PHILIPPINE HEART CENTER INSTITUTIONAL ETHICS REVIEW BOARD	Document Type **POLICY/STANDARD OPERATING PROCEDURE**	Document Code: POL-E-IRB-003
		Effective Date: April 2024
	Document Title **IERB MONITORING PROCEDURES**	Revision Number: 11
		Page: 1 of 35

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	February 2015	Change of Format	February 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	August 2021	Change of Format	August 2022
10	January 2024	Change of Format	January 2025
11	April 2024	Change of Format	April 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

Review of Protocol Amendments

3.1. Review of Protocol Amendments

3.1.1. Purpose

To describe the Institutional Ethics Review Board (IERB) review procedure for amendments of the protocol and related documents

3.1.2. Scope

This SOP applies to previously approved study protocols and related documents that are being amended later and submitted for approval to the IERB. Any amendment of the study related documents may not be implemented until reviewed and approved by the IERB.

3.1.3. Responsibilities

Chair/IERB members - approves the final decision for amendments submitted by the PI t the IERB.

Designated Reviewer - Reviews the amendments and recommends appropriate action.

Secretariat - Manages protocol amendment package submitted by the PI.

3.1.4. Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receive the protocol amendment package and check its completeness	Secretariat	Review of protocol amendments should be completed within 14 days when done through expedited review of minor protocol amendments.
2	Determine type of review & identify designated reviewers	Chair, Secretariat	
3	Forward amendment package to Designated reviewers	Secretariat, Designated Reviewer	
4	Discuss major amendment or report the expedited review results to the IERB during full board meeting	IERB Member	
5	Communicate IERB decision to PI	Secretariat, Chair	It may take longer for

6	File documents and the protocol database	Secretariat	major amendments depending on the schedule of full board meeting.

3.1.5 Detailed Instructions

3.1.5.1 Receive the protocol amendment package and check its completeness

A. The Secretariat shall properly inform the principal investigator to submit an application for amendment whenever there is any change regarding the composition of the study team, the study site, the protocol and related documents that it previously approved using the Amendment Application Form (FM-E-IRB-2019-072-Rev.04).

B. The Secretariat shall check the completeness of the protocol amendment package submitted by the PI. Secretariat also verifies whether the Protocol Code No. and forms used are correct.

C. The Secretariat shall record the submission in the protocol database.

3.1.5.2 Determine type of review & identify designated reviewers

A. Chair/Board Secretary shall review document to determine whether amendment is major or minor.

A.1 Major protocol amendments: increase risk to study participants and require full board review. These include but are not limited to the following:

A.1.1 Modification of treatment – addition or reduction of treatments

A.1.2 Any changes in inclusion/exclusion criteria

A.1.3 Change in study design

A.1.4 Additional treatment/s or the deletion of treatment/s

A.1.5 Change in method of dosage formulation, such as, oral to intravenous

A.1.6 Significant change in the number of subjects

A.1.7 Significant decrease or increase in dosage amount

A.1.8 Any other changes that will entail more than minimal risk.

A.2 Minor protocol amendments: those which are unlikely to compromise the integrity of the research or the welfare and rights of the participants and present no new ethical issues; and changes that are administrative in nature can be expedited.

B. The Secretariat shall identify the Designated Reviewer who did the initial review and verify IERB approval of the initial protocol submission.

C. If Designated Reviewers are not available to do the review, Chair and/or Board Secretary shall do the review provided they do not have COI. Otherwise, the Chair designates qualified members to do the review.

3.1.5.3 Forward amendment package to designated reviewers

A. Secretariat shall prepare protocol amendment package; photocopy relevant documents of previous review/s of the protocol that will provide the Designated Reviewers with background information that will facilitate the assessment of the proposed amendment/s.

B. Better still, the Designated Reviewers should go to the IERB office to review the pertinent documents in the protocol file and determine whether the proposed changes in the protocol will cause a change in the risk-benefit ratio of the approved protocol.

C. The Secretariat shall record the protocol amendment package in the Log for Outgoing Documents

D. The Secretariat shall send the protocol amendment package and relevant documents of previous review/s with the Notice of Review to the Designated Reviewer/s at least 10 days before the full board meeting.

E. The Designated Reviewer or his/her alternate shall review the amended documents and compare them with the previously IERB approved documents in the protocol file folder to assess if the proposed amendment/s would alter the risk/benefit ratio and to make appropriate recommendations using the IERB - part of Amendment Application Form (FM-E-IRB-2019-072-Rev.04).

F. Major protocol amendments shall be reviewed by full board while minor protocol amendments by expedited review by the Designated Reviewers/Chair/Board Secretary.

G. The following elements of review shall be included:

G.1 Change(s) to research protocol

G.2 Change(s) to consent form scripts

G.3 Change to study population

G.4 Addition of Study Site

G.5 Change to sample size

G.6 Initiation of new study phase

G.7 Changes of recruitment materials, data collection forms, instruments, questionnaires/surveys

G.8 Change to drug or device information for FDA regulated study

G.9 Change in conflict of Interest

3.1.5.4 Discuss the amendment or report the review result to the IERB during full board meeting

For Major Protocol Amendment

A. The Designated Reviewer or his/her alternate shall present the results of the review to the IERB during full board meeting.
B. The IERB shall decide whether or not there is a need for the PI to clarify, elaborate or explain further the amendment/s. The following are possible review decisions of the Board:
   B.1 Approved: no increase in risk
   B.2 Major changes required to the Protocol/Informed Consent
   B.3 Minor changes required to the Protocol/Informed Consent
   B.4 Disapproval

For Minor Protocol Amendment

A. The Designated Reviewer or his/her alternate shall submit the results of the review using the for-IERB portion of the Amendment Application Form (FM-E-IRB-2019-072-Rev.04).
B. The review decision shall be reported to the IERB during the full board meeting.

3.1.5.5 Communicate IERB decision to PI

A. Refer to SOP on Communicating IERB Decision to PI
B. The Secretariat shall prepare Research Protocol/ICF Amendment Approval Letter (FM-E-IRB-2019-048-Rev.05) for the Protocol Amendment, for signature of the Chair.
C. If the amendment is approved, the PI shall be requested to submit an amended copy of the study protocol or protocol related document with an updated version no. and date.

D. The Secretariat shall send the notification to the PI.

3.1.5.6 File documents and the protocol database

A. The Secretariat shall ensure that the version no. and date marked on the amended document are correct.

B. Keep a copy of all protocol amendment related documents in the protocol file folder and update the protocol database.

Review of Progress Reports

3.2 Review of Progress Reports

3.2.1 Purpose

To describe the Institutional Ethics Review Board (IERB) review procedures for progress report for renewal of IERB approval.

3.2.2 Scope

This SOP provides instructions for the review of progress reports that are required by the IERB to be submitted by the principal investigator to monitor the safety of participants enrolled in a study.

The annual report becomes the basis for continuing review of protocols the approval of which needs to be renewed every year.

This SOP applies to the conduct of any continuing review of study protocols involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the IERB may require more frequent submission of progress report.

3.2.3 Responsibility

Chair/Board Secretary - Determines the frequency of the continuing review based on the risk.
Determine type of review & identify designated reviewers.

Designated Reviewer - Reviews the reports to check completeness of the information and ensure that it is in accordance with the protocol and related documents approved by the IERB.

Secretariat - Reminds investigators to submit the progress reports one month before the due date, to forward the reports to the designated reviewers for review, and to communicate IERB decision to the

PI.

3.2.4 Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Reminds PI to submit continuing report at least 60 calendar days before the due date.	Secretariat	
2	Submit continuing review report on or before the due date	Principal Investigator	Review of protocol progress reports should be completed within 14 days when done through expedited review. It may take longer for full board review depending on the schedule of the full board meeting.
3	Check completeness of information in the report and forward to the designated reviewers.	Secretariat	
4	Determine type of review & identify designated reviewers	Chair/Board Secretary	
5	Review of Continuing review application	Designated Reviewer	
6	Discuss the progress report or report expedited review result to the IERB during full board meeting	IERB Member, Chair, Board Secretary	
7	Communicate IERB decision to PI	Secretariat, Chair	
8	File documents and protocol database	Secretariat	

3.2.5 Detailed Instructions

3.2.5.1 Reminds PI to submit continuing report at least 60 calendar days before the due date.

A. The Secretariat regularly checks the database and tracks due dates of continuing review of protocol approved by the IERB at least 60 calendar days before the due date of approval anniversary of the protocol.

B. The Secretariat notifies the PI to submit continuing review report and prepare and send a reminder letter/addressed to the PI using Continuing Review Notice Form (FM-E-IRB-2019-012 Rev.04) at least 60 calendar days before the due date of the report.

B.1 The frequency of the submission (semi-annually or annually) is determine by the Chair based on the level of risk.

C. The Secretariat files the notice in the protocol binder.

3.2.5.2 Submit continuing review report on or before the due date

A. The PI submit Continuing Review Form ((FM-E-IRB-2019-024 Rev.06) and progress report since the last review and document currently in use.

3.2.5.3 Check completeness of information in the report and forward to the designated reviewers.

A. The Secretariat receives and reviews the check the completeness of the submitted application for review package using Protocol Code No. and the form used are correct.

A.1 If the progress report is submitted after the due date, the secretariat shall require the PI to submit a violation report using the Deviation/Violation/Non-Compliance Report Form (FM-E-IRB-2019-026 rev 07).

A.2 Failure of the PI to submit a continuing review report within 30 calendar days after the deadline of submission will mean suspension of the study and recruitment of new subjects until compliance is met. A suspension notice will be communicated to the PI.

3.2.5.4 Determine type of review & identify designated reviewers

A. The Chair/Board Secretary determines the type of review whether for full board or for expedited review.

B. The Chair/Board Secretary identifies the designated reviewers.

3.2.5.5 Review of Continuing review application

A. The Designated reviewers conduct continuing review of progress reports if they are in accordance with the protocol and related documents approved by the IERB.

B. The Designated reviewers refer to the protocol file to check compliance with approval given by the IERB during initial review and upon submission of amendments.

C. In the review of the progress/annual report, the following are the key evaluation points:

C.1 Risk Assessment

C.1.1 The risks to the subjects are minimized

C.1.2 The risks to the subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be

expected to be gained from the study.

C.2 Adequacy of Informed Consent

C.2.1 Informed consent/Assent forms current (most recent)

C.2.2 Appropriate, new significant findings since the last continuing review that may be related to the subjects' willingness to continue participation provided to enrolled subjects (e.g., important toxicity or adverse event information)

C.3 Local Issues

C.3.1 Changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, medical license; involvement in numerous clinical trials)

C.3.2 Evaluation, investigation and resolution of complaints related to the research, if any

C.3.3 Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable national law, or standards of professional conduct of practice.)

C.3.4 Report from third party observation of the research (including the informed consent process) carried out

C.3.5 Investigator concerns about trial conduct at the local site (e.g., study coordinator ineffectiveness, inability of subjects to understand sections of the informed consent document required by institutional policies), if any.

C.4 Trial Progress

C.4.1 Start date of the study and expected duration

C.4.2 Total subject enrollment

a. Expected enrollment

b. Actual enrollment

c. Enrollment issues

C.4.3 Subject withdrawal

a. Number of subjects who withdrew

b. Lost to follow-up

c. Summary of reasons for withdrawal at local site

D. The IERB may also request the Principal Investigator to provide additional information, when necessary.

E. The Designated reviewers recommends approval of the continuing review report if there is no deviation or violation of IERB approval.

F. If there is any deviation or violation of approval given, the designated reviewer recommends appropriate action be taken by the PI (amendment of the protocol or consent form, etc.).

G. The Designated Reviewer/s must complete the review within 7days prior to the IERB meeting.

3.2.5.6 Discuss the progress report or report expedited review results to the IERB during full board meeting

For full board review of progress report:

A. The Secretariat shall collate the comments of the Designated Reviewers and include the application for renewal of IERB approval in the agenda.

B. The protocol file folder for continuing review, including relevant IERB meeting minutes, shall be made available during the meeting.

C. During the meeting, the Designated Reviewers present a summary of the progress of the research, any significant issues and their recommendation to full board.

D. The IERB members determine the need for the investigator to elaborate, explain or clarify any aspect of the progress/annual report as deemed necessary.

E. The following are the possible IERB decisions for continuing review:

E.1 Approved to continue for one (1) year

E.2 Request additional information

E.3 Recommend modification

E.4 Suspend:

E.4.1 enrollment of new subjects

E.4.2 research procedures in currently enrolled subjects

E.4.3 entire study

E.4 Disapprove renewal

F. Approval of progress report reviewed by the Designated Reviewers by expedited procedure is reported to the board meeting by the Chair/Board Secretary.

3.2.5.7 Communicate IERB decision to PI

A. The Secretariat shall take note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is

required.

B. The Secretariat shall prepare Notification of IERB Decision – Progress/Annual Report for signature of Chair.

C. The Secretariat shall send the notification to the PI

3.2.5.8 File documents and protocol database

A. The Secretariat shall keep the continuing review application package together with the review comments of the primary reviewer/s in the protocol file folder.

B. The Secretariat shall update the protocol database.

Review of Final Report

3.3 Review of Final Report

3.3.1 Purpose

To describe the Institutional Ethics Review Board (IERB) review procedures for final reports.

3.3.2 Scope

This SOP provides instructions for the review of final reports that are required by the IERB to be submitted by the principal investigator when the approved study is completed or when the study site is closed. The final report when approved by the IERB becomes the basis for initiation of the archiving procedure. This SOP applies to the review of final/closure report of a study protocol approved by the IERB.

3.3.3 Responsibility

Chair - Identifies Designated Reviewers

IERB Member/Designated Reviewer - Reviews the final study report for completeness before making copies for the Board meeting.

Secretariat - Includes the final report in the IERB meeting agenda

3.3.4 Process Flow/Steps

NO.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive the progress report package and check its completeness	Secretariat	Review of final report should take place within 14 days except when there is a delay in the due to the schedule of the full board
2	Identify Designated Reviewer IERB	Chair/ Secretariat	
3	Forward Final Study **Report** to designated reviewers for review	Secretariat, Designated Reviewer	
4	Approve the Final Study Report during IERB full board meeting	IERB Member, Chair, Board Secretary	
5	Communicate IERB decision to PI	Designated IERB Member	

6	File documents and protocol database	Secretariat	meeting

3.3.5 Detailed Instructions

3.3.5.1 Receive the progress report package and check its completeness

A. The submission shall include the accomplished Progress Report and the Final Study Report Form (FM-E-IRB-2019-025 Rev. 07).

B. The Secretariat shall verify the completeness of the submission and whether the Protocol Code No. and the forms used are correct.

3.3.5.2 Identify Designated Reviewers

A. The Secretariat shall identify the Designated Reviewers of the protocol from the protocol database.

B. If the Designated Reviewer is not available, the review shall be done either by the IERB Chair/Board Secretary, or qualified Member/s designated by the Chair/Board Secretary.

3.3.5.3 Forward Final Study Report to designated reviewers for review

A. The Secretariat shall record the Final Study Report package together with the Notice of Review and a copy of the latest version of the protocol in the Log of Outgoing Documents.

B. The Closure/Final Report package shall be forwarded to the designated reviewer/s at least 7 days before the full board meeting by the Secretariat.

C. The Designated Reviewer/s shall accomplish the review form by commenting and recommending appropriate action on the Final Study Report form (FM-E-IRB-2019-025 Rev. 07).

D. Designated Reviewer shall sign and date the form and returns the Final Study Report package to the Secretariat.

E. The following elements of review shall be added in the final report as follows: objectives, methodology, number of required participants, dissemination plan with the approved protocol and comments.

3.3.5.4 Approve the Final Study Report during full board meeting

A. The Designated Reviewer shall present the results of the review in the full board meeting.

B. The IERB decision can be any of the following:

B.1 Acknowledged/Accepted

B.2 Request for further information, specify

B.3 Recommend further action, specify

B.4 Approved: For archiving

3.3.5.5 Communicate IERB decision to PI

The Secretariat shall:

A. Take note of the decision and/or discussion during the board meeting in the meeting minutes and communicate with the PI only if further action is required.

B. Prepare Notification of IERB Decision – Review of Final Study Report for signature of the Chair.

C. Sends the notification to the PI

3.3.5.6 File documents and protocol database

A. The Secretariat shall file the accomplished, signed and dated Final Study Report and other related document in the protocol file folder.

B. Upon approval of the Final Study Report, classify the study protocol as inactive and transfer to storage cabinet for inactive files

C. Update the protocol database.

Review of Serious Adverse Events

3.4 Review of Serious Adverse Events

3.4.1 Purpose

To describe the Institutional Ethics Review Board (IERB) review procedures for serious adverse events

3.4.2 Scope

This SOP applies to the review of SAE and SUSAR reports submitted by investigators and sponsors to the IERB to comply with ICH GCP. The IERB reviews such reports to determine appropriate action to protect the safety of participants in an approved study.

ICH-GCP E6 defines a serious adverse event (SAE) or a serious adverse drug reaction (ADR) as any untoward medical occurrence that at any dose

- results in death,
- is life threatening,
- requires hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability or incapacity, or
- results in a congenital anomaly or birth defect.

A suspected unexpected serious adverse reaction (SUSAR) is a serious event the nature and severity of which is not consistent with the applicable product information. In the case of an unapproved investigational product, the event is not consistent with the Investigator's Brochure (IB). In the case of a licensed product, the event is not consistent with the approved package insert or summary of product characteristics.

3.4.3 Responsibilities

Chair/ IERB members	- Reviews SAE and SUSAR reports in terms of the manifestations, seriousness and types of adverse reactions, date, time and duration of occurrence, actions taken/recommended and classify if onsite or offsite.

- Determines whether the report was submitted promptly and monitored closely by the research team and whether measures have been undertaken to prevent or keep SAEs and SUSARs within manageable levels.
- Makes recommendations to ensure the safety of participants in the study.
- Decides on premature termination of the study when indicated or other actions, especially when protocol violations are committed.

Principal Investigator

- submits SAE and SUSAR reports

Secretariat

- Receives SAE and SUSAR reports from principal investigator and sponsor of researches that have been approved
- Forwards reports to the Chair
- Provides technical support in the documentation of the review, preparation/transmittal of the decision to the PI and other stakeholders.

3.4.4 Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receive SAE/SUSAR Report	Secretariat	14 days
2	Determine type of review and forward SAE Reports to appropriate reviewers	Board Secretary	
3	Review on-site and offsite SAEs	Designated Reviewer, IERB Member	
4	Discuss on-site SAE reports at full board to ensure patient safety	IERB Member, Chair, Board Secretary	
5	Communicate decision to PI	Secretariat, Chair	
6	File documents in protocol file folder and update SAE database	Secretariat	

3.4.5 Detailed Instructions

3.4.5.1 Receive SAE/SUSAR Report

A. The Secretariat shall check submitted documents for completeness and whether Protocol Code Number and form used are correct.

B. The Secretariat shall classify the SAE/SUSAR reports according to their origin or sites where they happened: on-site or off-site (within or outside the country).

3.4.5.2 Determine type of review and forward SAE Reports to appropriate reviewers

A. On-site SAEs and SUSARs shall be reviewed by the Designated Reviewer/s or by suitable members designated by the Chair/Board Secretary if the Designated Reviewer is not available to do the review.

B. Off-site SAEs shall be reviewed through expedited process by an IERB designated reviewer (preferably, a pharmacist or a pharmacologist) to note the trends in SAE occurrence.

C. The Board Secretary shall identify the Designated Reviewer of the protocol.

D. The Secretariat prepares the SAE Report package and forward to the Designated Reviewer/s at least 7 days before the full board meeting.

E. Designated Reviewer or designated Member shall recommend appropriate action to be done by the IERB.

3.4.5.3 Review on-site and off-site SAEs

A. The IERB shall adopt appropriate response depending on the site where the SAE/SUSAR happened.

B. For SAEs that occur onsite, the IERB shall analyze the investigator/sponsor's assessment (related, unexpected):

B.1 Assessment of the SAE is unlikely or unrelated to the study drug or article: The report is forwarded to the Chair for review and determination if the report should be reviewed at the convened full board meeting..

B.2 Assessment of the SAE is definitely, possibly, or probably related to the study drug or article: The report is added to the agenda for review at a convened full board meeting.

B.3 Assessment of the SAE is unexpected/unanticipated and definitely, possibly, or probably related to the study drug or article: The report is added to the agenda for review at a convened full board meeting.

C. For multicenter, international studies, note the IERB shall trend of occurrence of SAE / SUSAR in study sites in foreign counties and other local sites. For multicenter, national studies, note the IERB shall also nature (related or expected) of the SAE/ SUSAR.

3.4.5.4 Discuss on-site SAE reports at full board to ensure patient safety

A. Designated reviewers or designated member/s shall present the results of review to full board.

B. Full-board shall discuss on-site SAEs and its impact to patient safety.

C. After deliberation IERB shall decide on appropriate action as follows:

C.1 Request an amendment to the protocol or consent form

C.2 Request further information

C.3 Suspension of:

C.3.1 Enrollment of new research participants until further review by the IERB

C.3.2 All trial-related procedures (except those intended for the safety and well-being of the participants) until further review by the IERB

C.4 Termination of the study

C.5 Take note and continue monitoring

C.6 Conduct Study Site Visit.

D. Designated member shall report trends in off-site SAEs for full board information. This will be reported on a quarterly basis to full board.

3.4.5.5 Communicate decision to PI

A. The Secretariat shall prepare Notification of IERB Decision about SAE Report, for Chair's signature.

B. Forward the notice to the PI.

3.4.5.6 File documents in protocol file folder and update SAE database

A. The Secretariat shall file the documents in the protocol file folder.

B. The Secretariat shall encode the SAE or updates the SAE Database.

Review of Protocol Deviation/Violation/ Non-Compliance

3.5 Review of Protocol Deviation/Violation/Non-Compliance Report

3.5.1 Purpose

To describe the Institutional Ethics Review Board (IERB) review procedures for protocol deviation/violation/non-compliance report.

3.5.2 Scope

This SOP provides instructions for taking action and maintaining records of various types of protocol deviation/violation/non-compliance report

- It includes investigators who fail to comply with the procedures in the approved protocol or to comply with national/ international guidelines for the conduct of human research, including those who fail to respond to the IERB's requests.
- It also covers action taken by the IERB related to protocol deviation/violation/non-compliance reports submitted by the PI related to any event at the site that is not in compliance with the protocol documents previously approved by the IERB.

3.5.3 Responsibility

IERB Chair

- notifies the principal investigator of the IERB's decision and action in writing.
- Designates reviewer to go over the protocol deviation/violation/non-compliance report.

IERB members

- determines the nature and severity of the violation which includes substantial deviations which were not submitted for ethical review.
- evaluates and make decisions of current protocol that is found to have issues of protocol deviation/violation/non-compliance report based on the deviations/violations which could vary from warning, reprimand to suspension/termination of the approval that was granted.

Secretariat

- Receives properly filled-out protocol deviation/violation/non-compliance report submitted to the IERB.

- ensures that the issues as well as details of protocol deviation/violation/non-compliance report are included in the agenda of the IERB meeting.
- maintains file of investigators who are found to be non-compliant with national/international guidelines in the conduct of human research.
- provides technical support in the documentation of the review, preparation/transmittal of the decision to the PI

3.5.4 Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receive protocol deviation/violation/non-compliance report	Secretariat	14 days
2	Evaluate the Protocol deviation/violation/non-compliance report assigns designated reviewer	Chair/Board Secretary	
3	Forward protocol deviation/violation/non-compliance report to Designated Reviewers	Secretariat, Designated Reviewer	
4	Discuss/report during full board meeting for decision/information	IERB Member, Chair, Board Secretary	
5	Communicate decision to P	Secretariat, Chair	
6	File documents in protocol file folder and update protocol database	Secretariat	

3.5.5 Detailed instructions

3.5.5.1 Receive Protocol deviation/violation/non-compliance report

A. Reports of protocol deviation/violation/non-compliance may come directly from the PI, or as result of study site monitoring by the Clinical Monitor/Sponsor or the IERB Site Visit Team, or from related documents received by the IERB.

B. The IERB Members performing monitoring of the research study at the trial site may detect protocol deviation/violation/non-compliance report if the

implementation of the research is not conducted as per approved protocol or institutional, national or international standards.

C. It is the responsibility of the of the Principal Investigator to determine whether a protocol deviation/violation/non-compliance report is major or minor, and ensure proper reporting to IERB. If the PI is unsure whether the variance is a violation or deviation s/he should seek advice from the sponsor to ensure appropriate action is taken.

D. The Secretariat shall check submitted documents for completeness and whether Protocol Code Number and Protocol Deviation/Violation/Non-Compliance Report Form **(FM-E-IRB-2019-026 Rev. 07)** used are correct.

E. The Secretariat shall record the report in the Log of Incoming Documents.

3.5.5.2 Evaluation of protocol deviation/violation/non-compliance report Form (FM-E-IRB-2019-026 Rev. 07) and assign Designated Reviewer

A. The Chair/Board Secretary evaluates the Protocol deviation/violation/non-compliance report

A.1 Major protocol violation/deviation is a persistent protocol noncompliance with potentially serious consequences that could put patients' safety at risk or critically affect data analysis

A.2 Minor protocol deviation is a non-systematic protocol noncompliance with minor consequences, in terms of its effect on the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature

B. The Chair/Board Secretary assigns designated reviewers.

3.5.5.3 Forward Protocol deviation/violation/non-compliance report form (FM-E-IRB-2019-026 Rev. 07) to appropriate IERB Member/s

A. The Secretariat shall forward the package to the Designated Reviewer/s at least 7 days before the full board meeting.

B. Designated Reviewer/s shall assess if the protocol violation/deviation impacts on patient safety or the integrity of the data.

C. The assigned designated reviewer/s shall complete their review and recommend corrective actions, if any within 7 days after receipt.

D. The assign Designated Reviewer shall forward their assessment to the Secretariat.

E. The Secretariat shall include the Protocol Violation/Deviation Report in the meeting

agenda for the month

F. The assign Designated Reviewer shall report the result of the review decision in full board for discussion.

3.5.5.4 Discuss/report to full board for information or appropriate action

A. The Protocol deviation/violation/non-compliance report in a research study shall be discussed at full board meeting.

B. The Designated Reviewers shall present the result of their assessment to full board that deliberate on effects of the Protocol deviation/violation/non-compliance report on the rights and safety or research participants or integrity of data.

C. Possible decisions are as follows:

C.1 No further action required

C.2 PI must complete the Prompt Reporting

C.3 The corrective action described in this form below is acceptable. PI must issue a statement to the IERB that he/she has implemented the corrective action plan as described.

C.4 PI must submit an interim report to the IERB on _____ describing his/her progress in implementing the corrective action described below.

C.5 The attached corrective actions must be implemented.

C.6 The deviation/violation reported appears to represent serious or continuing non-compliance. Review according to that policy is required.

3.5.5.5 Communicate decision to PI

A. The Secretariat shall prepare the Notification Letter for signature of the Chair.

B. If correction and/or corrective action are required from the PI, the PI shall be requested to provide the information within two weeks.

C. A site visit may also be required by the IERB

.

3.5.5.6 File documents in protocol file folder and update protocol database

A. The Secretariat shall check if Protocol deviation/violation/non-compliance report is completely accomplished, signed and dated by Designated Reviewers and file the document in the protocol file folder.

B. Filed documents shall also include the Study Site Monitoring Visit Report, if a post-review study site visit was conducted.

C. The Secretariat shall record the Protocol deviation/violation/non-compliance report in the protocol violation/deviation database to facilitate tracking of repetitive violations/deviations of the same nature.

Responding to Participants' Requests/Queries

3.6 Responding to Participants' Requests/Queries

3.6.1 Purpose

To describe the Institutional Ethics Review Board (IERB) procedures related to research participants' requests and/or queries

3.6.2 Scope

This SOP applies to all queries and requests related to the rights and well-being of the research participants in studies approved by the IERB

.

3.6.3 Responsibility

Chair - designates IERB member to respond to query and presents the report to the board meeting

IERB member - investigates, records information, signs and date query forms

Secretariat - receives participant queries and requests related to their participation

- refers relevant issues to the Chair or members for the IERB to take appropriate action
- keeps records of all actions taken by the IERB

Participant - person who passed the inclusion criteria who asks/inquires the Secretariat of any issue concerning their rights as a participant.

3.6.4 Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receive the complaint or injury	Secretariat	7 days
2	Review the Research Participants Request/Query	IERB Chair/Board Secretary	
3	Discuss in convened meeting or report the decision/action taken to full board	IERB Member, Chair, Board Secretary	
4	Communicate IERB's	Secretariat, Chair	

	response		
5	File pertinent documents	Secretariat	

3.6.5 Detailed Instructions

3.6.5.1 Receive the complaint or injury

A. Any research participants, or other parties inquiries/complain about study protocol-related issues.

B. The Secretariat receives the Research Participants Request/Query Form (FM-E-IRB-2019-035 Rev. 03).

B.1 The Secretariat may assists to put the complaint in writing especially if the complainant or inquiring party is a research participant.

C. The Secretariat responds to inquiry, if it is within the authority its authority to do so or refers the complaint or inquiry to the Chair/Board Secretary for appropriate action.

D. The Secretariat records the submitted document in the Log of Incoming Documents.

3.6.5.2 Review the Research Participants Request/Query

A. The Chair or Board Secretary reviews the Research Participants Request/Query Form (FM-E-IRB-2019-035 Rev. 03).

B. The Secretariat may contact the PI to provide clarification or further information.

3.6.5.3 Discuss in a convened meeting or report the decision/action taken to full board

A. The Chair shall present a serious complaint to full board for discussion.

B. The IERB members discuss to take appropriate actions.

3.6.5.4 Communicate IERB's response

A. The Secretariat shall prepare response to the Research Participants Request/Query Form (FM-E-IRB-2019-035 Rev. 03) within 7 days from the time of review.

3.6.5.6 File pertinent documents

A. The Secretariat shall file the accomplished the Research Participants Request/Query Form (FM-E-IRB-2019-035 Rev. 03) together with the letter of

inquiry/complaint and excerpts of the meeting minutes when this was deliberated or reported in the protocol file folder.

B. The Secretariat shall update the protocol file.

Site Visits

3.7 Site Visits

3.7.1 Purpose

To describe the Institutional Ethics Review Board (IERB) procedures related to the conduct of site visits

3.7.2 Scope

This SOP applies to any visit made in any study site, on behalf of the IERB, to check compliance with IERB approved protocol and related documents, and national and international standards.

3.7.3 Responsibility

I. PRE-VISIT

Secretariat
- Facilitates finalization of and notification for the site visit.
- Notifies the PI in the identified study site for the visit within a week upon determination of the need for monitoring.

Chair
- designates IERB member/s to perform visit of the research projects approved by IERB.

Designated IERB members
- finalizes schedule for site visit.

II. DURING VISIT

Designated Member/s- Collects desired information using various appropriate approaches like review of documents, observation and interview.

III. AFTER VISIT

Designated Member/s- Prepares and communicate deviations/violations and situations which need immediate action in writing within 24 hours.
- Complete the report on situations which are not urgent within 10

working days.

- Presents the findings in the IERB meeting.

Secretariat

- Records and file the reports/findings accordingly

3.7.4 Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Select study site to visit	IERB Members	7 days
2	Create Study Site Visit Team	Chair/Board Secretary	
3	Prepare Study Site Visit Plan	Study Site Visit Team	
4	Notify PI of date of site visit	Chair/Board Secretary	
5	Conduct site visit and debrief study team	Study Site Visit Team	14 days
6	Present findings during full board meeting	IERB Members	
7	Communicate results of site visit and recommended actions, if any to PI	Secretariat	
8	File pertinent documents	Secretariat	

3.7.5 Detailed Instructions

3.7.5.1 Select study site to visit

A. The IERB Members may recommend to visit study sites for any of the following reasons: frequent occurrence of SAE, protocol violations, failure to submit progress reports, complaints about PI performance.

B. Visits may also be conducted to monitor implementation of risky protocols, PI with many ongoing studies or inexperienced PIs.

C. Study site visit may be conducted upon recommendation of Designated Reviewers.

3.7.5.2 Create Study Site Visit Team

A. The Chair/Board Secretary selects members of Study Site Visit Team and designates the Team Leader. Members should include the Designated Reviewers.

B. The Secretariat formally informs the Site Visit Team members of their assignment.

C. The Secretariat prepares the Study Site Visit package consisting of the latest

version of the approved protocol and informed consent documents, and other relevant documents,(like protocol deviation reports, on-site SAEs/SUSARs - initial and follow-up reports) and a copy of the Study Site Visit Report Form.

3.7.5.3 Prepare Study Site Visit Plan

A. The Study Site Visit Team prepares the Study Site Visit Plan that includes the following:
   A.1 Date and time of the planned visit
   A.2 Members of the Study Site Visit Team
   A.3 Objectives of the Visit
   A.4 Documents to be reviewed
   A.5 Persons to be interviewed
B. The Study Site Visit Team, in consultation with the Chair, is given access to documents in the protocol file folder of a study for monitoring. The Team may also photocopy some parts of the files (like advertisement materials, the informed consent form (ICF), case report form) for comparison with the documents used in the study site.

3.7.5.4 Notify PI of date of site visit

A. The Secretariat shall prepare the letter informing the PI of the planned study site visit signed by the Chair. Attached to the letter is the Study Site Visit Plan and the Study Site Visit Report form.

3.7.5.5 Conduct site visit and debrief study team

A. The Study Site Visit Team conducts the site visit as per the Study Site Visit Plan. Additional guide in the conduct of the visit is the Study Site Visit Report Form (FM-E-IRB-2019-031 Rev. 05).
B. At the end of the visit, the Study Site Visit Team shall present the findings to the Study Team and solicits feedback.
C. The Study Site Visit Team completes the Study Site Visit Report Form (FM-E-IRB-2019-031 Rev. 05).
D. The Study Site Visit Team resolves conflict by consensus.
E. The Study Site Visit Team submits within 7 calendar days from the date of the visit.
F. The Secretariat logs the submission in the Log of Incoming Documents.

G. The Secretariat includes the presentation of the study site visit report in the meeting agenda.

3.7.5.6 Present findings during full board meeting

A. The Study Site Visit Team presents the report during the full board meeting.

B. The IERB determines whether the rights, safety and welfare of research participants are compromised and appropriate recommendations to the PI, if any.

3.7.5.7 Communicate results of site visit and recommended actions, if any to PI

A. Based on the minutes of the meeting, the Secretariat prepares the Notification Letter – Study Site Visit for signature of the Chair.

B. The PI may be requested to provide additional information or documents or implement corrective actions.

3.7.5.8 File pertinent documents

A. The Secretariat files the Study Site Visit Report, excerpt of the minutes of the meeting when report was discussed and the Notification Letter (including the response from the PI, if any) in the protocol file folder.

Early Termination/Suspension of Study

3.8 Early Termination/Suspension of Study

3.8.1 Purpose

To describe the Institutional Ethics Review Board (IERB) procedures related to early termination/suspension of study implementation.

3.8.2 Scope

This procedure describes how the IERB proceeds and manages the premature or early termination of a protocol when subject enrollment is discontinued before the scheduled end of the study. Protocols are usually terminated at the recommendation of the Data Safety Monitoring Board (DSMB), the Scientific Director, sponsor, PI, by the IERB itself or other authorized bodies

3.8.3 Responsibility

Chair

- Signs the termination of any study that the IERB has previously approved when safety or benefit of the study participant is doubtful or at risk.
- Reviews the reasons for early termination and make a recommendation during full board meeting.

Principal Investigator

- prepares and submits a early termination/suspension of study form to IERB for study protocol termination.

Secretariat

- receives early termination early termination/suspension of study documentation
- ensures that the issues as well as details of early termination/suspension of study are included in the agenda of the IERB meeting
- stores and inactivates the protocol documents

3.8.4 Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receive application or recommendation for early termination/suspension of study form	Secretariat	7 days
2	Send early termination/suspension of study form to the Designated Reviewers	Chair, Secretariat, Designated Reviewer, IERB Member	
3	Review the early termination/suspension of study form	IERB Member	
4	Deliberate decision during full board meeting	IERB Member	14 days
5	Communicate REC decision 14 days to PI	IERB Chair, Secretariat	
6	File pertinent documents and update protocol database	Secretariat	

3.8.5. Detailed Instructions

3.8.5.1 Receive application or recommendation for early termination/suspension of study

A. The PI submits an application for early termination/suspension of study is submitted when an IERB approved study protocol is being recommended for termination before its scheduled completion.

Note: 1. This is done when the rights, safety and welfare of participants are threatened or upon the request of the PI or sponsor due to operational problems.

2. Recommendation for early termination/suspension of study may come from the Sponsor, DSMB, Scientific Director, IERB members, or other authorized bodies.

The Secretariat receives the study early termination/suspension of study package prepared and submitted by the principal investigator and verifies whether the Protocol Code Number and form used are correct, and the completeness of the Early Termination/ Suspension of Study Form (FM-E-IRB-2019-028 Rev. 07)

B. The Secretariat checks approval given by the IERB and type of review from the protocol data base.

C. The Chair assign Designated Reviewer.

3.8.5.2 Send Early Termination/Suspension of Study Form (FM-E-IRB-2019-028 Rev. 07) to the Designated Reviewers

A. The Secretariat sends the documents package of early termination/suspension of study to the Designated Reviewer/s.

3.8.5.3 Review the Early Termination/Suspension of Study Form (FM-E-IRB-2019-028 Rev. 07)

A. The Designated Reviewer/s assess the early termination/suspension of study issues and make recommendation. The designated reviewers review the safety data.

Note: It is important for the termination package to contain a plan to follow up the participants who are still active in the study.

B. The Secretariat includes the review of the study for early termination in the meeting agenda to be submitted for full board review.

3.8.5.4 Deliberate decision during full board meeting

A. The IERB deliberates on the effects of the early termination/suspension of study on the safety and welfare of study participants.

B. Final decision of the application are as follows:

B1. Approval

B2. Acknowledgment

B3. Further information required

3.8.5.5 Communicate IERB decision to PI

A. Based on the minutes of the meeting, the Secretariat prepares the Notification Letter – early termination/suspension of study for signature of the Chair.

Note: The PI may be requested to provide additional information or documents or implement actions to ensure the safety and welfare of subjects still active in the study.

3.8.5.6 File pertinent documents and update protocol database

A. The Secretariat files the Early Termination/Suspension of Study Form (FM-E-IRB-2019-028 Rev. 07), excerpt of the minutes of the meeting when report was

discussed and the Notification Letter (including the response from the PI, if any) in the protocol file folder.

B. Upon approval of the early termination/suspension of study application, the Secretariat classifies the study protocol as inactive and transfer the protocol file folder to storage cabinet for inactive files.

C. The Secretariat updates the protocol database.