



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

CHAPTER 3: POST APPROVAL PROCEDURES

REVIEW OF PROGRESS REPORT	SOP No.	14
	Version No.	03
	Version Date	07-10-2023
	Effective Date	07-17-2023

1. STATEMENT OF POLICY

The ERC shall require the submission of progress reports at a frequency based on the level of risk of the study as decided by the Primary Reviewers and ERC Chair. This requirement shall be explicitly stated in the Approval Letter. EVHRDC ERC monitors the progress of research and accomplishment of goals of the Principal Investigators. Hence, ERC requires them to report on the progress of their research work every 6 months or at intervals appropriate for the degree of risk and duration of the study protocol. For minimal risk protocols, the Principal Investigators are required to submit a progress report once a year, together with the continuing review application (*see SOP No. 18 Continuing Review Application*), if applicable. For protocols with more than minimal risk, the Principal Investigator is required to submit a progress report every 6 months. Frequency of submission of progress report is indicated in the **Form 27.1 Approval Letter**. The ERC Staff Secretary sends **Form 14.1 Reminder Letter** to the Principal Investigator at least sixty (60) days before the due date.

2. OBJECTIVE/S OF THE ACTIVITY

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted.

3. SCOPE AND APPLICABILITY

This SOP applies to the management and review of progress reports submitted by the Principal Investigator while the study is on-going or has ended. This SOP begins with the receipt and entry to the logbook of incoming documents and the protocol database and ends with filing of progress report and committee decision in the protocol file. It also describes the follow up of progress reports by the ERC Staff Secretary to the PIs as decided from the initial approval of the protocol by the designated members of the ERC

in compliance with ICH-GCP requirements. Failure to submit progress reports should be reported as protocol deviation.

As a general rule, progress reports of Expedited Protocols will undergo Expedited Review while progress reports reviewed at Full Board should go through Full Board Review as well.

4. ROLES AND RESPONSIBILITIES

Compliance shall be the responsibility of the principal investigator (PI), ERC Staff Secretary and the ERC Members.

Principal Investigator - Submits the Progress Report Form with other protocol related 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: Submission of Progress Report	Principal Investigator
Step 2: Retrieval of pertinent protocol file	ERC Staff Secretary
Step 3: Notification of ERC Chair and Primary Reviewers	ERC Staff Secretary
Step 4: Determine the type of review	ERC Chair
Step 5: Communicate ERC decision	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 Submission of Progress Report

The Principal Investigator submits **Form 14.2 Progress Report**. The ERC staff secretary receives the progress report and enters the date and pertinent information in the logbook of incoming documents (*See SOP No. 29 Management of Active Files (Administrative and Study Files)*).

6.2 Retrieval of pertinent protocol file

The staff secretary retrieves the corresponding protocol file for reference and guidance of the ERC Chair and Primary Reviewers.

6.3 Notification of ERC Chair and Primary Reviewers

The staff secretary notifies the ERC Chair and the previously assigned Primary Reviewers within three (3) working days after receipt of the progress report. He/she sends the pertinent protocol file to the ERC Chair and Primary Reviewers.

6.4 Determine the type of review

The ERC chair shall determine the type of review based on the policy that progress reports of protocols that underwent Full review in its initial submission shall undergo full review. Similarly, progress reports of protocols which underwent Expedited review shall undergo Expedited review (*see SOP No. 06 Full Review and SOP No. 07 Expedited Review*). The Primary Reviewers/secondary reviewers conduct review of the protocols if they are in accordance with the protocols and related documents approved by the ERC.

The primary reviewers/secondary reviewers recommend approval of the progress report if there is no deviation or violation of ERC approvals. If there are any deviations or violations as compared to the approved protocol of the ERC, the Primary Reviewers recommend that appropriate action be taken by the PI (e.g. amendment of the protocol or consent form or explanation of deviation or violation). *See SOP No. 13 Study Protocol Amendment and SOP No. 15 Management of Protocol Deviation and Violations Report.*

Approval of progress reports reviewed by the Primary Reviewers by expedited procedure is reported during the Full Board meeting. For protocols subject to Full Review, these are included in the Agenda of the next Full Board Review Meeting for discussion and decision.

6.5 Communicate ERC decision

The decision of the committee is communicated to the researcher within seven (7) working days after the final deliberation (*See SOP No. 27 Communicating the ERC Decision*).

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

The staff secretary files the progress report and a copy of the committee decision in the appropriate protocol folder and proceeds to update the pertinent protocol database.

7. FORMS AND TOOLS

Form 14.1 Reminder Letter

Form 14.2 Progress Report

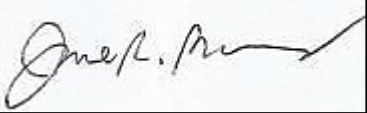

8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	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	First draft
2	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	Updated statement of policy
3	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	Updated statement of policy to specify the timeline of the submission of progress reports based on the

		Mr. Ricky T. Serrano Mr. Raymond G. Campo	degree of risk of the protocol
--	--	--	-----------------------------------

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: 07-10-2023	Date: 07-10-2023	Date: 07-10-2023