



ECR-03

Version number (1.0)

Effective date (01 Jun 2026)

CRITERIA FOR EMERGENCY ETHICAL REVIEW DURING AN OUTBREAKS

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.

1. 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

2. 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

3. 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

4. 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

5. Revision History

Version	Date	Summary of changes
1.0	09-05-2026	First version of Eligibility Criteria for Emergency Ethical Review during an Outbreak