



Gullas College of *Medicine*
RESEARCH ETHICS COMMITTEE



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Date of Approval:	
Effectivity Date:	

SOP NO. 14 - REVIEW OF EARLY TERMINATION REPORT

Section 1. Policy Statement

The researcher(s) or sponsor may, for various reasons (poor enrollment, high incidence of SAE/SUSARs, funding), decide to terminate the research before it is completed.

The REC may also choose to terminate the study before it is completed when the safety of the participant(s) cannot be further assured or is doubtful, OR because of any of the following

- The research was not being conducted in accordance with the GCM REC's requirements.
- The research was associated with unexpected serious harm to participants.
- It presented unmanageable risks to the safety, health, or welfare of participants.
- It engaged in significant non-compliance with institutional, national, or international ethical guidelines.
- It did not conform to institutional policies and procedures

The GCM REC Chair has the authority to impose a temporary suspension or termination of study activities if immediate risks to participant safety are identified, prior to a full Committee meeting.

Section 2. Objective of the Activity

A review of an early termination of the study aims to ensure the safety and welfare of the human participants and that the decision made by the REC adheres to the principle of fairness. It is also aimed at promoting the integrity of GCM

In either case, a full Committee review for an early termination of the study will be conducted.

Section 3. Scope

This explains how the REC will handle the suspension or early termination of a protocol before the scheduled end of the study. This SOP begins with the researcher(s) or sponsor submitting a report (Form 14,1) for early study termination, or with a REC member identifying situations or conditions outlined in the policy and concludes with the REC's decision to suspend or terminate the study.

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1: Researcher(s) or sponsor obtains a blank form for an Early Termination report, fills it up, and submits it to the REC	Researcher or sponsor	1 day
Step 2: Receipt of the early termination report and entry into the RMSS database (Form 4.7), the Filing Form Log (Form 4.7a) and Form 4.9 (Protocol Folder Index)	Administrative Secretary	
Step 3: Retrieval of pertinent protocol file	Administrative Secretary	
Step 4: Notification of Chair and Primary Reviewers	Member Secretary	3 days post-receipt
Step 5: Creation of a Research Integrity Team	REC Chair	7 days
Step 6: Full review (SOP on Full Review (SOP 6)	Primary Reviewers and Members	1 day Every 3 rd Saturday of the month
Step 7: Communication of committee action (Form 4.6, a Decision letter template) and update of the protocol folder index (Form 4.9). Filing Folder Log (Form 4.7a) and RMSS DATABASE	Chair Member Secretary Administrative Secretary	10 days post-meeting
TOTAL		22 days

Section 5. Description of Procedures

Step 1: Researcher(s) or sponsor obtains a blank template for an Early Termination report, fills it up, and submits it to the |REC.

The researcher(s), REC member, or sponsor will obtain and fill up Form 14.1 (Early Termination Report Form), and submit it to the REC.

Step 2: Receipt of the early termination report (Form 14.1) and entry into the RMSS database (Form 4.7), record entry in the Filing Form log (Form 4.7a), and Form 4.9 (Protocol Folder Index).

The Administrative Secretary receives the application, checks its completeness, and documents the submission in the Protocol Folder Index (Form 6.1), records the entry in the Filing Form (Form 4.7a) and the RMSS Database (Form 4.7).

Step 3: Retrieval of pertinent protocol file.

The Administrative Secretary shall retrieve the protocol from the Active Files to collate the documents of the protocol and to determine the identity of primary reviewers. S/he submits them to the Member Secretary.

Step 4: Notification of Chair and Primary Reviewers.

The Member Secretary evaluates the submission in the context of the documents and notifies the Chair and awaits further instruction. The Chair instructs the Member Secretary to issue a Notice to Review (Form 4.3) to the concerned Primary Reviewer and include the submission for a full Committee review in the next regular REC meeting. The Primary Reviewer prepares and submits his/her evaluation of the requested termination to the REC

● **Step 5: Creation of a Research Integrity Team (RIT).**

The REC chairperson or the Center for Health Research & Innovation creates a Research Integrity Team (RIT). The team investigates the report. The RIT **reports** to REC on the next REC meeting or during an emergency meeting as the case maybe.

● **Step 6: Full review (SOP on Full Review (SOP 6)).**

The Member Secretary prepares the reports, and Agenda to be presented in the REC meeting.

The review should ensure the implication of the early termination on the rights, safety, and welfare of the study participants, in the form of a set of procedures. The procedures may include adapting specific provisions for continued access to protective mechanisms and information by the study participants.

Step 7: Communication of committee action (Form 4.6, a Decision letter template) and update of the protocol folder index (Form 4.9). Filing Folder Log (Form 4.7a) and RMSS DATABASE

The Member Secretary will make the minutes of the meeting (SOP 20 – Preparing the Minutes of the Meeting) take note of the decision and/or discussion during the Committee meeting, draft a Decision letter (Form 4.6) and send it to the Chair for signature and when signed send it to the PI or sponsor.

Section 6. Forms

Form 4.3 – Notice to Review

Form 4.6 - Decision Letter Template
 Form 4.7 – RMSS database
 Form 4.7a – Filing Form log
 Form 6.1 – Protocol folder Index
 Form 14.1 - Early Termination Report Form
 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	17 Oct 2024	Ronald Catacte	Form labels Content
3	05 June 2026	Nino Ismael Pastor	Form labels Few content

Section 8. References

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