



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

**CHAPTER 4: DOCUMENTATION AND ARCHIVING**

<b>COMMUNICATING THE ERC DECISION</b>	SOP No.	27
	Version No.	03
	Version Date	11-28-2022
	Effective Date	01-01-2023

### 1. STATEMENT OF POLICY

The ERC must be clear, informative, and timely in communicating its decisions. The ERC shall communicate its decisions to the researcher within 30-60 working days after the receipt of a complete set of submission documents. The communication document shall include clear instructions/recommendations for the guidance of the researcher, must be written on the official stationery of the ERC, and signed by the chair.

The decisions in the review of protocols are as follows but not limited to: approved (**Form 27.1 Approval Letter**), minor or major modification/s (**Form 27.2 Letter of Modification**), and disapproved (**Form 27.3 Notification of ERC Decision**).

### 2. OBJECTIVE/S OF THE ACTIVITY

The activity aims to ensure consistency, efficiency and transparency in the process of communicating the ERC decision to the Principal Investigator.

### 3. SCOPE/APPLICABILITY

This provides instructions related to the preparation of ERC communication to the Principal Investigator and the management of such documents.

### 4. ROLES AND RESPONSIBILITIES

Compliance is the responsibility of the ERC and consortium ERC Staff Secretary, and the ERC Chair.

**ERC Chair** - checks and signs the decision letters and forms.

**ERC Staff Secretary** - prepares the approval letter, letter of modification, notification of ERC decision form, form for document receipt and recommended action, letter of approval of amendments and the certificate of exempt from review.

## 5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Finalization of recommendations of the committee	ERC Members
Step 2: Transfer of information from meeting minutes to ERC decision forms or templates	ERC Member Secretary, ERC Staff Secretary
Step 3: Approval of the ERC decision documents	ERC Chair
Step 4: Transmittal of ERC decision to researcher	ERC Staff Secretary
Step 5: Filing of protocol-related documents and updating of the Protocol Database	ERC Staff Secretary

## 6. DESCRIPTION OF PROCEDURES

### 6.1 Finalization of recommendations of the committee

- Full Review – See **SOP No. 06 Full Review** for the finalization of the ERC recommendations.
- Expedited Review – See **SOP No. 07 Expedited Review** for the finalization of the ERC recommendations.
- Exempt from Review – See **SOP No. 08 Exempt from Review** for the finalization of the ERC recommendations.

### 6.2 Transfer of information from meeting minutes to ERC decision forms or templates

After the finalization of the reviewers' recommendations and approval of the minutes, the ERC staff secretary, under the supervision of member secretary, prepares the:

- Form 8.2 Certificate of Exemption from Ethics Review
- Form 27.1 Approval Letter
- Form 27.2 Letter of Modification
- Form 27.3 Notification of ERC Decision
- Form 27.4 Letter of Approval of Amendments
- Form 27.5 Letter of Document Receipt and Recommendation of Further Action
- Form 27.6 Letter for Clarificatory Interview

### 6.3 Approval of the ERC decision documents

The ERC chair reviews, approves and signs the decision documents within 7 working days from the decision of the committee for full review or the decision of the Primary Reviewers for expedited review.

### 6.4 Transmittal of ERC decision to researcher

After the approval, the ERC staff sends the signed results of the review via email (online). The process including the signing of the decision documents takes 7 working days after approval of the decision documents.

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

All meeting deliberations and decisions regarding a protocol are filed in the specific protocol folder. Likewise, copies of the assessment forms of that particular protocol are filed in this folder. Filing follows a protocol file index or recording chronologically. This folder is then kept in a locked filing cabinet in the ERC office. Digital folders of each protocol of active documents are kept in a Protocol Google Drive. Once the protocol is completed or terminated, this protocol is transferred to the ERC's Google drive and hard drive. The ERC protocol database is then updated.

## 7. FORMS AND TOOLS

Form 8.2	Certificate of Exemption from Ethics Review
Form 27.1	Approval Letter
Form 27.2	Letter of Modification
Form 27.3	Notification of ERC Decision
Form 27.4	Letter of Approval of Amendments
Form 27.5	Letter of Document Receipt and Recommendation of Further Action
Form 27.6	Letter for Clarificatory Interview

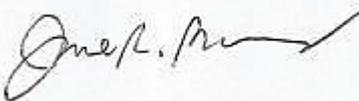
## 8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	12/05/2012	ERC	First draft
2	10/23/2015	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.
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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: 
<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: 11-28-2022	Date: 11-28-2022	Date: 11-28-2022