CARAGA STATE UNIVERSITY
RESEARCH ETHICS BOARD

STANDARD OPERATING PROCEDURE	Effective Date: 6/5/25
SOP No: 11B	
Version No: 2025-01	Revision No: 1
Date of Approval:	

TITLE	REVIEW OF SAEs AND SUSARs
POLICY STATEMENT	*The REC shall require the submission of reports of SAEs and SUSARs SUSARs as soon as possible but no later than 15 calendar days after the event has come to the attention of the researcher. The evaluation of the SAEs and SUSARs shall be conducted by the Subcommittee that will be constituted by the Chair as needed on SAEs and SUSARs whose recommendation shall be submitted to the REC for final action.*
OBJECTIVE OF THE ACTIVITY	*Review of SAE and SUSAR reports aims to ensure that the safety and welfare of human participants in the study site are safeguarded and that information on SAEs and SUSARs are properly documented and evaluated.*
SCOPE	*This SOP applies to the review of reports of SAEs in various studies and SUSARs in clinical trials. This SOP begins with the receipt and documentation of submission of report of SAEs and SUSARs in the logbook and ends with the filing of all related documents and update of the protocol database.*

Workflow

STEP	ACTIVITIES	RESPONSIBILITY	INTERFACE
1	Receipt and documentation of submission of report of SAEs and SUSARs in the logbook	STAFF SECRETARY	
	↓		
2	Retrieval of pertinent protocol file	MEMBER SECRETARY	
	↓		
3	Notification of Chair	MEMBER SECRETARY	
	↓		
4	Submission of report to the SAE subcommittee	MEMBER SECRETARY	
	↓		
5	Inclusion of report of Subcommitee in the agenda of the next regular REB meeting.	MEMBER SECRETARY AND	

		CHAIR	
	↓		
6	Communication of REB action to the Principal Investigator/Researcher	MEMBER Secretary and Chair	SOP 21 on Communication REC Decisions
	↓		
7	Filing of all related documents and Update of the protocol database	STAFF SECRETARY	SOP 23 on Management of Active Files

Description of Procedures

Step 1 - Receipt and documentation of submission of report of SAEs and SUSARs in the logbook/database: *The Staff Secretary receives the accomplished SAE/SUSARs report and enters the submission into the logbook. The REB Secretary notes whether the submission is within the required timeline.*

Step 2 - Retrieval of pertinent protocol file: *The Member Secretary retrieves the identity of the primary reviewers (if there is no SAE/SUSAR subcommittee) and a tabulation of earlier SAE/SUSAR reports.*

Step 3 - Notification of Chair: *The Member Secretary notifies and sends the report and the retrieved documents to the Chair by email.*

Step 4 - Submission of report to SAE Subcommittee or point person: *The Chair forwards the report and pertinent documents to the primary reviewers (or to the SAE/SUSAR Subcommittee) for action which should not be later than 3 days prior to the next committee meeting.*

Step 5 - Inclusion of report of SAE Subcommittee or point person in REC meeting agenda: *The suggested action/decision of either the primary reviewer or the SAE/SUSAR Subcommittee is included in the Agenda of the next meeting (see SOP on Preparing the Meeting Agenda). for ratification or discussion and final decision. Possible actions include: notation with no further action required, further information or action required or suspension of recruitment.*

Step 6 - Communication of REB recommendation to the Principal Investigator/researcher: See SOP on Communicating REB decisions.

Step 7 - Filing of all related documents and update of the protocol database: See SOP on Managing Active Files (SOP 23).

6.Glossary

SAE (Serious Adverse Events) - - is an event observed during the implementation of a study where

the outcome is any of the following

- Death

- Life threatening
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/ birth defect
- Required intervention to prevent permanent impairment or damage (devices)
- Other serious (important medical) events

whether or not it is related to the study intervention.

SUSAR (Suspected Unexpected Serious Adverse Reactions)- is a noxious response to a drug that is not described in the Investigator's Brochure nor in the drug insert.

SAE Subcommittee – a group of individuals with the necessary expertise, assigned by the REB to review SAEs and SUSARs and provide the pertinent recommendation for action of the REB.

Principal Investigator - the lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial.

Sponsor- an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial.

Researcher-Initiated Studies – are research activities whose conceptualization, protocol development and implementation are done by a researcher or group of individuals who may request for external funding support.

Sponsored-Clinical Trials – are a systematic study on pharmaceutical products in human subjects (including research participants and other volunteers), whose conceptualization, protocol development and support for their conduct are the responsibilities of sponsors who manufactured the products, in compliance with the requirements of regulatory authorities.

Forms

F06-01 Reportable Negative Event Report
Form C01-01 Decision Letter Template

History of SOP

Version No.	***Date***	***Authors***	***Main Change***
1	*2025 May 6*	*Marianne R. Edulan* *Dr. Nueva Joy Perucho*	*First Draft*

References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

FDA Circular 2020-003 Guidelines for Phamaceutical Industry on Pharmacovigilance