RNEC

REV-05 **Version number (2.0)** **Effective date (01 Jan 2026)**

Exempt Ethical Review of Research Protocols

Definitions

- **Exempt review**: An administrative determination that a study meets criteria for exemption from full RNEC review. It is a category of ethical review for research that involves no more than minimal risk and fits specific criteria, such as anonymous surveys, educational assessments, or secondary use of de-identified data.
- **Minimal risk**: The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during routine examinations.
- **Exempt Categories**: Predefined types of minimal-risk research that may qualify for exemption (e.g., anonymous surveys, de-identified secondary data).

1. Purpose

To define the process by which RNEC reviews and acknowledges research protocols that qualify for exempt review, while ensuring compliance with national laws and ethical standards. Exempt review applies to research involving no more than minimal risk that falls within predefined exemption categories. Although exempt studies do not require ongoing RNEC oversight, they must comply with fundamental ethical principles. Only the Rwanda National Research Ethics Committee (RNEC) Chairperson, or designated reviewer may grant exemption. Principal Investigators (PIs) may not self-exempt.

2. Scope

This SOP applies to:

- New protocol submissions requesting exemption
- Secondary data studies using publicly available data or documents.
- Involves secondary analysis of de-identified data or biological samples.
- Involves anonymous surveys or questionnaires without sensitive information.
- Educational or training evaluation studies, and quality improvement studies eligible for exemption
- Principal Investigators, RNEC Secretariat, Chairperson, and designated reviewers.
- Does not include vulnerable populations or sensitive topics (e.g., sexual behavior, illegal activities).

3. Responsibilities

(1) Principal Investigator (PI):

- Submits exemption request with supporting justification and required documents.
- Provide accurate description of study
- Not initiate research before exemption determination
- Notify RNEC of any changes affecting exemption status

(2) RNEC Secretariat:

- Receive exemption requests
- Conduct administrative screening of submission for completeness and eligibility.
- Log submissions
- Forward to Chairperson/designated reviewer
- Communicate exemption determinations to PI
- Maintains records of exempt reviews in RNEC archives

(3) RNEC Chairperson/Designated Reviewer:

- Determine eligibility for exemption
- Confirms exempt status and issues acknowledgment
- Document exemption category and rationale
- Refer non-qualifying studies to expedited or full review

4. Eligibility Criteria for Exempt Ethical Review

A study may qualify for exemption only if ALL apply:

(1) The research involves no more than minimal risk

(2) No direct interaction or intervention with participants

(3) The research does not involve sensitive topics

(4) The research does not include vulnerable populations (except limited educational contexts)

(5) The research does not involve identifiable data or specimens, participants cannot be identified either directly or indirectly.

(6) Disclosure of data would not place participants at risk

If any criterion is not met, the study must be reviewed under expedited or full committee procedures. Detailed eligibility criteria for emergency ethical review is provided in Appendix A from 4 of this SOP.

5. Procedures

Step 1. Submission

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

Step 2. Administrative Screening

Secretariat verifies completeness, version control and required documents. Incomplete applications are returned

Secretariat acknowledges receipt within **3 working days**

Step 3. Exemption Determination

Chairperson or designated reviewer assesses the eligibility for exemption, the risk level, population (no vulnerable population), identifiability, sensitivity (non-sensitive data) and the category fit.

Determination:

- Exempt approved
- Exempt approved with conditions
- Not exempt ➡ referred to expedited or full committee review.

Step 4. Documentation

Reviewer records the exempt category, the rationale and date of determination

Step 5. Communication of Decision

Secretariat issues written determination to PI within **5 working days**, including the exemption status, the category, conditions (if any) and investigator responsibilities.

Step 6. Record Retention

Exempt studies are logged in RNEC archives

RNEC retains records for minimum **10 years**

6. Required Documents

The following documents should be submitted for exempt ethical review request. Incomplete submissions shall be returned.

- Exemption request form
- Study protocol and summary
- Data collection tools (if applicable)
- Description of data sources
- Data protection plan
- Justification for exemption (e.g., use of de-identified data)
- Investigator CV

7. Investigator Responsibilities after Exemption

PI must:

- Conduct study as described

- Maintain confidentiality
- Report any changes
- Submit amendments if scope changes

8. Compliance

- Failure to comply may result in revocation of exemption, requirement for full review and institutional notification.
- RNEC reserves the right to reclassify any submission as requiring expedited or full Board review if new information arises. Exempt studies remain subject to monitoring and compliance checks.

9. Quality Assurance

RNEC shall:

- Periodically audit exempt determinations
- Review SOP every 3-5 years
- Train staff and reviewers

10. Revision History

Version	Date	Summary of changes
1.0	**11-05-2026**	First RNEC SOP for Exempt Ethical Review of Research Protocols.

Appendix A. Eligibility 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 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) Prospective recruitment with identifiers
(9) Transfer of identifiable data (International or third party)
(10) Direct interaction with participants (survey, questionnaire, interview, focus group discussion)