RNEC

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Eligibility Criteria for Accelerated Ethical Review

Definitions

- **Accelerated Ethical Review**: A full ethical review conducted on a shortened timeline, using modified workflows, but maintaining all ethical and regulatory requirements.
- **Urgent Protocol**: A protocol requiring rapid review because delays would significantly affect scientific validity, participant safety, public health relevance, funding or operational feasibility.
- **Not Eligible for Expedited Review**: Protocols involving more than minimal risk, investigational products, vulnerable populations, or complex interventions.

1. Purpose of this Guidance

This guidance helps researchers and RNEC determine whether a protocol qualifies for Accelerated Ethical Review. Accelerated Review is intended for time-sensitive studies requiring rapid review, but which are not emergencies, are not eligible for expedited review and still require full RNEC consideration.

2. Core Principle

This SOP applies to: A protocol may qualify for Accelerated Ethical Review when: Delays associated with routine full committee timelines would significantly compromise the scientific validity, participant safety, operational feasibility, regulatory compliance, funding opportunity, or public health relevance of the research. However:

- Accelerated review is not automatic
- Research quality and ethical rigor must remain unchanged
- Poor planning by investigators is not sufficient justification

3. Eligibility Criteria

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.

4. 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

5. 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

6. 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

7. Revision History

Version	Date	Summary of changes
1.0	**09-05-2026**	First version of eligibility criteria for accelerated ethical review.