



Gullas College of *Medicine*
RESEARCH ETHICS COMMITTEE



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SOP NO. 13 - REVIEW OF THE FINAL REPORT

Section 1. Policy Statement

The REC requires a final report not later than 8 weeks after the end of the study. Final reports shall undergo either expedited or full review.

Section 2. Objective of the Activity

The final report ensures that the implementation of the study complies with the approved protocol. It shall also check if the study promoted the safety and welfare of the study participants and if the data and information it generated were protected until the study was completed.

Section 3. Scope

This SOP describes the steps in managing and evaluating the final report(s) from the Principal Investigator(s) at least 8 weeks after the end of their study. The first step is the reception of the final report(s) form (Form 13.1) and ends when the report and related documents have been entered into the Protocol Folder Index (Form 4.9) and the RMSS database (Form 4.7) and the Filing Form Log (Form 4.7a) are updated.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt of final report (Form 13.1) and entry into the Protocol Folder Index (Form 6.1), Filing Form log (Form 4.7a) and the RMSS database (Form 4.7) And the Filing Form Log (Form 43.17a).	Administrative Secretary	1 day
Step 2: Retrieval of pertinent protocol file	Administrative Secretary	
Step 3: Notification of Chair and Primary Reviewer	Member Secretary Chair	3 days post-receipt
Step 4: Expedited (SOP 4) or Full review (SOP 5)	Chair, REC Members	1 day Every 3 rd Saturday of the month
Step 5: Communication of committee action (SOP 21-Communication) in an REC Decisions letter (Form 4.6)	Member Secretary Chair	7 days post-meeting

Step 6: Filing the Final Report (Form 13.1) and related documents into the correct protocol folder and update of the protocol folder index (Form 4.9) and the (Form 4.7) RMSS DATABASE and the Filing Form Log (Form 4.7a).	Administrative Secretary	10 days post-meeting
TOTAL		22 days

Section 5. Description of Procedures

Step 1: Receipt of final report (Form 13.1) and entry into the Protocol Folder Index (Form 6.1), Filing Form log (Form 4.7a) and the RMSS database (Form 4.7) And the Filing Form Log (Form 43.17a).

The Principal Investigator (PI) formally downloads or obtains Form 13.1 (Final Report Form) from the Research Ethics Committee (REC). After ensuring all sections are thoroughly accomplished and signed, the PI submits the final report dossier to the REC Secretariat. Upon delivery, the Administrative Secretary executes an immediate administrative intake audit:

The Administrative Secretary evaluates the final report to ensure all necessary study closure metrics, cumulative enrollment data, protocol deviation summaries, and safety overviews are complete. Incomplete submissions are rejected immediately and returned to the PI with an itemized deficiency notice.

Once the submission passes the completeness check, the Administrative Secretary officially logs and registers the transaction across the following data-management systems to preserve an uncompromised audit trail:

- Logs the transaction metadata into the Research Management Support System (RMSS) Database (Form 4.7).
- Records the precise intake entry in the REC Filing Form Log (Form 4.7a).
- Updates the master physical and digital Protocol Folder Index (Form 6.1) allocated to that specific study.

Step 2: Retrieval of pertinent protocol file.

Following successful entry logging, the Administrative Secretary accesses the secure institutional archives to extract the complete historical file of the research protocol. The secretary compiles a comprehensive close-out dossier, which must include: the originally approved baseline protocol, the latest authorized version of the Informed Consent Form (ICF), cumulative progress reports, safety logs, and all past committee decision letters. Once compiled, the Administrative Secretary securely transfers this unified historical folder along with the newly received Form 13.1 to the Member Secretary for preliminary administrative assessment

Step 3: Notification of Chair and Primary Reviewer

The Member Secretary evaluates the newly submitted final report against the study's historical dossier to confirm systemic alignment. During this process, the Member Secretary identifies the original primary reviewer(s) who managed the lifecycle of the protocol.

The Member Secretary drafts a formal Notice to Review (Form 4.3) and endorses the complete package to the REC Chair for executive authorization. Upon receiving the Chair's approval and explicit instructions, the Member Secretary formally dispatches the Notice to Review, the Final Report (Form 13.1), and all matching historical protocol documents to the designated primary reviewer(s). The primary reviewer evaluates the close-out materials against the study's history and synthesizes their findings into a comprehensive evaluation report, which is signed and submitted back to the REC Secretariat.

Step 4: Expedited (SOP 5) or Full review (SOP 6)

The methodology for evaluating the final close-out report is strictly determined by the risk classification and initial review framework utilized during the protocol's lifecycle:

- Expedited Review Pathway (SOP 5): Protocols that were initially categorized as low-risk and processed via an expedited track will undergo an expedited close-out evaluation by the primary reviewer(s) and the Chair.
- Full Committee Review Pathway (SOP 6): Protocols that initially required full Committee oversight are mandated to undergo full committee deliberations.

For full Committee items, the Member Secretary integrates the final report and the primary reviewer's evaluation findings into the provisional agenda. Operating under institutional guidelines, the Member Secretary drafts the Notice of Meeting (Form 17.1) and the Provisional Agenda (Form 18.1), routing them to the Chair for signature before distributing them to all standing REC Committee members.

During deliberations, the committee evaluates whether the study objectives were ethically achieved and votes to issue one of the following definitive regulatory decisions:

The final report is officially approved, and the study is formally registered as closed in good standing.

The final close-out is deferred pending the submission of specific clarifying data, metrics, or investigator statements.

Further Action Required: The Committee mandates explicit operational steps (e.g., participant notifications, post-study data monitoring, or safety interventions) that the PI must fulfill before formal closure is granted.

Step 5: Communication of committee action (SOP 21 Communication REC Decisions) in a Decision letter (Form 4.6)

Following the conclusion of the review cycle, the Member Secretary meticulously finalizes the Minutes of the Meeting (Form 20.1), capturing the exact consensus, rationale, and voting metrics of the committee. The completed minutes are routed to the REC Chair for validation and official sign-off. Once the minutes are signed, the Member Secretary drafts a formal Decision Letter (Form 4.6) that precisely mirrors the committee's mandates. The letter is reviewed, approved, and signed by the REC Chair, and the Secretariat coordinates its immediate electronic or physical transmission to the Principal Investigator in strict accordance with SOP 21 (Communicating REC Decisions).

Step 6: Filing the Final Report (Form 13.1) and related documents into the correct protocol folder and update of the protocol folder index (Form 4.9) and the (Form 4.7) RMSS DATABASE and the Filing Form Log (Form 4.7a).

Upon completion of the communication cycle, the Administrative Secretary re-collects the entire physical and digital paper trail from the Member Secretary. This includes the finalized Final Report (Form 13.1), the primary reviewer's evaluation notes, the signed meeting minutes, and a duplicate copy of the officially issued Decision Letter (Form 4.6). The Administrative Secretary securely returns these items to their designated master protocol folder. To officially conclude the administrative lifecycle of the research study, the secretary executes a final system-wide synchronization by updating the Protocol Folder Index (Form 4.9), recording the close-out in the REC Filing Form Log (Form 4.7a), and updating the status entry inside the master RMSS Database (Form 4.7) to label the study as officially completed.

Section 6. FORMS

- Form 4.3 – Notice to Review
- Form 4.6 – Decision letter
- Form 4.7 – RMSS database
- Form 4.7a – Filing Form log
- Form 4.9 – Protocol Folder Index
- Form 13.1 – Final Report Form
- Form 18.1 – Meeting Agenda
- Form 20.1 – Minutes of the Meeting

Section 7. History

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
1	11 June 2024	NINO ISMAEL S. PASTOR	DRAFT
2	16 October 2024	NINO ISMAEL S. PASTOR	Form labels Contents
3	05 June 2026		

Section 8. References

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