



Gullas College of *Medicine*
RESEARCH ETHICS COMMITTEE



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SOP NO. 22 - MANAGEMENT OF INCOMING/OUTGOING COMMUNICATION

Section 1. Policy Statement

All communications shall be recorded accurately and appropriately in each Protocol Folder Index (Form 4.9), and the Research Monitoring Surveillance Database (Form 4.7) for research-related communications in the RMSS (Form 4.7), the Filing Form Log (Form 4.7a) and/or in Form 1.9 (ARTS) for administrative communications. Incoming communications shall be acted upon promptly.

Section 2. Objective/s of the Activity

This aims to establish accountability to an efficient and effective communication tracking system.

Section 3. Scope

This SOP covers REC procedures to organize incoming and outgoing communications and documents to guide an appropriate REC response. It begins with sorting incoming/outgoing communications, storing or filing incoming/outgoing communications, and updating the Protocol Folder Index (Form 4.9) for the concerned protocol, and the RMSS DATABASE (Form 4.7) for research-related communications or in Form 1.9 (ARTS) for administrative communications. All shall be entered in the Filing Form log (Form 4.7a).

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Sorting of incoming/outgoing communications	Administrative Secretary	1 day upon receipt
Step 2: Recording in the RMSS (Form 4.7), Filing form Log (Form 4.7a) of incoming/outgoing communications	Administrative Secretary	
Step 3: Acting on incoming communications	Chair or Member Secretary	5 days post-receipt
Step 4: Filing of incoming/outgoing communications and updating of the Protocol File Index for the concerned protocol (Form 4.9) and the	Administrative Secretary	1 day post-action

RMSS (Form 4.7) for research-related communications or in Form 1.9 (ARTS) for administrative communications. All shall be entered in the Filing Form Log (4.7a)		
	TOTAL	7 days

Section 5. Description of Procedures

Step 1: Sorting of incoming/outgoing communications

All incoming and outgoing correspondence must be subjected to a rigorous taxonomy and sorting protocol immediately upon receipt or generation.

Every piece of communication entering or leaving the REC must feature a clear, descriptive, and unambiguous subject line. Materials must be explicitly categorized into one of the following recognized institutional document classes:

- Official Memoranda (Internal institutional directives)
- Formal Letters (External or sponsor-driven correspondence)
- Electronic Mail (Digital transmissions requiring tracking)
- Form 4.6 (REC Decision Letters)
- Form 21.1 (Official Approval Letters)
- Form 17.1 (Notice of Meetings and Agendas)
- Formal Invitations (For independent consultants or guest advocates)
- Miscellaneous/Other Regulatory Documents

The Administrative Secretary is responsible for physically and digitally sorting these documents into their respective processing streams. Crucially, the Administrative Secretary must document not just the primary document, but also all subsequent responses, board actions, and administrative instructions linked to that specific file. The Member Secretary shall directly supervise the classification and sorting process to ensure that sensitive or urgent protocol-related communications are prioritized for board review.

Step 2: Recording in the RMSS (Form 4.7), Filing form Log (Form 4.7a) of incoming/outgoing communications

Once a document has been classified and sorted, it must be permanently logged into the committee's registry systems to establish an uncompromised administrative audit trail.

The Administrative Secretary must immediately enter the metadata of all incoming and outgoing communications into the master RMSS for the concerned protocol (Form 4.7) and Filing Form Log (Form 4.7a). Under the close supervision of the Member Secretary, the Administrative Secretary must verify that every entry is complete and includes the following tracking parameters without exception:

The exact calendar date and timestamp when the communication was officially received or sent.

A concise summary of the purpose of the communication, including any associated protocol reference numbers.

- The full name, title, and institutional affiliation of the sender, complete with their verified wet or digital signature.
- The full name and signature of the specific REC Secretariat staff member who accepted the document.
- The type of document entered

A clear description of the immediate administrative action taken or the next steps triggered by the communication (e.g., Forwarded to Chair, Filed in Protocol Folder, Deferred to Full-Board Meeting).

Step 3: Acting on incoming communications

All incoming communications must be acted upon using a strict hierarchy of administrative authority.

The Member Secretary is empowered to independently draft and execute responses to routine administrative inquiries, provided these actions fall squarely within their delegated authority and the REC Chair is kept fully apprised of the matter. If an incoming communication involves policy interpretations, legal matters, severe protocol violations, or items exceeding the Secretariat's mandate, the Member Secretary must immediately escalate and refer the matter to the REC Chair. Following explicit instructions or directives from the Chair, the Member Secretary shall draft the official institutional resolution or response. To maintain legal and institutional accountability, ALL outgoing communications must receive the final review, approval, and signature of the REC Chair before dispatch.

All external and official outgoing correspondence must be printed or digitally rendered exclusively on the official GCM institutional letterhead to certify its authenticity.

Step 4: Filing of incoming/outgoing communications and updating of the Protocol File Index and RMSS DATABASE for research-related communications or in Form 1.9 (ARTS) administrative communications. All shall be entered in the Filing Form log (Form 4.7a).

The final stage of the communication lifecycle requires immediate, synchronized archiving across both physical and digital repositories to fulfill regulatory compliance standards.

A. Research- and Protocol-Related Communications

Hard copies of communications tied to an ongoing or completed study must be filed immediately in that study's specific, dedicated protocol folder. The Protocol Folder Index (Form 4.9), which is affixed to the inside front cover of the binder, must be updated chronologically by the Administrative Secretary every single time a new document is inserted. Concurrently, the digital tracking profile for that protocol must be updated within the cloud-secured Research Monitoring Surveillance System (RMSS) Database (Form 4.7) and the Filing Form Log (Form 4.7a).

B. Administrative and Governance Communications

Communications that deal with general committee operations, institutional policies, or non-protocol governance must be routed away from study files and logged securely within Form 1.9 of the Automated Research Tracking and Submission System (ARTSS).

C. Final Chain of Custody Securement

For both research and administrative hard copies, the Administrative Secretary must record the exact storage location and filing date into the physical Filing Form Log (Form 4.7a) and the digital RMSS (Form 4.7) attached to the locked, fireproof storage cabinets.

This multi-tiered data storage and encryption process shall be executed by the Administrative Secretary under the strict quality-assurance verification of the Member Secretary, in full compliance with SOP 23 - Managing Active Files.

Section 6. Forms

Form 4.7a – Filing Form Log

Form 4.9 - Protocol Folder Index

Form 4.7 - Research Monitoring Surveillance System

Form 4.7a – Filing Form Log

Form 1.9 Administrative Research Tracking System

Section 7. History of the SOP

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
1	6.28.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.30.24	Aljoriz Dublin & Nino Ismael Pastor	Forms, Form labels, Content
3	06.06.26	Nino Ismael Pastor	Form labels, Few Content

Section 8. References

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