RNEC

REV-08 **Version number (1.0)** **Effective date (01 Jun 2026)**

Informed Consent in Human Participant Research

Definitions

- **Informed Consent**: A voluntary agreement by a competent individual to participate in research after receiving, understanding, and considering all relevant information.
- **Assent**: Affirmative agreement from a minor or individual lacking full legal capacity to participate in research.
- **Legally Authorized Representative (LAR)**: An individual authorized under applicable law to provide consent on behalf of another person.
- **Voluntariness**: Participation free from coercion, undue influence, intimidation, or inappropriate incentives..
- **Deferred Consent**: Consent obtained after enrolment when immediate consent was not feasible and delay would compromise participant welfare or scientific validity.

1. Purpose

This SOP describes the ethical and procedural requirements for obtaining, documenting, maintaining, and monitoring informed consent in research involving human participants. The SOP aims to ensure that:

- Participation in research is voluntary
- Participants receive adequate information
- Participants understand the research before agreeing
- Participant autonomy, dignity, rights, safety, and welfare are protected
- Consent procedures comply with ethical and legal requirements

2. Scope

This SOP applies to all new research protocols involving human participants requiring RNEC review. The SOP applies to adults capable of consent, vulnerable populations, minors requiring assent and parental permission, illiterate participants, emergency and deferred consent situations, and remote/electronic consent procedures.

3. Responsibilities

(1) Principal Investigator (PI) is responsible for:
- Ensuring valid consent is obtained
- Training research staff
- Using RNEC-approved consent forms
- Maintaining consent records
- Reporting consent deviations

(2) Research Staff is responsible for:
- Conducting consent discussions
- Assessing participant understanding
- Protecting voluntariness
- Documenting consent appropriately

(3) RNEC is responsible for :
- Reviewing consent materials
- Assessing adequacy of consent procedures
- Approving waivers or alterations of consent
- Monitoring compliance

4. General Requirements for Informed Consent

- Consent shall be, voluntary, informed, comprehensible, documented appropriately, and obtained before research procedures begin.
- Participants shall have adequate time for decision-making, opportunity to ask questions, and freedom to refuse or withdraw.

5. Essential Elements of Informed Consent

The following information shall be provided:

(1) **Study Information**
Title and purpose of the study, why the participant is invited, the study procedures, and the duration of participation.

(2) **Risks and Discomforts**
Foreseeable risks, potential side effects, psychological and social risks, and confidentiality risks.

(3) **Benefits**
Direct participant benefits, community and public health benefits, and clarification if no direct benefit exists.

(4) **Alternatives**
Alternative treatments or procedures where applicable.

(5) **Confidentiality**
How data will be protected, data sharing practices, and limits to confidentiality.

(6) **Compensation and costs**
Payments or reimbursements, treatment costs, and injury compensation (if applicable).

(7) **Voluntary Participation**
Participants shall be informed that participation is voluntary, refusal will not affect care or services. and that withdrawal may occur anytime.

(8) **Contact Information**
Provide researchers' contacts for research questions and emergencies, and RNEC participant rights or complaints.

6. Consent Process Procedures

Step 1. Preparation

Before obtaining consent:

- Use RNEC-approved template only
- Ensure privacy and verify participant eligibility
- Confirm language appropriateness.

Step 2. Conducting Consent Discussion

- The researcher shall explain study clearly, use non-technical language, encourage questions, assess participant understanding, and avoid coercion.
- Participants shall receive sufficient decision-making time.

Step 3. Assessment of Understanding

Researchers should confirm understanding through teach-back methods, open-ended questions, and clarification discussions.

Step 4. Documentation of Consent

- Consent should be documented through signature or thumbprint.
- Consent may be documented through electronic, or audio/video recording (if RNEC-approved).
- Participants shall receive a copy of the signed consent form (both information sheet and certificate).

7. Language Requirements

- Consent documents shall use understandable language, avoid technical jargon, and be translated into participant languages where necessary.
- Common languages may include Kinyarwanda, English, French, or other languages as appropriate.
- Translated forms shall undergo quality verification.

8. Illiterate Participants

- For illiterate participants:
  - Consent shall be read aloud
  - An impartial witness shall be present
  - Participant may provide thumbprint
  - Witness shall sign confirming accurate explanation
- The witness shall be independent, and not belong to the research team.

9. Vulnerable Populations

- Additional protections are required for children/minors, pregnant women, prisoners, refugees, persons with cognitive impairment, and economically or socially disadvantaged persons.
- Safeguards shall minimize coercion, undue influence and exploitation.

10. Assent Procedures for Minors

Step 5. Parental/ Guardian Permission

Required unless waived by RNEC.

Step 6. Minor Assent

- Assent should be obtained when minors are capable of understanding (7 -17 years old).
- Assent materials shall be age-appropriate.

Step 7. Dissent

A child's refusal should generally be respected unless:

- Life-saving intervention involved
- RNEC-approved exceptions apply

11. Emergency and Deferred Consent

Deferred consent may be used when:

- Immediate consent impossible
- Urgent intervention necessary
- RNEC approval obtained

Consent shall be sought as soon as feasible afterward.

12. Waiver or Alteration of Consent

The RNEC may approve waiver/alteration if:

- Research poses minimal risk
- Rights/welfare not adversely affected
- Research impracticable without waiver
- Additional information provided when appropriate

This is applicable for instance for de-identified retrospective record review, or routine surveillance datasets.

13. Remote and Electronic Consent

- Electronic consent may include digital signatures, online forms, or audio/video consent.
- The process shall ensure identity verification, data security, participant understanding, and privacy protection.
- Participants shall receive a copy of consent form.

14. Re-Consent

Participants shall be re-consented when:

- New risks identified or major protocol changes occur
- Long-term follow-up continues or participant reaches legal age.

15. Compensation and Undue Influence

- Compensation shall reimburse reasonable expenses and not constitute coercion.
- Compensation shall be RNEC-approved and large incentives require careful justification.

16. Consent in Community-Based Research

- Researchers shall respect community structures and conduct community engagement.
- Researchers shall clarify distinction between community permission and individual consent.
- Community approval does not replace individual consent.

17. Storage and Retention of Consent Documents

- Consent records shall be securely stored, remain confidential, and be accessible only to authorized personnel.
- Retention periods shall comply with RNEC regulations for a minimum of **10 years**.

18. Monitoring and Compliance

- The PI shall monitor the proper implementation, staff adherence, and documentation completeness.
- RNEC may conduct audits, monitoring visits, and spot checks.

19. Non-Compliance and Deviations

Serious deviations shall be reported promptly to the RNEC. Examples include:

- Using unapproved consent forms or missing signatures.
- Enrolling participants before consent.

20. Confidentiality

Consent documents containing identifiers shall be securely stored separately from study data and have restricted access.

21. Training Requirements

Research staff involved in consent shall receive training on human subjects protection, consent procedures, cultural sensitivity, vulnerable populations, and confidentiality.

22. Quality Assurance

RNEC shall:

- Periodically audit consenting processes of approved research protocol.
- Review SOP every 3-5 years, and train investigators, staff and reviewers.

23. References and Ethical Framework

(1) Law N° 015/2022 of 29/06/2022 relating to research on a human being (View/Download).
(2) Ministerial Order N° 002/MoH/2023 of 21/03/2023 relating to Rwanda National Research Ethics Committee on a human being (View/Download).
(3) Law Nº 003/2018 of 09/02/2018 Establishing the Rwanda Food and Drugs Authority, and Determining its Mission, Organization and Functioning (View/Download).
(4) Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Participants (2024) (View/Download)
(5) CIOMS - International Ethical Guidelines for Health-related Research Involving Humans (2016) (View/Download)
(6) ICH - Guideline for Good Clinical Practice E6 (R3) View here
(7) WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) (View/Download)
(8) RNEC Ethical Guidelines (View/Download)

24. Revision History

Version	Date	Summary of changes
1.0	**11-05-2026**	(a) First RNEC SOP for Informed Consent in Human Participant Research