revised are identified and the type of review for the resubmission is defined.

C. 10.4 The chair reports the approved protocols reviewed by expedited procedure and the protocols exempted from review.

D. The Secretariat attaches the following:

D.1 Name and signature of the person who prepared the minutes

D.2 Name and signature of the Secretariat to indicate the contents have been verified and corrected

D.3 Name and signature of the Chair who approved the minutes with the date of approval

E. The Board Secretary finalizes minutes of the meeting incorporating final corrections..

F. The Secretariat distributes the final version of the minutes of the meeting together with the Notice of Meeting for the next IERB meeting.

4.3.5.3 Approve minutes of the meeting

A. During the next full board meeting, the Chair asks the members to approve the Minutes.

B. The IERB members may suggest further corrections.


C. The IERB members approve the Minutes.

D. The Chair signs approval after the meeting.

4.3.5.4 File minutes of the meeting

A. The Secretariat files approved meeting minutes in the folder for Meeting Minutes.

B. Excerpts of meeting minutes may be extracted and filed in specific protocol file folder.

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 15 of 27 |

Communicating IERB Decision to the PI

4.4 Communicating IERB Decision to the PI

4.4.1 Purpose

To describe the procedure for communicating Institutional Ethics Review Board (IERB) decision to the PI.

4.4.2 Scope

This SOP provides instructions related to the preparation of IERB communication to the PI and the management of such documents.

4.4.3 Responsibility

The Secretariat to prepares the Approval or Notification Letter to the PI to be signed by the IERB Chair.


4.4.4 Process Flow/Steps

| NO. | ACTIVITY | PERSON/S RESPONSIBLE | TIMELINE |
|-----|---|----------------------|---|
| 1 | Prepare Notification/ Approval Letter to PI | Chair, Secretariat | Email: 3 days Physical copy: 10 days |
| 2 | Send Notification/ Approval Letter to PI | Secretariat | |
| 3 | File Notification/ Approval Letter to PI | Secretariat | |
| 4 | Update protocol database | Secretariat | |

4.4.5 Detailed Instructions

4.4.5.1 Prepare Notification/Certificate of Approval to PI

- A. Based on the final version of the Minutes of the Meeting, the Secretariat prepares the IERB communication to the PI in duplicate copies using the standard SOP template.
- B. For the Notification Letter, the Secretariat copies the list of recommendations from the meeting minutes to communicate them to the PI.
- C. The Chair signs and dates the Notification/Certificate of Approval.

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 16 of 27 |

Note: All Notification/ Certificate of Approval should be ready within 10 calendar days after the meeting date for full board meeting or 10 calendar days after receipt of expedited review results.

4.4.5.2 Send Notification/Certificate of Approval to PI


- A. The Secretariat informs the PI/Research Assistant that the original copy of the Notification or Certificate of Approval is ready for pick-up.
- B. The Secretariat emails a scanned copy of the Notification/ Certificate of Approval to the PI.
- C. The Secretariat logs the Notification/ Approval in the Log of Outgoing Document when the original copies are released.

4.4.5.3 File Notification/Approval Letter to PI

- A. The Secretariat files a duplicate copy of the Notification/Approval Certificate in the protocol file binder.

4.4.5.4 Update protocol database

- A. The Secretariat updates the protocol database

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 17 of 27 |

Management of Active Study Files, Documents and Records

4.5 Management of Active Study Files, Documents and Records

4.5.1 Purpose

To describe the Institutional Ethics Review Board (IERB) procedures related to the management of active study files.

4.5.2 Scope


This SOP provides instructions related to the management of active study files that include protocol submissions, all documents that reflect all actions taken by the IERB before completion of the study. It also provides instructions for the maintenance and storage of other IERB documents that include SOPs, IERB membership files, agenda and meeting minutes, relevant international and national regulations and guidelines, etc.

4.5.3 Responsibility

- Secretariat**
- ensures that all study protocol files are prepared, circulated maintained, and kept securely for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time.
 - manages all protocol submissions and all documents that reflect all IERB actions and organize them into orderly files that are kept at the IERB office.

4.5.4 Process Flow/Steps

| NO. | ACTIVITY | PERSON RESPONSIBLE | TIMELINE |
|-----|---|--------------------|----------|
| 1 | File protocol and other protocol related documents in an organized manner | Secretariat | 7 days |
| 2 | Update protocol file folder regularly as documents come or are produced | Secretariat | |
| 3 | Store properly labeled protocol file folder in the | Secretariat | |

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 18 of 27 |

| | | | |
|---|--|-------------|--|
| | appropriately labeled file storage cabinet | | |
| 4 | Create an electronic protocol database and update it regularly with PI submissions and IERB decisions/ actions | Secretariat | |
| 5 | Keep other IERB files in storage cabinets | Secretariat | |

4.5.5 Detailed Instructions

4.5.5.1 File protocol and other protocol related documents in an organized manner

A. The Secretariat determines if the protocol files are considered active from the moment the protocols are received for initial review until such time they are inactivated either by its completion or termination or its withdrawal from the review process.

Note: Active protocol files are either those undergoing IERB review process or IERB approved ongoing studies.

B. The Secretariat uses a unique identifier or code to refer to protocol file for efficient file management and retrieval.

Note: Study Protocols shall be identified using a unique identification number known as Protocol Code No. given by the IERB as described in SOP 2.1 on Management of Initial Submission.

C. The Secretariat arranges the protocol in a protocol folder chronologically in an organized manner according to the Protocol database per type of submission (eg. initial submission, protocol amendment, progress report, SAE Reports, Protocol Violation/Deviation, etc.):

C.1 All versions of study protocol


C.2 Protocol related documents (ICF, CRF, recruitment materials, patient diary, IB, etc.)

C.3 Principal investigator and co-investigators' CVs and valid GCP Training Certificate, if required

C.4 Reviewers' assessment forms

C.5 Decision letters (notification letters or approval letter/s – initial and renewal)

C.6 Post-Approval submissions (protocol amendment, progress report, SAE report, protocol deviation/violation report, early termination report) and corresponding


| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 19 of 27 |

reviewers' assessment and IERB decision letters

- C.7 Participant queries/complaints, if any
- C.8 Site Visit Reports, if any
- C.9 Miscellaneous communication related to the protocol
- C.10 Final report
- D. The Secretariat files in a durable binder all protocol related documents in chronological sequence with the most recent file/document at the top, Update the Protocol database whenever a new document is filed.
- E. The Secretariat sticks a protocol file label (Protocol code no., title of the protocol, name of PI, sponsor on the front cover of the file binder.
- F. The Secretariat sticks a label with the Protocol No. on the side of the file binder.

4.5.5.2 Update protocol file folder regularly as documents come or are produced

- A. The Secretariat logs every protocol-related document received. This log shall contain at least the following items:
 - A.1 Date/Time received
 - A.2 Protocol Code No.
 - A.3 Study Title
 - A.4 Principal Investigator
 - A.5 Initial of Person who received the document
 - A.6 Type of Submission (eg. Protocol for Initial Review, Resubmitted Protocol, Application for Protocol Amendment, Protocol Violation/Deviation Report, SAE Report, etc.)
 - A.7 IERB Action Required.
- B. The Secretariat also logs protocol and protocol-related documents when they are forwarded to IERB members for review. This log shall contain the following items:
 - B.1 Date/Time Sent
 - B.2 Study Title
 - B.4 Receiving Person
 - B.5 Content of Document
 - B.6 Remarks
- C. The Secretariat adds the protocol-related paper files/documents are added to the protocol file folder on the day that they are submitted or accomplished (assessment forms, IERB decision letters).
- D. The Secretariat keeps all binders are kept in locked cabinets.

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|---|--|---------------------------------|
|  <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p> | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 20 of 27 |

4.5.5.3 Store properly labeled protocol file folder in the appropriately labeled file storage cabinet

The Secretariat:

- A. Places the protocol file binders in the shelf in vertical position and sequentially arranged according to their Protocol Code No.
- B. Labels the storage cabinet with the year when the protocols were submitted.
- C. Keeps all active study files in a secure filing cabinet, with access limited only to Chair and Secretariat.
- D. The Secretariat keeps the keys of file storage cabinets.

Note: Actives files can be accessed outside of regular protocol review in accordance with the SOP 4.6 on Maintaining Confidentiality of Study Files and IERB Documents.

4.5.5.4 Create an electronic protocol database and update it regularly with PI submissions and IERB decisions/ actions

The Secretariat:


- A. Creates an electronic database to contain a list of all protocols received by the IERB with sufficient columns to contain all protocol related information, PI submissions and action taken by the IERB from initial review to final report approval.

Note: The Study Protocol or related document shall be first entered into the IERB protocol database using its protocol code number, title, names of PI and sponsor, etc.

- B. Creates a secure protocol database to facilitate protocol monitoring including due dates of reports and determining active protocol status.

Note: The database should use an electronic format and password protected. It should have at least the following fields:

- B.1 Protocol Code
- B.2 Protocol title
- B.3 Department
- B.4 PI and details
- B.5 Submission date
- B.6 Full board or Expedited Review date
- B.7 Designated Reviewers
- B.8 Review decision
- B.9 Full board review meeting date

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|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 21 of 27 |

B.10 Approval date and expiration date

B.11 Due date for progress report


B.12 Date of approval

B.13 Date of final report

B.14 Schedule for discard/disposal from archive

C. Maintains a back-up copy of the protocol database in an external drive that is updated every 1st day of the month, or the following day if the day falls on a nonworking day.

D. Keeps other IERB files that include the SOPs, Membership Files, international and national guidelines and regulations, etc. in the office cabinets and regularly update them for reference of the IERB members.

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 22 of 27 |

Archiving of Inactive Study Files

4.6 Archiving of Inactive Study Files

4.6.1 Purpose

To describe Institutional Ethics Review Board (IERB) procedures related to archiving of terminated, inactive and completed studies

4.6.2 Scope

This SOP provides instructions to the Secretariat related to requirements for archiving completed study protocols after the final report or other relevant documents have been received.

4.6.3 Responsibility

Secretariat

- maintains and stores closed study protocol files and administrative documents
- retrieves files/documents when needed
- archives in an orderly manner all study protocol files that have been terminated, completed or are no longer active. They are kept together in a designated place in the IERB office where confidentiality and security of the documents can be maintained.


4.6.4 Process Flow/Steps

| NO. | ACTIVITY | PERSON RESPONSIBLE | TIMELINE |
|-----|---|--------------------|----------|
| 1 | Identify inactive protocol files | Secretariat | 7 days |
| 2 | Affix appropriate label to files for archiving & record in Database of Archived Documents | Secretariat | |
| 3 | Transfer files to the archiving room | Secretariat | |
| 4 | Update protocol database | Secretariat | |

4.6.5 Detailed Instructions

4.6.5.1 Identify inactive protocol files

- A. The Secretariat considers studies to be completed and inactive when:

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|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 23 of 27 |

A.1. The closure/final report of the study has been reviewed and approved by the IERB.

A.2. No further communication has been received by the IERB after one year.

A.3. Studies underwent early termination upon receipt of relevant information about termination.

A.4. The PI failed to submit the revised document(s) 2 weeks after initial presentation, the protocol is considered inactive.

A.4.1 The Secretariat sends notice to the PI and informing that the study protocol is categorized as inactive due to non-compliance.

A.4.1.1 If the PI is interested to continue the study protocol, he/she should then submit the required modification within 2 weeks.

A.4.1.2 If the PI failed to submit the revised document(s) at the end of extension, which make the protocol inactive, then the PI may appeal for reconsideration. If the Board approves the appeal, in that case, the PI should follow the requirement for resubmission. If no appeal is made within 90 (ninety) days, the protocol is archived.

B. The Secretariat removes the protocol file folders from the storage file cabinet for active studies, checks its contents..

C. The Secretariat fills out the Protocol for Archive Form (FM-E-IRB-2019-062 Rev.04) and file in designated binder.

D. The Secretariat shreds extra copies that are not needed.

4.6.5.2 Affix appropriate label to files for archiving & record in Database of Archived Documents


A. The Secretariat labels protocol file as inactive by attaching a red sticker and adding the year the study is declared inactive.

B. The Secretariat logs the protocol number and other protocol identifiers in the Database of Archived Documents.

4.6.5.3 Transfer files to the archiving room

A. The Secretariat transfers the protocol file to the designated secure archive room.


Note: 1. As in active study files, protocol files in the secure storage cabinet for inactive studies are arranged sequentially. The storage cabinet is properly labeled with the year in the original protocol code.

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|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 24 of 27 |

2. Protocols shall be archived for 5 years.(fellow/nurses) and 10 years (Clinical Trials). Archived protocols can be accessed in accordance with the SOP 4.6 on Maintaining Confidentiality of Study Files and IERB Documents.
3. After 5 years/10 years in the archive, the Secretariat fills out the Disposal of Documents by Shredding Form **(FM-E-IRB-2019-065 Rev. 030)** and transfer or shreds the protocol files from archive.

4.6.5.4 Update protocol database

- A. The Secretariat enters the archiving data accordingly in the protocol database.
- B. The Secretariat reviews entries in the protocol database for the protocol for archiving, to check if all fields are completely filled.

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|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 25 of 27 |

Maintenance of Confidentiality of Study Files and IERB Documents

4.7 Maintenance of Confidentiality of Study Files and IERB Documents

4.7.1 Purpose

To describe Institutional Ethics Review Board (IERB) procedures related to maintaining the confidentiality of the study files and other IERB documents.

4.7.2 Scope

This SOP provides instructions to the Secretariat related to maintaining the confidentiality of all study files and documents.

4.7.3 Responsibility


IERB members and Secretariat - signs the confidentiality agreement form that enforces confidentiality

Secretariat

- Ensures that guests/independent consultants signs confidentiality agreement
- Files confidentiality agreement in membership files
- Maintains log of requested documents

4.7.4 Process Flow/Steps

| NO. | ACTIVITY | PERSON RESPONSIBLE | Time Line |
|-----|---|------------------------------|---------------|
| 1 | Properly manage all active and Inactive IERB files | Secretariat, Board Secretary | Within 7 days |
| 2 | Receive request to access confidential files | Secretariat | |
| 3 | Approve and log in requests for access and retrieval of documents | Secretariat | |
| 4 | Supervise the use of retrieved confidential document | Secretariat | |
| 5 | Return document to the protocol file folder | Secretariat | |

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|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 26 of 27 |

4.7.5 Detailed Instructions

4.7.5.1 Properly manage all active and inactive IERB files.

A. The Secretariat properly handles original documents and copies of these documents during the day-to-day operation of the IERB to protect the confidentiality of study files and related documents.

Note: 1. Proper handling involves proper control and care in the distribution and storage of confidential documents of the IERB.

2. Study files submitted to the IERB and related documents shall be considered confidential, such as:

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

A.2 IERB documents (Meeting minutes, advice, and decisions)

A.3 Correspondence (with experts, auditors, study participants, etc.)

4.7.5.2 Receive request to access IERB confidential files

A. The Secretariat receives request to access IERB confidential files


Note: Access to IERB confidential documents shall be subject to the following limitations:

A.1 IERB members and secretariat with a signed Confidentiality Agreement and Conflict of Interest Agreement Form (FM-E-IRB-2019-006 Rev. 04) can access confidential documents outside of regular protocol review access, upon request.

A.2 Non-members can access specific documents by submitting a formal request. The Secretariat will require a Confidentiality Agreement Form for Non-Members Requesting Copies of IERB Documents (FM-E-IRB-2019-007 Rev. 05) to be signed by the person making the request, and approved by the Chair or Vice-Chair or designated IERB Member in the absence of the Chair.

A.3 Regulatory authorities can have full access to IERB documents provided it is within their mandate (e.g. FDA), and within a reasonable notice to make the files available.

A.4 The Secretariat records all transactions whenever any document of the IERB is accessed as described above.

| | | |
|---|--|---------------------------------|
|  PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 27 of 27 |

4.7.5.3 Approve and log in requests for access and retrieval of documents


- A. The Secretariat keeps a separate log in the protocol folder to record access as described above. It contains the following information:
- A.1 Study file code
 - A.2 Date borrowed
 - A.3 Name of borrower
 - A.4 Signature of borrower upon retrieval
 - A.5 Signature of Secretariat upon return of document to the file folder
 - A.6 Document copied
 - A. 7 Number of copies made
 - A.8 Number of copies received
- B. All requests for access are recorded by the Secretariat in the log before copies of any documents are released.

4.7.5.4 Supervise the use of retrieved confidential document

- A. The Secretariat generally allows access to IERB documents for room use only, but requests to make copies can be accommodated on a case to case basis.
- B. The Secretariat makes only the exact number of copies requested.
- C. The recipient signs the IERB log upon receipt of the copies.

4.7.5.5 Return document to the protocol file folder

- A. The Secretariat returns the documents in the protocol file folder in the storage cabinet after making sure that all documents are complete as per Protocol Database.

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|---|--|---------------------------------|
|  <p>PHILIPPINE HEART CENTER</p> <p>INSTITUTIONAL ETHICS REVIEW BOARD</p> | Document Type | Document Code: POL-E-IRB-004 |
| | POLICY/STANDARD OPERATING PROCEDURE | Effective Date: January 2024 |
| | Document Title | Revision Number: 9 |
| | DOCUMENTATION AND ARCHIVING | Page: 28 of 27 |