RNEC

REV-07 **Version number (1.0)** **Effective date (01 Jun 2026)**

Accelerated Ethical Review for Time-Sensitive Research Protocols

Definitions

- **Accelerated Ethical Review**: A compressed but full ethical review conducted outside routine timelines on a shortened timeline, using modified workflows, for protocols requiring urgent review for scientific, operational, regulatory, or feasibility reasons, but maintaining all ethical and regulatory requirements.
- **Full Committee Review**: Standard RNEC review conducted during scheduled meetings according to normal timelines.
- **Expedited Review**: Review of minimal-risk research by designated reviewers without full committee deliberation.
- **Minimal Risk**: Risk not greater than ordinarily encountered in daily life or routine medical care.
- **Time-Sensitive Research**: A protocol requiring rapid review because delays would significantly affect scientific validity, participant safety, seasonal implementation, funding opportunities, operational feasibility, regulatory deadlines, or data integrity.
- **Not Eligible for Expedited Review**: Protocols involving more than minimal risk, investigational products, vulnerable populations, or complex interventions.

1. Purpose

This SOP establishes procedures for an Accelerated Ethical Review pathway for research protocols that:

- Are not eligible for expedited review
- Do not qualify for emergency outbreak review
- Require rapid review due to time-sensitive scientific, operational, funding, regulatory, or participant safety considerations

The SOP ensures timely ethical review while maintaining full ethical and scientific standards.

2. Scope

This SOP applies to research that:

- Require review faster than routine full committee timelines
- Involve greater than minimal risk or issues requiring full REC consideration
- Do not arise from declared public health emergencies or outbreaks

Applicable studies may include:

- Time-sensitive clinical trials
- Seasonal or campaign-based studies
- Grant-dependent projects with strict timelines
- Rapid implementation research
- Multicountry synchronized studies
- Time-sensitive surveillance systems
- Policy-linked evaluations
- Studies with urgent participant safety implications
- Technology validation studies with operational deadlines

3. Responsibilities

(1) Principal Investigator (PI) shall:

- Submitting emergency ethical review request with supporting justification and required documents.
- Respond rapidly to queries and report safety issues promptly
- Maintaining protocol compliance

(2) RNEC Secretariat:
- Receive submissions and screen completeness
- Coordinate rapid communication
- Maintain records and track timelines

(3) RNEC Chairperson shall:
- Declare activation of emergency review procedures
- Assign reviewers and convene emergency meetings
- Issue emergency decisions

(4) Reviewers shall:
- Timely review and assess ethical acceptability
- Declaring conflicts of interest and maintaining confidentiality

4. Required Documents

The investigator shall submit:
- Accelerated review request form
- Full research protocol and summary
- Consent documents
- Investigator brochures (if applicable)
- Recruitment materials
- Data collection tools
- Statistical analysis plan
- DSMB charter (if applicable)
- Funding documentation
- Investigators CV
- Justification for accelerated review

5. Eligibility Criteria for Accelerated Ethical Review

A protocol may qualify for Accelerated Ethical Review if ALL the following apply:

(1) **The study requires full committee review**
The protocol is not minimal risk, includes vulnerable populations, involves interventions requiring full RNEC oversight, or raises significant ethical issues.

(2) **The study does not qualify for expedited review**
Studies such as clinical interventions, sensitive participant populations, invasive procedures, complex consent issues, or high privacy and confidentiality risks.

(3) **The study does not qualify for emergency outbreak review**
The protocol is unrelated to declared outbreaks or public health emergencies and does not require emergency public health response activation.

(4) **Delays would significantly affect:**
Scientific validity, participant safety, public health relevance, funding or regulatory deadlines, or operational feasibility.

Detailed eligibility criteria for emergency ethical review is provided in Appendix A from 6 of this SOP.

6. Research Commonly Eligible for Accelerated Review

Eligible studies may include:
(1) Clinical trials with urgent sponsor timelines
(2) Multicountry harmonized protocols
(3) Time-sensitive implementation studies
(4) Maternal/newborn seasonal surveillance
(5) AI validation studies
(6) Vaccine implementation studies outside outbreaks
(7) Educational calendar-based studies
(8) Rapid amendments affecting participant safety
(9) Registry studies with urgent policy implications

A. Research Not Eligible

The following are generally not eligible:

(1) Poorly prepared protocols
(2) Delays caused solely by investigator lateness
(3) Studies lacking scientific merit
(4) Studies requiring emergency outbreak procedures
(5) Routine low-priority academic submissions

7. Procedures

Step 1. Authority to Approve Accelerated Review

The RNEC Chairperson may authorize Accelerated Ethical Review upon determining eligibility.
The Chairperson may consult RNEC Vice Chairperson, Secretariat or Senior reviewers.

Step 2. Submission

PI submits accelerated review request with justification.
PI submits full research protocol and required documents via the RNEC submission platform after the Chairperson has authorised Accelerated Review.

Step 3. Administrative Screening

The Secretariat shall screen submissions within **3 working days** for:

- Completeness
- Eligibility for accelerated review
- Required documentation
- Administrative compliance

Incomplete submissions may be returned immediately.

Step 4. Reviewer Assignment

The Chairperson shall assign:

- Primary scientific reviewer
- Primary ethical reviewer
- Additional reviewers as needed

Step 5. Mode of Review

Reviews may occur through:

- Extraordinary RNEC meetings
- Virtual meetings or hybrid meetings
- Special accelerated session

Step 6. Quorum Requirements

Accelerated review meetings shall meet standard quorum requirements including:

- Scientific reviewer and Non-scientific reviewer
- Lay person or community representative where feasible

Step 7. Review Criteria and Considerations

Reviewers shall assess:

(1) **Scientific Validity**
Clear objectives, appropriate methodology, statistical rigor, feasibility, and adequate sample size.

(2) **Risk-Benefit Assessment**
Risks minimized, benefits justify risks, and safety monitoring adequate.

(3) **Participant Selection**
Equitable recruitment, protection of vulnerable populations, and fair inclusion or exclusion criteria .

(4) **Informed Consent**
Adequate disclosure, comprehension, voluntariness, and appropriate documentation.

(5) **Privacy and Confidentiality**
Data security and protection measures, anonymisation, storage procedures, and data sharing controls.

(6) **Community and Cultural Considerations**
Cultural sensitivity, stakeholder engagement, respect for local norms.

(7) **Safety Monitoring**
AE/SAE reporting, DSMB oversight, and interim analyses.

Step 8. Decision Categories

Possible outcome:

- Approved (Protocol approved without modifications).
- Approved with conditions (Minor modifications required before implementation).
- Deferred Decision (Major revisions required).
- Disapproved (Protocol ethically unacceptable).

Step 9. Communication of Decision

- Secretariat issues written decision to PI within **3 days**, including the approval status, conditions (if any), reasons for decisions, required modifications (if any), and and investigator responsibilities.
- Decisions is communicated electronically via RNEC digital platform or using official email address.

Step 10. Continuing Review

Accelerated approval does not alter:

- Continuing review obligations
- Safety reporting requirements
- Protocol deviation reporting
- Annual renewal requirements

Step 11. Protocol Amendments

Urgent amendments affecting participant safety, operational continuity or regulatory compliance, may undergo accelerated amendment review.

Step 12. Safety Reporting

Investigators shall report:

- Serious adverse events (SAEs) or unexpected events
- Protocol violations or data breaches

Fatal or life-threatening SAE should be reported to RNEC within 24 hours.
Other SAEs may be reported within 48 hours.

Step 13. Documentation and Record Keeping

The Secretariat shall maintain:

- Submitted documents
- Reviewer comments
- Meeting minutes and decisions
- Correspondence and safety reports

Records shall remain confidential and securely stored and retained for minimum **10 years**.

8. Timelines (Indicative)

Steps	Timeline
Administrative screening	Within 3 working days
Reviewer assignment	Within 2 working days
Ethical review	Within 48-72 hours
Reviewer assessment	Within 7 working days
Accelerated RNEC meeting	Within 14 working days
Communication of decision	Within 3 working days

9. Confidentiality

RNEC members and reviewers shall:

- Sign confidentiality agreements.
- Protect proprietary and participant information.
- Avoid unauthorized disclosure.

10. Conflict of Interest

Reviewers with conflicts shall declare conflicts, and recuse themselves from review and voting.

11. Compliance

- Accelerated review shall maintain respect for persons, beneficence, non-maleficence, justice, scientific validity, independence of ethical review, transparency and accountability.
- Accelerated timelines shall not reduce ethical rigor.

12. Quality Assurance

RNECshall periodically evaluate:

- Timeliness
- Consistency of decisions
- Compliance with ethical standards
- Quality of accelerated reviews

13. 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)

14. Revision History

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

Appendix A. Detailed Eligibility Criteria for Accelerated Ethical Review

A study may qualify for accelerated ethical review under the following criteria:

A. The Study Requires Full Committee Review

The protocol involves more than minimal risk or raises ethical issues requiring discussion by the convened RNEC. Typically eligible are studies involving:

- Clinical interventions or Invasive procedures
- Vulnerable populations, maternal or newborn interventions
- Sensitive data or complex consent processes
- Genetic research or AI-supported clinical decision systems
- International multisite studies

B. The Study Does NOT Qualify for Emergency/ Outbreak Review

The protocol is not linked to declared outbreaks, epidemics, pandemics , humanitarian emergencies or public health emergency declarations.

C. The Study Is NOT Eligible for Expedited Review

The protocol exceeds minimal-risk criteria defined in expedited review SOP. Usually NOT Expedited are protocols involving:

- Biological specimen collection beyond routine procedures
- Clinical trials or Experimental interventions
- Vulnerable populations with elevated risk
- Sensitive identifiable data
- Psychological distress risks
- Complex longitudinal follow-up

D. Delays Would Significantly Affect Scientific Validity

Routine review timelines could compromise data quality, recruitment feasibility, seasonal relevance, statistical power or scientific integrity. Common situations include:

- Seasonal or time-bound events
  - Rainy season diseases, agricultural cycles, school calendars, or vaccination campaigns
- Short recruitment windows
  - Rare diseases, migratory populations, or short-term service delivery campaigns

E. Delays Would Significantly Affect Participant Safety

Delayed review could expose participants to continued unsafe practices, inferior interventions or unnecessary risks.

F. Delays Would Significantly Affect Public Health Relevance

The study's usefulness for health policy or programming would diminish substantially if delayed.

G. Delays Would Significantly Affect Funding or Regulatory Deadlines

Review delays could jeopardize active grants, contractual obligations, regulatory milestones or international consortium timelines.

H. Delays Would Significantly Affect Operational Feasibility

Delays could compromise access to sites, availability of trained personnel, logistical coordination, equipment deployment, or synchronization with ongoing programmes.

Common Categories Appropriate for Accelerated Review

(1) Multicountry clinical study with synchronized launch
(2) Seasonal malaria surveillance
(3) Urgent safety amendment
(4) National implementation evaluation
(5) AI clinical validation study
(6) School-based adolescent study before school closure

Studies Usually NOT Eligible

(1) Minimal-risk anonymous survey
(2) Delayed student thesis submission
(3) Routine retrospective chart review
(4) Study without clear urgency
(5) Outbreak-related emergency study

Documentation Required from Researchers

Researchers requesting Accelerated Ethical Review should submit:

- Mandatory justification explaining why routine timelines are inadequate, the nature of time sensitivity and consequences of delay.
- Supporting Documentation
  - Funding deadlines and implementation calendars
  - Seasonal epidemiological data
  - Regulatory timelines
  - Operational schedules