



Gullas College of *Medicine*
RESEARCH ETHICS COMMITTEE



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SOP NO. 11B - REVIEW OF SERIOUS ADVERSE EVENTS

Section 1. Policy Statement

Approved Clinical trials may cause serious risks or hazards to human participants. The investigator must exert effort to monitor these suspected or unsuspected adverse reactions. Sponsors of these approved clinical trials must also cooperate with the investigator(s) to minimize or prevent these risks or hazards.

The REC shall require submitting PI/Sponsors to report Serious Adverse Events (SAEs) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) within 7 days after the event has come to the researcher's attention. The Primary reviewer will evaluate these events whose recommendation(s) shall be submitted to the REC for deliberation and final action.

Section 2. Objective of the Activity

Reviewing SAE's and SUSARs are done to safeguard human participants' safety and welfare by properly documenting, monitoring and evaluating SARs and SUSARs and recommending how to mitigate them.

Section 3. Scope

This SOP begins with the receipt of report of SAEs and SUSARs, and documentation in the protocol folder index (Form 6.1). It ends with the filing of all related documents and update of the protocol database (Form 4.7 – RMSS database).

Section 4. Workflow

ACTIVITY	RESPONSIBILITY	TIMELINE
Step 1 - Receipt of submission of the report of SAEs and SUSARs (Form 11B.1) in the logbook	Administrative Secretary	1 day
Step 2: Retrieval of pertinent protocol file	Administrative Secretary	
Step 3: Notification of Chair	Member Secretary Chair	

Step 4: Review of the SAE or SUSAR report	Primary Reviewer	3 days post-receipt
Step 5: Inclusion of report in the provisional agenda of the special REC meeting	Member Secretary Chair	
Step 6: Deliberations during the special meeting	Chair REC members	1-day special meeting
Step 7: Communication of REC action to the Principal Investigator/researcher (See SOP 21– Communicating REC Decision)	Member Secretary Chair	7 days post-meeting
Step 8: Filing of all related documents (See SOP 23 - Management of Active Files) and update the RMSS database (Form 4.7), Filing form Log (Form 4.7a), and the Protocol Folder Index (Form 4.9).	Administrative Secretary	10 days post-meeting
TOTAL		22 days

Section 5. Description of Procedures

Step 1 - Receipt of submission of the report of SAEs and SUSARs (Form 11B.1) in the logbook.

The Principal Investigator (PI) or clinical research team formally submits the accomplished **Form 11B.1 (Serious Adverse Event [SAE] / Suspected Unexpected Serious Adverse Reaction [SUSAR] Report Form)** to the Research Ethics Committee (REC) Secretariat. Upon arrival, the Administrative Secretary executes an immediate regulatory timeline audit:

- The Administrative Secretary cross-references the date of the investigator's initial awareness of the SAE/SUSAR against the exact date of receipt to determine compliance with the mandatory **seven-day (7-day) institutional reporting threshold**. The Administrative Secretary flags the submission's chronological compliance status and immediately briefs the Member Secretary regarding whether the report was received early, exactly within, or past the critical 7-day cut-off window.
- To establish an uncompromised audit trail, the Administrative Secretary officially logs the transaction across the following data-management systems:
 1. Enters the submission metadata into the **Research Management Support System (RMSS) Database (Form 4.7)**.
 2. Logs the document transfer in the **REC Filing Form Log (Form 4.7a)**.
 3. Formally updates the **Protocol Folder Index (Form 4.9)** designated for that specific research protocol.

Step 2 - Retrieval of pertinent protocol file:

Following initial system logging, the Administrative Secretary accesses the secure archives to retrieve the master protocol folder and all matching historical records

for the study in question. This comprehensive dossier must include the primary approved protocol, recent investigator brochures, participant safety logs, and informed consent forms. Concurrently, the Administrative Secretary identifies the original primary reviewers assigned to this protocol. The entire unified dossier, along with the newly received **Form 11B.1**, is then formally transmitted to the Member Secretary to undergo an immediate administrative screening.

Step 3 - Notification of Chair:

Upon reviewing the assembled safety dossier, the Member Secretary immediately escalates the SAE/SUSAR alert to the REC Chair using a multi-channel communication approach (including secure institutional email, telephonic voice calls, and SMS text notifications) to ensure prompt awareness. The Member Secretary forwards the electronic copy of the dossier to the Chair.

Upon evaluating the preliminary risk, the Chair issues a double directive to the Member Secretary:

1. Formally contact the designated primary reviewer(s) and securely dispatch the complete SAE/SUSAR report and historical dossier for urgent assessment.
2. Convoke a **Special Emergency REC Meeting**, which must be scheduled and executed strictly within **three (3) calendar days** from the initial institutional receipt of the safety report.

Step 4 – Review of the SAE/SUSAR report:

The assigned primary reviewer(s) execute an expedited, rigorous scientific and ethical evaluation of the reported event. The reviewer analyzes the event against the historical safety data of the investigational product, evaluating the causality, severity, and overall threat profile posed to the ongoing safety of human participants. Following this independent evaluation, the primary reviewer details their clinical-ethical findings by completing **Form 11B.2 (SAE/SUSAR Assessment Report)** and signs off before returning the document to the Member Secretary for committee integration

Step 5. Inclusion of report in the provisional agenda of the special REC meeting

Call for a special meeting:

Upon receiving the primary reviewer's assessment, the Member Secretary integrates the critical safety review into the institutional agenda. Adhering strictly to the guidelines defined in **SOP 17 (Preparing the Meeting Agenda)**, the Member Secretary drafts a provisional agenda dedicated to this extraordinary Full Committee session. This agenda is presented to the REC Chair for official authorization and signature. Once signed, the Member Secretary distributes the authorized meeting agenda, along with copies of **Form 11B.1** and the reviewer's

Form 11B.2, to all standing REC Committee members to facilitate pre-meeting brief reviews.

Step 6 – Deliberations during the special REC meeting:

The REC Committee convenes the Special Meeting under a strict quorum. The Chair introduces the case, and the Committee enters intense deliberations, closely scrutinizing the primary reviewer's **SAE/SUSAR Assessment Report (Form 11B.2)**. The committee systematically evaluates whether the event alters the risk-benefit ratio of the study and votes to implement an official regulatory action. The final Committee directive may include, but is not limited to, the following outcomes:

- **No Further Action Required:** The safety event is deemed expected, successfully mitigated, or unlinked to the intervention.
- **Continuous Monitoring:** The study remains active but requires localized oversight and heightened safety reporting.
- **Mandate a Site Visit:** The Committee orders an unscheduled post-approval monitoring site visit to audit compliance on-site.
- **Information/Action Required:** The Committee requests additional laboratory metrics, investigator clarifications, or a formal revision of the Informed Consent Form (ICF).
- **Suspension of Recruitment:** Active participant enrollment is frozen immediately pending further safety investigations, though currently enrolled participants may continue treatment if safe.
- **Termination of the Study:** Complete and immediate withdrawal of ethical clearance, bringing all research activities to a permanent halt due to unmitigated safety hazards.

Following the final vote, the Member Secretary records the detailed minutes of the session and synthesizes the final Committee consensus into a comprehensive draft of the **Decision Letter (Form 4.6)**.

Step 7: Communication of REC action to the Principal Investigator/researcher (See SOP 21– Communicating REC Decision).

The Member Secretary finalizes the **Decision Letter (Form 4.6)**, ensuring it contains explicit legal, ethical, and procedural mandates reflecting the committee's decision. The finalized letter is routed to the REC Chair for review, validation, and official signature. Once signed, the Member Secretary processes and dispatches the document to the Principal Investigator, institutional sponsors, and relevant regulatory bodies in strict compliance with the protocols established under **SOP 21 (Communicating REC Decisions)**.

Step 8: Filing of all related documents (See SOP 23 - Management of Active Files) and update the RMSS database (Form 4.7), Filing form Log (Form 4.7a), and the Protocol Folder Index (Form 4.9).

Upon completion of the communication cycle, the Administrative Secretary re-collects all physical and digital documentation generated throughout the emergency review process (including the initial safety report, primary reviewer notes, signed emergency minutes, and the issued Decision Letter). Operating under the administrative guidelines of **SOP 23 (Management of Active Files)**, the Administrative Secretary permanently archives these documents within the master protocol folder. To finalize the administrative lifecycle, the entries are recorded in the **REC Filing Form Log (Form 4.7a)**, the main **RMSS Database (Form 4.7)** is updated, and the physical **Protocol Folder Index (Form 4.9)** is synchronized to guarantee flawless record integrity.

Section 6. Forms

- Form 4.6 - Decision Letter
- Form 4.7 - RMSS database
- Form 4.9 - Protocol Folder Index
- Form 11B.2 – SAE/SUSAR Assessment Report

Section 7. History of SOP

<i>Version No.</i>	<i>Date</i>	<i>Authors</i>	<i>Main Change</i>
1	06/05/2024	NINO ISMAEL S. PASTOR	First draft
2	10.15.24	Dr. Julius Mario	Form labels Contents
3	06.06.26	Nino Ismael Pastor	Form labels, few content

Section 8. References

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