RNEC

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

Annual Renewal and Continuing Review of Approved Research

Definitions

- **Annual Renewal/ Continuing Review**: A periodic ethical review of an ongoing study to determine whether approval may continue.
- **Approval Period**: The time during which the study is authorised to proceed, usually 12 months.
- **Progress Report**: A structured report submitted by investigators summarizing study status, enrolment, deviations, and safety issues.
- **Active Protocol**: A study that has received RNEC approval and is currently ongoing.
- **Lapse of Approval**: Expiration of approval when the PI fails to submit a continuing review report on time.

1. Purpose

This SOP describes the procedures for Annual Renewal (Continuing Review) of approved research protocols to ensure ongoing protection of research participants and continued scientific and ethical acceptability of the study throughout its lifecycle. Annual renewal confirms that:

- Risks remain acceptable
- The study is being conducted according to the approved protocol
- Participant protections are maintained
- The risk-benefit balance remains favourable

2. Scope

This SOP applies to:

- All research protocols requiring annual ethical approval
- Minimal-risk and greater-than-minimal-risk studies
- Studies reviewed under full committee or expedited procedures
- Early reviews if significant new information emerges (e.g., safety concerns).

It applies to Principal Investigators (PIs), REC Secretariat, Chairperson, and RNEC members.

3. Responsibilities

(1) Principal Investigator (PI):

- Submits continuing review request with supporting documents at least **30 days** before approval expiry.
- Submits Progress Report including recruitment status, adverse events, deviations and violations, and amendments (if any)
- Pays continuing review fees and submit proof of payment.
- Ensure informed consent compliance and study remains compliant with RNEC requirements
- Maintain data protection
- Cease study activities if approval lapses
- Provide monitoring and safety oversight reports
- Halt study activities if approval lapses

(2) RNEC Secretariat:

- Track protocol approval expiry dates and lapses
- Notify investigators of continuing review deadlines
- Receive renewal submissions and conduct administrative pre-review for completeness
- Assign submissions for review
- Ensure timely review of submissions
- Communicate RNEC decisions to PIs

- Maintain documentation and records of all continuing review actions

(3) RNEC Chairperson:

- Determines review pathway (expedited or full committee)
- Assigns reviewer(s)
- Endorses renewal decisions
- Authorizes suspension or termination if required
- Ensures timely review and decision.

(4) Designated Reviewer/ RNEC Members:

- Conduct ethical and scientific assessment of continuing review reports.
- Review safety information and compliance
- Complete Annual Renewal Assessment Form
- Recommend outcome whether renewal, conditional renewal, or suspension

4. Procedures

The following section provide step by step procedures which are summarized the procedure flowchart (**??**).

Step 1. Reminder and Submission

- Secretariat sends renewal reminder **60 days** before protocol approval expiry.
- PI submits renewal package at least **30 days** days before protocol approval expiry. If approval lapses, the protocol is considered suspended, and no further research activity may occur until renewal is granted.
- All documents submitted via the RNEC Online Platform.

Step 2. Administrative Screening

- Secretariat Secretariat verifies completeness of all required documents, forms and versions dated, and acknowledges receipt within **5 working days**.
- Incomplete applications are returned.

Step 3. Determine Level of Review

Chairperson decides:

- Expedited renewal (minimal-risk studies with no issues)
- Full committee renewal (greater risk or concerns)

Step 4. Ethical and Scientific Review

- Chairperson assigns primary reviewer(s).
- Reviewer evaluates the study progress, recruitment status, adverse events, protocol deviations, consent compliance, data protection, benefit–risk balance, and scientific validity.
- Reviewer completes Annual Renewal Assessment Form.
- Board deliberation (or expedited if minimal risk and no major changes).

Step 5. Decision

Possible outcomes:

- Approved
- Renew with conditions
- Require amendment before renewal
- Suspend study (Reasons)
- Terminate study (Reasons)

Chairperson endorses decision.

Step 6. Communication of Decision

- Secretariat issues written decision including approval period, conditions (if any), and reporting obligations within **7 working days**.
- Renewal approvals are valid for **3 - 12 months** depending on the risk assessment.
- PIs are reminded of the next renewal deadline.

Step 7. Handling Lapses in Approval

If renewal is not granted before expiry:

- All study activities must stop immediately
- PI must notify participants if necessary
- RNEC determines corrective actions

Step 8. Documentation and Archiving

- Secretariat archives renewal submission, reviewer assessments and decision letters
- Records retained for minimum **10 years**.

5. Criteria For Renewal Approval

Approval may be granted only if:

- Risks remain acceptable
- No serious non-compliance
- Consent obtained appropriately
- Confidentiality maintained
- Study remains scientifically valid
- Adverse events addressed

6. Required Documents

PIs must submit:

- Continuing Review/ Annual Renewal Request Form.
- Progress Report, including:
  - Recruitment status summary (number screened, enrolled, withdrawn, completed).
  - Summary of amendments since initial approval.
  - Safety updates (adverse events reports, SAEs, DSMB reports if applicable).
  - Summary of protocol deviations/violations.
  - Status of data collection and analysis.
  - Publications or preliminary results (if available)
- Current protocol and informed consent forms
- Updated study documents, if amended (protocol, consent forms, investigator brochures).
- Updated risk-benefit assessment
- Any changes in investigators or study site
- Declaration of COIs (if new ones exist).
- Evidence of continued insurance coverage (for clinical trials).

Incomplete submissions shall be returned.

7. Timelines (Indicative)

Steps	Timeline
Expedited	Within 15 working days after submission
Full board review	Next RNEC meeting

8. Compliance

- Non-compliance may result in conditional approval, suspension, termination, and/or institutional notification
- Failure to submit renewal requests on time will result in automatic suspension of the study.
- Protocols with continuing risk concerns may be subject to more frequent reviews (e.g., every 3 - 6 months).

9. Quality Assurance

RNEC shall:

- Audit ongoing studies
- Review renewal outcomes annually
- Review SOP every 3-5 years
- Train investigators, staff and reviewers

10. 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)

11. Revision History

Version	Date	Summary of changes
1.0	**11-05-2009**	First RNEC SOP for Standard Review Workflow