RNEC

REV-01 **Version number (2.0)** **Effective date (01 Jun 2026)**

Submission of Research Protocol to RNEC

Definitions

- **Protocol**: A written description of a research project, including objectives, methods, ethical considerations, consent, data collection tools, data management and analysis plan, and safety monitoring.
- **Principal Investigator (PI)**: The individual responsible and qualified for the preparation, conduct, and reporting of a research study.
- **Submission package**: All documents required by RNEC for review (protocol, consent forms, recruitment materials, questionnaires, etc.) as listed in the submission form.
- **Minimal risk**: The probability and magnitude of harm or discomfort not greater than those ordinarily encountered in daily life.
- **Exempt/ Expedited/ Full review**: Levels of RNEC review depending on risk, population, procedures.

1. Purpose

To provide investigators and study teams with a standard, stepwise process for preparing and submitting a research protocol involving human participants to the RNEC, ensuring complete documentation, ethical review, regulatory compliance, and timely decision-making.

2. Scope

This SOP applies to all new research protocols involving human participants (including and not limited to clinical, biomedical, epidemiological, social, behavioural, health systems, environmental, and traditional medicine studies) conducted under the auspices of the institution and requiring RNEC review. Covers initial submission for full review, exempt, expedited, accelerated, and emergency review. However, it does not cover amendments and continuing review (renewals).

3. Responsibilities

- **Principal Investigator (PI) or Co-Principal Investigator (Co-PI)**: Prepare the study protocol and all required documents, complete the RNEC submission form, pay application fees, ensure accuracy, and submit before deadlines.
- **Co-Investigators/ Research Staff**: Assist in documents' preparation, ensure all members complete required training (e.g., human-subjects protection), and sign relevant forms.
- **RNEC Secretariat**: Oversee submission requirements, receive submissions, conduct initial completeness check (pre-review), acknowledge submission, allocate to reviewers, convene the meeting (if full board), communicate decision.
- **RNEC Chairperson**: Issues assignments to reviewers and convenes board and expedited review meetings.
- **RNEC Members**: Declare Conflict of Interests (CoIs), provide scientific and ethical review, deliberate, and make a decision on the applications.

4. Procedures and Steps for Submission

Step 1. Preparation of Protocol and Documents

- Draft the study protocol including background & justification; objectives (primary/secondary); study design; population and sample size; inclusion and exclusion criteria; recruitment and consent process; procedures/interventions; data collection instruments; data management and analysis plan; monitoring of safety (if applicable); ethical considerations (risks and benefits, confidentiality, vulnerable populations, insurance and compensations).
- Prepare informed consent and assent forms (in appropriate language for participants, and in En-

glish) including all required elements (purpose, procedures, risks, benefits, voluntary participation, withdrawal, confidentiality, contact information).
- Prepare recruitment materials (flyers, ads, scripts) if any.
- Prepare data collection instruments (Case Report Form (CRF), questionnaires, interview guides, surveys instruments).
- Prepare any additional required forms: e.g., conflict of interest disclosures, training certificates (human-subjects protection), site/ investigator CVs, funding/grant info, data safety monitoring plan (if applicable), instrument translations.
- Ensure forms are signed where required (PI, co-investigators).
- Check that all documents adhere to RNECs formatting, versioning (version number and date), and Kinyarwanda and other languages requirements.
- Ensure compliance with national and international guidelines.
- The calendar for RNEC meetings is a displayed on the RNEC website (View Calendar).

Step 2. Submission Package & Forms to RNEC

- Complete the RNEC application form and make sure to select correct protocol type: Clinical or Non-Clinical Trial (View Calendar).
- Pay the applicable RNEC submission fees.
- Assemble the submission package: protocol, consent/assent, instruments, recruitment materials, investigator CVs, training certificates, budget and funding information, the proof of payment, as specified in the checklist.
- Submit the package to RNEC submission platform before the submission deadline (Access Rhinno)
- Receive acknowledgment of submission from RNEC office (log number, date, tracking).
- Incomplete applications returned for correction.

Step 3. RNEC Pre-Review (Completeness Check)

- The RNEC Secretariat conducts a pre-review and completeness check to ensure all required documents are included, forms are correctly completed, signatures are present, and training is current, using the RNEC Submission form Checklist
- If incomplete: RNEC Secretariat returns to PI with list of missing items and resubmission timeline.
- Only complete submissions will be placed on the review agenda.

Step 4. RNEC Review Process & Decision

- Based on risk level, the RNEC will either: exempt review, expedited review, or full board review.
- For full board: Regular meeting held, quorum present, primary & secondary reviewer(s) assigned.
- RNEC evaluates the submission against criteria (e.g., risks minimised, risks reasonable relative to benefits, equitable subject selection, informed consent adequate, data confidentiality, etc.)
- The PI may be invited to attend the meeting in person or virtually to answer questions.
- After review the RNEC takes a decision: Approve, Approve with minor modifications, Major modifications required, or Disapprove.

Step 5. Notification of Decision

- RNEC Secretariat issues a formal decision letter to the PI: either approval (with expiry date), conditional approval (pending modifications), or disapproval (with reasons).
- If modifications are required: PI responds with revised documents, noted changes, and resubmission within specified timeline of **30 days**.
- Research may commence only after RNEC approval letter has been received.
- The RNEC office retains all documents (protocol, consent, correspondence) in compliance with records-retention policy and Data Protection Law.

Step 6. Post-Approval Obligations

- Any amendments or changes to the protocol (e.g., revision of consent form, recruitment procedures, study staff) must be submitted to the RNEC for review before their implementation
- Continuing review and renewal (if required) should be requested before expiration of the approval
- Reporting of unanticipated problems, adverse events, non-compliance to the RNEC per regulations
- Study closure: Submission of final report and indication of disposition of data/ specimens, publication intentions

5. Timelines (Indicative)

Steps	Deadline
Submission of complete package	At least 15 working days before next RNEC meeting
RNEC Pre-Review and screening	Within 5 working days after submission of complete package
Response to RNEC queries	Within 5 working days of request
Notification of RNEC Decision	Within 5 working days after RNEC Board meeting
PI to submit required modification	Within 30 days after RNEC Board meeting
Expiry of RNEC approval (if continuing review required)	At approval letter date + 12 months (or as specified)
Submission of amendment	Prior to implementation of change
Study closure report	Within 30 days of end of study

6. Required Documentation and Formatting

The following documents are the core documents that each applicant must submit:

A. Required Documentation for All Protocols

(1) Completed and signed RNEC submission form
(2) Full Study Protocol (version-controlled, dated and signed)
(3) English Informed Consent/Assent Forms
(4) Kinyarwanda Informed Consent/Assent Forms
(5) English Data Collection Tools (ie., CRFs, Questionnaires, Interview guides, etc.)
(6) Kinyarwanda Data Collection Tools (ie., CRFs, Questionnaires, Interview guides, etc.)
(7) CVs of all Investigators and study team
(8) Valid certificates of Ethics/Human-subjects protection training (PI and all research team)
(9) Proof-of-payment of review fees according to review type
(10) Conflict of Interest Disclosure

B. Additional Documentation for Clinical Trial Protocols

The submission package for clinical trial protocols must include the following additional documents:

(11) Investigator Brochure / Product Information (if applicable).
(12) Clinical Trial Agreement between sponsor and clinical research site
(13) Recruitment Materials (ads, posters, scripts, social media messages)
(14) Investigators valid GCP Training Certificates (not more than 2 years of PI and study team)
(15) Insurance/Indemnity Certificate (if applicable)
(16) Funding Statement/ grant information (if applicable)
(17) Data safety monitoring plan (if applicable)
(18) Data Safety Monitoring Board charter (if applicable)
(19) Material Transfer Agreement, if biological samples to be sent to third party laboratory outside Rwanda
(20) Summary of previous study (i.e. Pre-clinical, Phase 1 & Phase II studies, etc... where applicable)

C. Additional requirements for student protocols

The following are the additional requirements to the core requirements for student protocols to be submitted as research projects (i.e. MSc or PhD thesis):

(11) Recommendation letter from the student's academic institution, confirming the student enrollment into the academic program at institution and endorsing the student' research proposal.
(12) Copy of student's identification card from academic institution
(13) Local supervisor/mentor covering letter and CV for students registered with Universities outside Rwanda

D. Outline and Formatting of the Study Protocol

The Study Protocol should align with the RNEC recommended template for research protocol Documents must be submitted in the following formatting:

- Font: Any font as by PI preference (Times New Roman, Arial, etc), 10-12 pt.
- Line spacing: single 1.5.
- Pagination with version and date on footer.
- All files in searchable PDF or Microsoft Word.
- Line numbers in the left margin

7. Submission Portal and Method

Applicants must submit research projects to RNEC through:

- Submissions made via the RNEC Online Ethics Review Portal (Access Rhinno).
- Each submission receives a Reference Number for follow-up.
- Resubmissions and Amendments linked with the initial Protocol Reference Number.
- Clinical trials should concurrently be submitted to Rwanda FDA

8. Statement on SOP Adherence

No study may commence without formal RNEC written approval. Resubmission deadlines: within 30 days if conditional approval. Approved protocols are valid for 1 year, (12 months), renewable via continuing review.

9. 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)

10. Revision History

Version	Date	Summary of changes
1.0	**11-05-2009**	(a) First RNEC SOP
2.0	**09-05-2026**	(a) Added local regulatory references (b) Revised to include electronic submission process