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REVISION HISTORY

Rev No.	Review Date	Description of Change	Date of Next Review
0		Original	August 2012
1	February 2012	Change of Format	February 2013
2	May 2014	Change of Format	May 2015
3	March 2015	Change of Format	March 2016
4	November 2015	Change of Format	November 2016
5	July 2017	Change of Format	July 2018
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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

Management of Initial Protocol Submission

2.1. Management of Initial Protocol Submission

2.1.1 Purpose

To describe the Institutional Ethics Review Board (IERB) procedure for managing the submission of the initial protocol package for review – from the time of receipt to filing of the initial protocol package in the Active File storage cabinet.

2.1.2 Scope

This procedure applies to all protocols submitted to the IERB for ethical review and regulatory review for PFDA.

The **IERB** accepts the following protocols for review: 1) PHC-funded researches, which include studies qualified for SJREB review 2) non-PHC-funded researches which include studies qualified for SJREB review, 3) researches referred from the PNHRS, PCHRD, DOST, PHIC, PHREB, DOH,, CHED, industry organizations, etc on the condition that the host hospital/institution where the proposal will be done accepts the review of Philippine Heart Center IERB and agrees to abide by the rules and regulations that the Philippine Heart Center IERB follows. The other research sites also agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the Committee may deem necessary. These conditions should be written in a document and signed by other hospitals/ institutions that accept Philippine Heart Center IERB review. 4) Regulatory review of protocols received from PFDA.

2.1.3. Responsibility

Chairman/ **Board Secretary** - Determine the type of review and assign the designated reviewer.

Secretariat - Manages all protocol submissions to the IERB. It covers the actions to be done from the time of submission to the filing of the initial protocol package in the Active Study File cabinet.

2.1.4. Process Flow/Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Receive the initial protocol package for review and check for completeness of the documents submitted	Secretariat	To be done within 7 working days
2	Assign a permanent code to the protocol package	Secretariat	
3	Log the received protocol package in the Protocol Database	Secretariat	
4	Give a receiving copy (for PHC-funded protocols); a cover letter confirming receipt or a duplicate copy of the protocol stamped with date and signature of secretariat (for non-PHC- funded protocols) to the person submitting the package	Secretariat	
5	Issuance of SOA for the PI and provision copy of OR (for non-PHC funded protocols)	Secretariat	
6.	Notify the Chair/Board Secretary regarding receipt of protocols, determine the type of review and assign designated reviewer/s and Independent Consultant/s if needed.	Secretariat Chair/Board Secretary	
7	Prepare the protocol review package for distribution to the designated reviewers	Secretariat	
8	File the initial protocol package in a properly labeled Protocol File folder and place it in the Active Study File cabinet	Secretariat	

2.1.5. Detailed Instructions

2.1.5.1 Receive the initial protocol package for review and check the completeness of the documents submitted

A. Upon receipt of the initial protocol packaged the Secretariat:

A.1 Ensures that the Initial IERB Application Form with Study Summary (FM-E-IRB-2019-021 Rev. 06 are completely filled out, signed and dated by the researcher.

A.2 Requires submission of the endorsement from the department and the technical review committee for research protocol of resident physicians (on training), and fellows.

A.2.1 Submission of Technical Review Form (FM-E-CRD-CTR-2020-035 Rev. 00) from the TRC indicates question or comments of the reviewer.

A.2.2 Ensures that the Principal Investigator complied all the modification required by the TRC before submitting to the IERB.

A.3 Checks for approval and endorsement from the thesis adviser/panel for doctoral or masteral thesis of employees of **Philippine Heart Center** or other researchers (not connected with the hospital).

B. All **Philippine Heart Center** funded protocols need technical review. The Technical Review Committee should have addressed the technical issues in the study protocol.

C. For non-**Philippine Heart Center** funded protocols, a document stating that the research protocol has undergone and passed technical review should be attached to the study protocol submitted for ethical review.

D. Upon submission of the initial protocol for **Philippine Heart Center IERB** review, the principal investigator or his/her representative ensures that the protocol follows the standard protocol format and contains a Protocol Summary Sheet

2.1.5.2 Assign a permanent code to the protocol package

A. The Secretariat assigns a permanent code to the protocol for efficient file management, it is necessary to use a unique identifier to refer to this file, the Protocol Code Number. This code number is given as follows:

A.1 PHC.IERB.xx (type of protocol).xx (year). number (chronological number based on order of receipt).

A.1.1 01 for fellow

A.1.2 02 for nurses

A.1.3 03 for Clinical Trial

A.1.4 04 for Consultant

A.1.5 05 PFDA**,** yyyy (year) –number

A.1.6 06 Others

B. For example, if the protocol entitled "Clinical Drug Trial of on Pediatric Patients" is the first protocol received in 2017, the code **PHC.IERB.03.17.01** is used to identify this protocol. The code is communicated to the researcher/principal investigator in all communications regarding the protocol.

2.1.5.3 Log the received protocol package in the Protocol Database

A. After ensuring the completeness of the initial protocol package, the Secretariat logs the pertinent data in the electronic protocol database.

B. As soon as subsequent data is available, the Secretariat completes the required protocol details in the protocol database.

2.1.5.4 Give a receiving copy (for PHC-funded protocols); a cover letter confirming receipt or a duplicate copy of the protocol stamped with date and signature of secretariat (for non-PHC- funded protocols) to the person submitting the package.

A. The Secretariat gives a receiving copy to the person submitting the package and/or a duplicate copy of the protocol with stamped, date and signature of the Secretariat.

B. The Secretariat instructs the person submitting the package to inform the researcher/PI to use the Protocol Code Number to identify the protocol in all submissions and in all his/her communications to the IERB.

2.1.5.5 Issuance of SOA for the PI and provision copy of OR (for non-PHC funded protocols).

A**.** The Secretariat issues Statement of Account (SoA) to the PI. After payment of the IERB Review fee, the PI gives copy of the Official Receipt to the Secretariat**.**

B. The Secretariat stamps "RECEIVED", date and sign of the Secretariat.

2.1.5.6 Notify the Chair/Board Secretary regarding receipt of protocols, determine the type of review and assign designated reviewer/s and Independent Consultant/s if needed.

A. The Secretariat notifies the Chair regarding the receipt of protocol.

B. The Chair determine the type of review and assign designated reviewer**/**s and Independent Consultant/s if needed.

B.1 There are four (4) types of protocol review as follows:

B.1.1 Exempt from review – for negligible risk protocols

B.1.2 Expedited review – for low-risk protocols

B.1.3 Full-Board review – for medium to high-risk protocols

B.1.4 SJREB review (3 or more study sites)

B.2 The following are some types of documents/researches that may be exempt from review:

B.2.1 Exempt from review

B.2.1.1 Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.

B.2.1.2 Provided that protocols do not involve more than minimal risks or harms, the following may be considered by the IERB for exemption from review:

B.2.1.2.1 Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;

B.2.1.2.2 Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), if the following criteria are met:

B.2.1.2.2.1 There will be no disclosure of the human participants' responses outside the research that could

reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation; and

B.2.1.2.2.2 The investigator records the information obtained in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

B.2.1.2.3 Protocols that involve the use of publicly available data or information.

B.3 Expedited review - Minimal/low risk health research that requires personal information:

B.3.1 About a topic that should not result in causing social stigma

B.3.2 Does not involve vulnerable populations

B.3.3 Retrospective studies using anonymized data from medical records

B.3.4 Studies using simple questionnaires without identifiers

B.3.5 Laboratory research that uses anonymized human tissue/specimen

B.3.6 Resubmission/modification with minor decision during full board meeting

B.3.7 Amendments with minor revision

B.3.8 Continuing / Progress report that approved on expedited during initial review.

B.3.9 Final study that approved on expedited during initial review.

B.3.10 Offsite SAE/SUSARs.

B.4 Full board review may be about the following:

B.4.1 Human health research involving medium to high risks to human participants

B.4.2 Intervention studies involving experimental treatments like clinical trials

B.4.3 May involve vulnerable populations who should be protected

B.4.4 Involves private information that may cause stigma

C. The Chair/Board Secretary designates at least two IERB members to be the designated reviewers of the protocol regardless of whether the type of review is expedited or full board.

C.1 Designated reviewers are selected on the basis of expertise related to the protocol

C.2 The medical/scientific reviewer analyzes the scientific and ethical aspects of the protocol using the IERB Reviewer's Evaluation Form (FM-E-IRB-2019-043 Rev. 08) while the non-medical member focuses on the ICF and informed consent procedure.

D. If the IERB membership does have the needed expertise, the Chair/Board Secretary chooses from the roster of Independent Consultant. If none is available, a consultant with the needed expertise is recruited as per SOP on Selection of Independent Consultant (SOP No. 1.2).

2.1.5.7 Prepare the protocol review package for distribution to the designated reviewers

A. The timeline from receipt of complete package to distribution to designated reviewers within 7 working days.

B. The initial protocol review package consists of all the documents in the initial protocol package plus blank copies of the IERB Reviewer's Evaluation Form (FM-E-IRB-2019-043 Rev. 08) and email to the designated reviewers.

2.1.5.8 File the initial protocol package in a properly labelled Protocol File folder and place it in the Active Study File cabinet

A. The Secretariat writes the IERB Protocol Code Number of the protocol on the side of the file binder. On the front cover of the protocol binder, write the following:

A.1 IERB Protocol Code Number

A.2 Full title of the research

A.3 Name of the Principal Investigator and Co-Investigator/s

A.4 Sponsor Protocol Code Number

A.5 Name of the Sponsor

B. The Secretariat files the properly-labeled protocol file folders in the appropriate shelf of the storage cabinet for active study files taking note of the sequence of protocol code numbers on the file binders.

Use of Study Assessment Forms

2.2. Use of Study Assessment Forms

2.2.1. Purpose

To describe the Institutional Ethics Review Board (IERB) procedures related to the use of study assessment forms in ethics review.

2.2.2. Scope

This SOP applies to the use of evaluation/assessment forms in the review and assessment of protocols and related documents submitted to IERB for its initial review and approval.

The IERB uses 4 different evaluation/assessment forms that are accomplished by individual reviewers. All comments, evaluation, recommendations and the initial decision of each reviewer regarding a protocol are all noted in these forms.

The forms are designed to standardize the review process and to facilitate reporting of recommendation and comments given to each individual protocol and related documents. These are:

A. IERB Reviewer's Evaluation Form (FM-E-IRB-2019-043 Rev. 08)
B. SJREB Form 2 Protocol Assessment Form
C. SJREB Form 3 Informed Consent Assessment Form
D. FDA Clinical Trial Assessment Form

2.2.3. Responsibility

IERB member - Fills out and signs the evaluation/assessment form along with recommendation and comments they might have after reviewing each study protocol.

Secretariat - Distributes copies of the evaluation/assessment form to be filled out by IERB members with specific protocol, including the reasons for that recommendation.

- Files evaluation forms that were filled out.

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2.2.4. Process Flow/Steps

2.2.4.1 For PHC-Funded Protocols, Non-PHC-Funded protocols, Protocol that qualifies for SJREB review

NO.	ACTIVITY	PERSON(S) RESPONSIBLE
1	Fill out the IERB Reviewer's Evaluation Form or the SJREB Form 2 Protocol Assessment Form/SJREB Form 3 Informed Consent Assessment Form when reviewing the study protocol and related documents.	Designated Reviewers
2	Submit accomplished IERB Reviewer's Evaluation Form or SJREB Form 2 Protocol Assessment Form/ SJREB Form 3 Informed Consent Form Assessment Form to the Secretariat within 7 days after receipt of documents	Designated Reviewers
3	Compile accomplished evaluation form for review by the Chair/Board Secretary	Secretariat
4	File copies of accomplished evaluation form and other review documents in the protocol binder	Secretariat

2.2.4.2 For Protocol for Regulatory review from the PFDA

NO.	ACTIVITY	PERSON(S) RESPONSIBLE
1	Fill out the FDA Clinical Trial Assessment Form when reviewing the PFDA protocols and related documents.	Designated Reviewers
2	Submit accomplished FDA Clinical Trial Assessment Form to the Secretariat within 10 days for the vaccine trial, and 25 days for non-vaccine trial after receipt of documents.	Designated Reviewers
3	Compile accomplished assessment forms to be presented on either a separate scheduled meeting or during a board meeting	Secretariat
4	Send the digital copy of the assessment form after the decision has been made by the board.	Secretariat

5	File copies of accomplished assessment forms and other review documents in the filing binder	Secretariat

2.2.5 Detailed Instructions

2.2.5.1 For PHC-Funded Protocols, Non-PHC-Funded protocols, Protocol that qualifies for SJREB review

2.2.5.1.1 Fill out the IERB Reviewer's Evaluation Form or SJREB Form 2 Protocol Assessment Form/ SJREB Form 3 Informed Consent Form Assessment Form when reviewing the study protocol and related documents.

A. The Designated Reviewer reads the protocol and related documents, and complete the assessment forms.

B. The Designated Reviewer (medical) performs literature review to ensure updated knowledge about the protocol.

C. The Designated Reviewer accomplishes the IERB Reviewer's Evaluation Form (FM-E-IRB-2019-043 Rev. 08) **or** SJREB Form 2 Protocol Assessment Form/ SJREB Form 3 Informed Consent Form Assessment Form. The medical reviewer focuses on the scientific and ethical issues while the lay reviewer focuses on the ethical issues and informed consent

D. The IERB Reviewer's Evaluation Form (FM-E-IRB-2019-043 Rev. 08) part 1 or the SJREB Form 2 Protocol Assessment Form allows review of the technical and ethical issues as follows:

D.1 Rationale and significance of the study

D.2 Objectives of the study

D.3 Review of literature

D.4 Sample size

D.5 Methodology and data management

D.6 Inclusion/exclusion criteria

D.7 Control arms (placebo, if any)

D.8 Withdrawal or discontinuation criteria

D.9 Vulnerability determination

D.10 Risk/ benefit assessment

E. The IERB Reviewer's Evaluation Form (FM-E-IRB-2019-043 Rev. 08) part 2 or SJREB Form 3 Informed Consent Form Assessment Form enables review of the informed consent and ethical issues as follows:

E.1 Full disclosure of information, including risks

E.2 Benefits that may be derived from the study

E.3 Use of understandable language, with appropriate translation

E.4 Voluntary participation

E.5 Confidentiality

E.6 Appropriate person to sign the consent form

2.2.5.1.2 Submit accomplished IERB Reviewer's Evaluation Form (FM-E-IRB-2019-043 Rev. 08) **or SJREB Form 2 Protocol Assessment Form/ SJREB Form 3 Informed Consent Form Assessment Form to the Secretariat within 7 days after receipt of documents**

A. The Designated Reviewers sign, date the evaluation/assessment forms and submit to the Secretariat within 7 days from date of receipt of the protocol review package.

2.2.5.1.3 Compile accomplished evaluation form for review by the Chair/Board Secretary

A. The Secretariat checks whether the form is complete, compile the completed assessment forms and submit these to the Board Secretary/Chair.

B. The Board Secretary/Chair reviews the compiled checklists. If the protocol is for expedited review, the Board Secretary/Chair determines if there are no conflicting recommendations and if there is an agreement in the review/decision. If there are conflicting recommendations and/or disagreements in the review decision, the Board Secretary/Chair forwards the protocol for Full board review.

2.2.5.1.4 File copies of accomplished evaluation forms and other review documents in the protocol binder

A. The Secretariat files accomplished evaluation forms in the protocol binder.

2.2.5.2 For Protocol for Regulatory review from the PFDA

2.2.5.2.1 Fill out the FDA Clinical Trial Assessment Form when reviewing the PFDA protocols and related documents.

A. The Designated Reviewer reads the protocol and related documents, and complete the assessment form.

B. Designated Reviewers and independent consultant performs literature review to ensure updated knowledge about the protocol.

C. The IERB designated reviewer accomplishes the FDA Clinical Trial Assessment Form

2.2.5.2.2 Submit accomplished FDA Clinical Trial Assessment Form to the Secretariat within 10 days for the vaccine trial, and 25 days for non-vaccine trial after receipt of documents.

2.2.5.2.3 Compile accomplished assessment forms to be presented on either a separate scheduled meeting or during a board meeting.

A. The Secretariat checks whether the forms are complete, print and distribute the assessment to those present in the meeting.

2.2.5.2.4 Send the digital copy of the assessment form after the decision has been made by the board.

A. The Secretariat email the digital copy of the assessment form to the PFDA.

2.2.5.2.5 File copies of signed assessment form and other related documents in the filing binder.

Exempt from Review

2.3 Exempt from Review

2.3.1 Purpose

To describe the Institutional Ethics Review Board (IERB) procedures for the review of protocols that qualify for exemption from review.

2.3.2 Scope

This SOP applies to the review of a study protocol submitted to the IERB that qualifies for exemption from review.

2.3.3 Responsibility

Chair - Assess if protocol qualifies for exemption from review, designates a member to assess if protocol, approves exemption.

IERB Member - Designated by the Chair and is responsible for the assessment whether the submitted protocol qualifies for exemption from review.

Secretariat - Prepare and issue communication to the PI and file documents

2.3.4 Process Flow/ Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Review a study protocol applying for exemption from review	Chair/Designated Member	**To be done within 7 days**
2	Approve the exemption or recommend to expedited or fullboard review	Chair	
3	Issue a Certificate of Exemption	Secretariat	
4	Prepare a report of protocols that are exempt from review	Secretariat	
5	Communicate the decision to the PI	Secretariat	
6	File copy of the documents in the	Secretariat	

	protocol binder and update protocol database for exemption from review		

2.3.5 Detailed instructions

2.3.5.1 Review a study protocol applying for exemption from review

A. The Chair or a designated IERB member who do not have any conflict of interest reviews the study protocol applying for review exemption.

B. The Chair or a designated IERB member then evaluates the study protocol using the Checklist for Exemption from Protocol Review (FM-E-IRB-2024-096 Rev.00). The following Criteria for exemption:

B.1 Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.

B.2 Provided that protocols do not involve more than minimal risks or harms, the following may be considered by the IERB for exemption from review:

B.2.1 Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;

B.2.2 Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), if the following criteria are met:

B.2.2.1 There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to `their financial standing, employability, or reputation; and

B.2.2.2 The investigator records the information obtained in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

B.2.3 Protocols that involve the use of publicly available data or information.

2.3.5.2 Approve the exemption or recommend to expedited or full board review

A. The Chair or the designated reviewer approves the exemption or recommends for expedited or full board review.

B. If the protocol does not meet the Exemption Criteria, the Chair re-classifies the protocol for expedited or full board review

2.3.5.3 Issue Certificate of Exemption

A. If the protocol qualifies for exemption from review, the Secretariat prepares a Certificate of Exemption from Ethics Review using form (FM-E-IERB-2019-087 Rev.00.

2.3.5.4 Prepare a report of protocols that are exempt from review to full board

A. The Secretariat prepares a report to the next full board meeting to include details of all protocols exempted from review.

2.3.5.5 Communicate the IERB decision to the PI

A. The Secretariat prepares Certificate of Exemption from Ethics Review (FM-E-IERB-2019-087 Rev.00 and forwards to the Chair for signature.

B. The Secretariat issues the Certificate of Exemption to the Principal investigator.

2.3.5.6 File copy of the documents in the protocol binder and update protocol database.

A. The Secretariat file the properly-labeled binder in the active files.

B. The Secretariat updates the protocol database.

Expedited Review

2.4 Expedited Review

2.4.1 Purpose

To describe the Institutional Ethics Review Board (IERB) procedures for the review of protocols that qualify for expedited review.

2.4.2 Scope

This SOP applies to the initial and continuing review and approval of study protocols with minimal risks to study participants.

2.4.3 Responsibility

Chairman/ Board Secretary	-	To assess a protocol submission that qualifies for expedited review and assign designated reviewers.
Designated Reviewer	-	Evaluate the protocol using the evaluation form utilized for full board review to evaluate the scientific and ethical merits of the protocol.
Secretariat	-	Prepare communication to the PI and file the documents.

2.4.4 Process Flow/Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Determine that the submission qualifies for expedited review.	Board Secretary/Chair	7 days
2	Assign designated reviewers (medical/scientific and a non medical/non scientific members).	Board Secretary/Chair	
3	Send the protocol package to the designated reviewers	Secretariat	
4	Review the documents with the use of the evaluation form.	Designated Reviewer	14 days

5	Return the accomplished evaluation form to the Secretariat.	Designated Reviewer	
6	Collate and reviews the assessment forms to take appropriate action.	Secretariat	7 days
7	Communicate the IERB decision to the PI	Secretariat	
8	Prepare a list of all expedited review results and report to full board	Secretariat	
9	File copies of the documents in the protocol file folder and update the protocol database	Secretariat	

2.4.5 Detailed instructions

2.4.5.1 Determine that the submission qualifies for expedited review.

A. For initial review:

A.1 The secretariat manages the protocol package.

A.2 The secretariat informs the chair

A.3 The Chair/Board Secretary checks and approve if the submitted protocol qualifies for expedited review.

B. The following are types of protocols is subjected to expedited review after initial submission:

B.1 Protocols of a non-confidential nature (not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities or cause psychological stress to the people involved.

B.2 Protocols **not** involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent).

B.3 Protocols that involve collection of anonymized biological specimens for research purposes by noninvasive means (e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).

B.4 Research involving data, documents or specimens that have been previously collected

B.5 Proposed continuing review of previously expedited protocols, minor protocol amendments and end of study reports.

B.6 Minimal/low risk health research that requires personal information (ex. Review of medical records), about topic that should not result in causing social stigma, in retrospective studies using anonymized data, in health studies using simple questionnaires without identifies, in laboratory research that uses anonymized human tissue/specimen.

C. Specifically if the IERB decision for the minor modification, the study shall qualify for expedited review.

D. Submissions after initial review may qualify for expedited review as follows:

D.1 Administrative revisions, such as correction of typing errors

D.2 Addition or deletion of non-procedural items, such as the addition/change in study personnel or changes in their address or contact number, change in laboratories, and the like.

D.3 The research activity includes only minor changes from previously approved protocol.

D.4 Minor protocol amendments that do not change the risk/ benefit assessment

D.5 Major protocol amendment that do not change the risk/ benefit ratio

D.6 Progress/Final reports that were initially reviewed by expedited review and that do not deviate from approval given by the IERB.

D.7 SAEs that are off-site provided these are not SUSARs.

2.4.5.2 Assign designated reviewers (medical/scientific and a non medical/non scientific members) to review the submitted documents.

A. The Chair/Board Secretary assigns a Medical/Scientific Reviewer (IERB member or Independent Consultant) to review the scientific and ethical merits of the protocol related documents.

B. The Chair/Board Secretary assigns a non medical/ non scientific member to review the ICF.

2.4.5.3 Send the protocol package to the designated reviewers

A. The Secretariat contacts the Designated Reviewers to determine if they can review the protocol documents within the fourteen (14) day deadline. If not, another designated reviewers is identified.

B. The Secretariat sends the protocol package and the corresponding evaluation/assessment forms to the designated reviewers.

2.4.5.4 Review the documents with the use of the evaluation form.

A. The Designated Reviewers reads the protocol and related documents, and complete the IERB Reviewer's Evaluation Form (FM-E-IRB-2019-043 Rev. 08).

B. The IERB designated medical reviewer and non-medical reviewer evaluates the submitted documents by using the evaluation form.

C. The Designated Reviewers decides whether the protocol can be approved, for modification or disapproved.

2.4.5.5 Return the accomplished assessment form to the Secretariat

A. The Designated Reviewer signs and date the evaluation form and return them to the Secretariat within fourteen 14 days from receipt of the protocol review package.

B. The Secretariat checks for completeness of the assessment forms.

2.4.5.6 Collate and review the assessment forms to take appropriate action.

A. The Secretariat reviews the completed assessment forms to determine if there is agreement in the review/ decision.

A.1 If the decision is for major modification, the protocol elevates to a full board review only if the modification will increase the risk to participant.

A.2. If the decision is for minor modification, the Secretariat consolidates the comments and recommendations and communicates to the PI.

A.3. If the decision is approval, the Secretariat communicates to the PI.

A.4. All decision letters at expedited review should be forwarded to the Chair who may examine the decision and sign the decision letter to be given to the PI.

2.4.5.7 Communicate the IERB decision to the PI.

A. The Secretariat communicates approval to the PI and use the Decision Letter for Protocol Approval template (FM-E-IRB-2019-045 Rev. 08).

B. In case revision is required, the secretariat sends the recommendations to the PI using the Modification and Disapproval Letter template (FM-E-IRB-2019-056 Rev. 05) to comply with the required modifications and resubmit the documents to the IERB.

2.4.5.8 Prepare a report of protocols that are approved on expedited review to full board meeting

A. The Secretariat prepares a list of protocols approved through expedited review and include in the agenda of the meeting

B. The Chair reads the reports of all approved protocols during the full board meeting.

2.4.5.9 File a copy of the documents in the protocol file folder and update the protocol database.

A. The Secretariat files a copy of the approved documents in the protocol file binder.

B. The Secretariat updates the protocol database.

Full Board Review of Submitted Protocols

2.5 Full Board Review of Submitted Protocols

2.5.1 Purpose

To describe Institutional Ethics Review Board (IERB) procedures when the protocol submissions are classified for full board review

2.5.2 Scope

This SOP applies to the IERB full board review and approval of study protocols during initial and continuing review.

2.5.3 Responsibility

Chair

- Determines if a protocol is qualified for full board review
- Assigns a Designated Reviewers
- Presides the IERB full board meeting and determines quorum
- Sees to it that preliminary requirements related to the declaration of conflict of interest and confidentiality agreement and other related matters are complied with
- Moderate discussion by identifying common findings and dissenting opinion, reconcile contradicting views, integrate and summarize findings
- Directs the discussion for a consensus decision
- Ensures that the documentation is accurate and covers all significant points
- Signs decision form

Vice Chair

- Presides the IERB full board meeting and determines quorum in the absence of the Chair

Board Secretary	- Determines if a protocol is qualified for full board review - Assigns Designated Reviewers - Supervises the Secretariat in preparing the meeting agenda - Take minutes of the meeting
Designated Reviewer/ IERB Member	- Thoroughly reviews the study protocols before the meeting, and accomplish and submits the evaluation forms - Makes observations, comments during the meeting, gives recommendations/decision - Attends full board meeting and vote - Signs decision form - Reviews the resubmitted documents
Principal Investigator	- Presents the protocol or study during the board meeting/attend IERB meeting and wait if there is an item for clarification.
Secretariat	- Prepares and sends the protocol package to the board members - Checks the evaluation forms for completeness - Prepares the agenda for the full board meeting (FM-E-IRB-2019-050 Rev. 07), sends notice of meeting (FM-E-IRB-2019-032 Rev. 05), and prepares template of the minutes of meeting (FM-E-IRB-2019-033 Rev. 07) - Prepares the IERB Decision Form (FM-E-IRB-2019-017 Rev. 06) to be signed by all members present - Prepares the attendance sheet to be signed by the members present (FM-E-IRB-2019-055 Rev. 04) - Sends the 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.

2.5.4 Process Flow/Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Determine if the submission should undergo full board review.	Board Secretary/ Chair	7 days
2	Assign Designated Reviewers	Board Secretary/Chair	
3	Send the protocol package to the Designated Reviewers/Board Members	Secretariat	
4	Review the documents with the use of the Evaluation form	Designated Reviewer/Board members	7 days
5	Return the accomplished assessment forms to the Secretariat.	Designated Reviewer/Board members	
6	Discuss and decide on the protocol and related documents during a convened full board meeting	IERB Members	7 days
7	Communicate the IERB decision to the PI and **SJREB;** allocate 14 days for the PI to comply	Secretariat	1 -5 days for digital copy and within 10 day for printed copy; for SJREB within 7 working days (secretariat); 14 days (PI)
8	File copies of the documents in the protocol file folder and update the protocol database	Secretariat	7 days

2.5.5 Detailed Instructions

2.5.5.1 Determine if the submitted protocol documents should undergo full board review.

A. The Chair/ Board Secretary screens the protocol to identify those that should be discussed at full board.

A.1. For initial review: The Chair/Board Secretary goes over the submitted protocol and decide if it should undergo full board review based on assessment of risks.

A.1.1 The following are types of protocols that is reviewed at a convened full board meeting:

A.1.1.1 Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3)

A.1.1.2 Phase 4 intervention research involving drugs, biologics or device

A.1.1.3 Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc.; or about sensitive issues that may cause social stigma, psychological, legal, economic and other forms of social harm

A.1.1.4 Intervention protocols involving vulnerable subjects (patients with incurable diseases, persons in nursing homes, patients in emergency situations, ethnic minority groups, homeless persons, refugees, minors and those incapable of giving consent) that require additional protection from the IERB during review

A.1.1.5 Protocols that involve collection of identifiable biological specimens

A.1.1.6 The FDA, SJREB and PHC protocols have different review procedures.

A.2. For resubmissions: If the initial IERB decision is for major modification

A.3. For continuing review: submissions undergo full board reviews as follows:

A.3.1 Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/ exclusion criteria, safety issues, etc.)

A.3.2 Major amendments that change the risk/ benefit ratio

A.3.3 Major protocol violations/deviations

A.3.4 Progress reports of ongoing studies that involve medium to high risks to human subjects/ participants

A.3.5 Site SAEs/SUSARs

2.5.5.2 Assigns designated reviewers to review the protocols.

The Chair/ Board Secretary:

A. Assigns a Designated Reviewer (IERB member or Independent Consultant) to review the scientific and ethical merits of the protocol related documents.

2.5.5.3 Sends the protocol package to the Designated Reviewer/Board members

A. The secretariat prepares and send the protocol package to the board members.

2.5.5.4 Review the documents with the use of the IERB Reviewer's Evaluation Form.

A. The Designated Reviewers/Board Members read the protocol and related documents, and complete the assessment forms. The IERB members accomplishes the IERB Reviewer's Evaluation Form (FM-E-IRB-2019-043 Rev. 08).

B. The reviewers recommend the type of decision for initial review of protocol related documents as follows:

B.1 Approved

B.2 Minor modification required

B.3 Major modification required

B.4 Disapproved

C. All items to be revised in minor and major modifications shall be summarized.

D. The reviewers also check the CV or information about the investigators (including GCP training for clinical trials), the study sites and other protocol related documents, including advertisements:

D.1 Consider whether study and training background of the principal investigator are related to the study.

D.2 Look for disclosure or declaration of potential conflict of interest.

E. The reviewers determine if the facilities and infrastructure at study site are suitable for the study.

F. The advertisements, recruitment materials, and research tools shall be subject to review.

2.5.5.5 Return the accomplished evaluation form to the Secretariat

A. The Designated Reviewers/Board Members signs, date the IERB Reviewer's Evaluation form (FM-E-IRB-2019-043 Rev. 08) and return them to the Secretariat within 7 days from receipt of the protocol review package.

B. The Secretariat checks completeness of the IERB Reviewer's Evaluation form (FM-E-IRB-2019-043 Rev. 08) and includes it in the agenda of the next full board meeting.

2.5.5.6 Discuss and decide on the protocol and related documents during a convened full board meeting

A. The IERB conducts a full board meeting to discuss and make a decision about the protocol and related documents. (Refer to SOP on Conduct of Review Meeting)

B. The members of the IERB attending the full board meeting shall approve the following:

B.1 Principal and Co-Investigators and members of the research team

B.2 Protocol

B.3 Informed Consent

B.4 Advertisements or recruitment materials

B.5 Study sites covered by the application

C. The IERB members votes on specific items to arrive at a decision as follows:

C.1 Approval (when no further modification is required)

C.2 Minor modification (requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.)

C.3 Major modification (requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data)

C.4 Disapproval (due to ethical or legal concerns) Reasons for vote of disapproval should be noted in the minutes and communicated to the PI.

D. If the study is approved, the IERB determines the frequency of continuing review.

E. All meeting deliberations and decision regarding a protocol is noted in the meeting minutes. (Refer to SOP on Preparation of Meeting Minutes)

F. All SJREB decisions shall be reported to the board meeting including site specific issues such as, but not limited to, qualifications of PI, research sites, and appropriate ICFs.

2.5.5.7 Communicate the IERB decision to the PI and SJREB; allocate 14 days for the PI to comply

A. The Secretariat sends all IERB decisions is communicated to the PI 1 to 5 days for digital copy and within 10 days for printed copy. For the SJREB protocol, sends IERB decision within 7 working days after the meeting.

A.1 Approval: The secretariat prepares the Decision Letter for Protocol Approval to be signed by the Chair.

A.2 Minor modification: The secretariat prepares a notification letter using the Modification and Disapproval Form template (FM-E-IRB-2019-056 Rev. 05), to inform the PI of the required revisions in the protocol, ICF or any related document. The resubmitted documents undergoes Expedited Review before approval is granted. The IERB members reviews and check compliance to recommendations of the resubmitted documents, before granting approval.

A.3 Major Modification: The Secretariat prepares the notification letter using the Modification and Disapproval Form template (FM-E-IRB-2019-056 Rev. 05) to inform the PI of the required revisions in the protocol, the ICF or related document. The resubmitted documents is referred to Designated Reviewers and discussed at Full Board Review, once more before approval is granted.

A.3.1 All major changes in the study design and procedures that increase risk to study participants shall undergo full board review.

A.4 Disapproval: The Secretariat prepares the notification letter using the Modification and Disapproval Form template (FM-E-IRB-2019-056 Rev. 05) to inform the PI of IERB decision. The reasons is clearly stated in the notice.

A.4.1 Disapproval (due to ethical, legal or scientific concerns). Reasons for vote of disapproval should be noted in the minutes and communicated to the PI.

A.5 (Refer to SOP on Communicating IERB Decisions to the Researcher/PI)

2.5.5.8 File copies of the documents in the protocol file folder and update the protocol database.

A. The Secretariat files copies of the approved documents in the protocol file folder.

B. The Secretariat updates the protocol file folder.

C. The Secretariat updates the protocol database.

Review of Resubmission

2.6 Review of Resubmission

2.6.1 Purpose

To describe the procedures of Institutional Ethics Review Board (IERB) when the protocol resubmissions are received.

2.6.2 Scope

This SOP applies to the IERB review and approval of study protocols recommended for minor or major modifications during initial and continuing review.

2.6.3 Responsibility

Designated Reviewer
- Reviews the compliance to the required modification of the resubmitted protocols and related documents.

Principal Investigator
- Submits revised protocol and highlights modifications / changes made

Secretariat
- Ensures the completeness of the resubmitted documents
- Includes the protocol resubmission in the meeting agenda

2.6.4 Process Flow/Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Receive the resubmitted protocol package	Secretariat	
2	Send the protocol package to the designated reviewers	Secretariat	
3	Review the resubmitted documents by the Designated Reviewer	Designated Reviewer	
4	Recommend action or give	Designated	7 days

	decision to the resubmission	Reviewer	
5	Discuss and decide on resubmitted documents for major modifications	IERB Members	
6	Accomplish the Decision Letter for Protocol Approval and communicate the IERB decision to the PI	Secretariat	
7	File copies of the documents in the protocol file folder and update the protocol database	Secretariat	

2.6.5 Detailed Instructions

2.6.5.1 Receive the resubmitted protocol package

A. The Secretariat receives the resubmitted protocol documents from the PI.

B. The Secretariat checks the resubmitted protocol packages and if the resubmitted report form is properly filled out using the Resubmission Report Form (FM-E-2019-022 Rev. 06).

B. The Secretariat logs in the Incoming Log Book.

2.6.5.2 Send the protocol package to the designated reviewers

A. The Secretariat sends the protocol package to the Designated Reviewers for review.

2.6.5.3 Review the resubmitted documents by the Designated Reviewer

A. The Designated Reviewers reviews the resubmitted documents and compare it with the requirements for modification in the Resubmission Report Form (FM-E-2019-022 Rev. 06)

2.6.5.4 Recommend action or give decision to the resubmission.

A. The designated reviewers returns the resubmission package indicating their recommended action or decision

A.1 Resubmitted protocols under expedited review: the Designated Reviewers recommend further modification or approves the document

A.2 Resubmitted protocols under full board review with Major Modification: the Designated Reviewer recommends action to either approve, further modification (major or minor).

A.2.1 With Minor modification: goes to expedited review.

A.2.2 With Major modification: goes to full board discussion. Major modification means major changes in scientific and ethical components (e.g. study design, ICF issues).

A.3 Resubmitted protocols under full board review with Minor Modification: the Designated reviewer recommends further modification or approves the document.

A.4 If by the 2nd resubmission the investigator has not yet complied with recommendations, a meeting should be called to facilitate resolution of issues between the reviewer and the PI.

2.6.5.5 Discuss and decide on resubmitted documents for major modifications.

A. The Designated Reviewer reads the recommendations in the full board meeting

B. IERB members votes to endorse or not to endorse the recommendation for approval.

2.6.5.6 Accomplish the Decision Letter for Protocol Approval **and communicate the IERB decision to the PI**

A. For approved resubmitted protocols, the Secretariat prepares the Decision Letter for Protocol Approval (FM-E-IRB-2019-045 Rev. 08) that the Chair should sign.

B. The IERB decision is communicated to the PI.

2.6.5.7 File copies of the documents in the protocol file folder and update the protocol database.

A. The Secretariat files copies of the approved documents in the protocol file folder.

B. Update the protocol file folder.

C. Update the protocol database.

Note: the whole resubmission process should be done within 14 days

Management of Appeals

2.7 Management of Appeals

2.7.1 Purpose

To describe the procedures of Institutional Ethics Review Board (IERB) when the PI is submitting an appeals for the disapproved proposal.

2.7.2 Scope

This SOP covers procedures that begin with the receipt of the appeal and ends with communicating the IERB's action to the PI and updating the protocol.

2.7.3 Responsibility

Chairman
- Instruct the secretariat to include the appeal in the agenda of the meeting.
- Present the contents of the appeal and lead the discussions.

Designated Reviewer
IERB Members
- Review and summarize the protocol and previous issues the protocol as background to the appeal

Principal Investigator
- May be called in for further clarification of issues and step out after the IERB taken up the issues for clarification.

Secretariat
- Communicate decision to the PI and file documents,

2.7.4 Process Flow/Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Receipt of an appeal	Secretariat	
2	Retrieval of pertinent protocol file	Secretariat	

3	Notification of Chair and Designated Reviewer/s	Secretariat	14 days
4	Inclusion in Agenda of the next full board meeting	Chair/Designated Reviewer/Secretariat	
5	Discuss and deliberation on the appeal	IERB Members	
6	Communication of IERB action (See SOP Full Board Review)	Secretariat	
7	File copies of the documents in the protocol file folder and update the protocol database	Secretariat	

2.7.5 Detailed Instructions

2.7.5.1 Receipt of an appeal

A. The Secretariat receives the letter of appeal and pertinent documents.

B. The Secretariat logs in the Incoming Log Book.

2.7.5.2 Retrieval of pertinent protocol file

A. The Secretariat retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, ICF, research tools and other related documents.

2.7.5.3 Notification of Chair and Designated Reviewers

A. The Secretariat notifies the Chair and the Designated Reviewers about the letter of appeal and other related documents and awaits further instructions.

2.7.5.4 Inclusion in the Agenda of the next full board meeting.

A. The Chair instructs the Secretariat to include the appeal in the agenda of the next full board meeting, to ensure that the retrieved protocol and related documents are available during the meeting.

B. The Secretariat informs the researcher to be available on the scheduled meeting in case there is an need for further clarification.

2.7.5.5 Discuss and Deliberation on the Appeal.

A. The Designated Reviewers summarizes the protocol and previous discussion of the issues in the protocol as background to the appeal.

B. The Chair present the contents of the appeal and leads discussion.

C. The Principal Investigator may be called in for further clarification of issues.

C.1 The Principal Investigator asks to step out after the IERB has taken up the issues for clarification.

D. The IERB members decides (by consensus) whether to accept any or all of the points raised in the appeal.

2.7.5.6 Communication of IERB Action.

A. The Chair summarizes the decision points and instruct the Secretariat to prepare the draft decision letter in Modification and Disapproval Form template (FM-E-IRB-2019-056 Rev. 05) for his/her finalization and forwarding to the researcher (Refer to SOP on Communicating IERB Decisions to the Researcher/PI).

2.7.5.7 Filing of Documents and update the protocol database.

A. The Secretariat files all documents in the protocol file folder.

B. Update the protocol file folder.

C. Update the protocol database.

Protocols that Qualify for SJREB Review

2.8 Review of Protocol that Qualifies for SJREB Review

2.8.1 Purpose

To describe Institutional Ethics Review Board (IERB) procedures for the protocols that qualify for SJREB review related to the multi-site research. PHC is a DOH hospital and should participate in SJREB meetings to review all multicenter protocols as prescribed in the DOH AO no. 2017-0021.

2.8.2 Scope

This SOP applies to the IERB review of study protocols to be implemented in at least three sites in the Philippines. Sponsors and researcher who choose to do their studies in 3 or more site may submit their protocol to PHC and to SREB. The SJREB requires the site RECs to agree and abide with the procedures that SJREB follows. All research sites should agree to provide the necessary environment to ensure the safe and ethical conduct of research, including oversight and stewardship functions as necessary, to monitor the conduct of the study.

2.8.3 Responsibility

Chairman	-	Assigns designated reviewer (IERB member or Independent Consultant) to review the scientific and ethical merits of the protocol related documents.
Designated Reviewers	-	Reviews the Protocol and accomplishes the SJREB Form 2 Protocol Assessment Form/ SJREB Form 3 Informed Consent Form Assessment Form. The medical reviewer focuses on the scientific and ethical issues while the lay reviewer focuses on the ethical issues and informed consent recommendations/decision.

- Attends SJREB review meeting and presents findings and recommendations to SJREB.

Secretariat
- Communicates the decision to the Principal Investigator, SJREB.
- Files the communication and other related documents.

2.8.4 Process Flow/Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Receive study protocols qualified for SJREB review	Secretariat	To be done within 7 working days
2	Receives request from SJREB for reviewers	Secretariat	
3	Assigns REC Member/Independent consultant as designated reviewer	Chair/Board Secretary	
4	Coordinated with SJREB Secretariat Staff regarding reviewers/PHC representative	Secretariat	
5	Notify the designated reviewer for review and request to attend SJREB meeting	Secretariat	
6	Accept or decline invitation for SJREB review	Designated Reviewer/Independent Consultant	
7	Conduct of study protocol review	Designated Reviewer/Independent Consultant	7 days
8	Attend SJREB meeting	Designated Reviewer	
9	Include in the next full board meeting	Secretariat	
10	Notify the principal investigator about the decision	Secretariat	10 days

2.8.5 Detailed Instructions

2.8.5.1 Receive study protocol qualified for SJREB Review.

A. Multi-site protocols involving at least three (3) sites in the Philippines with at least one (1) DOH hospital are endorsed for single joint review.

B. PHC-IERB receives an invitation from SJREB to participate in the review of specific protocol.

C. Study protocols with parallel submissions to SJREB are processed by PHC-IERB through expedited review. The designated reviewer will review site-specific issues while SJREB is on-going. The PHC-IERB accepts the decision made by SJREB.

2.8.5.2 Receive request from SJREB for reviewers.

A. The SJREB may request primary reviewer for study protocols included for SJREB review.

B. The SJREB may request for primary reviewers who are members of PHC-IERB or independent consultant.

2.8.5.3 Assigns REC Member/Independent consultant as designated reviewer.

A. The Chair or Board Secretary assign REC member/Independent consultant to review the study protocol.

2.8.5.4 Coordinated with SJREB Secretariat Staff regarding reviewers/PHC representative.

A. The Secretariat coordinates with the SJREB Secretariat regarding the request for reviewers/PHC representative.

B. Study protocols may be assigned to an independent consultant if there are no available experts among the regular members.

2.8.5.5 Notify the designated reviewer for review and request to attend SJREB meeting.

A. The Chair/Board Secretary assigns designated reviewers to the study.

B. The Secretariat notifies the assigned designated reviewers and forward the complete study protocol package from SJREB.

C. The Secretariat invites the reviewer to attend the SJREB full board meeting.

2.8.5.6 Accept or decline invitation for SJREB review.

A. The Designated reviewer accepts or declines request for review through REC Secretariat.

2.8.5.7 Conduct study protocol review as SJREB designated reviewer.

A. The Secretariat notifies the designated reviewers for protocol assignments and send protocol package.

B. The Designated reviewers acknowledges receipt of study protocol for review.

C. The Secretariat may forward the hard copy of the study protocol to the reviewers upon request.

D. The Designated reviewers review the study protocol and informed consent documents in accordance with the assessment points and elements details in SJREB Form 2 Protocol Evaluation Form and SJREB Form 3 Informed Consent Evaluation Form.

E. The Designated reviewer accomplishes the SJREB Form 3 and SJREB Form 2, completely signed and dated, forward the electronic from through e-mail, or returns the signed paper-based review to the Secretariat on or before the date indicated or given by SJREB.

2.8.5.8 Attends SJREB meeting

A. The Designated reviewer attends SJREB meeting.

B. In the event that the reviewer agrees to review but cannot attend the meeting, the Chair assigns a representative to present the reviewer's assessment during the SJREB meeting.

2.8.5.9 Include in the agenda of the next full board meeting.

A. Upon receipt of the SJREB decision, the Secretariat includes the protocol in the next full board meeting.

B. The designated reviewers present the result of the review during the SJREB meeting, and the site specific concerns and make recommendations.

C. The Board accepts the decision of the SJREB and summarize the site-specific recommendations and take action.

2.8.5.10 Notify Principal Investigator of the decision regarding protocol submission.

A. The Secretariat prepares a notification letter or the to send to the PI summarizing all site-specific recommendations and/or its action.

A.1 When the decision is for modification, the PI is informed using the Modification and Disapproval Letter template (FM-E-IRB-2019-056 Rev 05) to address any site=specific concerns/issues and submit the revised document(s)

B. The Secretariat then sends the Boards recommendations and its action to the SJREB. Once the SJREB issues its final decision and sends the endorsement to the IERB, the PHC-IERB accepts the decisions made by SJREB.

C. Once approved, the PHC-IERB issues a Decision Letter for Protocol Approval (FM-E-IRB-2019-045 Rev 09). citing the specific documents approved by the SJREB and IRB.

FDA Regulatory Review

2.9 FDA Regulatory Review

2.9.1 Purpose

To differentiate the purpose and procedures of regulatory review from the standard IERB procedures

2.9.2 Scope

This provides instructions to review and approval of FDA protocols from the Philippine Food and Drug Administration (PFDA). Regulatory review shall focus on technical issues about the study designs for clinical trial procedures of design including randomization, software and protocol SOPS. Assignment of Designated Reviewers: The eegulatory review panel should be made up of scientific experts and experienced clinicians /trialists with proper academic qualifications and experience. Communication of regulatory review decisions: Submit regulatory review decisions to PFDA who will communicate them to the sponsor.

2.9.3 Responsibility

Chair

- Assigns Designated Reviewer/s and/or Independent Consultant
- Presides the Regulatory review meeting
- Moderate discussion by identifying common findings and dissenting opinion, reconcile contradicting views, integrate and summarize findings
- Directs the discussion for a consensus decision
- Ensures that the documentation is accurate and covers all significant points

Vice Chair

- Presides the Regulatory review meeting in the absence of the Chair

Board Secretary
- Takes minutes of the meeting

Designated Reviewer/
- Thoroughly reviews the study protocols before the meeting, and accomplish and submits the evaluation forms
- Presents the protocol or study during the board meeting

IERB Independent Member
- Makes observations, comments during the meeting, gives recommendations/decision
- Attends board meeting

Secretariat
- Prepares the agenda for the regulatory review meeting (FM-E-IRB-2019-050 Rev. 07), sends notice of meeting (FM-E-IRB-2019-032 Rev. 05), and prepares template of the minutes of meeting (FM-E-IRB-2019-033 Rev. 07)
- Prepares the attendance sheet to be signed by the members present and independent member (FM-E-IRB-2019-055 Rev. 04)
- Sends the recommendation or comments to the sponsor
- Sends the signed FDA Clinical Trial assessment Form version 1.2
- 16July 2012 to PFDA email address
  Files the assessment form and flash drive of the digital copy of protocol package.

2.9.4 Process Flow/Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	.Assign Designated Reviewer/s	Chair/ Board Secretary	
2	Send the protocol package to the Designated	Secretariat	7 days

	Reviewers/Independent Consultant member		
3	Review the documents with the use of the Evaluation form	Designated Reviewer/Independent Consultant Member	10 days (vaccine trial) 25 days (non-vaccine trial)
4	Return the accomplished assessment forms to the Secretariat.	Designated Reviewer	
5	Present and discuss the protocol on a regulatory review meeting	Designated Reviewer	
6	Communicate the IERB decision to the Sponsor/CRO and allocate 30 days for the Sponsor/CRO to comply	Secretariat	7 days (secretariat); 30 days (Sponsor/CRO)
7	Sign FDA Clinical Trial assessment form	Chair	7 days
8	Send signed Assessment Form to PFDA	Secretariat	
9	File copies of the documents in the protocol file folder and update the protocol database	Secretariat	

2.9.5 Detailed Instructions

2.9.5.1 Assign Designated Reviewers

A. The Chair/ Board Secretary assigns designated reviewer and independent consultant reviewer.

2.9.5.2 Send the protocol package to the Designated Reviewers/Independent Consultant member

A. The secretariat prepares and sends the protocol package to the Designated Reviewer and Independent Consultant,

2.9.5.3 Review the documents with the use of the evaluation form.

A. The Designated Reviewers and Independent Consultant member reads the protocol and related documents, and complete the assessment forms.

B. The Designated Reviewers accomplish the FDA Clinical Trial Assessment Form version 1.2 16July 2012.

C. The Designated Reviewers/Independent Consultant recommends the type of decision for initial review of protocol related documents as follows:

C.1 Approved

C.2 Approval pending (waiting for the response for the clarification)

C.3 Disapproval

D. The Designated Reviewers/Independent Consultant also checks the CV or information about the investigators (including GCP training for clinical trials), the study sites and other protocol related documents, including advertisements:

D.1 Consider whether study and training background of the principal investigator are related to the study.

D.2 Look for disclosure or declaration of potential conflict of interest.

E. The Designated Reviewers/Independent Consultant determines if the facilities and infrastructure at study site are suitable for the study (Level III PHREB Accredited.

2.9.5.4 Return the accomplished assessment form to the Secretariat

A. The Designated Reviewers accomplishes the assessment form and return them to the Secretariat within 10 days for vaccine trial and 25 days for non-vaccine trial from receipt of the protocol review package.

B. The Secretariat checks completeness of the assessment form and includes it in the agenda of the next full board meeting.

2.9.5.5 Present and discuss the protocol on a regulatory review meeting

A. The IERB conducts a Regulatory Review meeting to discuss and make a decision about the protocol and related documents.

B. The members of the IERB attends the meeting approves the following:

B.1 Principal Investigators and members of the research team

B.2 Protocol

B.3 Study sites

C. The IERB members arrives at a decision as follows:

C.1 Approval (when no further modification is required)

C.2 Deferred (waiting for the response for the clarification)

C.3 Disapproval

D. All meeting deliberations and decision regarding a protocol is noted in the meeting minutes.

2.9.5.6 Communicate the IERB decision to the Sponsor/CRO and allocate 30 days for the Sponsor/CRO to comply

A. All IERB decisions is communicated to the Sponsor/CRO.

A.1 Approval: The secretariat sends the FDA Clinical Trial Assessment Form version 1.2 16July 2012 to be signed by the Chair.

A.2 Deferred: The secretariat sends a clarification to the Sponsor/CRO and allocate 30 days upon receipt of the clarification.

The resubmitted documents undergoes Expedited Review before approval is granted. The Chair/Designated Reviewer/Independent Consultant reviews and checks compliance to recommendations of the resubmitted documents, before granting approval.

A.3 Disapproval: The Secretariat sends FDA Clinical Trial Assessment form to be signed by the Chair. The reasons is clearly stated in the FDA Clinical Trial Assessment Form version 1.2 16July 2012.

2.9.5.7 Sign FDA Clinical Trial assessment form.

A. The Chair signs the accomplished assessment form.

2.9.5.8 Send signed Assessment Form to PFDA.

A. The Secretariat sends the signed accomplished assessment using FDA Clinical Trial Assessment Form version 1.2 16July 2012.

2.9.5.9 File copies of the documents in the protocol file folder and update the protocol database

A. The Secretariat files copies in the filing folder.

B. The Secretariat updates the FDA protocol database.

Conduct of Online Preparation and Meeting

2.10 Conduct of Online Preparation and Meeting (Refer to SOP 4.2 Conduct of full board meeting)

2.10.1 Purpose

The SOP describe Institutional Ethics Review Board (IERB) procedures in conducting online preparation and meeting.

2.10.2 Scope

This SOP describes the IERB procedures to prepare and conduct of online meeting.

2.10.3 Responsibility (for details…

Chair
- Meeting Host and call the meeting order and remind the attendees of the conflict of Interest (CoI)
- Displays the Agenda and Minutes of the meeting

Vice Chair
- Meeting Host
- Calls the meeting order and remind the attendees of the conflict of Interest (CoI) in the absence of the Chair

Board Secretary
- Takes the minutes of the meeting
- Ensures that the documentation is accurate and covers all significant points

IERB Member
- Attends online meeting
- Participates in the meeting

Principal Investigator
- Presents and screen share the presentation of the protocol during the board meeting

Secretariat
- Sends the link of the meeting
- Informs the members to join in the online meeting
- Records the online meeting

2.10.4 Process Flow/Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Opening the meeting	Secretariat	
2	Application Review, Discussion and Voting Procedure	Secretariat/Chair	
3	Closing the Meeting.	Secretariat	

2.10.5 Detailed Instructions

2.10.5.1 Opening the meeting.

A. The Chair calls the meeting to order and asks for the disclosure of the Conflict of Interest (CoI) of those present

A.1 IERB Member with a conflict of interest in any item on the agenda should declare their conflict of interest during the roll call.

A.1.1 The Member with conflict of interest will be moved to the waiting room during discussion

B. The Meeting Host displays the list of the Board Members and takes note of their attendance in the meeting.

C. An IERB member takes a picture for documentation after informing those who are present.

D. The Board secretary takes minutes of the meeting.

E. The Chair displays and reads the Agenda of the Meeting and requests a motion to approve.

F. The Chair displays the Minutes of the last meeting and requests a motion to approve.

2.10.5.2 Application Review, Discussion and Voting Procedure.

A. The Chair displays the agenda on the shared screen.

B. The Chair introduces the first protocol for initial review application. If a member of the board declares CoI, the meeting host moves the member to the waiting room and admit once the discussion in over.

B.1 For initial review:

B.1.1 The Meeting Host shall allow the PI to be in the meeting room.

B.1.2 The Chair shall welcome the PI and introduce to the members of the Board.

B.1.3 The PI shares screen to the meeting and present the protocol

B.1.4 The Chair asks the members if they have any questions or comments in response to the protocol presented.

B.1.5 The Board member with question or comments raises their hands in the zoom interface, ask their question and the Chair identify who would like to speak.

B.1.6 The Board member/s then asks the question and make recommendations to the PI.

B.1.7 The Chair asks the PI to leave the meeting room for deliberation.

B.1.8 After the PI presentation and discussion, the Board secretary/member share screen the notes taken from the discussion and summarizes the recommendation.

B.1.9 The Chair asks the members to vote and announces the decision.

B.2 Protocol for Modification, Protocol for Clarificatory interview; Application for Protocol withdrawal, Protocol Amendment, Continuing review/Progress Report/Annual Report, End of Study Report, SAE Report, Site Monitoring Visit Report, Protocol Deviation/Non-Compliance/Violation Report and Early Study Termination Application:

B.2.1 The Chair announces the next item in the agenda of the meeting:

B.2.2 The Chair asks the designated reviewer to summarize result of the review of the resubmission

B.2.3 The Designated Reviewer gives decision to the resubmission

B.3 Protocol for Expedited Review

B.3.1 The Chair present the Protocol reviewed on expedited review.

2.10.5.3 Closing the Meeting.

A. The Chair announces that the last item has been discussed and asks the Secretariat if there are any outstanding item, question, commends or expedited items that need for additional discussion.

B. The Board members who have item to discuss raises their hands, type their questions/comment in the chat box that they have something to say.

C. The Chair will go through the item that needs for further clarification.

D. The Chair asks the secretariat for the next tentative meeting.

E. The Chair will confirm that all pending matters have been satisfactory resolved and declares that the IERB meeting is over and signaling the meeting host to end the meeting.

F. The meeting host ends the meeting.