



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

CHAPTER 4: DOCUMENTATION AND ARCHIVING

MANAGEMENT OF INCOMING AND OUTGOING COMMUNICATIONS	SOP No.	28
	Version No.	02
	Version Date	11-28-2022
	Effective Date	01-01-2023

1. STATEMENT OF POLICY

All communications shall be recorded accurately and appropriately in a physical log book and electronic database. Protocol-related communications are separated from administrative communications. Incoming and outgoing communications shall be acted upon promptly.

Incoming communications include Application for Ethical Review, Request Letters from Principal Investigators such as request to conduct research and other inquiries pertaining to research, endorsement letters from the Technical Review Board and other endorsee from outside entities, request for extension of ethical clearance and post-approval reports.

Outgoing communications include decisions of the Ethics Review Committee, reminder letters and responses to requests. On request for ethical clearance extension, the decision of ERC shall be based on the record of progress report and other reports pertinent to continuing review.

2. OBJECTIVE/S OF THE ACTIVITY

The management of ERC incoming and outgoing documents/communications aims to establish accountability and an efficient and effective tracking system.

3. SCOPE AND APPLICABILITY

This SOP begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications.

4. ROLES AND RESPONSIBILITIES

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

ERC Chair - reviews and signs all communications of ERC.

ERC Member Secretary - supervises the staff secretary in the management of incoming and outgoing communications and other documents.

ERC Staff Secretary - Prepares communications such as decision letters, reminders letters, reply letters and other relevant communications. The ERC Staff Secretary stamps and logs all received communication in the logbook of received documents. The ERC Staff Secretary sends all outgoing communications through e-mail or by forwarding personally to Principal Investigators and/or other receiving entities.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Sorting of incoming/outgoing communications	ERC Staff Secretary
Step 2: Recording of the details of incoming/outgoing communications	ERC Staff Secretary
Step 3: Acting on communications	ERC Chair, ERC Member Secretary, ERC Staff Secretary
Step 4: Filing of incoming/outgoing communications and updating of respective Databases	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 Sorting of incoming/outgoing communications

The ERC Staff organizes both the incoming and outgoing communications. He/She sorts these communications as follows:

A. Administrative related

1. Incoming
2. Outgoing

B. Protocol Related

1. Incoming
2. Outgoing

6.2 Recording of the details of incoming/outgoing communications

The staff secretary, supervised by the member secretary, then records in a log which also functions as a log of submissions if the communication is protocol related or administrative related. These logs should have at least the following elements:

Administrative related

- Date of communication received / sent
- Name of ERC party contracted
- Content of communication
- Notation of any follow-up necessary
- Contact information (address, telephone number, and e-mail) of sending party
- Name and signature of individual who received the communication and completed the record

Protocol related

- Date of communication submission
- Name of ERC party contracted
- Study information, i.e. sponsor, protocol number, principal investigator, etc.
- Content of communication or submission
- Notation of any follow-up if necessary
- Type of submission (if communication refers to a submission)
- Contact Information (address, telephone number, and email) of sending party
- Name and signature of individual who received the communication and completed the record.

6.3 Acting on communications

The ERC chair or the ERC member secretary, after being informed by the ERC staff secretary, initiates and finalizes the response on incoming communications. The ERC chair reviews and signs the outgoing communications.

6.4 Filing of incoming/outgoing communications and updating of respective Databases

The ERC staff secretary, with the supervision of the member secretary, files a copy of the communication in the:

- a. Protocol file folder – for protocol related communication
- b. Other appropriate ERC Communications folder – for administrative communication
- c. Digital Folder – is filed in the hard drive and Google drive

Communication is filed in each folder with the most recent on top of the previous communications. **Form 28.1 Submission Log and Form 28.2 Study Protocol Database** are updated.

7. FORMS AND TOOLS

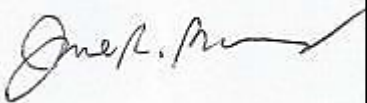

Form 28.1 Submission Log
 Form 28.2 Study Protocol Database

8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	11/21/2019	ERC	First Draft
2	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.

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