



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

CHAPTER 4: DOCUMENTATION AND ARCHIVING

MANAGEMENT OF ACTIVE FILES (ADMINISTRATIVE AND STUDY FILES)	SOP No.	29
	Version No.	06
	Version Date	07-10-2023
	Effective Date	07-17-2023

1. STATEMENT OF POLICY

The ERC needs to classify its protocol files into active or inactive. Considerations include proper labeling and manner of storage. Active files shall be kept in a secured cabinet, arranged in an orderly manner that shall allow easy identification and retrieval. Access to the active files shall be governed by **SOP No. 31 Maintenance of Confidentiality of Study Files and ERC Documentation**.

2. OBJECTIVE/S OF THE ACTIVITY

The management of active files ensures accessibility, easy retrieval of current files, and protection of those that require confidentiality.

3. SCOPE/APPLICABILITY

This SOP covers procedures done related to protocols accepted for review, undergoing review, or has been approved by the ERC. This SOP begins with the classification and coding of active files and ends with the periodic updating of the file.

4. ROLES AND RESPONSIBILITIES

Systematic coding of all documents shall be established by the ERC Staff Secretary with the approval of the ERC Chair.

ERC Staff secretary - organizes and ensures easy retrieval of active files.

Member secretary - supervised the staff secretary on the tasks.

ERC Chair - ensures the fulfillment of this task.

5. WORKFLOW

ACTIVITY	RESPONSIBILITY
Step 1: Classification and coding of active files	ERC Member Secretary, ERC Staff Secretary
Step 2: Preparation of the protocol folder	ERC Staff Secretary
Step 3: Periodic updating of the protocol file	ERC Staff Secretary
Step 4: Updating of the electronic protocol database	ERC Staff Secretary

6. DESCRIPTION OF PROCEDURES

6.1 Classification and coding of active files

The staff secretary under the supervision of the member secretary classifies active files for protocols as follows:

- Initial Submission
- Resubmission
- Progress Report
- Amendment
- Protocol Deviation and Protocol Violation
- Serious Adverse Event (SAE) or Suspected Unexpected Serious Adverse Reaction (SUSAR)
- Reportable Negative Event (RNE)
- Early Termination
- Continuing Review
- Final Report
- Appeals
- Site Visit

The staff secretary assigns a code to the Initial Submission and indicates the same for the rest of the submissions related to the initial submission. The code consists of the year and the serial number that indicate the sequence order of receipt.

For example, a protocol received in 2022 as the 10th submission in that year will be coded as 2022-010.

Non-protocol related active files are also classified as follows:

- CVs of ERC members
- Training of ERC members
- Agenda
- Minutes of the Meeting

- Accreditation files
- ERC Work and Financial Plan
- Administrative Files

6.2 Preparation of the protocol folder

The staff secretary files all documents pertaining to a study in a vertical folder that is labeled on the front cover and along the spine with: Protocol Code -Study Title - Proponent's Family Name - Sponsor or Funding Agency. The staff attaches a **Form 29.1 Protocol Index** on the inside front cover that indicates the contents of the folder.

6.3 Periodic updating of the protocol file

The staff ensures that the documents are filed in chronological order such that the most recent documents are topmost. These documents include the following.

- Research protocol
- Protocol evaluation Form
- Informed Consent Evaluation Form
- Minutes of the Meetings
- Decision Letters
- Decision Form
- Approval Letter
- Reminder Letters
- Protocol report forms
- Other protocol related documents

The staff secretary updates the protocol index each time a new document is added to the file. The protocol folder is periodically checked for orderliness and completeness.

6.4 Updating of the electronic protocol database

The staff regularly updates the protocol database to ensure timely monitoring including due dates of reports and determining active protocol status. The database should use an electronic format and password protected. It should have at least the following fields:

- Protocol Code
- Title of Proposal
- Principal Investigator
- Institution
- Funding Agency
- Type of Research
- Type of Review
- Date of Initial Submission
- Primary Reviewers
- 1st Date of Deliberation
- Decision
- Date of Letter to PI
- Date of Resubmission/s

- Date of Deliberation
- Actions Taken
- Date of Letter to PI
- Date of Approval
- Expiration of Clearance
- Post Approval Reports including:
 - Study Protocol Amendment
 - Progress Report
 - Protocol Deviation and Violations Report
 - SAE and SUSAR Reports
 - RNE Reports
 - Early Study Termination Application
 - Continuing Review Application
 - Appeals
 - Site Visit Report
 - Final Report
- Archiving

7. FORMS AND TOOLS

Form 28.1	Submission Log
Form 28.2	Study Protocol Database
Form 29.1	Protocol Index

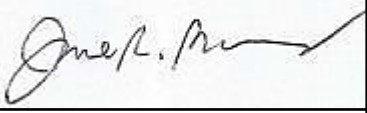

8. HISTORY

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	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	Updates on procedures and policy.

		Atty. Alma Sonia Q. Sanchez-Danday Mr. Ricky T. Serrano Mr. Raymond G. Campo	
5	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 description of procedures
6	07/10/2023	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	Added archiving in the list of fields found in the protocol database

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: 07-10-2023	Date: 07-10-2023	Date: 07-10-2023