Gullas College of *Medicine* **RESEARCH ETHICS COMMITTEE**	Version No:	Draft
	Date of Approval:	
	Effectivity Date:	

SOP NO. 11A - REVIEW OF REPORTABLE NEGATIVE EVENTS (RNE) REPORT

Section 1. Policy Statement

A Report of a negative event (RNE) is a formal, mandatory report submitted by a Principal Investigator (PI) to a Research Ethics Committee (REC) of the GCM, detailing any unexpected, untoward, or harmful incident that occurred during the conduct of a research study. The GCM REC requires the submission of an RNE not later than three (3) days after it has come to the attention of the PI. The REC shall conduct an emergency meeting based on the harm or risk it involved.

Section 2. Objective of the Activity

RNE reviews are performed to protect the safety and welfare of human participants, safeguard and promote the integrity of the research team. and to document accurately the RNE.

Section 3. Scope

This SOP begins with the receipt of submission of an RNE report, and documentation in the Protocol Folder Index (Form 6.1) of the proposal and ends in the filing of all related documents into the protocol folder index (Form 6.1) and the RMSS DATABASE (For 4.7).

Section 4. Workflow

ACTIVITY	**RESPONSIBILITY**	**TIMELINE**
Step 1: Receipt of an RNE report (Form 11A.1) and documentation of submission of the RNE report in the protocol folder index (Form 6.1), Filing Form (Form 4.7a), and the (Form 4.7) RMS DATABASE.	Administrative Secretary	1 day
Step 2: Retrieval of pertinent protocol file	Administrative Secretary	
Step 3: Notification of Chair	Member Secretary	3 days post-receipt
Step 4: Call for a Special Meeting	Chair	
Step 5: Deliberation on the RNE	REC members	1-day emergency meeting

Step 6: Communication (Form 4.6, Decision Letter), of REC action (SOP 21- Communication of REC Decisions) to the PI/researcher, sponsor, and/or to the Institutional authority.	Member Secretary Chair	7 days post-meeting
Step 7: Filing of all related documents (SOP 23 - Management of Active Files) and updating of the Protocol Index Folder (Form 4.9), Filing Form log (Form 4.7a) RMS database (Form 4.7)	Administrative Secretary	10 days post-meeting
	TOTAL	

Sept 5. Description

Step 1: Receipt of an RNE report (Form 11A.1) and documentation of submission of the RNE report in the protocol folder index (Form 6.1), Filing Form (Form 4.7a), and the (Form 4.7) RMS DATABASE.

The Principal Investigator (PI) or authorized research representative submits the accomplished **Form 11A.1 (Report of a Reported Negative Event [RNE])** to the Research Ethics Committee (REC) Secretariat. Upon delivery, the Administrative Secretary formally receives the document and conducts an immediate compliance check regarding submission timelines.

The Administrative Secretary cross-references the date of the negative event against the date of submission to verify compliance with the mandatory **three-day (3-day) institutional cut-off period**. If the report is submitted beyond this strict window, the Administrative Secretary flags the noncompliance and formally escalates the delay to the Member Secretary for tracking and potential disciplinary action.

To maintain absolute traceability, the Administrative Secretary logs the submission across all official tracking platforms by:

1. Entering the receipt details into the **Research Management Support System (RMSS) Database (Form 4.7)**.
2. Registering the entry in the **REC Filing Form Log (Form 4.7a)**.
3. Updating the physical and digital **Protocol Folder Index (Form 6.1)** allocated to that specific research study.

Step 2: Retrieval of pertinent protocol file

Following database documentation, the Administrative Secretary extracts the complete historical archive of the approved protocol from the secure repository. This step requires compiling the primary protocol, previous amendments, safety logs, and participant consent templates. Concurrently, the Administrative Secretary reviews past committee minutes to identify the originally assigned primary reviewers for this specific protocol. Once the complete dossier is assembled and the primary reviewers are identified, the materials are formally

turned over to the Member Secretary to facilitate an expedited preliminary risk assessment.

Step 3: Notification of Chair

The Member Secretary conducts an immediate review of the RNE report along with the retrieved protocol history to evaluate the severity of the event and its impact on participant safety. The Member Secretary then formally briefs the REC Chair regarding the critical nature of the situation. Based on the perceived level of risk, vulnerability of participants, or systemic implications of the reported negative event, the Member Secretary provides a recommendation to the Chair regarding whether the gravity of the RNE warrants the invocation of an extraordinary emergency session.

Step 4: Call for a Special Meeting

Upon evaluating the brief, the REC Chair officially directs the Member Secretary to convoke a Special Emergency Meeting. The Member Secretary constructs the formal session agenda using **Form 18.1 (Meeting Agenda Template)**, explicitly placing the critical RNE review at the forefront of business. This drafted agenda is routed to the Chair for final approval and signature.

Depending on the context of the event, the Member Secretary, under the guidance of the Chair, issues formal invitations to the Principal Investigator, core research team members, institutional experts, or relevant community stakeholders, requiring them to attend the initial phase of the session to provide eyewitness testimonies, technical clarifications, or context-specific data.

Step 5: Deliberation on the RNE

The special emergency meeting is called to order by the Chair, requiring a designated quorum of REC members. The session proceeds via a strictly structured dual-phase adjudication process:

- **Phase I: Fact-Finding and Hearing:** The Chair presents a comprehensive summary of the RNE report. The committee then interviews the invited PI, research team, or stakeholders. The collective body thoroughly evaluates the specific negative event(s) affecting the participants or research staff, evaluates the immediate effectiveness of any mitigating interventions deployed by the study team, analyzes the depth of community assistance required, and assesses the overall structural impact of the event on the integrity of the research.
- **Phase II: Executive Session and Voting:** Following the fact-finding phase, the Chair officially excuses the PI, research team, and external stakeholders from the room. The REC members enter a closed executive session to deliberate on the ethical and safety implications. The committee

must vote to execute one or a combination of the following regulatory actions:

- Recommend the immediate suspension of all study procedures until the negative event is thoroughly resolved or mitigated.
- Issue a total withdrawal of ethical clearance, effectively terminating the research study.
- Mandate the immediate submission of a comprehensive Corrective and Preventive Action (CAPA) plan to mitigate future risk or harm.
- Require a mandatory, formal amendment to the protocol design, inclusion criteria, or informed consent documents.
- Uphold the original ethical clearance without modifications, provided the risk has been successfully neutralized.

The Member Secretary carefully records the official minutes of the session, capturing the rationale behind the votes and the definitive decision. Immediately following adjournment, the Member Secretary drafts a formal **Decision Letter (Form 4.6)** reflecting the committee's mandates and submits it to the Chair for final sign-off.

Step 6: Communication of REC action to the PI/researcher, sponsor, (Form 4.6, Decision Letter Template), (See SOP 21-Communication of REC Decisions), and/or to the Institutional authority.

Once the **Decision Letter (Form 4.6)** is scrutinized and signed by the REC Chair, the Member Secretary coordinates its immediate dissemination in strict compliance with **SOP 21 (Communication of REC Decisions)**. The Member Secretary ensures that certified copies of the official directives are securely dispatched to the Principal Investigator, the funding sponsor, and, if required by institutional risk guidelines, escalated directly to the Vice top-tier Institutional Authority or regulatory bodies overseeing research compliance.

Step 7: Filing of all related documents (SOP 23, Management of Active Files) and Update of the protocol folder index (Form 6.1) and the RMSS DATABASE (Form 4.7).

Following the dispatch of the regulatory mandates, the Administrative Secretary re-collects all physical and digital documentation generated throughout this emergency review cycle—including the initial RNE report (Form 11A.1), primary reviewer notes, signed emergency meeting minutes, and the issued Decision Letter (Form 4.6). Adhering to the administrative standards outlined in **SOP 23 (Management of Active Files)**, the Administrative Secretary permanently archives these files within the master protocol folder and synchronizes the records across all tracking platforms by executing final updates in the **Protocol Folder**

Index (Form 4.9), the **REC Filing Form Log (Form 4.7a)**, and the main **RMSS Database (Form 4.7)**.

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 11A.1 Report of RNE

Section 7. History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	6.27.24	NINO ISMAEL S. PASTOR	DRAFT
2	10.15.24	Ronald Catacte	Form labels contents
3	06.05.26	NINO ISMAEL S. PASTOR	Form labels, few content

Section 8. References

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