



Gullas College of *Medicine*
RESEARCH ETHICS COMMITTEE



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Date of Approval:	
Effectivity Date:	

SOP NO. 26 - MANAGEMENT OF QUERIES AND COMPLAINTS

Section 1. Policy Statement

The REC shall promptly and accurately address all queries and complaints from clients, patients, community members, research participants, or other stakeholders while exercising due diligence.

All queries and complaints shall be referred to the Chair, who will determine whether they can be resolved by the Member Secretary or the primary reviewer, or if they require a full Committee decision.

Complaints involving minimal risk shall be referred to the primary reviewers for resolution. Complaints involving more than minimal risk shall be elevated to a special meeting within 48 hours for deliberation by the committee *en banc*, with the primary reviewers leading the discussion.

Section 2. Objectives

The objective of this SOP is to define the procedures for managing all requests, queries, and complaints regarding GCM research in order to foster public trust and institutional confidence in the GCM REC.

Section 3. Scope

This SOP applies to the entire lifecycle of managing stakeholder input. The workflow begins with the receipt, logging, and acknowledgment of requests, queries, or complaints regarding GCM research. It extends through inclusion in the REC meeting agenda, documentation of the formal response, and notification of the stakeholders, and concludes with the final update to the Protocol Folder Index.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Receive the query or complaint	Administrative Secretary	1 day
Step 2: Review the query/complaint	Member Secretary Chair	2 days-post receipt

Step 3: Discuss in a convened meeting or report the decision/action taken to the full Committee	Chair REC members	1 day: regular or special meeting
Step 4: Communicate REC response	Member Secretary Chair	2 days post- meeting
Step 5: File pertinent documents	Administrative Secretary	
TOTAL		6 days

Section 5. Description of Procedures

Step 1: Receive the query or complaint

The request, query, or complaint related to research participation or research protocols may come from research participants, community members, or other interested parties. The Administrative Secretary receives, studies, and writes/documents the request, query, or complaint on Form 26.1 (Query/Complaint form). The Administrative Secretary records the submitted document in the Filing Form Log (Form 4.7a), RMSS (Form 4.7) of that concerned research and the Protocol Folder Index (Form 4.9) of the research in question). The Administrative Secretary responds to the request, query, or complaint if it is within his/her authority to do so or refers this to the Member-Secretary for appropriate action.

Step 2: Review the query/complaint

The Member-Secretary reviews the request, query, or complaint. The Member Secretary responds to the request, query, or complaint if it is within his/her authority to do so but informs the Chair or refers this to the Primary Reviewer for appropriate action and informs the Chair about the request, query, or complaint.

The reviewer assesses the query/complaint for the level of risk generated by the query/complaint. The primary reviewer may act if the risk is minimal. If the query/complaint generates more than minimal risk, the Primary Reviewer will refer it to the Chair who decides to call an emergency Full Committee meeting within 48 hours.

A request, query, or complaint is considered serious if it may hurt the integrity and reputation of the REC, any of its members, or the safety and well-being of participants, community members, and/or other stakeholders

The PI may be contacted to provide clarification or further information.

Step 3: Discuss in a convened meeting or report the decision/action taken to full Committee.

The REC Chair calls for an emergency Full Committee meeting for discussion of a serious requests, queries, or complaints. The REC members arrive at a decision, and the primary reviewer(s) accomplish the Form 26.2 (Complaint Resolution Form).

The primary reviewer(s) accomplish Form 26.2 - Complaints Resolution Form for minimal risk complaints.

For more than minimal risk, the committee may choose any of the following options:

- Constitute a site-visiting team to gather more information, verification, and clarification regarding the source and cause/s of the complaint for its early resolution.
- Designate the primary reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution.
- Formulate recommendation if satisfied with the adequacy of information:
 - request for explanation/justification from the researcher
 - accept the request/demand of the participant
 - suspension of further recruitment
 - amendment of protocol and re-consent of participants
 - others

Step 4: Communicate REC response.

The Member Secretary may respond to the query or complaint if it is within the Competence to do so but must inform the Chair.

For minimal risk complaints, the primary reviewer(s) accomplish Form 26.2 (Complaints Resolution Form) and asks the Member Secretary to send it to the Complainant but first ask the Chair's approval and notation before sending it to the Complainant(s).

For complaints with more than minimal risk, the REC members arrive at a decision during a Full Committee meeting, and after the discussion, the primary reviewer(s) fill-up Form 26.2 (Complaints Resolution Form). The Member Secretary then sends the duly signed Form by the Chair or any communication to the complainant(s) (See SOP 21 - on Communicating REC Decisions).

Step 5: File pertinent documents

The Administrative Secretary collects and files the accomplished Forms, communication documents/letters, the letter of request, inquiry, or complaint, the excerpts of the meeting minutes when this matter was deliberated or reported, and other related documents in the correct protocol folder.

The REC Administrative Secretary updates the protocol folder index (Form 4.9), records the entry in the Filing Form Log (Form 4.7a) and the RMSS DATABASE (Form 4.7).

Section 6. Forms:

- Form 4.7 – RMSS Data Base
- Form 4.7a – Filing Form Log
- Form 4.9 – Protocol Folder Index
- Form 26.1 – Query Complaint Form.
- Form 26.2 - Complaints 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
	11.05.24	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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