Uganda National Council for Science and Technology

"A prosperous Science and Technology Led Ugandan Society."

National Guidelines for Research Involving Humans as Research Participants: 2025 Revisions

Outline

- Review process
- New sections added
- Revisions Examples:
  - section 3 - Oversight of other committees
  - section 4 - RECs: establishment and functions
  - section 5 - Informed Consent process and documentation
  - section 8 - AEs, SAEs & Other reportable events
  - section 10- Reseachers' and their institutions' responsibilities
  - section 14- Human Materials
- Dissemination plan
- Conclusion

Multidisciplinary Taskforce - 22 members

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- Assoc Prof. Joseph Ochieng (Vice Chairperson)
- Ms. Beth Mutumba Mutebi (Secretary)
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Objective of the Revision of the Guidelines for Research involving humans as research participants

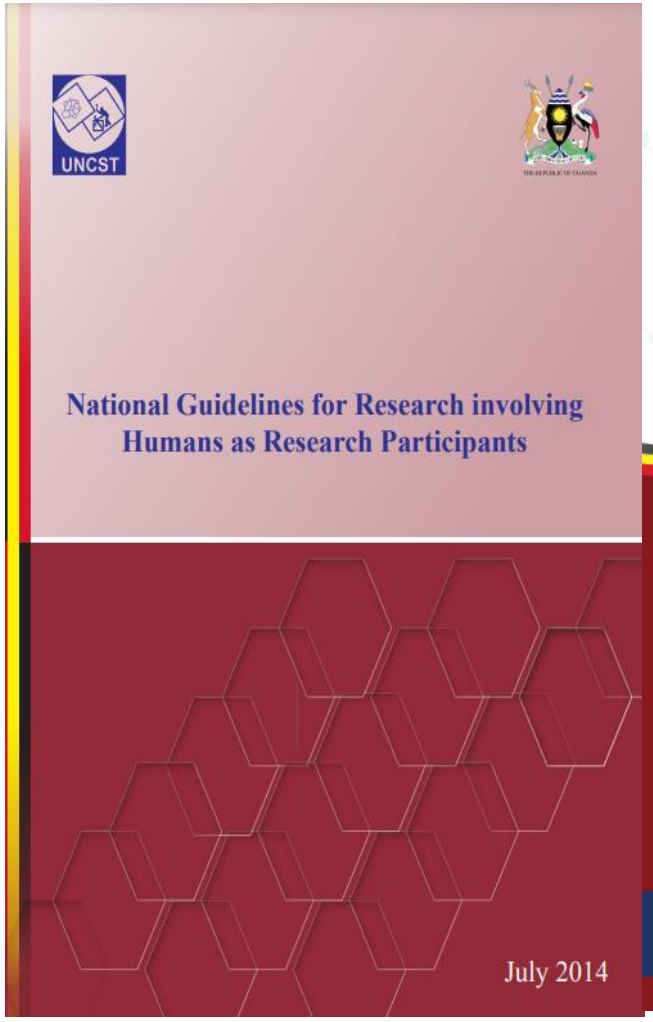
To consider *changing conditions, and new information and practices* in research ethics

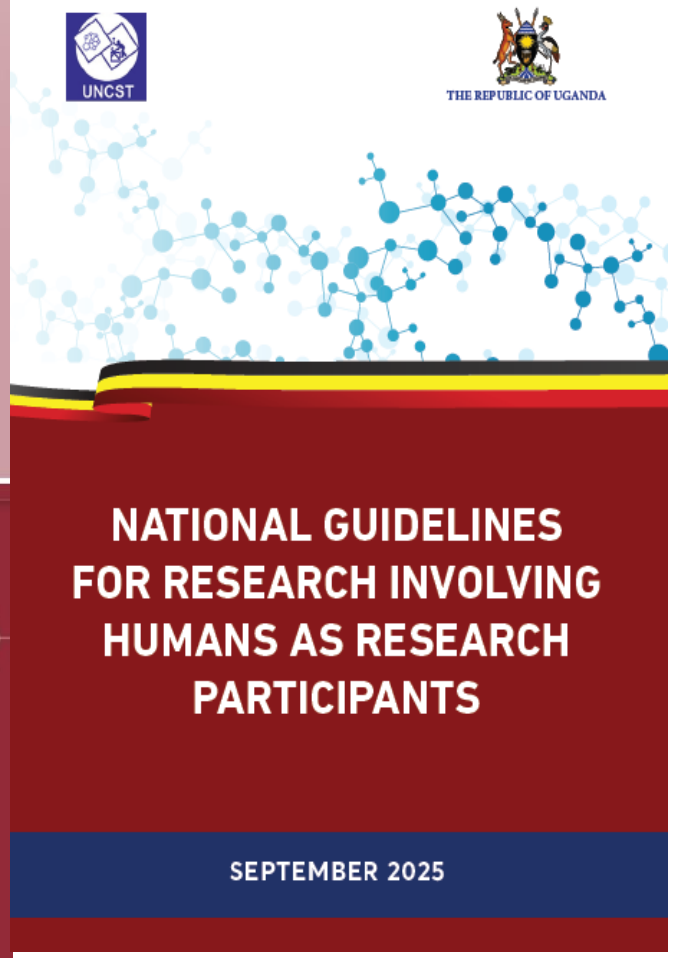
To strengthen regulatory framework for research on humans as research participants

To assist individuals & organizations to plan and conduct and/or participate in research while ensuring sound scientific and ethical principles

Review process – Since 2018

- Multidisciplinary task force meetings supported by a secretariat at UNCST
- Review of the existing 2014 guidelines
- Reference made to international research guidance documents
- Stakeholder engagement with RECs, MDAs, researchers, communities
- Consultations, literature review, Consensus development





Scope of Application for the Guidelines

All research involving humans as research participants in Uganda, including research in *humanities and social sciences*, *natural sciences, engineering & technology, medical, health and agricultural sciences* e.g research done by:

- Public, private, inter-governmental and non-governmental organizations, and by individuals or groups
- In a foreign country on biological materials and data collected from Uganda

- *Program evaluations*
- *Implementation research*
- *Surveillance, forensics*
- *Research during public health emergency*
- *Research involving medical tourism & medical camp participants*
- *Traditional and complementary medicine*

New Sections

- 24 sections
- 10 sections completely new
- Annexes /templates

Section 9: Research In Emergency Situations

Expanded the previous subsection with a new standalone section to include principles for compassionate use, Monitored emergency use of unregistered and investigational interventions (*lessons learnt in COVID-19)*

Section 11: Advanced Therapeutic Medicinal Products And Diagnostics

Section 11.2: on tissue and organ transplantation to be implemented in line with the Uganda Human Organ Donation and Transplant Act 2023.

Section Research involving manipulation of the human germline or heritable genome not permissible

New Sections

Section 13 Genetics & Genomics Research (GGR)

Provides guidance on conduct of Genetics and Genomics Research, Informed Consent for GGR, genetic counselling, genetic testing, return of results, privacy & confidentiality, commercialization and benefit sharing, pathogen genetics & genomics, stigma & risk determination

Section 15: Bio Banks

Provides for establishment and regulatory oversight of biobanks.

Cross refenced with the National Research Biobanking Guidelines- (*Need to build capacity in Uganda where samples are tested in-country*)

New Sections

Section 16: Research Data

Provides guidance on data storage, source document disposal, use of ddigital technologies & electronic records, Artificial Intelligence in research and open databases including digital migration. *(Section aligned with the Data Privacy and Protection Act-2019)*

Ownership of data shall be clearly stated in the research protocol and DTAs shall be reviewed and approved by REC a UNCST (Section 17.3)

Section 17: Partnerships & Collaborations

Provides guidance on data use and sharing i.e. research benefits, data ownership including elements of DTAs

Section 18: Capacity Building

Emphasises need for institutions to conduct capacity building programs for staff especially in new and emerging technologies

New Sections

Section 20: Research Integrity

Provides guidance on identification of Research integrity issues, reporting mechanisms, management mechanisms, responsible conduct of research.

(Research Integrity Code of Conduct under development)

Section 21: End Of Study Obligations

Provides guidance on end of study and close out of a study. It also provides for requirements for end of study.

Section 22: Post Research Responsibilities

Provides guidance on post research responsibilities across all categories of research i.e. post trial access, post research availability and post research care.

(To be considered at the conception of the study with a dedicated section on it)

Section 3 - Establishment Data & Safety Monitoring Board

- **Section 3.7.3.1 Establishment Data and Safety Monitoring Board**

Expounded on the role of the DSMB which is an independent group of experts established by study sponsors to review safety data *during interventional studies including psychological and behavioral studies*

- For clinical trials, DSMB shall be established for the conduct of *Phase IIb & III trials* other high risk non interventional studies shall have a safety monitoring plan

- Membership on a DSMB shall comprise of at least three persons with competence in the area of study……. *a local researcher* with experience and knowledge of research

- **Section 3.7.4** Establishment of Safety Monitoring Committee for Phase I and Phase IIa of a clinical trial, based on risk categorization. Its composition shall be submitted to the REC

Additional revisions- Section 3

Section 3.7.1 National Committee for the Certification of Biobanks in Uganda

Requirement for certification of Biobanks by the National committee established by the UNCST to offer independent, scientific, and ethical oversight of biobanks.

Section 3.7.5.3 Term of CAB members *shall be four (4) years renewable once* and a member can serve one institution at a time. A CAB shall serve up to a maximum of *three related research* studies within the same institution

Section 3.7.5.5 Independence of CAB & Reporting. The CAB shall provide an *annual report to the PI for submission to the REC and UNCST*

Section 3: National Biosafety Committee

Section 3.7.6 National Biosafety Committee (NBC) is the national reference point for biosafety, biotechnology and biosecurity matters under the UNCST. NBC accredits *Institutional Biosafety committee*

Uganda ratified to the Cartagena Protocol on Biosafety in 2001 and; The UNCST was designated as the Competent National Authority for regulatory oversight of Genetically Engineered (GE) research and development initiatives

Section 4 Establishment and functions of RECs

Section 4.3 (a) Composition, diversity & varying backgrounds of members. Having a member with training in bioethics, epidemiology biostatistics-**desirable**

Section 4.3 (h) Membership on a given REC will be three years. After serving for three years, a member is eligible for reappointment twice subject to satisfactory performance

Section 4.5.2.1 Guidance on Fast Track /speedy review: A researcher may request fast track review. REC reserves the right to accept or reject the request. occur as an extra ordinary meeting of the REC

Section 4 - Joint Scientific and Ethical Reviews

Section 4.5.4 A Joint Scientific and Ethical Reviews is a review where research documents are reviewed jointly by the NRAs (UNCST, UNHRO and NDA), REC, or IACUCs, NBC, subject matter experts and relevant stakeholders.

Examples include: research using uncommon and complex study designs e.g CHIMs-Controlled Human Infection Models; research in public health emergencies e,g COVID-19, Ebola; innovative treatments, new and emerging technologies with limited information on their use in humans, animals or plants in terms of risks and benefits, emerging and re-emerging infectious agents and toxins, genetic testing and modification etc.

(Separate and comprehensive guidance document being launched today-21st October 2025. It does not only affect human participant research but all categories of research)

Section 4 – Review of Uncommon or Complex studies

Section 4.5.5 UNCST shall designate RECs to review uncommon and complex Studies, Phase I Clinical Trials and High-risk Studies or the RECs shall refer to the UNCST for Joint Scientific and Ethical review. However, institutions of affiliation shall train the RECs to ensure capacity to review studies.

Section 4.5.7 Review of studies using routine data abstracted from clients' records or other record sources: Clients may not be reasonably available to provide informed consent. Investigator shall request the *REC for a waiver of consen*t to use these records for research.

Mechanisms shall be put in place to ensure protection of rights of privacy & confidentiality in relation to *identifiable data* such as anonymization & de-linking

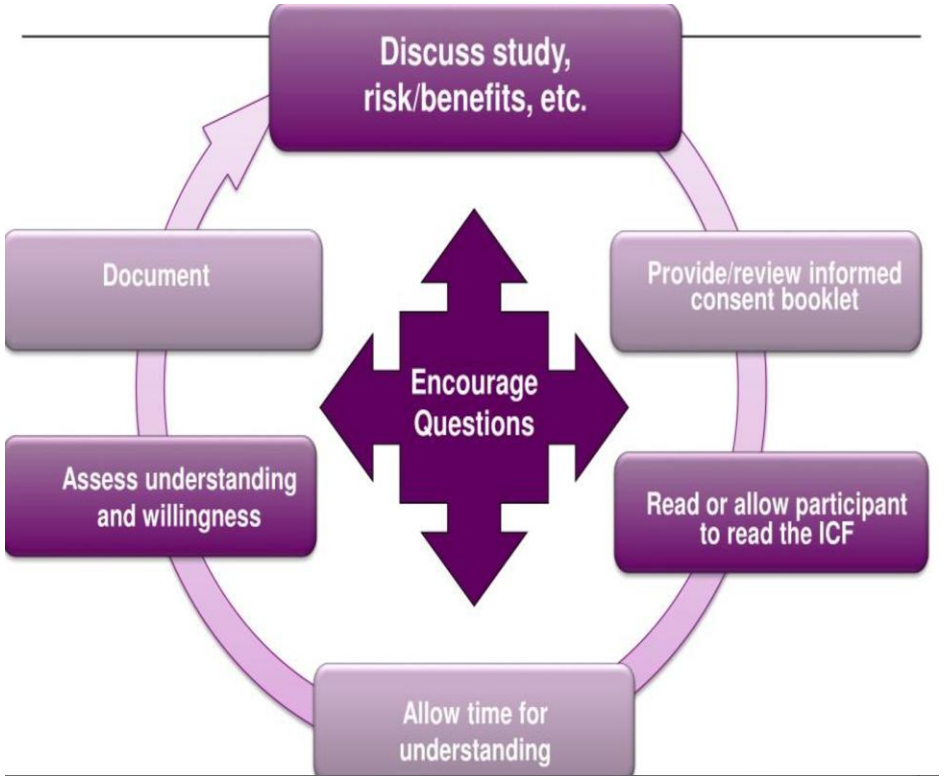
Section 4 - Off-site & On-site Study Monitoring

Section 4.6 Types of monitoring: Off-site & On-site monitoring; Off site monitoring of studies away from the research site can be done *virtually or remotely*, monitors do not visit the site to review the data and related documents. Emphasis on confidentiality and privacy.

Section 4.11 The REC emphasises **r**eview of a *site assessment report* submitted by the PI for a clinical trial. *Pre-inspection* shall be carried out based on risk assessment at the determination of the REC.

Section 5: Informed consent process

Reference to Section 7(1) of the *Data Protection and Privacy Act (2019)*



Section 5.2 General Requirements for Informed Consent Process, Investigator/ designee shall *not interpret* & shall only read out or allow the potential/ prospective participant to read the approved and stamped informed consent forms

Section 5.4 Documentation of verbal consent is done by the investigator who writes a record of having obtained the consent. information leaflet containing *adequate information* for a potential participant to make an informed decision shall be *approved and stamped by the REC*

Section 5 – Consenting for children

Informed consent shall be obtained from the parents or guardians according to the Children (Amendment) Act 2016 is categorized as follows:

a) **Legal guardianship** which is granted by court order from the High Court.

b) **Customary guardianship.** Family members appoint a guardian in accordance with their customs, culture or tradition. Section 43(4) of the Children (Amendment) Act 2016 . The customary guardian should indicate in writing that he/she is the appointed customary guardian.

d) **Guardianship by agreement**. In this case the parent of a child may, by agreement or deed, appoint any person to be a guardian. There must be an agreement or deed which is dated and signed by the parent in the presence of two witnesses one of whom is the probation and social welfare officer and the other must be a local councillor at LC1

Section 5 – Assent of Children

Section 5.6 Assent Children 14-17 years of age who have drug or alcohol dependency or a STI; or are pregnant, married, have a child or cater for their own livelihood are defined as *children* according to the Constitution of the Republic of Uganda, 1995 Article 34 (7)

A researcher intending to conduct research involving children shall obtain informed consent from the *parents or guardians*. Guardianship according to the Children (Amendment) Act 2016

In the event that the parents/guardians of the *children cannot be reasonably traced*, and the child needs to participate in research, the researcher shall apply to *court for an order to waive the consent requirement*

Researcher shall ensure continued adequacy of the informed consent process, *& re-consent research participants when they attain age of majority (18 years)*

Section 5 – Blanket and e-Informed Consent

Section 5.5 Provides guidance on consent types. It emphasises that blanket consent also known as open consent when a research participants agree to use their bio-specimens and/or associated data in any field of study beyond the primary study *shall not be acceptable in Uganda.*

Section 5.8 E-Informed Consent (eIC), Documentation, controls for electronic documents.*E-consenting procedures & signatures shall* follow the Uganda Electronic Transactions Act, 2011 & Electronic Signatures Act, 2011. Guidance provided on minimum standards for establishment of research E-Systems (*the REC and researcher can use the checklist embedded)*

Section 8 - AEs, SAEs, & Other Reportable Events

Section 8.3 — Reporting Serious Adverse Events, Unexpected Events and Suspected, Unexpected Serious Adverse Reactions (SUSARs)

- Interventions with potential long-term effects may require extended follow up and monitoring for SAEs. These may include investigations involving *genetically modified substances, gene therapy and DNA-based* compounds. The monitoring period *shall be determined by the REC* on a case-by-case basis

Section 8.2 — Management of AEs & Unexpected Events

- *Study site clinicians* shall make the *initial and final assessment of relatedness of AEs* to the study intervention. Other parties like independent medical monitors or members of the trial steering committee may give advice to the study teams

- Staff & clinical facilities where research is going to be conducted shall be *licensed/approved* for patient care

Section 8.4 — Other reportable events

- Other reportable events defined as an *unanticipated problems* involving risks to participants or communities or continuing noncompliance to the national research regulatory standards. E.g notifiable diseases, criminal acts, injury, social, economic, or psychological harm, death and life-threatening events. These shall be reported to the REC & UNCST as soon as possible.

Section - 10 Responsibilities of researchers and institutions

Section 10.1 Responsibilities of researcher: Ensure Training of research teams *before research commencement of a clinical trial* GCP, HSP and RCR: For Social behavioural studies HSP and RCR: For Laboratory related studies GCLP, GCP, HSP and RCR.

Section 10.3 Responsibilities of researcher's Organization of Affiliation: Research institutions shall have in place *a data protection officer* as required under Section 6 of the DPPA-2019-NITA (U)

Section 14 – Human Materials Acquisition, Exchange, Storage

- **Section 14.1 Acquisition:** For specimens obtained under routine clinical care for which the clinician intends to conduct future research, consent shall be obtained from the patient as detailed in the National Research Bio-banking Guidelines- January 2021

- **Section 14.4 Exchange/Transfer of human materials for research purposes:** The MTA shall be reviewed and approved by the appropriate REC, and final clearance and approval shall be sought from UNCST.

- **Section 14.7 Storage of human materials** shall be for a minimum of *5 years beyond w*hich the PI shall submit a report on the stored materials and a request for approval for continued storage if needed.

Section 16.6 Artificial Intelligence in research

The main ethical issues that need to be addressed by the research protocol include:

a. Informed consent to use data.
b. Safety and transparency.
c. Algorithmic fairness and biases.
d. Data integrity.
e. Data privacy.
f. Data ownership

Dissemination plan

- Fora such as FRECU, ANREC, STI National Science week.
- Integration of practices in regulatory SOPs.
- Training programs by UNCST.
- Outreach programs on UNCST services in different geographies
- Media platforms: website etc.

Timing is Right

- Return of ANUREC after 4-year gap
- Increasing distrust in science (politicians, policy makers, public)
- Current Global health environment
- Increasing domestic financial investment - Pathogen economy
- Uganda's steady emphasis on science
- Uplifting Uganda's research enterprise

Conclusions

Revised Guidelines are real. Regulators and researchers should implement them to improve process flows and standards

Emphasis on guideline-based review by Research Regulators

Optimize Uganda's science enterprise involving humans as research participants

Corrections and Suggestions

Send them to: UNCST P. O. Box 6884, Kampala

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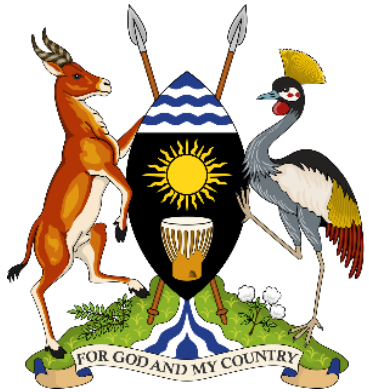

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Audience