



Gullas College of *Medicine*
RESEARCH ETHICS COMMITTEE



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Date of Approval:	
Effectivity Date:	

SOP NO. 23 - MANAGEMENT OF ACTIVE FILES

Section 1. Policy Statement

The Research Ethics Committee (REC) should maintain a rigorous information-management framework. The security and confidentiality of all files shall be strictly maintained in compliance with the Data Privacy Act. Hard copies of documents must be safeguarded in secured cabinets within a locked room. Digital records must be backed up twice by the Administrative Secretary before the end of each working day, with one backup copy securely held by the Member Secretary. To ensure security, efficient identification, and authorized access, all files shall remain under the custody of the Member Secretary. Access to these documents is strictly governed by the SOP on Managing Access to Confidential Files (SOP 25).

Section 2. Objectives

This SOP defines the procedures for receiving, labeling, retrieving, releasing, storing, and maintaining hard and digital copies of active files. It aims to ensure information accessibility, facilitate the efficient retrieval of current files, and guarantee the protection of confidential records.

Section 3. Scope

This SOP governs the organization and management of receiving, classifying, encoding, labeling, updating, storing, and maintaining documents—including initial submissions, resubmissions, and revisions—in accordance with existing regulations. The process begins with identifying the category of the received document and concludes with the periodic updating of the file.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Classification and coding of Active Files	Member Secretary	1-day post-receipt
Step 2.: Preparation of the Protocol Folder Index (Form 4.9) or Administrative Research Tracking System (Form 1.9)	Administrative Secretary	
Step 3: Storage of Active Files. Update	Administrative Secretary	1-day post-coding

protocol folder index (Form 4.9), RMSS (Form 4.7), or ARTS (Form 1.9). ALL are entered in the Filing Form Log (Form 4.7a)		
Step 4: Periodic updating of the Files: <ul style="list-style-type: none"> ● Protocol Folder Index (Form 4.9), ● Form 4.7a Filing Form Log ● RMSS DATABASE (Form 4.7), Approval Letter (Form 21.1) 	Member Secretary Administrative Secretary	PRN

Section 5. Description of Procedure

Step 1. Classification and coding of active files:

A protocol file is officially designated as "Active" immediately upon its initial submission to the REC Secretariat for ethical review. It remains in this state throughout its active implementation, continuing annual reviews, and post-approval monitoring phases. A file transitions to an "Inactive" state when the research lifecycle concludes. This occurs upon the submission and board acceptance of a Final Close-Out Report (e.g., a successful medical or academic proposal oral defense), an official written request for withdrawal by the Principal Investigator (PI), or an executive board action resulting in early termination.

All incoming documents must be classified into specific administrative or research tracks, logged in the RMSS (Form 4.7), Filing Form Log (Form 4.7a), Protocol Folder Index (Form 4.9) and/or the ARTS (Form 1.9) indexed across institutional systems.

Research-Related Files (Protocol Folder Index Form 4.9) or in (RMSS Database Form 4.7)

Initial submissions, resubmissions, chronological protocol versions, related study documents (Informed Consent Forms [ICFs], Case Report Forms [CRFs], recruitment advertisements, patient diaries), formal amendments, decision letters, approval letters, continuing review applications, progress reports, serious adverse event (SAE) logs, suspected unexpected serious adverse reaction (SUSAR) reports, protocol deviation/violation filings, site visit reports, patient queries/complaints, and early termination or final close-out reports.

Administrative Files (Administrative Research Tracking System (ARTSS - Form 1.9) or REC Meeting Files (Form 20.2)

Institutional emails regarding operations, administrative incident reports, REC activity invitations, institutional memoranda, notices

of meetings, provisional and final agendas, previous meeting minutes, safety and strategic blueprints, work and financial plans, purchase requests, equipment maintenance records, and general secretariat records.

Every research proposal submitted shall immediately be assigned a unique, immutable alphanumeric identity code by the Secretariat. This tracking number must be utilized across all subsequent correspondence, amendments, and Committee actions. The standardized construction of the institutional code follows a strict chronological model:

[Year of Submission]–[Month/Day of Receipt]–[Sequential Four-Digit Identifier]

Example 1 (First Submission of the day): 2026 – 06/11 – 0001

Example 2 (Second Submission of the day): 2026 – 06/11 – 0002

Example n (Subsequent Submissions): 2026 – 06/11 – 000n

To enable rapid visual auditing within the secure archive room, the committee utilizes a strict, color-coded binding folder standard (1-inch-thick plastic binders with secure vertical fasteners). The PI is required to provide these folders upon submission or transition milestones. If the specified color binders are unavailable, a heavy-duty black binder may be substituted, provided a prominent, color-matching institutional sticker is permanently affixed to the center front cover.

- Blue Binders: Reserved exclusively for Active Files currently undergoing review or active field implementation.
- Green Binders: Reserved for Completed Files that have successfully submitted an approved Final Report.
- Black Binders: Reserved for Terminated Files that have been halted early due to safety or compliance issues.
- Yellow Binders: Reserved for Inactive/Withdrawn Files where research never officially commenced.

Step 2.: Preparation of the Protocol Folder Index (Form 4.9) or Administrative Research Tracking System (Form 1.9)

Upon submission of a new study, the PI must provide the primary active blue binder alongside four (4) empty, 1-inch-thick plastic binders in the remaining lifecycle colors (Green, Black, and Yellow) to accommodate future study transitions.

The Administrative Secretary is responsible for the physical assembly of the master research file. The front cover and the vertical spine of the active blue binder must be legibly labeled with the following metadata:

- REC Unique Protocol Code: (e.g., YYYY – MM/DD – NNNN- key word)
- Complete Study Title: (Including active version numbers and dates)
- Proponent Details: Full family name and initials of the Principal Investigator.
- Sponsorship Metrics: Name of the corporate sponsor, funding agency, or institutional grant provider.

To ensure internal inventory integrity, the Administrative Secretary must fill up the Protocol Folder Index (Form 4.9) and permanently paste it to the interior front cover of the binder. Under the direct supervision of the Member Secretary, every document embedded within the folder must be explicitly categorized, titled, and recorded on this index sheet in chronological order.

Step 3: Storage of Active Files. Update protocol folder index (Form 4.9), RMSS (Form 4.7), or ARTS (Form 1.9). ALL are entered in the Filing Form Log (Form 4.7a).

The storage of ethics committee files is highly regulated to preserve participant confidentiality and satisfy international audit readiness.

The pathway of a submitted protocol is shown below.

1. Active File Room
2. Study Concluded
3. Inactive Cabinet: after 5 Years
4. Executive Incineration Witnessed by Member Sec.

Active Blue binders must be stored horizontally and arranged in ascending sequential order according to their Protocol Code Number within the designated Active File Cabinet. This cabinet must remain locked at all times inside the restricted-access REC Secretariat Office. Access permissions are strictly limited to the REC Chair, Member Secretary, and authorized Administrative Secretary.

To optimize physical storage limits, the Member Secretary shall audit multi-center studies to ensure that central documents (e.g., investigator brochures, core protocols) are not redundantly duplicated across separate site folders. Storage units must feature explicit, high-visibility external face labels categorized by the Year of Protocol Submission. Inactive, completed, withdrawn, and terminated files are immediately moved to a separate Inactive Storage Cabinet. These files must be

retained in their physical format for a mandatory minimum period of five (5) years. Upon completing the 5-year retention cycle, the physical files must be destroyed via secure incineration or heavy-duty industrial shredding, executed in the mandatory presence of the Member Secretary to verify absolute data destruction. Validated digital clones of the archives may be maintained indefinitely within the cloud server database, contingent upon institutional data storage capacities.

**Step 4: Periodic updating of the Files: Protocol Folder Index (Form 4.9),
Form 4.7a
Filing Form Log , RMSS DATABASE (Form 4.7), Approval Letter (Form
21.1)**

The Administrative Secretary update the protocol folders regularly. New materials must be integrated chronologically, ensuring that the most recently received document sits topmost within its respective section. Every time a modification, report, or letter is filed, the Administrative Secretary must immediately append the item to the internal Protocol Folder Index (Form 4.9) on the inside front cover of the blue folder.

The active update cycle must capture and cross-reference the following:

- Amending text and revised protocol versions (stamped with approval dates).
- Corresponding sign-off and dated reviewer Assessment Forms for every submitted report.
- Official excerpts of the Minutes of Meetings where the specific protocol or its safety reports were tackled by the board.
- Final signed copy of the Approval Letter (Form 21.1) or associated decision communications.

Concurrently with physical filings, the Administrative Secretary must transcribe these updates into the digital RMSS Database (Form 4.7) and log the physical cabinet movement into the Filing Form Log (Form 4.7a), maintaining perfect symmetry between digital records and physical assets under the quality assurance of the Member Secretary.

Section 6. Forms:

Form 1.9 – ARTS
Form 4.7 – RMSS database
Form 4.7a – Filing Form Log
Form 4.9 - Protocol Folder Index
Form 21.1 – Approval Letter

Section 7. History of SOP

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
1	6.20.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.31.24	Aljoriz Dublin & Nino Ismael Pastor	Contents, Form labels, Form
3	06.06.26	Nino Ismael Pastor	Form Labels Few content

Section 8. References

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