



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

CHAPTER 3: POST APPROVAL PROCEDURES

CONTINUING REVIEW APPLICATION	SOP No.	18
	Version No.	04
	Version Date	04-25-2023
	Effective Date	04-30-2023

1. STATEMENT OF POLICY

All research protocols reviewed and approved by the committee which for a certain period of time must undergo continuing review to seek renewal of ethical clearance to assure the quality, safety, and security from ethical risks of the research protocol.

It is the policy of the ERC to grant ethical clearance or approval for a period of one year. Continuing review is required to be done at least once a year depending on the risk assessment of the study protocol which is determined during the initial review.

This is facilitated through the submission of **Form 18.1 Continuing Review Application**, 60 days before expiration of the Ethical clearance.

2. OBJECTIVE/S OF THE ACTIVITY

This activity primarily aims to ensure that the conduct of the study is in compliance with the properly approved protocol and that the safety and welfare of study participants are promoted and the integrity and validity of data protected beyond the period of initial ethical clearance and up to the end of the study. Ethical clearance is given for one year from the date of approval of the protocol. Renewal of the ethical clearance must be secured 60 days before its expiry. ERC Staff Secretary will send a Reminder Letter for Continuing Review to the PI 90 days before the expiry of ethical clearance.

3. SCOPE / APPLICABILITY

This applies to all researches approved by the EVHRDC ERC and are seeking renewal of ethical clearance.

4. ROLES AND RESPONSIBILITIES

Compliance is the responsibility of the Principal Investigator (PI), ERC Staff Secretary and the ERC Members.

Principal Investigator - Submits the application with pertinent documents.

ERC Staff Secretary- receives, determines the completeness and acknowledges receipt of documents.

ERC Chair - determine the type of review and identify the primary reviewers.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Notification of PI	ERC Staff Secretary
Step 2: Acknowledge receipt of submission	ERC Staff Secretary
Step 3: Determination of the type of review	ERC Chair
Step 4: Conduct of review	ERC Members
Step 5: ERC Staff Secretary communicates the results to the Primary Investigator	ERC Staff Secretary
Step 6: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 Notification of PI

The ERC Staff Secretary looks through the study protocols using the study protocol database and informs the Principal Investigator of the study protocol whose ethical clearances will expire at least 90 days prior to the expiration date of the ERC approval. This will be communicated to them using **Form 14.1 Reminder Letter**.

6.2 Acknowledge receipt of submission

The researcher submits **Form 18.1 Continuing Review Application** may it be through email or hard copy with a letter addressed to the ERC Chair 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 submission for completeness of the documents submitted within the submission date. If incomplete, the ERC Staff Secretary

immediately informs the researchers of other documents needed for submission. The staff secretary logs in the logbook and updates the study protocol database.

6.3 Determination of the type of review

The ERC Staff Secretary sends the continuing review application package to the ERC Chair. The ERC Chair will then determine if the submitted continuing review application will undergo full review or expedited review. The ERC Chair communicates its decision to the ERC Staff Secretary within three (3) working days.

6.4 Conduct of review

- o If classified under full review to follow **SOP No. 06 Full Review**
- o If classified under expedited review to follow **SOP No. 07 Expedited Review**

The decision points are:

- Grant renewal of the ethical clearance
Duration of Approval: from mm/dd/yyyy to mm/dd/yyyy
- Not grant the renewal of ethical clearance
Reason: _____
- ERC requests for other documents to be able to make the decision to grant renewal.

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.

- o For submitted request with major/ minor modifications, the ERC Staff Secretary sends signed **Form 18.1 Continuing Review Application** with **Form 27.3 Notification of ERC Decision**;
- o For approved application, the ERC Staff Secretary sends **Form 18.1 Continuing Review Application** with **Form 27.3 Notification of ERC Decision**.

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 documents in the study protocol file folder.

7. FORMS AND TOOLS

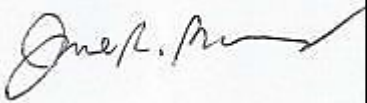

Form 14.1	Reminder Letter
Form 18.1	Continuing Review Application
Form 27.1	Approval Letter
Form 27.2	Letter of Modification
Form 27.3	Notification of ERC Decision

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

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: 
ETHICS REVIEW COMMITTEE	DR. JANE R. BORRINAGA, MD, FPCP ERC Chair	EXUPERIA B. SABALBERINO, MD, MPH, CESe EVHRDC Executive Committee Chair
Date: 04-25-2023	Date: 04-25-2023	Date: 04-25-2023