



Gullas College of *Medicine*  
**RESEARCH ETHICS COMMITTEE**



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Date of Approval:	
Effectivity Date:	

**SOP NO. 24 - ARCHIVING**

**Section 1. Policy Statement**

The Research Ethics Committee (REC) must formally close out study files to ensure that all research activities involving human participants are accounted for and concluded ethically. Terminated, completed, or inactive protocol files will be kept in a separate filing cabinet for five years, after which they may be incinerated or shredded. The protocol folder binders shall be as follows:

- Active files (Blue)
- Completed files (Green)
- Terminated files (Black)
- Inactive files (Yellow).

Approved proposals that have not been updated for five months may be considered inactive after informing the PI. Efficient retrieval of information from inactive files shall be kept for future reference and compliance with national and international guidelines

**Section 2. Objective/s of the Activity**

This SOP describes archiving inactive, terminated, or completed protocols guarantees well-organized retrieval of information from the files for future reference and observance of national and international guidelines.

**Section 3. Scope**

This SOP begins with the acceptance of final reports, early termination reports, identification of a protocol as inactive, inclusion of the files in the archives, and ends with updating the RMSS DATABASE (Form 4.7), Filing Form Log (Form 4.7a) and/or ARTSS (Form 1.9).

**Section 4. Workflow**

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>	<b>TIMELINE</b>
<b>Step 1:</b> Acceptance and selection of Final Report (Form 13.1) or Early Termination Reports (Form 14.1) and classifying a Protocol as Inactive.	(For final & terminal files): Chair & REC members  (For inactive files): Member Secretary, Administrative Secretary	1 day PRN
<b>Step 2:</b> Updating of corresponding protocol folder	Administrative Secretary	3 days post-acceptance/selection
<b>Step 3:</b> Transfer the protocol to another folder, place it in the archives, and update the RMSS DATABASE (Form 4.7), Filing Form Log (Form 4.7a) & Protocol Folder Index (Form 4.9)	Administrative Secretary	1-day post-update
<b>TOTAL</b>		<b>5 days</b>

## Section 5. Description of Procedures

### **Step 1: Acceptance and selection of Final or Early Termination Reports (Form 14.1), Final Report (Form 13.1), and classifying a Protocol as Inactive.**

The Administrative Secretary shall formally accept incoming close-out dossiers—specifically Form 13.1 (Final Close-Out Report) or Form 14.1 (Early Termination Report)—submitted by the Principal Investigator (PI). Upon verifying the completeness of the submission packet, the Administrative Secretary shall immediately alert the Member Secretary.

A research protocol folder shall be officially slated for transition out of active status under any of the following parameters:

- The study has reached its natural end, and a satisfactory Form 13.1 has been vetted.
- The study is halted prematurely by the sponsor, investigator, or board via Form 14.1 due to safety, funding, or recruitment issues.
- If a PI fails to respond to outstanding board conditions, submit mandatory modifications, or answer formal ethical queries within five (5) months from the documented receipt of an REC decision letter, the file is automatically classified as administratively non-compliant and marked for an "Inactive" transition.

The Member Secretary shall slate these pending closures and non-compliance files onto the draft agenda for the upcoming regular REC session. During the live

meeting, the full committee shall deliberate on the reports (per SOP 13 and SOP 14). The Committee will vote to officially declare the protocol status as Completed, Terminated, or Administratively Inactive, recording the final decision within the meeting minutes to legalize the file's state change.

**Step 2: Updating of corresponding protocol folder.**

Following the formal Committee action, the physical and digital records of the protocol must be immediately consolidated to reflect its new legal status.

The Administrative Secretary shall extract the specific, finalized excerpt from the approved meeting minutes detailing the board's decision regarding the study closure. This official minute's excerpt, along with the signed reviewer assessment forms and the original Form 13.1 or Form 14.1, must be physically filed directly into the corresponding study binder. This ensures that any external auditor can instantly verify the exact meeting date and rationale behind the study's official closure.

**Step 3: Transfer the protocol to another folder, place it in the archives, and update the RMSS DATABASE (Form 4.7), Filing Form Log (Form 4.7a), & Protocol Folder Index (Form 4.9).**

The final stage of the study closure lifecycle requires a thorough audit of the folder's contents before it is moved to long-term storage. It will follow the following steps:

1. Verify Folder Contents
2. Purge Duplicates/Drafts
3. Re-house into Green/Black/Yellow Binder
4. Sync RMSS (Form 4.7) & Filing Form Log (Form 4.7a)
5. Storage in Cabinets

The Administrative Secretary must perform a page-by-page audit of the folder against the Protocol Folder Index (Form 4.9) to confirm that all mandatory historical records—including all past versions of protocols, consent forms, amendments, and signed approval letters—are completely present. S/he shall carefully extract and securely shred all non-essential administrative clutter, such as duplicate physical printouts, intermediate working drafts, and informal sticky notes, leaving a clean and concise regulatory dossier.

The Protocol Folder Index must be updated to reflect the final inventory, signed, and dated by the archivist. To maintain the visual integrity of the archive room as mandated by SOP 23, the physical documents must be extracted from their active blue binder and re-housed into a new 1-inch-thick plastic binder reflecting the board's final classification:

- Green Binder: For successfully concluded studies (Form 13.1).

- Black Binder: For studies halted early due to safety or compliance issues (Form 14.1).
- Yellow Binder: For studies abandoned by the investigator or declared administratively non-compliant via the 5-month rule.

The Administrative Secretary shall log into the cloud-secured Research Management and Submission System (RMSS) Database (Form 4.7) and change the status of the protocol from "Active" to its corresponding inactive designation (Completed, Terminated, or Inactive), capturing the final date of board closure. The new physical binder must be placed into the dedicated Inactive Storage Cabinet. The exact location, cabinet number, shelf row, and filing date must be logged into the master Filing Form Log (Form 4.7a). This entire archiving sequence shall be executed by the Administrative Secretary under the strict quality-assurance verification and final sign-off of the Member Secretary.

## Section 6. Forms

- Form 13.1 – Final Report
- Form 14.1 – Early Termination Report
- Form 4.7 – RMSS Database
- Form 4.7a – Filing Form Log
- Form 4.9 – Protocol Folder Index

## Section 7. History of SOP

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
1	6.26.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.31.24	Aljoriz Dublin & Nino Ismael Pastor	Form labels, content

## Section 8. References

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