RNEC

REV-04 **Version number (1.0)** **Effective date (01 Jan 2026)**

Expedited Ethical Review of Research Protocols

Definitions

- **Expedited review**: A review procedure in which one or more designated reviewers evaluate eligible protocols on behalf of the RNEC without convening a full committee meeting.
- **Minimal risk**: The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during routine physical or psychological examinations.
- **Minor amendment**: A protocol change that does not significantly affect participant risk–benefit balance, scientific validity, or informed consent.
- **Designated reviewer**: A qualified RNEC member appointed by the Chairperson to conduct expedited review.

1. Purpose

To describe the procedures for conducting expedited ethical review of research protocols that involve no more than minimal risk to participants and meet predefined eligibility criteria. Expedited review provides a streamlined mechanism for timely review while maintaining full ethical standards for participant protection.

2. Scope

This SOP applies to:

- New protocols involving minimal risk (e.g., surveys, non-sensitive behavioral studies)
- Administrative changes not affecting risk
- Minor amendments to previously approved protocols
- Continuing review (annual renewal) of minimal-risk studies with no major changes
- Cases requiring review outside regular full board meetings, provided they meet expedited criteria

This SOP applies to all RNEC members, Chairpersons, designated reviewers, and Secretariat staff

3. Responsibilities

(1) Principal Investigator (PI):

Submits expedited review request with supporting justification and required documents via RNEC digital submission platform

(2) RNEC Secretariat:

- Receive submissions
- Conduct administrative screening of submission for completeness
- Log submissions
- Forward to Chairperson/designated reviewer
- Tracks timelines
- Communicate decision to PI
- Maintains records of expedited reviews in RNEC archives

(3) RNEC Chairperson/Designated Reviewer:

- Confirms eligibility for expedited review
- Assigns designated reviewer(s)
- Reviews final recommendations
- Issues approval or referral decisions

(4) Designated Reviewer(s):

- Conduct ethical and scientific assessment
- Complete Reviewer Assessment Form
- Provide written recommendations of the outcome
- Request clarifications if needed

4. Eligibility Criteria for Expedited Ethical Review

A submission may qualify for expedited review only if:

(1) The research involves no more than minimal risk
(2) It fits recognized expedited categories, including:
   - Secondary use of existing anonymised data
   - Non-invasive surveys or interviews
   - Observational studies
   - Minor protocol amendments
   - Continuing review of minimal-risk studies
(3) No new vulnerable populations are introduced
(4) No invasive procedures are proposed
(5) Adequate informed consent and confidentiality safeguards are in place

Protocols not clearly meeting these criteria must be referred to full committee review. Detailed eligibility criteria for emergency ethical review is provided in Appendix A from 5 of this SOP.

5. Procedures

Step 1. Submission

- PI submits the protocol request with required documents via the RNEC submission platform
- Secretariat screens within 3 working days.

Step 2. Administrative Screening

The Secretariat:

Receive the protocol, amendment or renewal submission Verifies completeness (application form, protocol, consent documents, data collection tools, amendment summary if applicable), version control and required documents. Incomplete applications are returned.

Log submission and forward to Chairperson

Secretariat acknowledges receipt within **3 working days**.

Step 3. Eligibility Determination

Chairperson assesses whether the risk is minimal and that submission fits expedited category

If not eligible, ➟ submission is redirected to Full Board Review

Step 4. Assignment of Reviewer

Chairperson assigns at least one qualified reviewer with relevant expertise and no conflict of interest

Step 5. Ethical and Scientific Review

- One or more designated reviewers conduct the review.
- Reviewer assesses the scientific validity, the risk–benefit balance, participant selection, informed consent, data protection, privacy and confidentiality protections, and regulatory compliance.
- Reviewer completes Expedited Review Assessment Form and submits recommendation:
  - Approve
  - Approve with conditions
  - Refer to full committee
  - Disapprove
- Review completed within **14 days**.

Step 6. Decision by Chairperson

- Chairperson reviews recommendation and issues approval, requests minor modifications, or refers to full board committee.
- Chairperson documents the decision.

Step 7. Communication of Decision

Secretariat communicates the decision to PI within **10 working days**.

Approval letters must include:

- Protocol title and ID
- Approval period and conditions (if any)
- Reporting obligations

Step 8. Documentation and Archiving

- Secretariat files application, reviewer assessment, decision letter, and final approved documents.
- Records retained for minimum **10 years**.

6. Timelines summary

Steps	Timeline
Administrative screening	Within 5 working days
Reviewer assessment	Within 10 working days
Decision communication	Within 5 working days
Total target turnaround	Within 20 working days

7. Required Documents

- Expedited review request form.
- Study protocol and submission form (if initial submission)
- Protocol, summary of changes and amendment request form (if minor amendment)
- Protocol, progress report and request form (if annual renewal)
- Informed consent forms (if applicable)
- Data collection tools/questionnaires
- Investigator CVs (if not already submitted)

8. Reporting Requirements

- Investigators must report adverse events, protocol deviations, amendments and annual progress.
- Failure may result in suspension

9. Compliance

- Non-compliance may result in suspension, termination, and institutional notification.
- Expedited review is reserved strictly for minimal-risk research or minor amendments. Decisions must be ratified and documented in the minutes of the next Full Board meeting.

10. Quality Assurance

RNEC shall:

- Periodically audit expedited decisions
- Review SOP every 3-5 years
- Train 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 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)

12. Revision History

Version	Date	Summary of changes
1.0	**11-05-2026**	First RNEC SOP for Expedited Ethical Review of Research Protocols.

Appendix A. Eligibility Criteria for Expedited Ethical Review

A study may qualify for expedited review **only if ALL core criteria are met**.

A. Core Eligibility Criteria (Mandatory)

(1) **The research involves No more than minimal risk**
***Minimal risk means**: The probability and magnitude of harm or discomfort anticipated are not greater than those ordinarily encountered in daily life or during routine physical or psychological examinations.*
Examples of minimal risk:

- *Review of existing medical records (with safeguards)*
- *Non-invasive questionnaires*
- *Observational studies*
- *Interviews on non-sensitive topics*
- *Secondary analysis of de-identified data*
- *Minor protocol amendments not affecting risk*

Examples of Not minimal risk:

- *Any invasive procedures*
- *Any intervention (drugs, vaccines, biologics, devices, AI algorithms)*
- *Collection of biological specimens beyond routine care*
- *Sensitive behavioural research topics*
- *Any procedure that could cause more than temporary discomfort*

(2) **No vulnerable populations are involved**
Expedited review will not include studies involving vulnerable populations such as children, pregnant women, prisoners, refugees, cognitively impaired individuals, or economically or socially dependent populations. However, exceptions will be considered if the risk is minimal with strong justification and additional protections are well documented

(3) **Adequate informed consent and confidentiality safeguards are in place**
An expedited review should consider only standard written consent. However, expedited review may allow verbal consent or a waiver of consent only if the study includes minimal risk, the rights and welfare are not adversely affected, or it is impracticable to obtain consent (for a waiver).

(4) **Adequate privacy and confidentiality safeguards**
The study must demonstrate secure storage, limited access to study materials and data, de-identification of participants' data, and password protection and clear data retention policies. Weak data protection will not be considered for expedited review.

(5) **If risk is unclear, always refer to the full board assessment**.

B. Examples of studies that fit expedited review

Typical categories of studies that fit expedited review include:

(1) **Secondary use of existing data or specimens**

- Secondary analysis of fully anonymised or coded datasets and publicly accessible
- No new collection included
- Confidentiality protections in place and documented
- Collection of small biological samples already obtained for clinical care

(2) **Non-invasive data collection on non-sensitive topics including**:

- Chart reviews/ medical record abstraction by authorised health professional
- Surveys and interviews (non-sensitive interviews or questionnaires
- Focus groups (non-sensitive topics)
- Educational research by authorised educators
- Quality improvement with research intent (minimal risk)
- Observational research in public settings such as observation of public behaviour

(3) **Minor changes to previously approved research such as**:

- Recruitment wording
- Staff changes
- Clarification of procedures
- Small sample size adjustments
- Extension of study period

(4) **Continuing review/ annual renewal of minimal-risk studies**
Expedited review may be considered for continuing review of minimal-risk studies with no adverse events, no protocol violations, and no increase in risk.

C. Explicit exclusion criteria (must go to Full Board Committee)

(1) Clinical trials: drugs, vaccines, devices, biologics or artificial intelligence (AI algorithms)
(2) Invasive procedures of any king
(3) Biological specimen collection
(4) Genetic testing with identifiers
(5) Audio/video recording of identifiable persons
(6) Sensitive research topics (sexual behaviour, violence or conflict, illegal activities)
(7) Vulnerable populations
(8) Long questionnaires targeting large number of indicators
(9) Collection or storage of identifiable data
(10) Transfer of identifiable data (International or third party)
(11) Major protocol amendments or increased risk amendments:
Any change that may affect participant safety, risk–benefit assessment, scientific validity, study design, consent or participant understanding, eligibility or population, data identifiability, investigator or site qualifications
(12) Annual renewal of more than minimal-risk studies
(13) Any other situation that may increase the risks for participants