RNEC

PAC-04 **Version number (1.0)** **Effective date (01 Jun 2026)**

Protocol Deviations and Violations Reporting

Definitions

- **Protocol Deviation**: Any unplanned departure from the approved protocol, study procedures, or RNEC requirements that does not significantly impact participant safety, rights, or study integrity (e.g., missing a scheduled visit, minor delay in data entry).
- **Protocol Violation**: Any serious or significant deviation. A breach of protocol or RNEC requirements that affects participant safety, rights, or welfare, or compromises data integrity (e.g., enrolling ineligible participants, failure to obtain informed consent, non-reporting of SAEs).
- **Noncompliance**: Failure to adhere to ethical principles, RNEC-approved procedures, or regulatory requirements.

1. Purpose

To establish procedures for timely detection, reporting, and review of protocol deviations and violations in order to safeguard participant welfare and maintain study integrity.

2. Scope

This SOP applies to:

- All research studies approved by RNEC, including
- Both minor deviations, major violations and noncompliance.
- Investigators, sponsors, and institutions conducting research in Rwanda.

3. Responsibilities

(1) Principal Investigator (PI):
- Submits continuing review request with supporting documents.
- Submit complete continuing review reports on time
- Report deviations, violations, and adverse events promptly
- Provide monitoring and safety oversight reports
- Ensure study remains compliant with RNEC requirements
- Halt study activities if approval lapses

(2) RNEC Secretariat:
- Receives, logs, and forwards reports for review.

(3) RNEC Chairperson:
- Determines whether reported issues require expedited or full board review.

(4) RNEC Members:
- Review reported deviations/violations and recommend corrective action.

4. Procedures

Step 1. Identification

- Study team identifies and records deviation or violation.
- PI assesses significance (minor deviation vs. major violation).

Step 2. Documentation

- PI documents incident using Protocol Deviation/Violation Report Form.
- Includes: description, date, cause, corrective/preventive action.

Step 3. Reporting to RNEC

- Minor deviations: Summarized in annual continuing review reports.

- Major violations: Reported to RNEC within **7 days** of discovery.
- Serious breaches affecting participant safety: Reported within **48 hours**.

Step 4. RNEC Review

- Secretariat logs and assigns to Chair.
- Chair determines if expedited review is sufficient or requires full board deliberation.
- Corrective actions required may include: protocol amendment, participant re-consent, or study suspension.

Step 5. Communication of Outcome

- Secretariat communicates RNEC decision to PI within **7 working** days of review.
- PI responsible for implementing corrective actions and documenting compliance.

5. Required Documents

- Protocol Deviation/Violation Report Form.
- Description of incident and impact assessment.
- Corrective and Preventive Action (CAPA) plan.
- Supporting evidence (case report forms, monitoring reports, etc.).
- Updated protocol/consent forms if applicable.

6. Compliance

Failure to report protocol violations may lead to suspension or withdrawal of RNEC approval. Institutions must have internal SOPs aligned with this requirement.

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 Nº 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 Protocol Deviations and Violations Reporting.