RNEC

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Eligibility Criteria for Expedited Ethical Review

Definitions

- **Full board review**: A review conducted at a convened RNEC meeting with quorum, required for studies that involve more than minimal risk, vulnerable populations, or novel interventions.
- **Expedited review**: A faster review process conducted by Chairperson or designated RNEC reviewer(s) for initial studies involving no more than minimal risk, minor amendments, annual renewals of studies with minimal risk or urgent cases not requiring full board deliberation.

1. 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

2. Revision History

Version	Date	Summary of changes
1.0	**09-05-2026**	First version of Eligibility Criteria for Expedited Ethical Review.