



REV-03

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STANDARD FULL COMMITTEE REVIEW OF RESEARCH PROTOCOLS

Definitions

- **Full Committee Review:** A review conducted at a convened RNEC meeting with quorum present, where protocols are discussed and voted upon.
- **Quorum:** The minimum number of RNEC members required to conduct official business, including at least 2/3 of members (including at least one scientific and one non-scientific members) to conduct valid representation.
- **Greater than Minimal Risk:** The probability or magnitude of harm or discomfort is greater than ordinarily encountered in daily life or during routine physical/psychological exams.
- **Vulnerable Populations:** Groups with diminished autonomy or increased susceptibility to coercion, including children, pregnant women, prisoners, refugees, cognitively impaired persons, or economically dependent populations.
- **Standard Review Workflow:** A structured sequence of steps followed by RNEC in receiving, processing, reviewing, deciding on, and communicating outcomes of research protocols.
- **Primary Reviewer(s):** Designated RNEC member(s) assigned to critically evaluate the scientific, ethical, and regulatory aspects of a study.

1. Purpose

This SOP describes procedures for RNEC Full Committee Ethical Review of research protocols that involve more than minimal risk, vulnerable populations, complex designs, or other circumstances requiring deliberation by the convened Rwanda National Research Ethics Committee (RNEC).

The purpose is to ensure protection of research participants and maintenance of scientific and ethical standards prior to study initiation and throughout conduct.

2. Scope

This SOP applies to:

- New protocols' submission requiring full committee review
- Major amendments and revised documents
- Resubmissions or responses to RNEC major modification queries
- Studies involving vulnerable populations
- Interventional studies
- Protocols referred from expedited review
- Any research not qualifying for expedited procedures

This SOP applies to RNEC members, Chairperson, Secretariat, and Principal Investigators (PIs).

3. Required Submission Documents

PIs must submit:

- Completed RNEC submission form
- Full protocol (View RNEC Protocol Template)
- Informed consent documents
- Recruitment materials
- Data collection tools
- Investigator CVs (View RNEC CV Template)
- Site authorizations (for Clinical Trials)
- Study Budget (if applicable)
- Insurance or indemnity (if applicable)

Incomplete submissions shall not be scheduled.

4. Responsibilities

- (1) Principal Investigator (PI) shall:
 - Submit complete protocol application package
 - Respond to RNEC queries
 - Attend RNEC meeting when invited
 - Implement only RNEC-approved protocols
 - Provide timely revisions and maintain compliance
- (2) RNEC Secretariat shall:
 - Receive and log submissions, and conduct administrative screening for completeness
 - Prepare meeting agenda and distribute materials to members
 - Record minutes, communicate decisions and maintain records
- (3) RNEC Chairperson shall:
 - Determine review pathway, assigns reviewers and manages conflicts of interest
 - Preside over meetings and ensure quorum
 - Facilitate discussion and call for votes
 - Ensures impartiality and regulatory compliance
 - Endorse decisions
- (4) RNEC Members shall:
 - Conduct detailed scientific and ethical review of assigned protocols
 - Declare conflicts of interest and maintain confidentiality
 - Participate in discussion, deliberations, decisions recommendation and voting

5. Procedures

Step 1. Submission and Administrative Screening

- PI submits protocol package via RNEC digital portal at least **15 working days** before scheduled meeting.
- Secretariat screens for completeness within **5 working days**.
- Secretariat verifies:
 - Completeness of submission
 - Correct document versions
 - Signatures and required institutional approvals
 - Payment of review fees (if applicable)
 - Eligibility for type of review (full board or expedited)
- If incomplete → Returned to investigator
- If complete → category of review and logged.

Step 2. Scheduling for RNEC Review Meeting

- Eligible protocols placed on agenda
- Materials circulated to members at least 10 working days prior to meeting

Step 3. Primary Reviewer Assignment

- Chairperson appoints primary and secondary reviewers at least 2 reviewers.
- Additional scientific or subject-matter experts may be invited (if needed)
- Conflict-of-interest is checked
- Secretariat compiles the agenda and distributes protocols and supporting documents to members at least **10 working days** before meeting.
- Reviewers receive all documents and timelines.

Step 4. Convened RNEC Meeting

- Reviewers prepare written comments and submit to secretariat at least **2 days** before the meeting
- Meeting requirements are: quorum confirmed, conflicts of interest declared, and PI invited if clarification is needed.
- Primary reviewer presents protocol assessment findings.
- Discussion covers: scientific merit, risk-benefit balance, participant selection, consent process, confidentiality and data protection, community considerations, and regulatory compliance.
- Secretariat compiles the minutes
- Members with COI recuse themselves from discussion and voting.

Step 5. Decision Making

- Decisions is reached by majority vote of members present, excluding members with COI.
- Possible outcomes:
 - Approve
 - Approve with minor modifications
 - Require major revisions
 - Disapprove (Reasons documented)

Step 6. Documentation of Minutes

- Secretariat records attendance, quorum, summary of discussion, vote outcome and required modifications.
- Secretariat prepares meeting minutes and records decisions.

Step 7. Communication of Decision

- Written decision issued to PI within **7 working days**.
- Secretariat drafts decision letters including:
 - Approval status
 - Required revisions and comments
 - Deadlines for investigator response
 - Validity period
 - Conditions of approval
 - Reporting obligations
- Chairperson reviews and endorses the letter.
- Letters sent via RNEC digital platform and archived.

Step 8. PI Response to Conditions

- PI submits revised documents, including
 - Revised protocol
 - Response-to-comments matrix
 - Updated consent forms or data tools
- Secretariat performs completeness check ➔ assigns back to reviewers.
- Reviewers and Chairperson confirms compliance.

Step 9. Final Approval

- Approval letter issued after conditions satisfied.
- Possible outcomes:
 - Approved
 - Require further revisions
 - Disapproved (Reasons documented)

Step 10. Archiving

- All documents must be securely stored and retained for at least **10 years**.
- Secretariat must maintain:
 - Submission logs
 - Reviewer assignment logs
 - Protocols and all versions of submitted documents
 - Review comments and forms
 - Meeting minutes and decisions
 - Decision letters and communications
 - Investigator responses

6. Criteria for Full Committee Review

Protocols requiring full review include:

- Interventional studies
- Clinical trials
- Increased risk research
- Vulnerable populations
- Sensitive topics
- Genetic research

- Research including AI Algorithms
- International data transfer

7. Conflict of Interest Management

- Members with conflict declare interest, leave room during discussion, and do not vote.
- Conflict of interests are documented in minutes.

8. Timelines summary

Steps	Timeline
Administrative screening	Within 7 working days after submission
Minor amendments	Within 15 working days after submission
Major amendments	Next RNEC meeting

9. Compliance

- Non-compliance may result in suspension, termination and/or institutional notification.
- No protocol involving greater than minimal risk may be approved outside a Full Board Review.
- All decisions must be documented and archived in RNEC records.

10. Quality Assurance

RNEC shall:

- Conduct timely and fair reviews, and internal audits
- Follow a standardized workflow for all submissions and monitor timelines
- Ensure scientific validity, ethical soundness, and regulatory compliance
- Maintain full documentation for each review step
- Communicate decisions promptly and professionally
- Review SOP every 3-5 years
- Train Investigators, staff and reviewers

11. 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](#))

12. Revision History

Version	Date	Summary of changes
1.0	11-05-2026	First RNEC SOP for Standard Full Committee Review of Research Protocols.