RNEC

REV-06 **Version number (1.0)** **Effective date (01 Jun 2026)**

Emergency Ethical Review during Public Health Emergencies

Definitions

- **Emergency ethical review**: A rapid ethical review process conducted during public health emergencies to allow urgent implementation of time-sensitive research.
- **Outbreak**: Occurrence of disease cases exceeding normal expectations in a defined population or area.
- **Public Health Emergency**: An extraordinary event posing public health risk requiring immediate coordinated response.
- **Minimal Risk**: Risk not greater than ordinarily encountered in daily life or routine medical care.
- **Deferred Consent**: Consent obtained after emergency enrolment when prior consent is not feasible.

1. Purpose

This SOP describes the procedures for rapid ethical review of research protocols submitted during infectious disease outbreaks, epidemics, pandemics, or other public health emergencies requiring urgent implementation. The SOP aims to:

- Facilitate timely ethical review without compromising participant protection
- Ensure rapid generation of evidence needed for outbreak response
- Define emergency review pathways, responsibilities, timelines, and documentation requirements
- Maintain compliance with national and international ethical standards

2. Scope

This SOP applies to:

- All outbreak-related research submitted to RNEC.
- Emergency reviews conducted during epidemics, pandemics, humanitarian emergencies, public health crises, or emerging infectious disease outbreaks.

The SOP applies to clinical trials, diagnostic studies, surveillance studies, operational research, behavioural studies, registry studies, and digital health and AI-supported outbreak research.

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:

- Emergency review request form
- Research protocol and summary
- Investigator brochure (if applicable)
- Consent forms
- Recruitment materials
- Data collection tools
- DSMB charter (if applicable)
- Safety monitoring plan
- Community engagement plan
- Data protection plan
- Investigators CV

5. Eligibility Criteria for Emergency Review

A protocol may qualify for emergency review if:

(1) **Public Health Relevance**
The study directly addresses disease prevention, diagnostics, surveillance, treatment, transmission dynamics, infection control or health system response.

(2) **Urgency**
Delay in review would harm outbreak response, delay life-saving interventions, reduce scientific validity or impair public health action.

(3) **Scientific Validity**
The protocol demonstrates clear objectives, appropriate methodology, sound statistical plan, and feasible implementation.

(4) **Risk-Benefit Balance**
Potential benefits justify foreseeable risks.

(5) **Feasibility of Ethical Safeguards**
Adequate provisions exist for consent, confidentiality, safety monitoring and vulnerable population protections.

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

6. Research Eligible for Emergency Review

Eligible studies may include:

(1) Vaccines and Therapeutic trials
(2) Diagnostic accuracy studies
(3) Contact tracing studies
(4) Surveillance systems
(5) Genomic sequencing studies
(6) Behavioural response studies
(7) AI-supported outbreak screening tools
(8) Registry studies
(9) Rapid operational assessments

A. Research Not Eligible

The following generally require routine review:

(1) Non-urgent academic studies
(2) Studies unrelated to outbreak response
(3) Poorly designed studies
(4) Research lacking scientific merit
(5) Projects without immediate public health relevance

7. Procedures

Step 1. Submission

PI alerts the RNEC Chairperson and Secretariat about the potential emergency protocol submission, indicating the date on the following emails: *chair@rnec.rw*, *secretariat@rnec.rw*, and *info@rnec.rw*.

PI submits emergency request with protocol and required documents via the RNEC submission platform

Step 2. Administrative Screening

The Secretariat shall screen submissions within **24 hours** for:

- Completeness
- Relevance to outbreak response
- Qualification for emergency review
- Required supporting documents

Incomplete submissions may be returned immediately.

Step 3. Rapid Review Activation

The RNEC Chairperson may activate emergency review procedures upon:

- Official outbreak declaration
- Government emergency notification
- Institutional emergency determination

Step 4. Mode of Review

Reviews may occur through:

- Virtual meetings, teleconference, or Email circulation
- Ad hoc emergency subcommittees
- Hybrid meetings

Step 5. Quorum Requirements

Emergency review quorum shall be made with at least 5 reviewers including:

- RNEC Chairperson or delegate
- Scientific reviewer
- Non-scientific reviewer
- Lay person or community representative where feasible

Step 6. Review Process and Considerations

Reviewers shall assess:

(1) **Scientific Validity**
Sound methodology, appropriate sample size, feasibility, clear analysis plan.

(2) **Risk-Benefit Assessment**
Clinical risks, public health benefits, risk minimisation measures.

(3) **Informed Consent**
- Feasibility under outbreak conditions
- Alternative consent methods
- Deferred consent justification
- Remote consent procedures

(4) **Vulnerable Populations**
Additional safeguards and fair inclusion or exclusion.

(5) **Privacy and Confidentiality**
Data security, anonymisation, and public health reporting obligations.

(6) **Community Engagement**
Communication strategy, stigma mitigation, and cultural appropriateness.

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

Step 7. Decision Categories

Possible outcome:

- Approved (Protocol approved without modifications).
- Conditional Approval (Minor clarifications required before implementation).
- Deferred Decision (Major concerns requiring substantial revision).

- Disapproved (Protocol ethically unacceptable).

Step 8. 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 9. Continuing Review

Approved studies remain subject to:

- Periodic progress reports
- Safety reporting and protocol deviation reporting
- Interim review where applicable

The REC may suspend studies if risks increase unexpectedly, ethical violations occur, or scientific validity becomes compromised.

Step 10. Protocol Amendments

All amendments shall undergo rapid review before implementation unless necessary to eliminate immediate hazards.

Emergency safety changes may be implemented immediately but must be reported within 48 hours.

Step 11. 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 12. 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 summary

Steps	Timeline
Administrative screening	Within 24 hours
Reviewer assignment	Within 24 hours
Ethical review	Within 48-72 hours
Communication of decision	Within 24 hours after decision
Fatal/life-threatening SAE	within 24 hours after occurrence
Other SAEs: within 72 hours	Within 48 hours after occurrence

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

- Emergency review shall uphold respect for persons, beneficence, non-maleficence, justice, scientific validity, community engagement, transparency, and equity in access and participation
- Emergency conditions shall not justify lowering ethical standards.

12. Quality Assurance

RNECshall periodically evaluate:

- Timeliness of emergency reviews
- Consistency of decisions
- Compliance with ethical standards
- Lessons learned from outbreak responses

13. Revision History

Version	Date	Summary of changes
1.0	**11-05-2026**	First RNEC SOP for Emergency Ethical Review during Disease Outbreaks and Public Health Emergencies.

Appendix A. Detailed Eligibility Criteria for Emergency Ethical Review

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

A. Official declaration of a public health emergency

Rapid review procedures activate only when a national public health authority or an international body (e.g., WHO) declares an outbreak to be a public health emergency. This declaration formally authorizes accelerated ethics review.

B. The Research Addresses an Urgent Public Health Need

The proposed study must directly relate to:

- Prevention, diagnosis, surveillance, treatment, or control of the outbreak
- Understanding transmission dynamics
- Evaluating emergency interventions
- Rapid operational or implementation research needed for outbreak response

C. Time-sensitive research essential to outbreak response

Emergency review is justified when:

- Delayed review would result in significant harm, compromise the ability to collect critical data, prevent timely evaluation of diagnostics, treatments, or vaccines, or undermine public health decision-making.
- Standard timelines could delay life-saving interventions, impair outbreak containment, reduce scientific validity due to rapidly changing epidemiology, or prevent timely evidence generation for public health action.

The protocol should justify why immediate implementation is necessary and why normal review timelines are impractical

D. The Study Has Potential for Direct or Important Societal Benefit

The study should reasonably contribute to:

- Improved patient outcomes and reduced transmission
- Strengthened outbreak response and faster diagnosis or surveillance
- Public health decision-making

Low-value or purely academic projects do not qualify for emergency.

E. Risks Are Reasonable in Relation to Potential Benefits

The RNEC must determine that:

- Risks are minimised as much as possible
- Benefits justify remaining risks
- Appropriate safety monitoring exists

Special attention is given to:

- Experimental interventions
- Vulnerable or quarantined populations
- Use of unregistered products

F. Scientific Validity Is Adequate

Even during emergencies:

- Research must still be methodologically sound
- Sample size and analysis plans must be justified
- Poor-quality science is considered unethical

Emergency conditions do not justify scientifically weak studies.

G. The Protocol Includes Appropriate Informed Consent Procedures

The study must describe:

- Isolated or critically ill patients
- Remote consent, verbal consent or deferred consent (if applicable)
- Illiterate participants

Waivers or alterations of consent must be clearly justified.

H. Protection of Vulnerable Populations

Outbreaks often involve and disproportionately affect vulnerable groups:

- Critically ill patients, Pregnant women, Children, Prisoners, Refugees, or Quarantined communities.

The protocol must include adequate protections and additional safeguards for participants and avoid exploiting vulnerable populations.

I. Feasibility of rapid review without compromising quality

RNEC must be able to:

- Conduct a high-quality review quickly
- Use modified SOPs (parallel processing, shortened timelines)
- Ensure scientific and ethical rigor despite time pressure

J. Need for parallel rather than sequential processes

During emergencies, RNEC recommends occurrence of simultaneously steps , such as:

- Document drafting and translations
- Regulatory approvals (parallel submission to Rwanda FDA for Clinical Trials)

This parallelization is a key criterion for emergency review readiness.

K. Community Engagement and Risk Communication

This is especially important in infectious disease outbreaks. The study should include plans for:

- Community engagement
- Addressing stigma and misinformation
- Culturally appropriate communication
- Returning results when relevant

L. Data and Safety Monitoring Mechanisms Exist

Depending on risk level, the protocol should include:

- Adverse event reporting
- Interim safety reviews
- DSMB procedures (for higher-risk trials)
- Rapid reporting to authorities

M. Confidentiality and Public Health Reporting Are Balanced

The RNEC evaluates:

- Data privacy protections
- Secure handling of surveillance data
- Legal obligations for outbreak reporting
- Balancing confidentiality with public health response needs

Examples of Typical Studies Eligible for Emergency Review

(1) Vaccine trials during epidemics
(2) Diagnostic accuracy and validation studies
(3) Rapid implementation studies
(4) Therapeutic evaluations and trials
(5) Surveillance and registry studies
(6) Genomic sequencing studies
(7) AI-supported outbreak detection systems
(8) Behavioural assessments and risk perception studies
(9) Contact tracing studies
(10) Mortality surveillance systems

Studies Usually NOT Eligible

These generally should undergo normal review:

(1) Non-urgent academic projects
(2) Secondary analyses unrelated to outbreak response
(3) Minimal public health relevance

(4) Studies without immediate applicability

Common Operational Features of Emergency Review

During outbreaks RNEC may:

- Convene ad hoc emergency meetings
- Use rolling submissions
- Conduct virtual reviews
- Allow conditional approvals
- Use rapid turnaround timelines (24-72 hours)
- Delegate review to emergency subcommittees