



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

CHAPTER 3: POST APPROVAL PROCEDURES

REVIEW OF FINAL REPORT	SOP No.	21
	Version No.	03
	Version Date	11-28-2022
	Effective Date	01-01-2023

1. STATEMENT OF POLICY

The ERC shall require the submission of the final report not later than 4 weeks after the end of the study. “End of Study” is defined as follows:

- For Regional Research Funded (RRF) projects – “End of Study” refers to the date of the dissemination of the study to stakeholders.
- For non-RRF projects - “End of Study” will be based on the submitted Gantt chart of the Principal Investigator.

2. OBJECTIVE/S OF THE ACTIVITY

The activity aims to ensure timely submission of the final report in accordance with the approved protocol for the project.

3. SCOPE / APPLICABILITY

This applies to all researches approved by the EVHRDC-ERC which is due for completion.

4. ROLES AND RESPONSIBILITIES

Principal Investigator – submits the final report form with other protocol related documents upon completion

ERC Staff Secretary – determine the completeness and acknowledges receipt of the documents

ERC Chair – instructs staff secretary to include the final report in the agenda and presides the meeting

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Send reminder to the Principal Investigator	ERC Staff Secretary
Step 2: Submission of Final Report	Principal Investigator
Step 3: Log date of submission	ERC Staff Secretary
Step 4: Notify ERC Chair	ERC Staff Secretary
Step 5: Distribution of copy to ERC Members	ERC Staff Secretary
Step 6: Deliberation during ERC meeting	Primary Reviewers
Step 7: Communicate ERC decision	ERC Staff Secretary
Step 8: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 Send reminder to the Principal Investigator

The ERC Staff Secretary looks through the **Form 28.2 Study Protocol Database** for the protocols due for final report at the end of the month. The ERC staff then informs the respective researcher of the study protocol whose ethical clearances will expire to submit a Final Report at least a month in advance of the due date of the project. This will be communicated to them using the **Form 14.1 Reminder Letter**. The PI is requested to submit **Form 21.1 Final Report** within thirty (30) days of receiving the letter. If no submission is received within the indicated grace period, the committee will be constrained to implement standard procedures for non-compliance with reportorial requirements. This may result in a recommendation for withdrawal of ethical clearance; and the study file subsequently inactivated and archived.

6.2 Submission of Final Report

The researcher submits the Final Report using **Form 21.1 Final Report**, 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 indicated in the final report. This comprises the final report package.

6.3 Log date of submission

The ERC Staff Secretary receives the complete documents submitted by the Principal Investigator. The ERC Staff Secretary logs the date of submission.

6.4 Notify ERC Chair

The ERC Staff Secretary sends the study protocol to the ERC Chair. All final report submissions will undergo full review.

6.5 Distribution of copy to ERC Members

Copies of the final report package are distributed to the primary reviewers and/or ERC members for review. The Primary Reviewer/s accomplish the review by commenting and recommending appropriate action on the Final Report form.

6.6 Deliberation during ERC meeting

The Primary Reviewers present the results of the review. The ERC decision can be any of the following:

- Approve
- Request information, specify
- Recommend further action, specify
- Pending for major clarification

6.7 Communicate ERC Decision

After the committee makes a decision on the Final Report of the protocol and officially signed by the ERC Chair, the staff secretary informs the PI of this decision within seven (7) working days (*see SOP No. 27 Communicating the ERC Decision*).

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

The ERC staff secretary shall log the date of approval of the final report and transfer the study protocol folder to the inactive files. The study protocol record will be made available for three (3) years in the archives after the expiration date.

7. FORMS AND TOOLS

Form 14.1 Reminder Letter

Form 21.1 Final Report

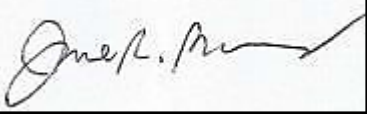

8. HISTORY

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

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.
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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: 11-28-2022	Date: 11-28-2022	Date: 11-28-2022