



**Eastern Visayas Health Research and Development Consortium-  
Ethics Review Committee (EVHRDC-ERC)  
STANDARD OPERATING PROCEDURE**

**CHAPTER 2: INITIAL REVIEW PROCEDURES**

<b>REVIEW OF RESUBMITTED STUDY PROTOCOL</b>	SOP No.	11
	Version No.	05
	Version Date	07-10-2023
	Effective Date	07-17-2023

**1. STATEMENT OF POLICY**

The ERC shall require the resubmission of protocols for either minor or major modification/s within thirty (30) days and not exceed sixty (60) days after receipt of the **Form 27.2 Letter of Modification**.

Protocols initially classified for expedited review but with minor or major revisions shall still undergo expedited review upon resubmission for as long as minimal risk is not elevated. Protocols initially classified for full review shall be subject to expedited review if with minor revisions and to full review if with major revisions upon resubmission.

Protocol resubmissions approved through the expedited review will be reported during the Full Board Review Meeting. Resubmission of protocols initially classified for a full review with major revisions will be included in the agenda of the nearest Full Board Review Meeting for discussion and decision.

**2. OBJECTIVE/S OF THE ACTIVITY**

It aims to ensure systematic, organized, independent, efficient, and comprehensive conduct of review for resubmitted study protocols.

**3. SCOPE / APPLICABILITY**

This activity guides the officers and members, and other persons who may be involved in the conduct of the review.

**4. ROLES AND RESPONSIBILITIES**

Compliance is the responsibility of the officers and members, and other persons who may be involved in the conduct of Full Review and Meeting.

**ERC Chair** - assigns review to members on deck; dialogues with reviewer/s regarding reviewer's decision; communicates result of review to the Principal Investigator.

**ERC Staff Secretary** – delivers relevant documents to the reviewer/s, files all communications, decisions and protocols; and includes expedited protocol in the next meeting's agenda for confirmation and information of committee members.

**Reviewer/s** - conducts review; fills out the checklist forms needed; submits accomplished checklist to the ERC chair; and dialogues with the Chair when necessary.

**Principal Investigator** – submits complete protocol package for resubmission; complies with recommendations of the ERC.

## 5. WORKFLOW

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Principal Investigator submits revised protocol	Principal Investigator	15 <sup>th</sup> day of the month
Step 2: ERC Staff Secretary endorse the submitted form to the ERC Chair	ERC Chair, Primary Reviewers, ERC Staff Secretary	3 days
Step 3: Review of the resubmitted protocol	Primary Reviewers and Independent Consultants (if applicable)	7 days
Step 4: Presentation of review findings and recommendations during the meeting	Primary Reviewers if Expedited Review; All ERC Members if Full Board Meeting	Same day of meeting
Step 5: ERC Staff Secretary communicates the results to the Primary Investigator	ERC Staff Secretary	7 days
Step 6: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary	7 days

## 6. DESCRIPTION OF PROCEDURES

### 6.1 Principal Investigator submits revised protocol

The researcher submits the revised proposal through the ERC Staff Secretary together with the document deemed relevant by the investigator to clarify information in relation to the research protocol. The ERC Staff Secretary checks the completeness of the submission including all needed actions based on the recommendations/suggestions provided using **Form 11.1 Review of Resubmitted Study Protocol**.

### 6.2 ERC Staff Secretary endorse the submitted form to the ERC Chair

The ERC Staff Secretary endorses the revised study protocol together with other relevant documents to the ERC Chair. The ERC Chair will then determine if the submitted resubmitted protocol will undergo full review or expedited review. Type of review may be classified according to the following

- o **Expedited Review** - This is applicable for protocols for minor revisions.
- o **Full Review** - This is applicable for protocols for major revisions.

### 6.3 Review of resubmitted protocol

For full review, **SOP No. 06 Full Review** is followed. The protocol package to be distributed by the ERC Staff Secretary includes **Form 11.1 Review of Resubmitted Study Protocol** and other relevant documents.

For expedited review, it will follow **SOP No. 07 Expedited Review**. ERC Staff Secretary sends **Form 11.1 Review of Resubmitted Study Protocol** and other relevant documents to the Primary reviewers assigned.

### 6.4 Presentation of review findings and recommendations during the meeting

The Primary Reviewers (if Expedited Primary Reviewer Meeting) or the ERC Members (if Full Review) will discuss and provide recommendations during the meeting.

Decision points for resubmitted protocols are:

- Approve
- Minor Modification
- Major Modification
- Disapprove
- Decision withheld until needed clarification is given and accepted

### 6.5 ERC Staff Secretary communicates the results to the Primary Investigator

The decision of the committee is communicated to the researcher within seven (7) working days after the final deliberation. The ERC can suspend ethical clearance or subject recruitment until noncompliance issues are addressed. In addition, ERC may opt to withdraw ethical approval according to the following circumstances: (1) fraud and (2) unresolved serious safety issues.

- o For submitted requests with major/ minor modifications, the ERC Staff Secretary **Form 27.2 Letter of Modification**. The form includes instructions that:
  - Modified part should be underlined and bold-faced with indicated page where the revisions were made; and
  - Include footer in all pages that indicates both the DATE and VERSION NUMBER of the resubmitted study protocol, ICF and other documents forming part of the protocol.
- o For an approved application, the ERC Staff Secretary sends **Form 27.1 Approval Letter**.

### 6.6 Filing of protocol-related documents and updating of the Protocol Database

The ERC Staff Secretary then logs the date of decision of the application and stores the revised protocol in the study protocol file folder.

## 7. FORMS AND TOOLS

Form 11.1	Review of Resubmitted Study Protocol
Form 27.1	Approval Letter
Form 27.2	Letter of Modification

## 8. HISTORY

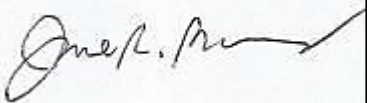

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	10/23/2015	ERC	First draft
2	12/05/2019	ERC	Updates on Procedures

3	11/28/2022	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	Updates on procedures and policy.
4	04/25/2023	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	Revised description of procedures and added timeline in the Workflow
5	07/10/2023	Dr. Jane R. Borrinaga Ms. Sarah B. Delorino Engr. Florentino L. Quiñones Ms. Noreen S. Buhat Fr. Charles Gingco Dr. Jose Carlo K. Del Pilar Ms. Erleta S. Piñero Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	Revised decision points and added additional steps in the description of procedures

## 9. REFERENCES

- World Medical Association Declaration of Helsinki, 2013
- ICH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2)

- WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
- International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016
- National Ethical Guidelines for Health and Health Related Research 2017
- Philippine Health Research Ethics Board Standard Operating Procedures 2020
- BatMC RERC SOP 2020

Prepared by:	Reviewed and Approved by: 	Approved by: 
<b>ETHICS REVIEW COMMITTEE</b>	<b>DR. JANE R. BORRINAGA, MD, FPCP</b> ERC Chair	<b>EXUPERIA B. SABALBERINO, MD, MPH, CESe</b> EVHRDC Executive Committee Chair
Date: 07-10-2023	Date: 07-10-2023	Date: 07-10-2023