RNEC

PAC-03 **Version number (1.0)** **Effective date (01 Jun 2026)**

Reporting and Reviewing Serious Adverse Events

Definitions

- **Adverse Event (AE)**: Any unfavorable or unintended sign, symptom, or disease temporally associated with the use of a study intervention, whether or not related.
- **Serious Adverse Event (SAE)**: Any event that results in death, is life-threatening, requires hospitalization or prolongation of hospitalization, results in disability or incapacity, is a congenital anomaly or birth defect.
- **Suspected Unexpected Serious Adverse Reaction (SUSAR)**: An unexpected serious adverse reaction judged to be caused by the study intervention.
- **Unanticipated Problem (UP)**: Any incident, experience, or outcome that is unexpected, related to the research, and indicates new or increased risk.
- **Unexpected SAE**: An SAE not previously identified in the investigator's brochure, protocol, or consent documents.
- **Causality**: The assessment of whether the AE/SAE is related to the study intervention.
- **Safety Monitoring Plan**: A predefined system for identifying, assessing, and managing safety events during the study.
- **Safety Report**: A structured report submitted to RNEC describing an AE, SAE, or unanticipated problem.

1. Purpose

To define the procedures for timely reporting, review and management of SAEs)/ USAE to protect participants' safety and ensure compliance with ethical and regulatory requirements.

2. Scope

This SOP applies to:

- All RNEC approved protocols.
- Investigators, sponsors, and study teams conducting research in Rwanda.
- All SAEs occurring at study sites, regardless of causality.

3. Responsibilities

(1) Principal Investigator (PI):
- Ensures timely detection, assessment, and reporting of SAEs.
- Ensures that relevant authorities (Rwanda FDA, RBC, sponsors, DSMBs) are notified as required.

(2) Study Team:
- Monitors participants and documents safety events.

(3) Sponsor:
- Ensures safety oversight, independent monitoring, and reporting to regulatory bodies.

(4) RNEC Secretariat:
- Logs SAE reports, ensures timely review, and escalates urgent cases.

(5) RNEC Chairperson:
- Assigns reviewers and may call expedited meetings for urgent cases.

(6) RNEC Members:
- Review SAE reports and recommend corrective measures.

4. Procedures

Step 1. Detection and Initial Reporting

- PI/study team documents SAE details immediately upon occurrence.
- Initial report to RNEC within **48 hours** (using SAE Reporting Form

Step 2. Follow-Up Reporting

PI submits detailed follow-up report within **10 days**, including:

- Description of event.
- Medical management provided.
- Assessment of causality and expectedness.
- Impact on study protocol and participants.

Step 3. RNEC Review

- Secretariat logs and assigns reviewers.
- Expedited review for life-threatening/ fatal events.
- Recommendations may include protocol amendment, participant re-consent, or study suspension.

Step 4. Communication

- Secretariat communicates decision to PI within **5 working days** of review.

5. Required Documents

- SAE Initial Report Form (submitted within 48 hrs).
- SAE Follow-Up Report (within 5 working days).
- Hospital/medical records.
- Causality assessment report.
- Corrective and Preventive Action (CAPA) plan.
- Study Monitoring Report DSMB.

6. Compliance

Failure to report SAEs on time may result in suspension of the protocol. All unexpected SAEs must be reported immediately and followed up with corrective actions.

7. Quality Assurance

RNEC shall:

- Periodically audit expedited decisions
- Review SOP every 3-5 years
- Train staff and reviewers

8. References and Ethical Framework

(1) Law N° 015/2022 of 29/06/2022 relating to research on a human being (View/Download).
(2) Ministerial Order N° 002/MoH/2023 of 21/03/2023 relating to Rwanda National Research Ethics Committee on a human being (View/Download).
(3) Law N° 003/2018 of 09/02/2018 Establishing the Rwanda Food and Drugs Authority, and Determining its Mission, Organization and Functioning (View/Download).
(4) Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Participants (2024) (View/Download)
(5) CIOMS - International Ethical Guidelines for Health-related Research Involving Humans (2016) (View/Download)
(6) ICH - Guideline for Good Clinical Practice E6 (R3) View here
(7) WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) (View/Download)
(8) RNEC Ethical Guidelines (View/Download)

9. Revision History

Version	Date	Summary of changes
1.0	**11-05-2026**	First RNEC SOP for Reporting and Reviewing Serious Adverse Events