



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

**CHAPTER 4: DOCUMENTATION AND ARCHIVING**

<b>MAINTENANCE OF CONFIDENTIALITY OF STUDY FILES AND ERC DOCUMENTATION</b>	SOP No.	31
	Version No.	02
	Version Date	04-25-2023
	Effective Date	04-30-2023

## **1. STATEMENT OF POLICY**

The EVHRDC ERC's duty is to maintain the confidentiality of all protocols and other documents. All documents shall be systematically organized, filed, coded, and labeled for preservation and easy retrieval.

The ERC properly handles the original documents and copies of these documents during the day-to-day operation of the EVHRDC ERC to protect the confidentiality of study files and control and care in the distribution and storage of confidential documents of the ERC.

Study files submitted to the ERC and related documents are considered confidential, such as:

- Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert's opinions, or reviews)
- EVHRDC ERC documents (Meeting minutes, advice, and decisions)
- Correspondence (experts, auditors, study participants, etc.)

The EVHRDC ERC will adhere to the applicable provisions of the Data Privacy Act of 2012.

## **2. OBJECTIVE/S OF THE ACTIVITY**

To describe the EVHRDC ERC procedures related to maintaining the confidentiality of the study files and other ERC documents.

### 3. SCOPE AND APPLICABILITY

This SOP provides instructions to the EVHRDC ERC Staff Secretary related to maintaining the confidentiality of all study files and documents.

### 4. ROLES AND RESPONSIBILITIES

**ERC Chair** – reviews and approves the request to access files.

**ERC Staff Secretary** - ensures that confidentiality is maintained in the management of all study files and records and supervises the access of files.

### 5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Requests for access to confidential files	ERC Member, Non-member
Step 2: Approval of request for access and retrieval of documents	ERC Chair, ERC Vice-Chair
Step 3: Supervise the use of retrieved confidential document	ERC Staff Secretary
Step 4: Return document to the protocol file folder	ERC Staff Secretary

### 6. DESCRIPTION OF PROCEDURES

#### 6.1 Requests for access to confidential files

A request to access the confidential files is submitted using **Form 31.1 Request to Access ERC Files**.

#### 6.2 Approval of request for access and retrieval of documents

Access to EVHRDC ERC confidential documents is subject to the following limitations:

- ERC members and staff with a signed confidentiality Agreement and Disclosure of Conflict of Interest can access confidential documents outside of regular protocol review access, upon request.
- Non-members can access specific documents by submitting a formal request. The ERC staff secretary will require a signed **Form 31.1 Request to Access ERC Files** for confidentiality agreement. The ERC Chair will approve the request.

- Only ERC officers, which include the ERC Chair, ERC Vice-Chair, and ERC Member Secretary can approve access to confidential documents.
- Regulatory authorities have full access to EVHRDC ERC documents provided it is within their mandate (e.g. FDA) and upon reasonable notice to make the files available signed by the recognized official of the regulatory authority (e.g. FDA Director).

The staff secretary makes a record every time a document of the EVHRDC ERC is accessed as described above.

**Form 31.2 Log of Request for Copies of Documents**, a log filed in the protocol folder is dedicated for purposes of recording access as described above, which contains the following fields of information:

- Study file code
- Date borrowed
- Name of borrower
- Signature of borrower upon retrieval
- Signature of EVHRDC ERC Staff upon return of document to file box
- Document copied
- Number of copies made
- Number of copies received

All requests for access are recorded by the staff secretary in the log before copies of any documents are released.

### **6.3 Supervise the use of retrieved confidential document**

Access to documents is generally room use only, but requests to make copies can be accommodated on a case to case basis. The staff secretary makes only the exact number of copies requested. The recipient signs **Form 31.2 Log of Request for Copies of Documents**.

### **6.4 Return document to the protocol file folder**

The ERC staff secretary is responsible for returning the documents in the protocol file folder in the file storage cabinet after making sure that all documents are complete as per **Form 29.1 Protocol Index**.

## **7. FORMS AND TOOLS**

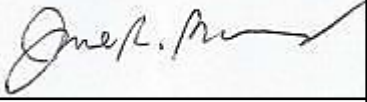

Form 29.1	Protocol Index
Form 31.1	Request to Access ERC Files
Form 31.2	Log of Request for Copies of Documents

## 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	Revised statement of policy and 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: 
<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: 04-25-2023	Date: 04-25-2023	Date: 04-25-2023