



Gullas College of *Medicine*
RESEARCH ETHICS COMMITTEE



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SOP NO. 15 - MANAGEMENT OF APPEALS

Section 1. Policy Statement

Appeals from PI, researcher(s), sponsor(s), or other stakeholders may also be filed against the REC decisions about the protocol and its documentation. Appeals will be discussed during a full Committee meeting.

The REC shall consider these appeals. Appeals shall be considered BY THE REC during full Committee meetings and a decision communicated to the appellant within four weeks of the full Committee meeting. Appeal must be filed with the REC chair within 30 days of the decision of the REC. It should state the grounds upon which the appeal is filed.

Section 2. Objective of the Activity

The objective of appealing is to ensure a transparent, fair, and comprehensive review of the appeal against a REC decision.

Section 3. Scope

This SOP starts with the receipt of the appeal request and ends with updating the Research Monitoring System Database (Form 4.17) and the Protocol Folder index (Form 6.1).

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receipt of an appeal & updating the Protocol Folder Index (Form 4.9), RMSS (Form 4.7) & the Filing Folder Log (Form 4.7a)	Administrative Secretary	1 day
Step 2: Retrieval of pertinent protocol file	Administrative Secretary	
Step 3: Notification of Chair and Primary Reviewer(s).	Member Secretary	3 days post-receipt
Step 4: Inclusion in the Agenda of the next regular (or emergency) meeting.	Member Secretary Chair	
Step 5: Discussion of and deliberation on	Chair and REC Members	1 day

the appeal during a full Committee meeting		Every 3 rd Saturday of the month
Step 6: Communication of committee action (SOP 21 Communicating REC Decision)	Member Secretary Chair	7 days post-meeting
Step 7: Filing of documents & updating the Protocol Folder Index (Form 4.9), RMSS (Form 4.7) & the Filing Folder Log (Form 4.7a)	Administrative Secretary	10 days post-meeting
TOTAL		22 days

Section 5. Description of Procedures

Step 1: Receipt of an appeal & updating the Protocol Folder Index (Form 4.9), RMSS (Form 4.7) & the Filing Folder Log (Form 4.7a)

The Administrative Secretary officially receives the formal letter of appeal submitted by the principal investigator or sponsor. Upon receipt, the Administrative Secretary conducts a preliminary administrative review to verify that the appeal package is complete and contains all necessary evidentiary information (London, 2018). The submission must explicitly include the following components:

- **Target of Appeal:** A clear identification of the specific Research Ethics Committee (REC) decision(s) or clauses that the proponent wishes to appeal.
- **Justification and Grounds:** A detailed, written justification outlining the specific ethical, scientific, or administrative grounds for each point of contention.
- **Official Correspondence:** A copy of the original, formal REC decision letter that prompted the appeal.
- **Historical Review Comments:** Copies of the official comments, stipulations, or queries previously provided by the Committee during the initial REC review process.
- **Prior Communications:** Documentation of any and all prior correspondence regarding the disputed protocol or previous appeal attempts held with the Member Secretary, Committee Chair, or individual committee members.
- **Supporting Documentation:** Any additional literature, revised protocol sections, expert opinions, or secondary documents that serve to validate and support the proponent's appeal.

If the appeal package meets all the completeness criteria outlined above, the Administrative Secretary formally accepts the submission. S/he then logs the

pertinent details of the appeal into the **Protocol Folder Index (Form 4.9) of that proposal**, logs the physical entry in the **Filing Folder Log (Form 4.7a)**, and updates the digital records within the **RMSS Database (Form 4.7)** to ensure full institutional traceability. If the submission is incomplete, the investigator is notified to provide the Administrative Secretary officially receives the formal letter of appeal submitted by the missing components before further processing

Step 2: Retrieval of pertinent protocol file.

Once the appeal is logged, the Administrative Secretary securely retrieves the complete archival file corresponding to the protocol under question. This documentary assembly ensures that all historical context is available for the review. The gathered dossier must include:

- The initially submitted research protocol (along with any subsequently approved amendments).
- The exact Informed Consent Form (ICF) versions tied to the decision.
- All relevant research tools, questionnaires, data collection forms, and related investigator brochures.

The Administrative Secretary physically or digitally attaches these baseline reference materials to the newly received appeal letter. This comprehensive dossier is then systematically forwarded to the Member Secretary for initial executive screening.

Step 3: Notification of Chair and Primary Reviewer(s).

Upon receiving the compiled dossier, the Member Secretary immediately notifies the Committee Chair and awaits executive directives. The Chair performs a preliminary evaluation of the appeal's grounds to determine the appropriate course of action. S/he then instructs the member secretary to prepare an Appeal Evaluation Report (For 15.1) and attach to the dossier.

Following this evaluation, the Chair identifies and assigns the protocol to the original Primary Reviewer(s) who oversaw the initial protocol decision, ensuring continuity of expertise. The Chair then instructs the Member Secretary to distribute the appeal dossier to these designated reviewers. Concurrently, the Chair directs the Member Secretary to slate the appeal onto the provisional agenda of the next regularly scheduled Full Committee meeting, or to convene an extraordinary emergency meeting if the timeline or nature of the study dictates urgency.

Upon receiving the dossier, the Primary Reviewer(s) conduct a rigorous re-evaluation of the protocol against the grounds raised in the appeal, subsequently drafting a formal evaluation report to be presented to the REC.

Step 4: Inclusion in the Agenda of the next regular (or emergency) meeting.

Acting on the explicit directives of the Chair, the Member Secretary officially embeds the protocol appeal as an active item on the institutional agenda (Form 18.1) for the upcoming regular or emergency Full Committee meeting (See SOP 17, 18 & 19).

Once scheduled, the Member Secretary sends a formal meeting notice (Form 4.3 notice top Review) to the principal investigator/proponent. This communication instructs the researcher to be on standby or present during the designated time slot of the meeting, ensuring their availability to address any real-time inquiries or provide crucial clarifications requested by the board

Step 5: Discussion of and deliberation on the appeal during a full Committee meeting.

The Chair opens the meeting in accordance with SOP 16. Then the Primary Reviewer is called to summarize the historical trajectory of the protocol, highlighting the specific ethical or technical issues that sparked the initial decision and contrasting them against the current arguments raised in the appeal. The Committee Chair opens the floor for general panel discussion and takes leadership over the deliberation process. If the panel requires deeper insights, the Member Secretary calls the principal investigator into the meeting room for a formal clarificatory interview. The researcher is given the opportunity to clarify ambiguities or defend their scientific/ethical stance. Once the clarificatory interview concludes, the researcher is politely asked to step out of the room. The Committee enters an executive session to finalize deliberations in absolute privacy. The panel strives to reach a consensus regarding the merits of the case. The Committee officially votes to determine whether to accept the appeal in its entirety, accept only specific elements of the appeal, or uphold the original REC decision.

The Member Secretary records the proceedings in the Minutes of a Meeting (Form 20.1).

Step 6: Communication of committee action (SOP 21 – Communicating REC Decisions).

Associated Forms: Notice of Panel Action / Draft Decision Letter (Form 4.6)

Following the finalization of the committee's collective decision, the Chair synthesizes the core decision points, ethical rationales, and mandatory requirements. The Member Secretary records the proceedings in the Minutes of a

Meeting (Form 20.1). The Chair then instructs the Member Secretary to translate these points into a formal **Draft Decision Letter (Form 4.6)**. The Member Secretary drafts the letter, ensuring all administrative and ethical justifications are precisely articulated. This draft is submitted to the Committee Chair for meticulous final review, administrative approval, and official signature. Once signed and sealed, the final decision letter is dispatched to the appellant/proponent via secure institutional channels, adhering strictly to standard communication timelines.

Step 7: Filing of documents & updating the Protocol Folder Index (Form 4.9), RMSS (Form 4.7) & the Filing Folder Log (Form 4.7a).

Associated Forms: Protocol Folder Index (Form 4.9), Research Management Support System (RMSS Database - Form 4.7), Filing Folder Log (Form 4.7a)

Upon the conclusion of the appeal cycle, the Administrative Secretary collects all physical and digital artifacts generated throughout the process—including the appeal letter, supporting attachments, primary reviewer evaluation reports, relevant meeting minutes excerpts, and the signed final decision letter. S/he systematically files these documents into the investigator’s dedicated protocol folder to maintain an uninterrupted audit trail. Finally, to ensure institutional data integrity, the secretary logs the completion of the action by making a final entry in the **Filing Folder Log (Form 4.7a)** and completely updating both the **Protocol Folder Index (Form 4.9)** for the specific protocol and the centralized **RMSS Database (Form 4.7)** to reflect the newly adjudicated status of the protocol.

Section 6. Forms

- Form 4.6 – Decision letter
- Form 4.7 – RMSS database
- Form 4.7a -Filing Form
- Form 4.9 – Protocol Index File
- For 18. 1 - Meeting Agenda Template
- 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	1 st Draft
2	17 Oct 2024	Dr. Julius Mario	Form labels content
3		NINO ISMAEL S. PASTOR	Form labels content

Section 8. References

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