



ECR-02

Version number (1.0)

Effective date (01 Jun 2026)

ELIGIBILITY CRITERIA FOR EXEMPT ETHICAL REVIEW

Definitions

- **Exempt review:** Review category for certain studies involving minimal risk and meeting specific exemption criteria (e.g., anonymized data, educational research) that may be exempt from full review but still require RNEC acknowledgment.

1. Criteria for Exempt Ethical Review

A study may qualify for exempt ethical 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:

- Anonymous surveys on non-sensitive topics
- Review of fully de-identified records
- Educational assessments

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
- Psychological manipulation
- Any procedure that could cause more than temporary discomfort

(2) No Direct Interaction or Intervention with Participants

Exempt ethical review may be considered when there is no direct interaction or intervention with participants, except for very low-risk educational or anonymous survey activities. Exempt studies will typically involve existing and public data, anonymous questionnaires and public observations. However, they do not involve clinical procedures, physical examinations, experimental manipulation, or behavioural interventions.

(3) Participants cannot be identified (directly or indirectly)

At least one of the following must apply for exempt ethical review:

- Data are fully anonymised, or
- No identifiers are collected, and no re-identification is possible

If datasets contain names, IDs, dates of birth, addresses, photos, audio or video, codes linked to identities or GPS coordinates, etc, the study should not be exempted.

(4) Disclosure of data would Not place participants at risk

Even if anonymised, exemption is NOT allowed if disclosure could cause stigma, legal consequences, loss of employment, social harm, or psychological distress. Examples NOT exempt include sexual behaviour, illegal activities, domestic violence, HIV status, immigration status, etc.

(5) No vulnerable populations are involved

Typically excluded from exemption, unless strictly limited to anonymous educational activities: children (except anonymous educational testing), pregnant women, prisoners, refugees, cognitively impaired persons, economically dependent populations. If included, proceed with either an expedited or a full review.

B. Common Categories that may Qualify for Exemption

A study may be exempt if it falls entirely into one of the following:

(1) **Educational practices**

Research in established educational settings involving:

- Instructional strategies
- Curriculum comparison
- Classroom management methods

Must be normal educational practice and no impact on grades or progression.

(2) **Anonymous surveys, interviews, or questionnaires**

Provided that topics are non-sensitive, participants cannot be identified, or disclosure poses no risk. For examples:

- Job satisfaction surveys
- Knowledge assessments
- Service satisfaction

(3) **Observation of public behaviour** Where no interaction with people, no recording of identifiable data and behaviour occurs in public settings.

(4) **Secondary use of existing data or records**

Only if data are publicly available or data are fully de-identified before researcher access. Includes registry data (anonymised) and published datasets.

(5) **Quality improvement or program evaluation** If:

- Primary intent is service improvement
- No experimental manipulation
- No added participant risks
- Data anonymised

If intent is generalisable research → usually expedited or full board review.

C. Explicit Exclusion Criteria for Exempt Review

The following always require expedited or full review:

- (1) Clinical trials: drugs, vaccines, devices, biologics or artificial intelligence (AI algorithms)
- (2) Invasive procedures of any kind
- (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) Prospective recruitment with identifiers
- (9) Transfer of identifiable data (International or third party)
- (10) Direct interaction with participants (survey, questionnaire, interview, focus group discussion)

2. Revision History

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