TITLE	ARCHIVING
POLICY STATEMENT	In accordance with institutional and regulatory guidelines, research study files that have been terminated, completed, or declared inactive shall be securely archived in a separate storage area for **a minimum period of three years.** Additionally, studies for which the researcher has not resubmitted their proposals within three months following the receipt of the Notification Letter shall be classified as inactive and archived accordingly. During the archiving period, all relevant files will be managed in compliance with established security, access control, and document tracking protocols, ensuring the integrity and confidentiality of the archived records. These practices align with applicable institutional policies, international standards, and regulatory requirements, ensuring proper documentation and retrieval when necessary. all archiving of active files within the 5 years is kept on a cloud based repository with restricted access.
OBJECTIVE OF THE ACTIVITY	The objective of the SOP for archiving inactive, terminated, or completed protocols is to ensure compliance with national and international regulations for data storage and retrieval. It aims to facilitate efficient access to archived information for reference, audits, and regulatory reviews while maintaining data integrity and security. The SOP also ensures long-term retention of protocols according to legal and institutional requirements, streamlines the archiving process for efficiency, and supports readiness for audits and inspections by keeping organized and accessible records.
SCOPE	This Standard Operating Procedure (SOP) outlines the processes involved in the archiving of protocol-related documents that are classified as inactive, terminated, or completed. It begins with the receipt and verification of final reports or early termination notices, followed by the formal identification of a protocol's status as inactive. The SOP includes procedures for determining which documents are to be archived, ensuring secure and organized storage, and updating the protocol database to reflect the change in status. Additionally, it covers the systematic placement of the files into designated archive storage and defines the responsibilities related to maintaining access to archived materials for future reference, audits, or regulatory compliance. This SOP applies to all personnel involved in the documentation, storage, and retrieval of protocol-related files within the institution or organization.

Workflow

STEP	ACTIVITIES	RESPONSIBILITY	TIMELINE	INTERFACE
1	Acceptance of Final or Early Termination Reports and Identification of an Inactive File	REB MEMBERS, CHAIR		SOP REVIEW OF EARLY TERMINATION REPORTS, AND IDENTIFICATION OF A PROTOCOL AS INACTIVE
	↓			
2	Updating of corresponding protocol folder	STAFF SECRETARY		
	↓			
3	Transfer of the Protocol Folder in the Archives and Update of the Protocol Database	STAFF SECRETARY		

Description of Procedures

Step 1 - Acceptance of Final or Early Termination Reports and Identification of an Inactive File: The procedures for the acceptance of final or early termination reports and the identification of an inactive file are integral to maintaining the integrity and compliance of research oversight. Final reports and early termination reports are reviewed by the Research Ethics Board (REB) during a scheduled meeting. These reports are submitted by the researcher, proponent, or investigator and are placed on the agenda in accordance with the relevant standard operating procedures (SOP 13 Review of Final Report; SOP 14 Review of an Early Termination Report). During the meeting, committee members examine the content of the report to ensure that all ethical obligations and required documentation have been satisfactorily fulfilled. Once the review is complete and the committee is satisfied with the report, the members formally approve or accept it. The decision is then recorded in the official meeting minutes and communicated to the submitting party.

In parallel, the REB follows a defined process for the identification of an inactive file. An inactive file typically arises when a researcher, proponent, or investigator fails to respond to the REB's recommendations over a period of three months, despite having received appropriate reminders during that time. REB staff are responsible for monitoring such cases and, upon identifying a lack of response, inform the Member Secretary. The protocol is subsequently included in the agenda of the upcoming REB meeting. During this meeting, the committee reviews the case and, if deemed appropriate, formally declares the protocol as inactive. This status is documented in the meeting records, and a formal notification is sent to the concerned party to inform them of the committee's decision.

Step 2 - Updating of the corresponding active file: The procedure for updating the corresponding active file following the acceptance of a final or early termination report, or the declaration of a protocol as inactive, ensures accurate and up-to-date documentation within the

REB's records. Once the Research Ethics Board (REB) has approved a final or early termination report, or has formally declared a protocol inactive during a meeting, the Staff secretary is responsible for updating the relevant protocol folder. This involves filing the submitted final or early termination report, as well as including excerpts from the official meeting minutes that reflect the committee's decision. These documents serve as formal evidence of the protocol's closure or change in status. By systematically organizing and updating the protocol folder in this manner, the REB ensures proper documentation and traceability of all actions taken, thereby maintaining the integrity and completeness of the research oversight process.

Step 3 - Transfer of the Protocol Folder in the Archives and Update of the Protocol Database: The procedure for the transfer of the protocol folder to the archives and the update of the protocol database is carried out to ensure proper closure and long-term storage of completed or inactive protocols. After a protocol has been approved for final closure or declared inactive by the Research Ethics Board (REB), the Staff secretary reviews the corresponding protocol folder to verify the completeness of all required documents based on the protocol file index. During this review, any extraneous or irrelevant documents are removed to maintain an organized and accurate record. Once the folder is confirmed to be complete, it is transferred to the designated archive section for secure storage. Simultaneously, the staff updates the protocol database to reflect the final status of the protocol—whether completed or inactive. This step ensures that the REB's records are current, accessible for future reference, and aligned with documentation and regulatory standards.

Glossary

Final Report - is a summary of the outputs and outcomes of the study upon its completion. The REB requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

Early Termination - ending the implementation of a study before its completion.

Inactive Study - a study whose proponent has not communicated with the REB with regard to issues pertaining to the approval or implementation of the study - within a period of time required by the REB.

Active Study - is an ongoing study, implementation of which is within the period covered by ethics clearance.

Archiving- is the systematic keeping of protocol files in storage after the studies have been completed with final reports accepted, or terminated or declared inactive.

Confidentiality of Documents - pertains to the recognition and awareness that certain documents that have been entrusted or submitted to the REB must not be freely shared or disclosed.

Controlled document - pertains to the document that has been entrusted or submitted to the REB that must not be freely shared or disclosed such that it is appropriately tagged and its distribution carefully tracked, monitored and appropriately recorded.

Forms

Borrower's Log

History of SOP

Version No.	Date	Authors	Main Change
1	2025 Mav 15	MVJapitana	First draft

References

1. *Republic Act No. 9470 (RA 9470)*
2. *Implementing Rules and Regulations (IRR) of RA 9470*
3. *General Records Disposition Schedule (GRDS) issued by NAP*
4. *BOR Approved Administrative and Finance Manual incorporating the Records Management Manual*
5. *OP Memorandum No. 30, s. 2024 Inclusion of Records Inventory Report and Records Management Table Submission in the Office, Division and Individual Performance Commitment and Review Form*
6. *SD-DRC-01 University Records Disposition Schedule*
7. *PR-DRC-02 Control of External References Procedure*

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011

National Ethical Guidelines for Research Involving Human Participants 2022

Philippine Health Research Ethics Board Standard Operating Procedures 2020