



Gullas College of *Medicine*
RESEARCH ETHICS
COMMITTEE



Ethos Universitas
HONORARY COMPANION

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Date of Approval:	
Effectivity Date:	

SOP NO. 21 - COMMUNICATING REC DECISIONS

Section 1. Policy Statement

The REC is required to send out its decisions and research-related communications on or before the earliest of these two timelines:

- The 1st Friday of every month
- 10 working days after the regular REC monthly meeting

Note: This timeline is strictly conditional upon the REC receiving a complete set of required documents from the researcher.

When the researcher receives the communication, it must meet the following formal standards:

- Clear Content: It must include explicit instructions or recommendations to guide the researcher on their next steps.
- Official Branding: It must be written on the official REC stationery.
- Authentication: It must be officially signed by the REC Chair.

Section 2. Objective of the Activity.

This warrants that all stakeholders are correctly, exactly, and promptly informed of the results of deliberations of the REC.

Section 3. Scope

This SOP begins with the finalization of REC or reviewers' recommendations and ends with filing of the documents in the protocol folder and ends updating the Protocol Folder Index (Form 6.1) and the RMSS DATABASE (Form 4.7).

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Finalization of recommendations of the committee in case of a full review (SOP 6 Full	Member Secretary then Chair	1 day 1 st Friday every

Review)) or Finalization of recommendations of reviewers (in case of expedited (SOP 5 Expedited Review)		month @ 10 working days after the regular REC monthly meeting
Step 2: Transfer information from meeting minutes or reports to REC decision LETTER (Form 4.6)	Administrative Secretary supervised by Member Secretary	
Step 3: Approval of the REC decision document	Chair	
Step 4: Transmittal of REC decision to the researcher or concerned stakeholder. The Admin Secretary Fill-up Certificate of Exemption from Review (Form 4.1), Approval letter (For 21.1) or Decision Letter (Form 4.6)	Administrative Secretary Member Secretary REC Chair	
Step 5: Filing of the decision document in the correct protocol folder (SOP 23 - Managing Active Files), and update of the Protocol Folder Index (Form 4.9), and update the RMSS DATABASE (Form 4.7) and Filing form Log (Form 4.7a), .	Administrative Secretary	1 day 1 st Saturday of every month
TOTAL		11 days

Section 5. Description of Procedures

Step 1: Finalization of recommendations of the committee in case of a full review (SOP 6 Full Review)) or Finalization of recommendations of reviewers (in case of expedited (SOP 5 Expedited Review).

Following the official adjournment of an institutional review session, all evaluative findings must be systematically finalized and translated into actionable administrative text.

In accordance with SOP 6 (Full Review), the Administrative Secretary shall compile the collective determinations, voting outcomes, and specific ethical or methodological provisions recorded during full committee deliberations.

For Expedited Review (SOP 5 - Expedited Review), the Administrative Secretary shall compile the individual evaluation reports, queries, and specific technical corrections submitted by the designated primary reviewers. The Administrative Secretary, operating under the direct oversight of the Member Secretary, is responsible for accurately encoding these consolidated recommendations into the committee's master data management system. This ensures that no discrepancy exists between the live board discussions and the documented mandates.

Step 2: Transfer information from the meeting minutes or reports to Certificate of Exemption from Review (Form 4.1), REC decision letter (Form 4.6), or Approval letter (For 21.1) .

Once the review outcomes are verified, they must be converted into formal, legally binding correspondence tailored to the specific nature of the board's action.

Under the strict supervision of the Member Secretary, the Administrative Secretary shall extract data from the official meeting minutes or reviewer logs and populate the appropriate institutional templates.

Form 4.1 (Certificate of Exemption from Review) is generated for protocols determined to pose zero or negligible risk, officially exempting them from further oversight. Form 4.6 (REC Decision Letter) is utilized to convey detailed board actions requiring investigator action, specifically outlining mandates for Minor Modifications, Major Modifications, Disapprovals, or formal requests for Clarifications. Form 21.1 (Approval Letter) is issued exclusively when a protocol has met all scientific and ethical thresholds and is granted full clearance to commence data collection. Form 26.1 (Complaint Resolution Form) is compiled to address and document resolved grievances, whistle-blower reports, or participant complaints.

Before any document is cleared for external transmittal, the Member Secretary must conduct a thorough quality-assurance check on the drafts. Upon verification, the Member Secretary shall forward the dossier packet to the Chair for final executive endorsement, notation, and formal signing.

Step 3: Approval of the REC decision document

The Chair retains the ultimate legal and institutional accountability for all outgoing ethical communications and must validate each document before release.

The Chair shall perform a comprehensive review of each drafted decision letter, certificate, and approval document to ensure accuracy, professional tone, and compliance with institutional policies. To prevent administrative delays in ongoing research projects, the Chair must officially approve and sign all finalized decision documents within ten (10) calendar days following the conclusion of the regular REC meeting. This executive window aligns with the standard deadline arriving approximately on the first Friday of every month.

Step 4: Transmittal of REC decision to the researcher or concerned stakeholder. The Admin Secretary Fill-up Certificate of Exemption from Review (Form 4.1), Approval letter (For 21.1) or Decision Letter (Form 4.6).

To guarantee transparency and maintain an ironclad timeline for investigator notifications, a dual-channel transmittal protocol must be executed:

- Digital Dispatch Timeline: The Administrative Secretary must transmit an undatable, authenticated PDF copy of the signed REC decision document to

the Principal Investigator's (PI) registered institutional email account exactly ten (10) days after the regular meeting, or on or before the first Friday of every month.

- **Physical Handover Notification:** In the body of the digital transmittal email, the PI or their authorized research representative shall be formally instructed that the official, wet-signed physical hard copy has been archived and is ready for pickup from the REC Secretariat Office. The recipient must sign an acknowledgment logbook upon physical retrieval.

Step 5: Filing the decision document in the correct protocol folder (SOP 23 - Managing Active Files) and updating the Protocol Folder Index (Form 4.9), Filing Form log (Form 4.7a), and the RMSS DATABASE (Form 4.7).

All outward correspondence signed decision letters, and incoming investigator replies must be bound securely within the specific study's dedicated protocol folder. Under no circumstances may documents from separate research projects be co-mingled.

The Protocol Folder Index (Form 4.9) must be permanently pasted on the interior front cover of the binder file. Each time a new correspondence is added, the Administrative Secretary must immediately log the document chronologically on this index sheet. The placement of the binder within the locked, restricted-access filing cabinets must be tracked in real-time by updating the physical Filing Form Log (Form 4.7a) attached to that designated cabinet zone. Concurrently, the Administrative Secretary must access the cloud-secured Research Management and Submission System (RMSS) Database (Form 4.7).

The tracking profile for the respective protocol must be updated to reflect the current study life-cycle status (e.g., Approved, Pending Modifications, Exempted), including the exact dates of letter generation, transmittal, **and the Chair's sign-off, in full compliance with SOP 23 - Managing Active File**

Section 6. Forms

- Form 4.6 - Decision Letter
- Form 4.7 - RMSS DATABASE
- Form 4.7a – Filing Form log
- Form 4.9 - Protocol Folder Index
- Form 4.11 - Certificate of Exemption from Review
- Form 21.1 - Approval Letter
- Form 26.2 – Complaint Resolution Form

Section 7. History of 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	6.11.26	Nino Ismael Pastor	Form labels Few content

Section 8. References

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