



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

CHAPTER 4: DOCUMENTATION AND ARCHIVING

ARCHIVING FILES	SOP No.	30
	Version No.	04
	Version Date	11-28-2022
	Effective Date	01-01-2023

1. STATEMENT OF POLICY

Files of study protocols which have been terminated or completed or declared inactive shall be archived and kept in a separate storage from three (3) years to five (5) years depending on the type of protocol beyond which these will be disposed of in accordance with government rules.

- Retention Rules:
 - Inactive – 3 years;
 - Completed/Terminated – 3 years;
 - Clinical Trial – 5 years or as provided in the Clinical Trial Agreement, whichever is longer

2. OBJECTIVE/S OF THE ACTIVITY

Archiving inactive, terminated, or completed protocols ensures efficient retrieval of information from the files for reference and compliance with national and international guidelines.

3. SCOPE AND APPLICABILITY

This SOP includes procedures related to storage and retrieval of protocols that are classified as inactive, terminated or completed. This SOP begins with the acceptance of final or early termination reports and identification of protocols as inactive and ends with the inclusion of the files in the archives and update of the protocols database and disposal.

4. ROLES AND RESPONSIBILITIES

It is the responsibility of the ERC staff secretary, under the supervision of the Member Secretary, to archive in an orderly manner all protocol files that have been terminated, completed, or are no longer active. They are kept together in a

designated place in the office where confidentiality and security of the documents can be maintained.

ERC Staff secretary - organizes and files the protocols for archiving.

Member secretary - supervises the staff secretary on the tasks.

ERC Chair - ensures the fulfillment of this task.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Acceptance of final or early termination reports and identification of an inactive file	ERC Members
Step 2: Updating of the corresponding active file	ERC Staff Secretary
Step 3: Transfer of the protocol folder in the archives and update of the protocol database	ERC Staff Secretary
Step 4: Retrieval of documents from Archive Section	ERC Staff Secretary
Step 5: Disposal of archived protocol files	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 Acceptance of final or early termination reports and identification of an inactive file

The ERC members shall approve or accept the final report or early termination report of the protocol during a meeting (**See SOP No. 21 Review of Final Report; SOP No. 17 Early Study Termination Application**). In the identification of an inactive file, the staff secretary informs the Member Secretary of the failure of a concerned researcher/ proponent/investigator to respond to the recommendations of the ERC in the last six (6) months during which time the researcher/proponent/investigator has been appropriately reminded of the requirement. This is included in the agenda of the next meeting where the protocol is declared inactive. **Form 30.1 Archiving Notification** will be communicated to the Principal Investigator within seven (7) days after the board meeting.

6.2 Updating of the corresponding active file

The staff secretary files the Final or Early Termination report of the protocol in the corresponding protocol folder, including the excerpts of the minutes that approved the report or declared the protocol as inactive.

6.3 Transfer of the protocol folder in the archives and update of the protocol database

The staff secretary checks whether the documents listed in the protocol file index are complete and removes extraneous documents. The staff then transfers the folder to the archive section and updates the protocol database.

- An archive number is assigned to the protocol by adding the / (year of archiving) as a suffix to the original protocol code. For example, if the Final Report of a particular protocol 2010-002 is approved in 2012, the archiving code is 2010-002/2012.
- The archiving data should be entered accordingly in the **Form 28.2 Study Protocol Database** and **Form 30.2 Register of Archived Protocols**.
- The archived protocols shall be placed in an envelope labeled with the ERC code, Surname of the Principal Investigator, and the date of Inactivation.

6.4 Retrieval of documents from Archive Section

Only the ERC staff secretary can retrieve documents either from the active study files or from the archives. Archived protocols can be retrieved within the three-year archiving period in accordance with **SOP No. 31 Maintenance of Confidentiality of Study Files and ERC Documentation**.

6.5 Disposal of archived protocol files

- Archived files must be reviewed at the end of the year. At the end of each year, the ERC staff secretary generates:
 1. List of inactive protocols that are beyond three (3) years past its date of inactivation from the Study Protocol Database;
 2. List of completed and terminated protocols that are beyond three (3) years past its date of archiving from the Study Protocol Database;
 3. List of Clinical Trial protocols that are beyond FIVE (5) years past its date of archiving from the Study Protocol Database or the retention period as indicated in the Clinical Trial Agreement whichever is later.
- The ERC staff secretary submits the list to the ERC Chair for review, verification and approval of disposal in accordance with government rules.
- The ERC staff secretary retrieves the archived protocols and disposes the files accordingly using a paper shredder to be witnessed by an ERC member.
- The ERC staff secretary shall update the **Form 30.2 Register of Archived Protocols** as to date of actual disposal and the **Form 30.3 Register of Disposed Study Protocols**.

7. FORMS AND TOOLS

Form 30.1 Archiving Notification

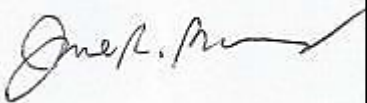

Form 30.2 Register of Archived Protocols
 Form 30.3 Register of Disposed Study Protocols

8. HISTORY

Version No.	Date (mm/dd/yyyy)	Authors	Main Change
1	01/26/2013	ERC	First Draft
2	10/23/2015	ERC	Updates on procedures
3	12/05/2019	ERC	Adopt recommendations from PHREB CSA
4	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: 
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Date: 11-28-2022	Date: 11-28-2022	Date: 11-28-2022