UNCST

THE REPUBLIC OF UGANDA

NATIONAL GUIDELINES FOR RESEARCH INVOLVING HUMANS AS RESEARCH PARTICIPANTS

SEPTEMBER 2025

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Document errors
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Additional information about the guidelines may be obtained from UNCST:
Plot 6, Kimera Road, Ntinda
P. O. Box 6884, Kampala.
Tel: +256-414-705500
Website: www.uncst.go.ug

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HON. MINISTER'S STATEMENT

The Government of Uganda recognizes Science, Technology and Innovation (STI) as a cornerstone of national transformation and a principal driver of the Ten-Fold Growth Strategy aimed at expanding Uganda's economy to a USD 500 billion GDP by 2040. As articulated in Vision 2040 and the Fourth National Development Plan (NDP IV), STI is a cross-cutting enabler of productivity, industrialization, export competitiveness, and value addition across all anchor sectors of the economy. Realizing this ambition requires that all research undertaken in Uganda is grounded in a robust ethical and regulatory framework that safeguards scientific integrity, ethical conduct, and the safety and dignity of all persons involved in the research enterprise.

The National Guidelines for Research Involving Humans as Research Participants, Edition 2025, reaffirm Uganda's unwavering commitment to protecting the rights, welfare, and dignity of individuals and communities who contribute to the generation of knowledge. At the same time, these Guidelines are a strategic economic instrument: providing the regulatory certainty required to de-risk research, attract long-term investment, and accelerate the translation of research outputs into commercially viable products, technologies, and services. By ensuring compliance with internationally accepted ethical standards, the Guidelines enable Ugandan innovations to access global markets, clinical trial networks, supply chains, and capital.

The revision of the 2014 Guidelines reflects Uganda's alignment with global and continental development frameworks, including the United Nations Sustainable Development Goals (SDGs 2030), the African Union Agenda 2063, and the Science, Technology and Innovation Strategy for Africa (STISA 2024–2034). Importantly, they also support implementation of the East African Regional STI Policy (2022–2033), strengthening regional regulatory harmonization and positioning Uganda as a preferred destination for cross-border research, advanced manufacturing, and innovation-driven industrial clusters.

Through the Uganda National Council for Science and Technology, working closely with the Uganda National Health Research Organization, the National Drug Authority, and other regulatory bodies, Government continues to strengthen integrated oversight mechanisms that promote ethical research, transparency, accountability, and meaningful community engagement. This coordinated regulatory architecture reduces transaction costs, shortens approval timelines, and improves predictability for researchers, innovators, manufacturers, and investors, thereby directly supporting industrial scale-up and commercialization.

The implementation of these revised Guidelines is expected to generate transformative outcomes for Uganda's research and innovation ecosystem in line with the Ten-Fold Growth Strategy. They will strengthen ethical and scientific rigor, enhance public confidence in research, and foster harmonization among regulatory agencies and institutional ethics committees, reducing duplication, improving efficiency, and accelerating responsible research to market. The Guidelines will also build national capacity for ethical review and oversight, support evidence-based policy and industrial planning, and anchor Uganda's transition from a factor-driven economy to a knowledge-, technology-, and innovation-driven economy.

In the medium to long term, these efforts will translate into tangible economic gains through the growth of high-value industries such as pharmaceuticals and biotechnology, medical devices, agri-biotechnology, digital health, advanced manufacturing, and data-driven services. By reinforcing the ethical and regulatory foundations of research, Uganda strengthens its ability to generate intellectual property, attract venture capital, enable technology transfer, and create high-skilled jobs, all key levers for productivity growth, export diversification, and industrial competitiveness.

As Uganda accelerates innovation for socio-economic transformation, these Guidelines serve as a critical enabler for attracting international research partnerships, crowding-in private sector investment, and supporting pathfinder industries under the Ten-Fold Growth Strategy. They nurture a culture of excellence, integrity, and accountability among scientists, institutions, and enterprises, while ensuring that innovation remains people-centered and ethically grounded. I therefore reaffirm my continued support, and the full cooperation of the Science, Technology and Innovation – Office of the President, in implementation of these guidelines, and leveraging responsible science and innovation as engines of industrialization, inclusive growth, and national prosperity.

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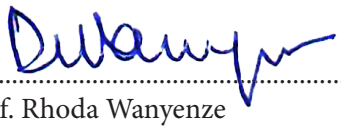
Hon. Dr. Monica Musenero Masanza
Minister for Science, Technology and Innovation
Office of the President
The Republic of Uganda

FOREWORD

The Uganda National Council for Science and Technology by virtue of its mandate of research oversight as accorded by the UNCST Act 1990 (CAP 211 as amended) developed National Guidelines for Research Involving Humans as Research Participants-July 2014. The revision of these guidelines was informed by the aspirations in the UN Sustainable Development Goals 2030, the Africa Agenda-2063, Science Technology and Innovation Strategy for Africa (STISA) -2024, The East African Regional Science, Technology and Innovation Policy 2022-2033 and the Uganda Vision 2040.

The UNCST appointed a multidisciplinary National Task Force (NTF) to lead the process of revising the 2014 National Guidelines for Research Involving Humans as Research Participants. The NTF reviewed and consulted existing national and international guidelines, relevant regulatory policies and guidelines. The guidance will facilitate conduct of high quality research, ensure safety, protect the rights and welfare of participants and their communities. The guidelines have been revised through consultative stakeholder engagement.



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Prof. Rhoda Wanyenze
Chairperson, UNCST Council

PREFACE

The purpose of research is to enhance society by generating and advancing knowledge that could benefit present and future generations. People who volunteer as research participants bear the burden of research in order to bring about future benefit. It is therefore, necessary to ensure that benefits are maximized and harm is avoided and the participants' rights and welfare are not compromised during the research process. These Guidelines strengthen the ethics and science systems in Uganda for carrying out research without compromising rights and welfare of individual research participants and communities.

The Guidelines are a revised version of the 2014 National Guidelines for Research involving Humans as Research Participants. The revisions are in keeping with changing conditions, new information and practices in the field of research ethics. The revised Guidelines reflect consensus among research stakeholders on norms and standards, which shall be adhered to, in order to assure research participants, of protection of their rights and welfare during and after research. The Guidelines are intended to assist individuals and organizations to plan and conduct and/or participate in research while ensuring sound scientific and ethical principles.

Readers who detect errors of omission or commission are invited to send corrections and suggestions to UNCST, P. O. Box 6884, Kampala. E-mail: info@uncst.go.ug.

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Executive Secretary
Uganda National Council for
Science and Technology

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Prof. Nelson K. Sewankambo
Chairperson
National Task Force

ACKNOWLEDGEMENT

The Uganda National Council for Science and Technology (UNCST) is grateful for the contribution from government of Uganda through the following Ministries, Departments and Agencies: Science, Technology and Innovation Secretariat- Office of the President (STI-OP) , Ministry of Health (MoH) , Ministry of Justice and Constitutional Affairs (MoJAC), Ministry of Finance, Planning and Economic Development (MoFPED) Uganda National Health Research Organization (UNHRO) and the National Drug Authority (NDA). The UNCST acknowledges the supplementary financial support from the Makerere University, College of Health Sciences Genetics and Genomics research program and the International AIDS Vaccine Initiative (IAVI). Sincere appreciation is extended to research institutions, Research Ethics Committees (RECs) , Institutional Animal Care and Use Committees (IACUCs), academia and all the stakeholders who have contributed towards the successful revision of these guidelines.

UNCST is particularly thankful to the members of the NTF for their voluntary contribution of time and technical expertise in the development of these guidelines. The members include; Prof. Nelson K. Sewankambo (Chairperson), Dr. Joseph Ochieng (Vice Chairperson), Ms. Beth Mutumba Mutebi (Secretary) , Principal State Attorney: Counsel Harriet Ityang, Principal State Attorney: Counsel Susan Nakabuye, Prof. Pauline Byakika Kibwika, Dr. Stella Neema, Dr. Samuel Okware, Dr. Helen Ndagijje, Dr. Hannah Kibuuka, Dr. Frederick Nelson Nakwagala, Dr. Stephen Okoboi, Dr. Adrian Jjuko, Dr. Racheal Kyeyune Byakyaita, Ms. Maria Musisi, Ms. Hellen Opolot, Ms. Winfred Nazziwa, Ms. Irene Semakula Seryazi, Ms. Dorcas Atuhaire, Mr. Musa Kwehangana, Ms. Dorcas Lamunu, and Dr. Christopher Ddamulira.

ACRONYMS

ACRECU	Accreditation Committee for Research Ethics Committees in Uganda
AI	Artificial Intelligence
ATMPs	Advanced Therapeutic Medicinal Products
CAB	Community Advisory Board
CAG	Community Advisory Group
CV	Curriculum Vitae
DPPA	Data Privacy and Protection Act-2019
DTA	Data Transfer Agreement
DSMB	Data and Safety Monitoring Board
EIA	Environmental Impact Assessment
eIC	Electronic Informed Consent
GGR	Genetics and Genomics Research
GCP	Good Clinical Practice
GCLP	Good Clinical Laboratory Practice
GMOs	Genetically Modified Organisms
HSP	Human Subject Protection
IACUC	Institutional Animal Care and Use Committee
ICs	Institutional Committees
ICF	Informed Consent Form
IBC	Institutional Biosafety Committee
JOSER	Joint Scientific and Ethical Review
MTA	Material Transfer Agreement
NEMA	National Environmental Management Authority
NHREB	National Health Research Ethics Advisory Committee
NBC	National Biosafety Committee
NDA	National Drug Authority
NFA	National Forest Authority
NRA	National Regulatory Agency
NTF	National Taskforce
PI	Principal Investigator
PRR	Post Research Responsibilities
RCR	Responsible Conduct of Research
R&D	Research and Development
REC	Research Ethics Committee
S&T	Science and Technology
SRC	Scientific Review Committee
SAE	Serious Adverse Event
SC	Scientific Committee
SOPs	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reactions
UCG	Uganda Clinical Guidelines
UNCST	Uganda National Council for Science and Technology
UNHRO	Uganda National Health Research Organization
UWA	Uganda Wildlife Authority

1.0 GENERAL PROVISIONS

1.1 Introduction

Uganda has unique health, environmental, social and economic challenges, which attract both local and international research interests. The number of research studies involving humans as research participants in Uganda has risen more than ten-fold since 1990. This increasing quest for knowledge and the search for novel remedies to health, environmental, social and economic challenges is commendable, but could, if unregulated, potentially expose research participants to a spectrum of risks. These guidelines provide a strengthened national system and framework for harnessing the benefits of research while ensuring the rights, interests, values and welfare of research participants and communities.

1.2 Rationale

Research is conducted for the benefit of society. It is important to have a coherent regulatory framework that promotes research, curtails risks and guards against unethical research. Research has inherent burdens, which individuals and communities who volunteer as research participants bear to bring about a future benefit. Individuals and communities shall not be unfairly denied the benefits of research or be unjustifiably exposed to potentially risky research. These guidelines are, therefore, necessary to ensure that research participant's rights and welfare are not compromised during and after research.

1.3 Objectives

The overall objective of these guidelines is to strengthen the regulatory framework for conduct of research involving humans as research participants without compromising their rights and welfare.

Specifically, these guidelines are to:

a. Provide mechanisms for protecting rights and welfare of research participants and communities.

b. Provide ethical standards and procedures for conduct of research. Ensure that researchers consider social and cultural values of participating communities.

c. Consider and align with policy provisions from various sectors that relate to the research process.

1.4 General Policy

a. Research and development including scientific investigations involving humans as research participants shall be conducted for the benefit of communities without causing unnecessary harm or inconvenience and shall not compromise rights and welfare of research participants. The research must comply with the national laws and guidelines and abide by the regulatory framework set herein.

b. UNCST in collaboration with UNHRO, NDA and other regulatory agencies shall have a mechanism for identification of areas of concern to develop policies and legislation.

c. Research regulatory agencies and stakeholders shall have mechanisms for knowledge and technology transfer, translation and innovation with a possibility of policy integration.

All research shall conform to the applicable policies and laws in Uganda. i.e. National Development Plan, Ministries and Agency policies and regulations such as: Uganda National Council for Science and technology Act CAP 209, 1990, National Drug Policy and Authority Act CAP 206, 1993, Uganda National Health Research Organization Act 2011, the Electronic Signatures Act 2011, the Electronic Transactions Act, 2011, the National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, the Data Protection and Privacy Act, 2019, The National Environment Act, 2019, the Traditional and Complementary Medicine Act, 2019, the Public Health Act, 2022 and Human Organ Donation and Transplant Act, 2022.

1.5 Scope of Application

These guidelines apply to all research involving humans as research participants in Uganda, including research in humanities and social sciences, natural sciences, engineering and technology, medical and health sciences, and agricultural sciences for example:

a. Research conducted in or by public, private, inter-governmental and non- governmental organizations, and by individuals or groups.

b. Research conducted in a foreign country on biological materials and data collected from Uganda.

c. Program evaluations and implementation research.

d. Surveillance, forensics and public health emergencies.

e. Research involving medical tourism and medical camp participants.

f. Traditional and complementary medicine research.

2.0 RIGHTS AND WELFARE OF RESEARCH PARTICIPANTS

2.1 Introduction

Research involving humans as research participants is defined as a systematic investigation involving persons, and directed to the advancement of knowledge, that cannot be regarded as an element in established practices or social practices and that involves either physical or psychological intervention or assessment, or generation, storage, and analysis of information referable to individuals and communities.

Research involving humans as research participants also includes research on any material obtained from a research participant, whether the participant is alive or dead.

Research involving humans as research participants includes:

a. Observational studies,

b. Interventional studies, that is, any experiment or study on one or more persons, which involves administration of a test product/ article, drug, treatment, procedure, or device, psychological interventions, social behavioral interventions, or economic interventions.

c. Basic scientific research to study biology of persons or organs and specimens thereof.

d. Systematic collection, storage, retrieval and analysis of data and information on humans.

2.2 Rights and Welfare of Human Research Participants and Communities.

Research shall be conducted in a manner that does not violate the rights and welfare of human research participants and communities. Research shall be responsive to the needs of the community.

2.2.1 Human Research Participants have a right to, interalia:

a. Participate in research or withdraw participation at any time without penalty.

b. Ownership of specimens, diagnostic results, data and access to research findings.

c. Be respected, including the right of their autonomy, culture, beliefs and values.

d. Information about the research (it is important to ensure that information is communicated in an understandable language, format and in a conducive environment at all stages of the research).

e. Protection against research related injuries, harm, exploitation, and any other forms of abuse.

f. Treatment and management of research related injuries.

g. Privacy and confidentiality of their participation, during and after the research.

h. The standard of health care that is established nationally.

i. Compensation for; time, inconvenience, effort and reimbursement for costs associated with their participation in research.

j. Receive the intervention that is proven to be beneficial.

k. Access to counselling and social support.

2.2.2 The researcher shall aim at ensuring adequate welfare of research participants and their communities. This shall be attained through the following:

a. Ensuring adequate compensation of research participants for time, inconvenience or costs associated with their participation such as transport costs.

b. Provision of health (ancillary) care beyond research related care.

c. Provision of collateral benefits to research communities.

d. Taking measures to ensure easy access by the community to the test drug, if proven beneficial.

2.3 Principles of Research Ethics

In order to protect the rights and welfare of human research participants, research shall be conducted in accordance with four basic research ethics principles, namely: respect for persons, beneficence, non-maleficence and justice. It is generally observed that these principles guide the conscientious preparation of protocols for scientific studies. They may be expressed differently and given different legal and moral weight in different settings, and their application may lead to different decisions or courses of action in those settings.

These principles are briefly described as follows:

a. Respect for persons incorporates at least two fundamental ethical considerations, namely:

   i) Respect for autonomy, which requires that those who are capable of deliberation about their personal choices shall be treated with respect for their capacity for self-determination.

   ii) Protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded protection against harm or abuse.

b. Beneficence refers to the ethical obligation to maximize benefits and to minimize harms to research participants. Risks of harm from research shall be reasonably justified by expected benefits, research design shall be scientifically acceptable, and researchers shall be competent to conduct research and to safeguard the rights and welfare of research participants.

c. Non-maleficence (i.e.. do no harm) prescribes that researchers shall not deliberately inflict harm, or evil on research participants.

d. Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. The principle refers primarily to distributive justice, which requires fair and equitable distribution of both burdens and benefits of participation in research.

3.0 REGULATORY OVERSIGHT OF RESEARCH

3.1 The Regulatory Process

Oversight of research involving humans as research participants in Uganda is a two-tier process which starts at the institutional level by Research Ethics Committees (RECs) and second at the national level by UNCST in collaboration with Uganda National Health Research Organization (UNHRO) for health-related studies. The UNCST liaises with the Research Secretariat in the office of the President on national security issues in respect to research conducted in Uganda. Additional regulatory oversight for clinical trials is provided by the National Drug Authority (NDA).

Where there is contradiction between local and international policies, the national laws and standards take precedence. If local bodies are of differing opinion, there will be room for dialogue, harmonization and arbitration by the UNCST. In the absence of local policies, laws and standards, international and regional guidelines may be followed.

The mandates of UNCST, UNHRO and NDA with respect to oversight of research are summarized below:

3.2 Oversight by Uganda National Council for Science and Technology

The UNCST is a semi-autonomous government agency established under the UNCST Act, 1990, Cap 211 of the Laws of Uganda, to develop and implement strategies for integrating Science and Technology (S&T) into the national development process, provide advice to the Government of Uganda on policy matters necessary for advancing S&T, oversee and coordinate research and development (R&D) in Uganda. Sections 4 and 5 of the UNCST Act, Cap 209 mandates UNCST to "act as a clearing house for information on research and experimental development taking place in scientific institutions, centres and other enterprises and on the potential applications of their results; and to work in close co-operation with and co-ordinate all scientific and technological activities of persons, institutions, sectors and organizations. "

In executing this mandate, UNCST registers and, in liaison with the Research Secretariat in the office of the President, clears all research intended to be carried out in Uganda. In so doing, UNCST registers research institutions and , issues research permits for the purpose of carrying out research. All persons intending to carryout research in Uganda shall register their research activities and obtain a research permit to facilitate conduct of research in the country. Prior to approval and registration with UNCST, one shall obtain approval from the Research Ethics Committee (REC), National Biosafety Committee (NBC) and/ or Institutional Animal Use and Care Committee (IACUC). Under normal circumstances, the registration process with the UNCST is accomplished within ten (10) working days. In addition, UNCST regulates importation of biological agents for research including germs, organisms in collaboration with other applicable regulatory agencies.

3.3 Oversight by National Drug Authority

The NDA regulates safety, quality, efficacy, handling and use of human drugs and drug related products, invitro diagnostics, public health products and medical devices in research, and monitors product safety and pharmacovigilance. The National Drug Policy and Authority Regulations (Conduct of Clinical Trials), 2014, which were made under section 40 and 64 of the National Drug Policy and Authority Act, Cap 198, in Part II subsection 3 provide that: (1) A person shall not start or cause to be started a clinical trial or conduct a clinical trial without the authorization of the Authority; (2) Authorization for clinical trial shall be granted for drugs registered under the Act and for drugs that are not registered under the Act.

3.4 Oversight by Uganda National Health Research Organization

Uganda National Health Research Organization (UNHRO) is established by Act of Parliament to create a sustainable culture of health research by providing policy and ethical guidelines and national coordination of and regulation of health research. UNHRO is mandated under section 6(e) of the UNHRO Act to register, renew and coordinate different types of health research in Uganda and promote multi-disciplinary and inter- sectoral research collaboration in a bid to establish essential national health research, which is consistent with the National Health Sector Strategic Investment and Development Plan and the UNHRO statutory mandates as spelt out in Section 6,7 and 12 of

the UNHRO Act 2011. UNCST shall consult UNHRO where applicable, on identified health protocols. This shall be undertaken through the National Health Research Ethics Advisory Board (NHREAB) established under UNHRO. The research shall follow established research regulatory processes as stipulated in these guidelines. Final research clearance and registration shall be done by UNCST.

The NHREAB is advisory and will provide advice on broader national political and safety issues related to research. It shall also provide advice related to arbitration on appeals from scientists. Expert working groups will support the Board as requested.

3.5 Submission requirements to the National Regulatory Bodies

3.5.1 Minimum submission requirements to UNCST

a. Approved protocol by an accredited REC/IACUC/IBC.

b. Approval letter and a minute extract from the meeting that approved the study.

c. Research forms

d. Letter of Introduction from the researchers' organization of affiliation.

e. Admission letter for academic research.

f. CVs for each investigator on the study team.

g. Administrative clearance (where the research is going to be conducted).

h. Proof of payment of research administration and clearance fees.

For additional details on the registration process please refer to the Research Registration and Clearance Policy and Guidelines: www.uncst.go.ug.

3.5.2 Minimum submission requirements to NDA

Researchers must file a copy of the NDA certificate authorizing the importation and/or use of the trial drug in Uganda with the relevant REC and UNCST. NDA shall verify the continued use and eventual disposal of unused trial drug. The researcher shall, inter alia, provide the following information about the drug to NDA:

a. Investigator's brochure.

b. A description of the drug.

c. Dosage form of the drug.

d. Composition (complete formula).

e. Active ingredients and other ingredients (adjuncts, excipients, preservatives, colour, flavour etc).

f. Pack size (weight or volume).

g. Quality control processes done.

h. Certificate of analysis.

i. Batch release certificate.

j. Stability studies done on the drug.

k. Authorization of the clinical trial from the country of origin.

l. Good Manufacturing Practice certificate of the plant from which drug was manufactured.

m. Containers in which products is packaged.

n. Labelling.

o. Relevant published literature on the drug.

3.6 Oversight by Research Ethics Committees

The RECs and IACUCs shall be accredited by the Accreditation Committee established by the UNCST. The Accreditation Committee for Research Ethics Committees in Uganda (ACRECU) is comprised of members appointed by the Executive Secretary of UNCST. Members of the ACRECU are appointed on a three (3) year, renewable once term limit. The ACRECU terms of reference are as follows:

a. Review and consider applications for accreditation from RECs and IACUCs in accordance with accreditation standards established by UNCST.

b. Conduct periodic assessment of performance of RECs and IACUCs and monitor compliance with set standards.

c. The objectives for accreditation are to:

d. Improve the efficiency and effectiveness of RECs and IACUCs operation:

e. Ensure that RECs and IACUCs provide the highest possible ethical standards and protection

to research participants and animal subjects; and build public trust and confidence in the national ethics review system.

The REC and IACUC Accreditation Committee will:

a. Ensure that RECs and IACUCs are well constituted, and members receive initial and continuous training in research ethics.

b. Facilitate coordination and networking of RECs and IACUCs in Uganda.

c. Provide opportunities for increased support to RECs and IACUCs functions.

d. RECs are established by organizations whose mandate includes carrying out research. Their primary function is to conduct initial and continuing review and approval of research studies, with the aim of protecting the rights and welfare of human research participants. RECs operating in Uganda must be accredited by the ACRECU. RECs shall monitor research activities to ensure compliance with scientific and ethical requirements in accordance with these guidelines.

3.6.1 Oversight by the Institutional Animal Care and Use Committee

For research involving both animals and human participants, approval shall be sought according to the National Guidelines for Use of Animals in Research and Teaching.

3.7 Oversight by Other Committees

There may be other committees involved in the research review process. These committees include:

3.7.1 National Committee for the Certification of Biobanks in Uganda

The Biobanks will be certified by the committee established by the UNCST to offer independent scientific, and ethical oversight of biobanks in Uganda to ensure compliance to laws, ethical, regulatory guidelines, policies and procedures. Refer to National Research Biobanking Guidelines, January 2021.

3.7.2 Scientific Review Committees

3.7.2.1 Establishment

Scientific Review Committees (SRCs) are set up within organizations as an internal review mechanism for research protocols. Where such committees formally exist, they shall approve research protocols for submission to a REC. SRCs shall be comprised of at least three experts. They are encouraged to have standard operating procedures (SOPs) to guide their functions. The SOPs shall specify, at least, the following:

a. Format of research protocol.

b. Frequency of SRC meetings.

c. Time allowance for members to read research protocols before the meeting date.

d. Number of research protocols that can be reviewed each time.

e. How decisions will be arrived at (by consensus or vote).

f. Records of meetings (minutes) and distribution requirements.

g. Procedure for resubmission of research protocols after revision.

h. Correspondence with the researcher (with reasons for every decision made clearly stated in writing). Members of SRCs may sign confidentiality agreements with their organizations to protect confidentiality of all information given to them. In addition, they shall not use information supplied in research protocols under their consideration for their own research studies or personal gain.

3.7.2.2 Functions

The primary function of a SRC is to review and evaluate all scientific aspects of research studies with emphasis on suitability, relevance and feasibility of the study. Specific issues that shall be scrutinized by the SRC include, but are not necessarily restricted to study design, objectives of the study, methodology, appropriate controls, statistical methods, and feasibility of the study.
The SRC shall establish lines of communication between the various departments within the organization and RECs.

3.7.3 Data and Safety Monitoring Board (DSMB)

3.7.3.1 Establishment

A DSMB is an independent group of experts established by study sponsors to review safety data during interventional studies including psychological and behavioral studies. It is to ensure that a study is conducted in accordance with provisions of the research protocol.

A DSMB shall be established before the commencement of an interventional study and its charter is submitted to the REC for review and approval. For clinical trials, this shall be established for the conduct of Phase IIb, and Phase III trials. Phase I, IIa and other high risk non interventional studies shall have a safety monitoring plan.

A DSMB shall comprise of at least three persons with competence in the area of study and including a bio-statistician. This shall include a local researcher with experience and knowledge of research.

In general, membership of the DSMB shall include:

a. Individuals knowledgeable in the processes of conducting interventional studies.

b. Individuals with relevant science and/or ethics qualifications and research experience.

c. The qualifications most relevant for a specific DSMB will depend on the type of the trial and product under investigation.

3.7.3.2 Functions

Functions of a DSMB are to:

a. Ensure safety of study participants.

b. Preserve the integrity and credibility of the trial.

c. Monitor the availability of definitive and reliable results in a timely manner.

d. Make decisions related to efficacy and safety, based on the submitted results and adverse event reports and recommend whether the study shall continue or not or be amended.

e. The DSMB shall report to the sponsor(s) of the trial:

f. Any concerns over occurrence of serious adverse events.

g. Any serious social harms.

h. Any concerns about the conduct of the trial.

i. Any concerns about data integrity.

j. Whether the study shall be terminated or continued based on interim safety and other study outcome data.

The DSMB shall determine the following before commencement of the study:

a. Mode and time-frame for receiving adverse events reports.

b. Frequency of receiving data.

c. Frequency of meetings to review data and adverse event reports (where there may be concern, the DSMB may choose to review data more frequently).

d. Channels of communication with the PI, sponsor and the REC.

3.7.4 Safety Monitoring Committee (SMC)

This shall be established for Phase I and Phase IIa of a clinical trial before commencement of a clinical trial and shall be based on risk categorization of the study. Its composition shall be submitted to the REC.

3.7.5 Community Advisory Boards (CABs)

A Community Advisory Board (CAB) also known as Community Advisory Group (CAG) is a group of individuals with diverse backgrounds, selected from the community to advise and facilitate dialogue between the community and the research team. The CAB is one approach among many, that researchers can use to understand the social and cultural dynamics of the research community as well as facilitate community understanding of the research (National Guidelines for Community Engagement in Research-2022). Further, CABs provide a platform for community members to voice concerns and priorities that otherwise might not be included into the researchers' agenda and advise about suitable research processes that are respectful of, and acceptable to the community.

3.7.5.1 Establishment

The formation of a CAB shall be the responsibility of the research institution and Principal Investigator (PI). This process includes soliciting and receiving recommendations of potential CAB members from organizations and structures broadly representing various sectors and stakeholders. The CAB members

shall be identified from communities where research is to be undertaken. Representatives shall be drawn from groups and organizations who can influence or are affected by the conduct and/or outcome of the research.

3.7.5.2 Composition

Each CAB shall be composed of at least five (5) members, with diverse backgrounds. Members of a CAB may include, but are not limited to the following: Individuals with understanding of local laws, cultural values and gender issues as well as social and economic dynamics which have potential to influence success of the proposed research Peer leaders, i) Political leaders, iii) Religious leaders, iv) Representatives from local government technical departments, v) public servants, vi) Non-Governmental Organizations, vii)Civil Society Organizations and Community Based Organisations. viii) Representatives of the research population, individuals representing potential and or former research participants ix) the Media, x) Experts in the area of the study.

3.7.5.3 Term for CAB Members

Term of membership on any CAB 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.

3.7.5.4 Functions

The primary function of a CAB is to advise researchers on the ways to identify and incorporate community concerns into their research activities. The CAB can contribute to the ethical and scientific quality, relevance, and acceptability of the proposed research, by advising the research team on:

a. Local, cultural community norms and values that may impact the proposed research.

b. Appropriate community entry, recruitment, retention, and compensation to individuals for participating in research.

c. Potential risks and benefits and how these could be addressed.

d. Safety, care and welfare in research and environmental protection.

e. The recruitment materials, informed consent process, informed consent documents, data collection tools among others.

f. The development and implementation of information, education, and communication materials for the research.

g. Effective methods for disseminating information about the research study and its outcomes.

h. The CABs shall not get involved in recruitment and follow up of research participants. The CAB's role and expectations shall be clearly stated in its charter.

3.7.5.5 Independence of the CAB

A CAB shall function with independence and impartiality to adequately represent the community and work for the protection of research participants and their communities. Efforts shall be made to ensure a cooperative dialogue between the research team and the CAB while maintaining the CAB's independence. The PI and/or designee shall facilitate some meetings that do not involve the research team to give CAB members opportunity to independently discuss matters that affect the research and its operations. The CAB shall provide an annual report to the PI for submission to the REC and UNCST.

3.7.6 The National Biosafety Committee

The National Biosafety Committee (NBC) is the national reference point for biosafety, biotechnology and biosecurity matters under the UNCST. The NBC provides technical advice on biosafety and maintains links with biosafety institutions through Institutional Biosafety Committees (IBCs). The NBC reviews biosafety, biosecurity and biotechnology components of research protocols, and recommends appropriate action. Where applicable, submission shall be made to the NBC prior to approval by REC/IACUC and clearance by the UNCST. Submission to the NBC shall require IBC clearance.

The NBC accredits the Institutional Biosafety Committees. Refer to the Institutional Biosafety Committee Standard Operating Procedures for additional information.

3.7.7 Institutional Biosafety Committees

3.7.7.1 Establishment

An institution that intends to conduct research using potentially hazardous materials in biosafety, biosecurity and biotechnology shall establish an IBC or shall have an affiliation with an existing IBC with similar or

closely related expertise and mandate. The IBC shall be composed of members drawn from the diverse fields of biological sciences and shall consist of not less than seven persons, at least three of whom shall have expertise in biosafety. The IBC may co-opt external expertise for a specified and defined period selected based on their area of expertise. A recommendation on an external expertise can be made by a IBC member or IBC chairperson in accordance with the policies of the institution that has established the IBC.

3.7.7.2 Functions of an IBC

An IBC shall perform the following functions:

a. Review and approve, laboratory experiments, contained use of genetically modified organisms GMOs, and regulated biological materials before submission to a REC/IACUC.

b. Regularly review, monitor and assess laboratory experiments, conditions of contained use, and adherence to relevant biosafety containment requirements.

c. Review applications to conduct confined testing, deliberate and controlled release, confined field trials, and general release and forward pertinent recommendations to UNCST or other national regulatory agencies as applicable.

d. Ensure that any information provided by applicants is correct and complete, before forwarding the application to the NBC / UNCST for consideration.

e. Conduct inspection or facility audit to ensure that conditions of contained use, lab conduct, confined field conduct align and comply with relevant national laws, regulations and pertinent terms and conditions of authorization.

f. Where applicable review suitability of a biobank establishment.

g. Assess field experiments to ensure that proposed risk assessment and risk management as well as emergency response measures are sufficient.

h. Undertake environmental risk assessment for the proposed intervention.

i. Supervise the destruction process of biohazardous substances and research product.

j. Provide interim and final reports every six-months for all active authorized regulated activities.

k. Maintain a record / database of all biosafety, biosecurity and biotechnology activities of the institution.

l. Liaise with national biosafety regulatory institutions and act as a contact point for biosafety regulatory procedures within the institution.

m. Advise the institution on biosafety capacity development needs.

n. To liaise with relevant research regulatory entities in the conduct of their roles.

o. In the performance of its functions, the IBC may constitute sub-committees for any purpose except in decision making on an application received.

4.0 ESTABLISHMENT AND FUNCTIONS OF RESEARCH ETHICS COMMITTEES

4.1 Introduction

Research Ethics Committees (RECs) are established by an organization to conduct initial and continuing review of research protocols and associated documentation with the primary goal of protecting rights and welfare of research participants. Organizations that conduct research involving humans as research participants may set up RECs in accordance with these guidelines. Where an organization cannot set up a REC, it may rely on a REC of another organization to review their research protocols, provided the REC is accredited by the ACRECU.

4.2 Establishment of a REC

An organization that wishes to establish a REC shall apply for accreditation of the REC at UNCST, with assurance that the organization shall comply with the requirements set forth in these guidelines. The assurance shall at the minimum include:

a. A statement of principles for protecting rights and welfare of human research participants. This may include an existing code, declaration, or statement of ethics principles, or a statement formulated by the organization itself.

b. Assurance of availability of staff, office and meeting space for the REC; and sufficient resources to support the REC's operations.

c. A list of REC members appointed by the head of the organization or his/ her designee. The members shall be identified by name, qualifications, profession, institution of affiliation and designation on the REC.

d. Standard operating procedures for the REC operations.

e. The ACRECU shall review the organization's application, and if satisfied, will accredit the REC. The REC shall not commence its activities until it has been accredited. For details refer to the guidelines for accreditation of RECs.

4.3 Composition of a REC

Each REC shall be composed of:

a. At least five (5) members, with varying backgrounds to ensure balanced and adequate review of research protocols. The REC members shall be sufficiently qualified by experience, expertise and diversity, including consideration of gender, cultural backgrounds and sensitivity to social issues of the communities from which research participants are drawn. Having a member with training in bioethics, epidemiology and biostatistics is desirable.

b. Each REC shall include at least one person not affiliated to the REC's institution.

c. Each REC shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.

d. Each REC shall include at least one lay person from the community.

e. No REC member may participate in the REC's initial or continuing review of any protocol for which the member has a conflict of interest, except to provide information as may be requested by the REC.

f. REC members and REC administrators shall receive a face-to-face training in human research participant protection (HSP) before initiation of REC activities and thereafter, shall undergo continuous education on Good Research Regulatory Practice (GRRP) at least once every three years. Additional training in other aspects of research ethics such as Responsible Conduct of Research (RCR) is desirable.

g. A REC may, at its discretion, invite individuals with competence in special areas to assist with the review of protocols, which require expertise beyond, or in addition to that available on the REC. These individuals do not vote at REC meetings.

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.

i. A person may not serve as a member in more than two RECs concurrently. REC members must guard against any tendencies of unethical conduct for example, they must protect the confidentiality of research documents and discussions.

A REC member shall not utilize the submitted protocol for his or her own use. The ethical acceptability of various aspects of a research protocol requires a thorough understanding of a community's customs, norms and traditions. The REC, therefore, must have competent members or consulting persons with such understanding.

4.4 Functions

The RECs are independent reviewers of research protocols; they ensure ethical and scientific conduct of research, and that participant's rights and welfare are not violated. The RECs shall review the science and ethics of the research protocols and all relevant documentation related to the study. RECs have a special responsibility to determine whether the objectives of a research study are responsive to the needs and priorities of the proposed target population and of Uganda in general. In view of this, the functions of any REC shall be to:

a. Maintain ethical and scientific standards of practice in research.

b. Protect research participants and researchers from harm or exploitation.

c. Preserve the research participants' rights and welfare.

d. Provide assurance to society of the protection of rights and welfare of research participants.

e. Ensure adherence to ethical conduct of research protocols.

Research by students (i.e.. college, tertiary institutions, undergraduate, masters) which presents no more than minimal risk, a notification by the REC to UNCST shall be required. All doctoral and post- doctoral fellows shall be required to submit to the REC and UNCST for clearance.

4.5 General Review Mechanisms

Each REC must have written SOPs to be followed in their review mechanism. The following are minimum requirements for a REC review:

4.5.1 General Requirements

a. RECs shall review protocols at convened meetings at which quorum is fifty percent (50%) of the REC members, including at least one lay member. Quorum shall be maintained at all times during the meeting and at voting. In order for the research protocol to be approved, it shall receive the approval of two third majority of REC members present at the meeting.

b. A REC shall meet as often as possible, but at least once every three months.

c. A REC shall notify researchers in writing about the outcome of review of the protocol within fourteen (14) calendar days from the date of review. In case the REC does not approve a research protocol, it shall include a written notification with reasons for disapproval.

d. A REC shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once a year, and shall have a plan for onsite monitoring of approved studies.

4.5.2 Other types of review

4.5.2.1 Fast Track /speedy review

A researcher may request for a fast track/speedy review of a protocol. The REC reserves the right to accept or reject the request. This review will occur as an extra ordinary meeting of the REC. The protocol shall undergo review by the full committee. This shall be at a convened meeting with quorum (at least 50% of the REC members) including one lay member. Quorum shall be maintained at all times during the meeting and at voting, as provided for in Section 4.5.1. and shall be done within 14 calendar days after submission of the protocol.

4.5.2.2 Expedited Review

a. The REC may use an expedited review process for only research involving no more than minimal risk or for minor changes to previously approved research protocols during a period of one year or less for which approval was given. Minor changes include such changes as addition of a collaborator or spelling corrections. Major changes include, but are not limited to, changes in the research methodology or a change in study procedures and these shall not be reviewed under expedited review mechanisms.

b. Expedited review process may be applied to annual renewal of studies, in which the only outstanding activity is data analysis and report writing. Each REC shall develop SOPs to guide the expedited review mechanism.

c. Expedited review may be done by the REC chairperson and/or one or more REC members and shall be done within 21 calendar days. The reviewers may exercise all of the authority of the REC except that the reviewers may not disapprove the research.

d. Each REC shall present all expedited review decisions at the next full REC meeting for ratification which shall be documented in the minutes.

e. The ACRECU may restrict a REC to conduct expedited review when it is determined that the REC is violating the process.

4.5.2.3 Exemption from REC Review

These are studies that are low risk, not requiring adherence to the regulations, including research informed consent, review. For example, use of publicly available unlinked data that does not identify individuals or communities; the researcher shall apply to the REC for exemption.

The REC Chairperson shall screen the application to ensure that the protocol satisfies the requirements and will thereafter, grant exemption within seven (07) working days.

The use of a checklist shall be required for review of studies by the REC and/or IACUC.

4.5.3 Review of Collaborative Research Studies

a. Collaborative research studies involve more than one organization locally and/or internationally. When conducting collaborative research, each participating organization is responsible for safeguarding the rights and welfare of research participants and complying with these guidelines. This may involve securing REC approvals from the foreign country prior to review and approval by the local REC and registration of the study by UNCST. Where desirable, participating organizations in a collaborative research study may have a joint REC review arrangement for that research study.

b. The local REC overseeing an international collaborative research study is the REC of record in view of its better understanding of cultural sensitivities of the population among which the proposed research is to be conducted. It is also better placed to monitor compliance with these guidelines during implementation of the study.

c. International collaborative research study shall have a Uganda- based PI/Co-PI listed on the protocol, who must be employed at and/or affiliated to a recognized local organization that is relevant to the area of the proposed research. The PI/Co-PI shall be qualified and competent to actively lead and/or supervise the research study. A collaborative agreement shall be signed by a legally authorized person at the local institution.

d. Where there is conflict between national and international policies, the Ugandan standards shall take precedence.

e. Where local bodies are conflicting, there shall be room for dialogue and harmonization by UNCST.

4.5.4 Joint Scientific and Ethical Reviews

Joint Scientific and Ethical Review (JoSER) is a form of review where research documents are reviewed jointly by the NRAs (UNCST, UNHRO and NDA) , Research Ethics Committee, or Institutional Animal Care and Use Committees (IACUCs) , NBC, Subject Matter Experts and relevant stakeholders. This review mechanism does not intend to replace the existing regulatory research oversight process as outlined in the National Research Guidelines and existing regulatory framework, but rather to optimize review timelines.

These reviews incorporate the expertise and synergies of the various stakeholders. Joint review shall be conducted for research that involves a novel technology, product, study design or intervention that addresses a public health need or/and emergency. The joint review committee will review the protocol to make the final review decision.

The UNCST shall serve as the secretariat for the initiated request for a joint review. Quorum of the primary REC shall be required for the joint review. The investigator/sponsor shall be responsible for any logistical requirements for the review meeting. The researcher shall then proceed with the national regulatory process of obtaining approval based on the outcome of the joint review, from the REC, UNHRO, NDA NBC, UNCST or other relevant regulatory organizations before commencement of the study. Joint reviews shall be initiated by; the investigator/sponsor, REC, NRAs and final determination shall be done by the UNCST.

Where possible joint monitoring of the research studies may be carried out by the REC together with UNCST, and where applicable, UNHRO, NDA and other relevant regulatory organizations.

Consideration for joint review may include but is not limited to the following:

a. Uncommon and complex study designs. These are studies that encompass a wide range of uncommon designs and multifaceted investigations for example, controlled human infection models, adaptive clinical trial design, stepped wedge trials and reverse pharmacology, among others.

b. Invasive and or investigational medical devices intended to treat, diagnose or prevent disease.

c. Research in public health emergencies.

d. Innovative treatments, investigational products or procedures for diseases. This could include new investigational products or registered products proposed for a new indication.

e. Unregistered product with limited information on use in humans, animals or plants in terms of risks and benefits

f. New and emerging technologies with limited information on their use in humans, animals or plants in terms of risks and benefits

g. Emerging and re-emerging infectious agents and toxins

h. Potentially hazardous material such as radioactive material

i. Genetic testing and modification in humans, plants, micro- organisms and animals

j. Invasive and endangered species

k. Use of human stem cells or fetal tissues in the prevention, treatment and diagnosis of disease.

l. Use of complementary and alternative medicinal products for prevention, treatment and diagnosis of diseases. This includes but is not limited to the use of herbal medicinal products, traditional, naturopathic medicine, and body-based practices such as reflexology.

m. Any other reason as deemed necessary by the ICs and/or NRAs.

The PI submits a completed assessment form. The assessment is performed by the REC/IACUC and submitted to UNCST for review. The final decision on whether a protocol is eligible for the joint review is made by the UNCST, based on the assessment by the REC/IACUC and/or any other reason as determined by the NRAs.

4.5.5 Review of Complex Studies, Phase I Clinical Trials and High-risk Studies.

UNCST shall designate RECs to review these 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.

4.5.6 Multiple Review

As a rule, a researcher shall submit his/her research protocol to the REC of his/her organization of primary affiliation or at an institution where he/she is going to conduct research. However, with justification, a researcher may request UNCST for permission to submit his/her protocol to another accredited REC. Where the organization of primary affiliation or host institution does not have a REC, the researchers are free to choose any of the accredited RECs to review their research protocols. Where a research protocol, has been approved by an accredited REC, such an approved protocol shall not undergo formal review by another REC in Uganda. For multi-center studies in-country, a single REC review shall be undertaken.

The organization where research is to be conducted shall grant administrative clearance for the study to be conducted even if that organization has a REC. The administrative clearance shall be submitted prior to UNCST approval. Administrative clearance is given by the head of the organization. It clearly specifies the conditions under which the research is to be conducted at the organization, including meeting minimal standards of the host institution, and any research costs such as bench or other administrative fees associated with the conduct of the research at the organization, which the researcher shall pay.

The approving REC has the primary responsibility for monitoring approved studies regardless of where they are conducted. The host institution where the research is to be conducted shall be made aware of the monitoring activity including the findings. Where the host institution has a REC, joint monitoring shall be conducted by the approving REC of the study and the REC of the host institution.

4.5.7 Review of studies using routine data

Many studies are carried out using data abstracted from clients' records or other record sources. The clients may not be reasonably available to provide informed consent. The Investigator shall request the REC for a waiver of consent to use these records for research. The REC and investigator shall ensure that privacy and confidentiality issues are well catered for. Relevant mechanisms shall be put in place to ensure protection of rights of privacy and confidentiality in relation to identifiable data. This shall include procedures such as anonymization and de-linking.

4.6 Types of monitoring

Research monitoring shall be done in two ways:

a. On site: This is monitoring performed at the research site. This can only be done physically.

b. Off site: This is monitoring of studies away from the research site. This can be done virtually or remotely and is where monitors do not visit the site to review the data and related documents but instead, the monitoring is done virtually. With the use of digital technology, this can be done from wherever the monitors are located. Research regulators shall review studies through different data sources including annual progress reports, ethics approvals, monitoring reports, serious adverse events (SAEs) reports, adverse events (AEs), suspected unexpected serious adverse reactions (SUSARs) reports, amendments, and de-identified research participants' documents. Consideration must be made to ensure privacy and confidentiality of participants.

4.7 REC Suspension of Approved Research

A REC shall have authority to halt, or suspend approval of research that is not being conducted in accordance with the REC's requirements or that has been associated with unexpected serious harm to research participants or that contravenes the UNCST guidelines.

The REC may suspend research when, for instance:

a. The researcher has implemented major changes to the research protocol without prior approval of the REC.

b. The researcher has failed to follow specific procedures or requirements enunciated by the REC in its initial review of the research protocol or

c. There is unexpected serious harm to research participants and/ or the community including, but not limited to, serious physical injury or death.

d. Any suspension of approval shall include a written statement of the reasons, together with what is required to be done for the suspension to be lifted and shall be reported promptly to the researcher(s) , host institution officials, UNCST and other relevant regulatory agencies.

4.8 REC Records

The RECs shall prepare and maintain adequate documentation of their activities, including the following:

a. Detailed written SOPs.

b. Copies of all research protocols reviewed, scientific evaluations that accompany the protocols, approved consent documents, progress reports submitted by researchers, reports of injuries to research participants and all related documents submitted with the protocols.

c. These records shall be kept either in hard or soft copy for at least five (5) years after closure of the research study.

d. Minutes of REC meetings, which shall be in sufficient detail to show attendance, conflicts of interests declared, actions taken by the REC and the vote including number of members voting for, against, and abstaining, the basis for requiring changes or disapproving research, and a written summary of discussions of controversial issues and their resolution. RECs shall provide a minute extract for approved protocols to the PI.

e. Copies of confidentiality agreements, CVs and training records of members and the REC.

f. Records of approvals, suspensions, amendments and continuing review activities.

g. Copies of all correspondence between the REC and researchers and/or their institutions.

h. Statements of significant new findings provided to research participants.

4.9 Basic Ethical Considerations for Approval of Research Protocols

In order to approve research covered by these guidelines, the REC shall determine that all of the following basic ethical considerations are satisfied:

a. The methods used are scientifically valid and practically feasible. The research protocol has a clear scientific objective, is designed using acceptable scientific principles, methods and reliable practices; and, where applicable, has sufficient power to test the study hypothesis.

b. The research study demonstrates value in terms of new knowledge to be generated and probably improvement in health care provision and general social wellbeing. There shall be foreseeable benefits to the individuals and community that is going to be studied, and risks shall be minimized.

c. Risks to research participants are minimized by using procedures consistent with sound research design and which do not unnecessarily expose research participants to risk. Risks, if any, should be reasonable in relation to anticipated benefits to the research participants, and the knowledge to be gained. Risks may include psychological, mental, social, physical and economic harms.

d. Benefits may include such aspects as medical care and treatment. They also include those that accrue to the wider community such as capacity building or enhancement of social amenities.

e. The selection of research participants is fair and equitable. In making this assessment the REC shall consider the purposes of the research and the setting in which the research will be conducted. It shall be particularly cognizant of special challenges associated with research on vulnerable populations.

f. Informed consent will be sought from each individual prospective research participant or the individual participant's authorized representative. Informed consent process will be documented in accordance with the provisions of these guidelines.

g. There are adequate provisions to protect privacy of research participants and to maintain confidentiality of personal identifiable information.

h. Additional safeguards have been included to protect vulnerable groups.

i. There shall be a provision for involvement of the community in the research process right from inception to post research period. The community in this context may be geographical or target population.

j. Research protocols shall adequately discuss the ethical issues likely to be encountered during the conduct of research and how they will be addressed.

k. Risk benefit analysis. Risks could be physical, psychological, social, economic and political.

4.10 Requirements for Submission to REC

All the RECs shall develop SOPs for submission of protocols and other requirements. Submissions shall be made electronically through the National Research Registration Information Management System (NRIMS) provided by UNCST.
At the minimum, the requirements shall include:

a. A complete research protocol with version and date this should have the title and list of investigators, summary/abstract, background to the study, problem statement, significance, justification, objectives, literature review, methodology, workplan, dissemination plan , community engagement plan, data sharing and ownership (where applicable), environmental impact assessment (where applicable), budget, references/ bibliography.

b. A site-specific implementation plan for multi-site studies.

c. Study instruments e.g. questionnaires, case report forms, videos, flip charts, data abstraction form and other data collection tools/forms.

d. Samples of trial drugs or devices (where applicable).

e. Informed consent documents in English and relevant local language (where applicable).

f. Data Sharing and Use Agreement (where applicable).

g. Material Transfer Agreement (where applicable).

h. Evidence that the researcher and the team are qualified, experienced and, where applicable, licensed, and have adequate facilities for safe and efficient conduct of research.

i. For foreign investigators, copies of work permits where applicable shall be submitted.

4.11 Obligations of a REC

The REC is obliged to:

a. Conduct initial and continuing/periodic review of research studies, including site monitoring visits.

b. Review of a site assessment report as submitted by the PI for a clinical trial. Pre-inspection shall be carried out based on risk assessment at the determination of the REC.

c. Review research protocols in a timely manner but in any case, within 60 calendar days from the date of receipt of a research protocol. In the case of annual continuing review, the REC shall maintain the same anniversary date of approval for any given research protocol.

d. Communicate outcome of the review within 14 calendar days from the date of REC review of the research protocol.

e. Respond to any allegations of ethical violations in research studies approved or rejected by the REC.

f. Liaise with other RECs within and outside the country for better conduct of its functions.

g. Prepare and submit annual reports of REC performance to the ACRECU.

4.12 Appeals

UNCST shall handle appeals arising from institutional RECs, IACUCs, research institutions and the community in consultation with other regulatory agencies. It will also act as an arbiter between a research applicant dissatisfied with a decision from the REC, IACUC, IBC and NBC.

A researcher who is dissatisfied with the REC, IACUC, IBC and NBC's decision may appeal to the Executive Secretary of the UNCST within 30 days from the date of receipt of REC decision. UNCST shall carry out an independent review in collaboration with other regulatory bodies where applicable.

For health research, UNCST shall carry out an independent review in collaboration with UNHRO.

5.0 INFORMED CONSENT PROCESS

5.1 Introduction

Section 7(1) of the Data Protection and Privacy Act (2019) provides that 'a person shall not collect or process personal data without the prior consent of the data subject. ' Consent is defined by section 2 to mean 'any freely given, specific, informed and unambiguous indication of the data subject's wish which he or she, by a statement or by a clear affirmative action, signifies agreement to the collection or processing of personal data relating to him or her. ' Consent is an oral declaration or written signature provided by participants, indicating a clear understanding and appreciation of the implication of an expressed agreement that allows for data collection and data processing. Consent shall be recorded, for example, in interviews, registration and application forms or electronic records. Data subject in these guidelines is referred to as research participant.

Informed consent is not just a form or a signature/mark/thumbprint but a process of information exchange between the researcher and research participants on the whole research process. Information provided shall be adequate, clearly understandable by the research participant with decision making capacity and the research participant shall voluntarily decide whether to or not participate. Respect for persons requires that research participants be given the opportunity to make choices about what shall be done to them.

5.2 General Requirements for Informed Consent Process

Except as provided elsewhere in these guidelines, no researcher shall involve an individual as a research participant unless the researcher has obtained informed consent of the individual or the individual's authorized representative. As an example, a community leader's permission for participation of community members in research should not replace the need for individual participants' informed consent.

A researcher shall seek such consent only after ascertaining that the prospective research participant has adequate understanding of the relevant facts and of the consequences of participation. The REC shall require the researcher to administer a comprehension test (or test of understandinto ensure that prospective research participants have acquired adequate understanding of the relevant facts and of the consequences of participation. Seeking consent shall be carried out under circumstances that provide the prospective research participant or the representative, sufficient opportunity to consider whether or not to participate and that minimize the possibility of undue influence. The information that is given to the research participant or the representative, whether it is conveyed orally, in writing or other delivery mechanism, shall be in a language and form understandable to the participant or their representative.

No informed consent, whether oral or written, shall include any exculpatory language through which the research participant or representative is: (1) made to waive or appear to waive any of the research participant's rights, or (2) appears to release the researcher, sponsor, organization, or its agents from liability.

The Investigator/designee shall not interpret and shall only read out or allow the potential/prospective participant to read the approved and stamped informed consent forms.

The RECs shall review the appropriateness of the informed consent process. The researcher as well as the REC shall ensure adequacy of the informed consent process, and re-consent research participants if there are changes in the conditions or procedures of the research study or if new information becomes available that could affect the research participant's willingness to continue in the research study.

5.3 Key Components of the Informed Consent Form

5.3.1 The information in the informed consent form, which is provided to each potential research participant, shall include the following:

a. A statement that this is a study rather than provision of clinical care (where applicable; that the study involves research; an explanation about the study; the estimated duration the research participant will take in the study; a description of the study procedures, and identification of any other procedures that are experimental.

b. A description of any reasonably fore seeable risks or discomforts that the research participant may experience.

c. Where relevant, a description of the benefits to the research participant and/or their communities that may reasonably be expected to result from the study including potential benefits of commercial value.

d. A statement describing the extent, if any, to which privacy and confidentiality of the research participant will be maintained including anonymization and de-identification of data and biological samples.

e. A statement about compensation and medical treatment available if injury occurs and where further information may be obtained.

f. Names and contact details of individual(s) who shall be contacted at any time in case of questions about the research study.

g. Names and contact details of individual(s) who shall be contacted at any time in case of questions about the research participants' rights and welfare.

h. The individual(s) obtaining informed consent shall be able to communicate in a language understandable to the research participant.

i. A statement that participation is voluntary, that refusal to participate will not result in a penalty or a loss of benefits to which the research participant is otherwise entitled, and that the research participant may discontinue participation at any time without penalty or loss of benefits to which the research participant is otherwise entitled.

j. Where applicable, a statement of how the researcher will provide or facilitate access to medical services to the research participant.

k. The nature, form and extent of compensation for study participation, e.g. reimbursement for transport, time, effort, inconvenience and refreshments.

l. A brief description of sponsors of the research study and the organizational affiliation of the researchers.

m. A statement that research participants will get feed back on findings and progress of the study, and that any new information that affects the study will be made available to research participants and/ or their health care providers including the research participant's willingness to continue his or her participation.

n. A statement that the study has been approved by an accredited Uganda based REC;

o. An explanation of circumstances under which the researcher may terminate the research participant's participation

p. An explanation of any additional costs to the research participant that may result from his or her participation in the research study.

q. A statement explaining the consequences of a research participant's decision to withdraw from the research study. Research participants may withdraw at any time without further notice. However, research participants shall be provided with a description of the procedures that are to be followed in order to give notice of their withdrawal. Researchers shall not follow up participants who have withdrawn from the study.

r. The approximate number of individuals participating in the research study.

5.3.2 Any of the following shall be provided to the research participant, based on the nature and conduct of the study:

a. A statement that a particular treatment or procedure under study may involve risk to the research participant, or to the embryo or fetus if the research participant is or may become pregnant, and that the risk is currently unforeseeable.

b. For new and emerging technologies and innovations in treatment and/or intervention, that have been shown to be efficacious efforts for post-research access shall be made.

c. A disclosure of relevant alternative procedures or courses of care or services, if any, that might be advantageous to the research participant.

d. A statement on whether, when, how and for how long any of the products or interventions proven by the research study to be safe and effective will be made available to the research participants at the end of the study and whether they will be expected to pay for them.

e. With regards to research involving the collection of human materials, an explanation shall be provided on how specimens will be managed at the end of the study. If the samples will be stored for future use, a separate consent shall be obtained (See section on storage of human materials).

f. That data and/or biological specimens may be used for commercial purposes and the extent to which the participants and/or their communities may benefit directly or indirectly.

5.4 Documentation of Informed Consent Process

The researcher shall document the informed consent process. This may be in form of handwritten notes about the discussions that transpire between the prospective research participant and the researcher. In addition, and except as provided in section 5.4.1 below, prospective research participants or their representatives shall sign/mark/thumbprint an informed consent form that is approved and stamped by a REC. The person obtaining the consent, and where applicable, the prospective research participant's witness shall also sign the form. Where the use of signed consent forms is not feasible, alternative viable methods like thumbprint shall be employed. A copy of the signed or otherwise completed consent form shall be offered to the prospective research participant or their representative.

The prospective research participant or their representative must be given sufficient time to read the consent form before he or she signs or places his/her thumbprint on the form indicating that he or she has read, understood and agreed to participate in the study. The consent form must be read to illiterate prospective research participants in the presence of a literate witness.

A surrogate/proxy shall consent for a prospective participant who is unable to comprehend information for participation in the study. When the participant is able to comprehend, he/she shall be re-consented to continue with study participation. Participants withdrawing from the study for any reason, will be required to consent on whether their samples and/or data may or may not be used in the research.

Verbal consent may be obtained in studies that present no more than minimal risk or in studies where for justifiable reasons written consent may not be feasible. Documentation of verbal consent is done by the investigator who writes a record of having obtained the consent. The information leaflet containing adequate information for a potential participant to make an informed decision shall be approved and stamped by the REC. The RECs reserve the right to determine when verbal informed consent may be appropriate and acceptable.

For some studies, a screening consent shall be separate from an enrollment consent. Information within the screening consent shall be study specific for determining eligibility.

5.4.1 Waiver of Requirement for Informed Consent

A REC may waive some of, or all the requirements for the researcher to obtain informed consent for some or all of the research participants if the REC determines that:

a. The research study carries no more than minimal risk, that is, risk that is no more than the risks encountered in daily life in a stable society.

b. The research study could not practically be carried out without the waiver or alteration. Whenever appropriate; the research participants will be provided with additional pertinent information after participation.

c. In situations where deception needs to be applied to achieve the objectives of the study.

d. If the only record linking the research participant and the research study would be the informed consent form which would cause risk to the research participant resulting from a breach of confidentiality.

e. The human materials and data have been de-identified or anonymized.

5.5 Other types of consent

5.5.1 Deferred consent

Deferred consent is a strategy used in emergency clinical research whereby participants are enrolled and included in research without prospectively providing consent. In a deferred-consent procedure, the participant or their representative is incapable of providing informed consent. The participant shall be consented once he or she is able to comprehend the information provided. Relevant documentation of this instance(s) shall be provided by the researcher.

Deferred consent shall be clearly justified by the researcher and the REC shall give approval to the research procedure under which the action is taken.

5.5.2 Tiered consent

This is a type of consent framework which gives the research participant multiple options to agree to or decline different aspects of research or research procedures. This allows for greater flexibility and autonomy in decision-making, as participants can choose the level of involvement that they are comfortable with.

5.5.3 Broad Consent

This is a consent framework which permits researchers to utilize bio-specimens and/or their associated data related to the primary area of study. On a case-by-case basis as approved by the REC and the UNCST, participants shall be reconsented for use of stored bio-specimens and/or their associated data in research not related to the primary area of study.

5.5.4 Blanket consent

Blanket consent also known as open consent is a framework where the research participant agrees to use their bio-specimen and/or associated data in any field of study beyond the primary study. This shall not be acceptable in Uganda.

5.6 Assent

Assent to participate in research shall be obtained from all children aged 8 to 17 years of age and for certain categories of people like mentally incapacitated individuals in accordance with their evolving capacity. The child's dissent takes precedence over the parent's or guardian's consent. For research involving more than minimal risk, parental consent shall be sought from both parents of a child unless one of the parents is reasonably unavailable.

The assent forms shall be in a language that is comprehensible by an eight-year -old. Where applicable relevant illustrations of the study procedures may be used. The researcher shall ensure continued adequacy of the informed consent process, and re-consent research participants including consent for continued storage of samples when they attain age of majority (18 years).

Children 14-17 years of age who have drug or alcohol dependency or a sexually transmitted infection; 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 is categorized as follows:

a. Legal guardianship which is granted by court order from the High Court. This one lapses when the child attains the age of 18 years or the guardian dies or suffers infirmity of body or mind.

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 defines Customary guardianship as parental responsibility of a Ugandan child by a Ugandan citizen resident in Uganda in accordance with the Customs, culture or tradition of the respective people. The customary guardian should indicate in writing that he/she is the appointed customary guardian.

c. 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 councilor at LC1.

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.

Assent for all other person's incapable of self-determination is obtained after consent from their representatives. Their dissent takes precedence over consent by the representatives.

5.7 Informed Consent by Pregnant Women

For interventional research involving pregnant women, informed consent shall be obtained from both the mother and father of the fetus. However, the father's consent shall not be required if: (i) the purpose of the research is primarily to meet the health needs of the mother; (ii) the father's identity and/or where abouts are unknown; (iii) the father is not reasonably available; (iv) the pregnancy resulted from rape or incest and (v) the father is incompetent to give consent. No provision of this subsection shall be construed as authorization to terminate a pregnancy where such termination would not otherwise be in conformity with current laws of Uganda relating to the termination of pregnancy.

5.8 E-Informed Consent (eIC)

Refers to the use of electronic systems and processes that employ any electronic media including text, mobile phone applications, graphics, audio, video, podcasts, passive and interactive websites and card readers to convey information related to the study and to obtain and document informed consent.

The E-Informed Consent (eIC) must contain all required components of informed consent. Use of eIC must obtain prior approval from the REC. The REC submission shall also include the appropriate information materials e.g videos and web-based presentations. The researcher shall demonstrate that the study population is able to comprehend and have the ability to use E-consenting mechanisms.

5.8.1 Documentation of E-consenting

This shall undertake the following form;

a. Digital signature means transformation of a message using an asymmetric cryptosystem such that a person having the initial message and signer's public key can accurately determine:

b. Whether the transformation was created using the private key that corresponds to the signer's public key; and Whether the message has been altered since the transformation was made.

c. An electronic signature is in electronic form affixed or logically associated with a data message, which may be used to identify the signatory in relation to the data message and indicate the signatory's approval of the information contained in the data message.

d. It means computer data compilation of any symbol or series of symbols executed, adopted or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature. To assist the participant in understanding the IC material, the eIC may use interactive electronic-based technology, which may include diagrams, images, graphics, videos, and narration. The eIC shall be for the intended audience, taking into consideration the participant's age, language, and comprehension level. The eIC may contain various methods to help an investigator assess the participants' understanding of the information being presented during the eIC process.

The copy provided to the participant may be in paper form, on an electronic storage device or via email. If the copy includes one or more hyperlinks to information on the Internet, the hyperlinks shall be maintained and information shall be accessible until study close-out. Measures for privacy and confidentiality of information shall be available at the research entity.

The REC and UNCST must be granted access to records and reports made by the investigator, including site-specific versions of the eIC, materials submitted to RECs, all amendments to the site-specific eICs, and all signed eICs. These shall be available at the site either in electronic or paper form.

5.8.2 Controls for electronic documents

Electronic documents systems can be closed or open. These shall require procedures designed to ensure authenticity, integrity, and when necessary, confidentiality of the electronic document, and to ensure that the signer cannot renounce the signed document as not genuine. Such procedure and controls shall include the following:

a. Validation of systems to ensure accuracy, reliability, consistent performance, and the ability to discern invalid or altered documents.

b. The ability to generate accurate and complete copies of documents in both human readable and electronic form suitable for inspection, review, and copying by REC or UNCST.

c. Protection of documents to enable accurate and retrievability throughout the document retention period.

d. Use of operational system checks to enforce permitted sequencing or steps and events as appropriate.

e. Use of authority checks to ensure that only authorized persons can use the system, electronically to sign documents, access the operation or computer system input or output device, alter a record or perform the operation at hand.

f. Determination that persons who develop, maintain or use electronic records and/or electronic signature systems have the education, training and experience to perform assigned tasks.

g. Use of appropriate controls over systems documentation including: adequate controls over the distribution of, access to, and use of documentation

for system operation and maintenance; revision and change control procedures to maintain an audit trail that documents time- sequenced development and modification of systems documentation.

h. In these guidelines for ease and interpretation and use, eIC has been categorized into;

i. On site: the documentation of informed consent is done in the presence of the investigator/ designee and the witness. This is applicable to both low risk and high-risk studies. The informed consent documentation shall have all the required components.

j. Off site: is only admissible for use in a minimal risk study. The documentation of informed consent is done without the presence of investigator/designee. The informed consent documentation shall have all the required components. For clinical trials and high risk studies, off site e-consent shall not be applicable except in special considerations as approved by the regulatory bodies.

The E-consenting procedures and signatures shall follow the Uganda Electronic Transactions Act, 2011 and the Electronic Signatures Act, 2011.

6.0 VULNERABLE GROUPS AND INDIVIDUALS

6.1 Introduction

Some groups or individuals are relatively (or absolutely) incapable of protecting their interests. They may have insufficient power, intelligence, knowledge, education, resources, strength, or other requisite attributes to protect their own interests. Individuals and groups conventionally considered vulnerable are those with limited capacity or freedom to freely consent or decline consent. These include, but are not limited to; children, older persons, street children, prisoners, the homeless, refugees, internally displaced persons, substance abusers, handicapped (mentally and physically) , armed forces personnel, terminally ill, pregnant women, fetuses and minority groups. In some cases, willingness to volunteer to participate in research is unduly influenced by expectation of benefits associated with their participation, or fear of retaliation from interested senior members of the hierarchy in case of refusal to participate.

Vulnerable groups and individuals need special considerations to ensure their protection. Researchers, whose research involves vulnerable groups and/or individuals, shall specify how they will address vulnerabilities.

6.2 Additional Protection for Vulnerable Populations

Certain communities may also be vulnerable. Characteristics that constitute vulnerability in such communities include one or more of the following:

a. Limited economic empowerment.

b. Conflict and post-conflict situations and inadequate protection of human rights.

c. Discrimination on the basis of health status.

d. Limited availability of health care and treatment options.

e. Communities in acute disaster and disease epidemics.

f. Communities that may criminalize certain behavior

6.2.1 To protect vulnerable individuals or groups/ communities, RECs shall ensure that:

a. Selection of communities is justified by the research goals.

b. Research is responsive to needs and priorities of the community where it is to be conducted.

c. Research can only be conducted in this group and individuals if the objectives of the research study cannot be addressed using non-vulnerable groups and individuals.

d. Risk of participating in research is justified by anticipated benefits.

e. The intervention or procedure presents experiences that are commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

f. The intervention or procedure is likely to yield generalizable knowledge about the group or individual's disorder or condition that is of importance for the understanding or amelioration of that disorder or conditions.

g. RECs shall co-opt a person knowledgeable about and has experience working with the vulnerable group and/or individuals.

h. For pregnant women and fetuses, relevant studies on animals and non-pregnant individuals have been completed.

7.0 CARE AND TREATMENT FOR RESEARCH PARTICIPANTS

7.1 Introduction

A care package for research participants shall be stated before initiation of a research study. Care and treatment for research participants shall be provided with the ideal aim of providing the best proven intervention and, at the least, shall be in accordance with the current Uganda Clinical Guidelines and other national guidelines and standards. In the absence of these standards, the researcher, REC, sponsor, UNCST in collaboration with UNHRO and other regulatory bodies shall agree on the care and treatment package to be provided.

The duration and sustainability of care and treatment for the research participant after the study shall be negotiated before initiation of the study. Sponsors are encouraged but not obliged to provide care and treatment for chronic and relapsing illnesses.

Researchers and sponsors are obliged to manage serious adverse events/harm related to the study (including paying associated costs thereountil they are fully resolved or stabilized. Researchers shall provide relevant follow up for research participants for the duration as approved.

Where mass treatment programs have been established by policy, the Principal Investigator may adopt this as a standard of care. The standard of care during medical tourism and medical camps will adhere to the guidelines of the Ministry of Health and Health Professional Councils.

7.2 Care for Research Participants in Control Groups

Research participants in a control group of a research study shall receive at least the national standard of care. Sponsors may provide care and treatment beyond what is recommended in the national guidelines.

A placebo or no intervention may be used in the control group where:

a. There is no proven intervention.

b. Withholding a proven intervention would expose the research participant to at most a mild and temporary discomfort or delay in relief of symptoms.

c. Use of a proven intervention as comparator would not yield scientifically reliable results and where use of a placebo or no intervention would not add any risk of serious or irreversible harm to the research participant.

Once the intervention being studied is demonstrated to be superior, the sponsor(s) shall as soon as possible offer it to research participants in the control arm.

7.3 Care for Research Related Injuries

The sponsor shall provide care until complete cure or stabilization of a research related injury. The affected research participant shall be given the optimal care available in the country. Research participants shall not waive their legal rights.

7.4 Referral of Research Participants

The researcher shall refer all research participants whose conditions may not be managed adequately within the expertise and licensure of the medical professionals at the study site, and/or where facilities or supplies at the study site do not allow adequate handling of the condition.

The referral process shall be adequately documented, and all referral guidelines shall be adhered to as stipulated in national guidelines on referral. Furthermore, researchers shall have prior arrangements with the referral facility to receive study participants who need additional care. Research participants shall always be informed of options available for management of their conditions including those outside the country. Where a referral has been made for a research related injury or a serious adverse event related to the study, the cost of referral and management of the condition shall be paid by the researcher and/ or study sponsor. Individuals who do not meet study inclusion criteria but need care shall be linked to care by the researcher.

7.5 Compensation for Research Related Injury

Subject to applicable laws in Uganda, research participants shall be entitled to compensation when they suffer injury classified as possibly, probably or definitely related to their participation in research. Sponsors shall ensure that research participants are entitled to free medical treatment for such injury and financial or other assistance as would compensate them equitably for any resultant impairment, disability or handicap. For clinical trials, medical treatment and compensation shall be covered through the mandatory clinical trial insurance.

A research related injury may be physical, social, economic or psychological, and may be classified as follows:

a. Definitely: When injury is directly caused by participation in a research study.

b. Probably: When injury is most likely explained by participation in a research study but when no definite proof of causality is evident.

c. Possibly: When explanation for injury is equally due to participation in a research study or other cause.

d. Unlikely: When injury is more likely explained by another cause other than participation in a research study.

e. Not related: When injury is clearly due to another cause other than participation in a research study.

Research participants shall not be asked to waive the right to compensation and shall retain legal rights to seek monetary compensation for research related injuries including settlements out of court, in accordance with applicable laws in Uganda.

Any research regulatory body, institution, researcher or participant and any other stakeholder may initiate the compensation process. The UNCST, UNHRO, research host institution, institution of affiliation and sponsor shall agree on an appropriate mechanism for arbitration.

7.6 Compensation for Participation in Research

Research participants shall be compensated for inconveniences, effort, time spent, and expenses incurred in taking part in a study such as travel costs as deemed relevant by the REC and UNCST. Compensation can be in kind. Refreshments and meals are not compensation for research participation but a welfare aspect for study participation. Research participants may also receive free medical services. The compensation or medical services shall not be out of proportion as to induce individuals to participate in research.

Compensation shall also be considered for screening procedures where applicable.

7.7 Incentives for Research Participation

Incentives can be given but shall not be considered a research benefit and shall not present undue inducement to potential participants as determined by the REC.

8.0 ADVERSE EVENTS, SERIOUS ADVERSE EVENTS AND OTHER REPORTABLE EVENTS

8.1 Introduction

Adverse event is any untoward occurrence to a participant enrolled in a trial who has received a trial intervention. The event may or may not be causally related to the intervention. The researcher shall identify, manage and promptly report serious adverse events to the REC and NDA with a notification to UNCST.

8.2 Defining Serious Adverse Events and Unexpected Events

8.2.1 A serious adverse event is an event, which:

a. Results in death.

b. Is life threatening.

c. Requires - patient hospitalization or prolongation of existing hospitalization.

d. Results in significant and persistent incapacity.

e. Is a congenital anomaly or birth defect.

f. Is an important medical condition in the opinion of the investigator.

8.2.2 An unexpected event is an event:

a. Which is previously unobserved or undocumented in humans under the health research intervention (or one substantially similar).

b. Whose nature or severity is not consistent with information in the investigators' brochure or other safety information known at the time.

c. Which is observed with higher frequency or severity than previously documented.

d. Unexpectedness shall not include events that may reasonably be extrapolated from in vitro and animal studies.

8.2.3 The relatedness of adverse events and unexpected events

The relatedness of adverse events and unexpected events to an intervention can be graded as follows by attending clinicians:

a. Definitely: When the event is directly caused by the intervention.

b. Probably: When the event is most likely explained by the research has intervention but when definite proof causality is not evident.

c. Possible: When explanation for event is equally due to research intervention or other cause.

d. Unlikely: When the event is more likely explained by another cause.

e. Not related: When the event is clearly due to another cause.

8.3 Management of Adverse Events and Unexpected Events

a. The research protocol shall clearly state how the researcher will identify, manage and report adverse events and unexpected events.

b. The 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 in this regard in a bid to strengthen capacity and provide quality assurance.

c. Before determination of relatedness, all Adverse Events care shall be provided to the research participant at the study's cost.

d. The staff and clinical facilities where research is going to be conducted shall be licensed/approved for patient care.

e. Where a participant cannot be adequately treated at the site, the researcher shall refer the participant to more advanced or specialized facilities for better management.

f. The researcher shall meet treatment costs for adverse events that are deemed possibly, probably, and definitely related to the study intervention.

g. The researcher shall properly document occurrence of serious adverse events or unexpected events and

their management.

h. Serious Adverse Events that are not resolved at the end of the study shall be followed up to resolution or stabilization.

8.4 Reporting Serious Adverse Events, Unexpected Events and Suspected Unexpected Serious Adverse Reactions (SUSARs)

Reporting requirements specifically include:

a. All serious adverse events regardless of relationship to the intervention.

b. All unexpected events of greater than moderate severity regardless of relationship to the intervention.

c. All Suspected Unexpected Serious Adverse Reactions

All SAEs, SUSARs and unexpected events of greater than moderate severity must be reported to the local REC and if appropriate to NDA as soon as possible and in any case no later than seven (7) calendar days of becoming aware of the event. A detailed report of all the above event s shall be submitted within seven (7) calendar days from the date of reporting to the REC. A notification of these events shall be made to the UNCST and a final report shall be submitted to the local REC, UNCST and if appropriate to NDA after resolution of the event.

Certain categories of interventions with potential long-term effects may require extended follow up and monitoring for SAEs. These may include investigations involving for example genetically modified substances, gene therapy and DNA-based compounds. The extended follow up and monitoring period shall be determined by the REC on a case-by-case basis. Children born by participants who become pregnant during trials shall be followed up for a minimum of two years.

8.5 Other reportable events

All other reportable events are defined as an unanticipated problem involving risks to participants or communities or continuing noncompliance to the established national research regulatory standards.

These could include notifiable diseases, criminal acts, injury, social harm, economic harm, psychological harm, deaths and life-threatening events in studies and any other event deemed reportable by the law and the investigator. These shall be reported to the REC and UNCST as soon as possible and in any case not later than fourteen (14) calendar days. Other events include:

a. All events associated with protocol violations regardless of severity and relationship to any intervention.

b. When criteria for stopping or pausing a study as stipulated in the protocol are met.

c. Any event mandated by regulatory bodies.

d. Any event stipulated in the protocol as reportable to the regulatory bodies.

This section on other reportable events shall apply to non-interventional studies

8.6 Protocol Violations and Deviations

Protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the REC.

Any change, divergence, or departure from the study design or procedures of a research protocol that affects the participants' rights, safety, or wellbeing and/or the completeness, accuracy and reliability of the study data constitutes a protocol violation.

Changes or alterations in the conduct of the research which do not have a major impact on the participants' rights, safety or well-being, or the completeness, accuracy and reliability of the study data are considered minor protocol deviations.

When any of these occur, the PI shall report to the REC. Protocol violations and deviations should be avoided except for purposes of intervening when a participant's life is in danger.

The report shall contain the following information:

a. Title of the study,

b. Name of principal investigator

c. Organizational affiliation,

d. Date of report,

e. Date(s) when the event occurred,

f. Brief description of what happened,

g. Any effect on the study,

h. Any adverse events arising from the violation and deviation,

i. Management and follow up of violation or deviation and steps to avoid recurrence of the violation.

For a violation and major deviation, notification to the REC and where applicable the collaborating organization's REC and UNCST shall be made by the principal investigator within seven (7) calendar days of becoming aware of the event.

For a minor deviation, notification to the REC and where applicable the collaborating organization's REC and UNCST shall be made by the principal investigator within annual report.

9.0 RESEARCH IN EMERGENCY SITUATIONS

9.1 Introduction

Research in emergency situations raises unique ethical issues that need to be appropriately appreciated and addressed. Emergency conditions arise out of medical, public health and disaster situations. The complexity and sensitivity of research in this area involves balancing the need to advance knowledge and improve emergency care with the imperative to protect the rights, safety, and wellbeing of research participants and their communities. The following principles shall apply to research in emergency situations-

a. Competence of the study team to conduct scientifically valid, sustainable, and beneficial research.

b. Compassion to attend humanely to the comfort and dignity of all research participants and their communities taking into consideration the context.

c. Respect of persons in ensuring safety, privacy, rights, and personal welfare of all research participants, emphasizing the need to respect the right to self-determination irrespective of the emergency context.

d. Impartiality, treating equitably those associated with the research and avoiding exploitation.

e. Maintaining integrity and honesty of the research process.

f. Responsibility in all aspects of the science and ethics of research.

g. Collaboration and coordination with other researchers and agencies, where appropriate.

9.2 Compassionate use

Compassionate use sometimes referred to as expanded access is a treatment option that allows the use of an unauthorized medicine. Under strict conditions, products in development can be made available to individual patients or groups of patients who have a disease without authorized therapies and who cannot participate in clinical trials. Compassionate use is not a substitute for properly conducted clinical trials. It does not provide adequate grounds for proper risk/benefit analysis nor informed decision making by the participants.

Domains under which Compassionate use is implemented:

a. Chronically or seriously debilitating disease.

b. A life-threatening disease that cannot be treated satisfactorily by an authorized medicinal product.

c. Disease outbreaks where there is no proven treatment.

9.3 Monitored Emergency Use of Unregistered Investigational Interventions (MEURI)

This refers to a protocol developed to use unproven clinical interventions outside clinical trials during public health emergencies. Unlike clinical trials, the primary objective of MEURI is not to investigate a drug's efficacy and/or safety, but to obtain direct therapeutic benefit for a given patient. Pre-clinical studies should have been completed; however, the product's full safety and efficacy profile in humans and dosage guidelines may not be fully established. MEURI shall therefore not be implemented as usual research process but shall undergo regulatory oversight by REC, UNCST, UNHRO and NDA to ensure safety and welfare of participants as well as data integrity for evidence-based policy change.

9.4 General provisions

Safety and efficacy data collected during compassionate use programmes are generally methodologically inferior to well conducted clinical trials and therefore such programs shall not ordinarily replace clinical trials for investigational purposes. The general requirements shall include:

a. The product to be used must have received favorable opinion for compassionate use by the Director General of Health Services of Ministry of Health.

b. It should be demonstrated that the patients' needs the treatment, and that there are no alternative treatments that may offer better outcomes.

c. A plan for monitoring safety and efficacy.

d. The investigator shall write a protocol describing the known literature, justification for use, community engagement plan, detailed data management plan. Safety monitoring shall be done by a DSMB.

e. There shall be provision of written informed consent.

f. Characteristics of the disease condition and rationale for proposed intervention shall be clearly written.

g. The protocol shall be reviewed by the REC and/or NBC, UNCST, UNHRO and NDA preferably by the joint review mechanism.

10.0 RESPONSIBILITIES OF RESEARCHER, SPONSOR AND RESEARCHER'S ORGANIZATION OF AFFILIATION

10.1 Researcher

The Principal Investigator is responsible for the overall conduct and supervision of the research study. Specifically, the researcher shall:

a. Ensure that the research protocol is fully developed.

b. Demonstrate ownership of the research protocol (e.g. by signing the protocoand ensure that it is strictly followed at study implementation.

c. Implement changes/amendments to the research protocol with prior approval of the REC, except when necessary to eliminate an apparent immediate hazard or danger to research participants.

d. Promptly investigate all serious adverse events (SAEs) and take relevant actions to ensure safety of all research participants. The SAEs and actions taken shall be reported to the REC, research partners and the sponsor in accordance with specified timelines.

e. Provide adequate care for research participants in accordance with these guidelines.

f. Take reasonable steps to provide research participants with an intervention that has been proven to be effective except if the study is a clinical trial.

g. Advise in writing to the REC, UNCST and other relevant regulatory agencies about early termination of the study and the reasons for the termination.

h. Ensure good documentation of all study procedures and data.

i. Ensure data integrity.

j. Ensure capacity building component in different forms relevant to the study.

k. Ensure timely feedback on the research process and findings.

l. Take all reasonable steps to engage with the community/stakeholders.

m. Investigators shall engage with relevant ministries and/or agencies, and study sponsors in case the intervention is proved efficacious, it can be made available to the community.

n. Prospectively register clinical trials in a publically available registry at the UNCST.

o. Have adequate time to implement/ supervise the study and shall be reasonably present and active at the study site.

p. Notify the institution, REC and UNCST about study closure.

q. Ensure research teams have undertaken training and complied with:
   i. GCP, GCLP, HSP and RCR for clinical trials
   ii. HSP and RCR for social behavioral studies
   iii. GCLP, GCP, HSP and RCR for laboratory related studies.

Such trainings shall be approved by UNCST.

Guidance on the required training

Initial face-to-face training before study commencement is encouraged. Research teams shall receive training before initiation of study activities and thereafter, undergo continued research ethics education at least once every three years.

a. A researcher shall be qualified and licensed to carry out the particular study being proposed. Foreign investigators shall have a valid work permit where applicable especially when actively involved in the research implementation within Uganda.

b. For a clinical trial, ensure that he/she is a competent and qualified clinician.

c. Ensure mechanisms for dissemination of research findings.

d. Ensure publications are shared with the research regulatory agencies.

10.2 Sponsor

The sponsor is responsible for providing all the necessary financial support for implementation of the research study, including post-research obligations. Specifically, the sponsor shall:

a. Approve the final study report whether or not the research study has been completed.

b. Cause the timely reporting and management of adverse events.

c. Be responsible for participant compensation or indemnity in the event of research- related injuries, disability, or death, in accordance with applicable Ugandan laws and regulations.

d. Make provisions for research agreement between the sponsor and the researcher's institution of affiliation in Uganda.

e. Ensure occupational safety and health for the research teams.

For clinical trials involving investigational drugs and devices the sponsor shall:

a. Provide the REC and all other regulatory authorities, a description and sample of the investigational or comparator drugs.

b. Provide a dossier (research protocol and investigator's Brochure).

c. Ensure that the investigational product and any comparator products are of quality and are subject to quality assurance procedures.

d. Promptly provide the investigator with any relevant new information that arises during the course of the trial, including information relating to product safety.

e. Be responsible for the proper packaging and labelling of the investigational product(s) or medical device. The investigational and comparator products must be labelled in conformity with the research protocol and the labelling must state that the product is for investigational purposes only.

f. Retain sufficient samples of each batch of the investigational products under study and a record of analyses and the study sample characteristics so that, if necessary, an independent laboratory may check the product for quality control or bioequivalence.

10.3 Researcher's Organization of Affiliation

The researcher's organization of affiliation both public and private shall supervise and monitor research activities of the researcher(s). Specifically, the organization shall:

a. Establish, and/or designate a functional accredited REC(s) to review their research protocols in accordance with the provisions of these guidelines.

b. Ensure that they have qualified and competent, and where necessary, licensed researchers to carry out the research studies at the organization.

c. Facilitate the smooth implementation of research studies conducted at the organization, and dissemination of research findings.

d. Take measures to train and mentor the organization's staff in skills necessary to achieve the organization's research development goals. Such training shall include regular courses in Responsible Conduct of Research (RCR) , research ethics and where applicable Good Clinical Practice (GCP) and Good Clinical Laboratory Practices (GCLP).

e. Research institutions shall have mechanisms for the dissemination and translation of research findings into policy.

f. Take disciplinary action against researchers for non-compliance with these guidelines and this shall be through development and operationalization of research misconduct and conflict of interest policies.

g. Ensure occupational safety and health for the research teams.

h. Indemnify research teams.

i. Have in place internal quality control and quality assurance mechanisms.

j. Have in place a data protection officer as required under Section 6 of the Data Privacy and Protection Act (DPPA-2019).

k. Register with the Personal Data Protection Office as required under Section 29 of the DPPA-2019.

l. Handle issues of research integrity and misconduct

m. Perform all other duties as required by the relevant laws.

10.4 Research host institution responsibilities

The responsibilities shall include:

a. Provision of space and necessary facilities for research implementation.

b. Monitor research progress as deemed necessary.

All stakeholders shall maintain adequate and accurate source documents as hard copies or electronic. All research records shall meet standards for source documentation practices; attributable, legible, contemporaneous, original, accurate, complete, consistent, and available.

11.0 ADVANCED THERAPEUTIC MEDICINAL PRODUCTS AND DIAGNOSTICS

11.1 Introduction

Advanced Therapeutic Medicinal Products (ATMPs) are medicines for human use that are based on genes, tissues or cells. They offer ground breaking new opportunities for the treatment of disease and injury. Some ATMPs may use one or more medical devices as an integral part of the medicine.

Research in advanced therapeutic products such as research in gene editing techniques, tissue invasive intervention devices and stem cells research shall be submitted for Joint Scientific and Ethical review.

Research that involves manipulation of the human germ line or heritable genome is not permissible.

11.2 Tissues and organ transplant research

Organ and tissue donation is when a person (a donor) donates their organs or tissues to another person (a recipient). These include, but are not limited to, ocular (corneas and scler, cutaneous (skin, dermis) musculoskeletal, cardiovascular and birth tissues and organs.

Research on tissue and organ transplant shall follow the Ministry of Health applicable standards in reference to the Uganda Human Organ Donation and Transplant Act 2023 and shall follow the established research regulatory framework.

12.0 TRADITIONAL AND COMPLEMENTARY MEDICINE RESEARCH

12.1 Introduction

Traditional and complementary medicine is knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Generally, traditional and complementary medicine research is subject to the same ethical standards as conventional research practices. The research shall follow scientifically reliable procedures and observe the fundamental ethical principles of autonomy, beneficence and justice and the ethical review process outlined in these guidelines.

12.2 Additional considerations for traditional knowledge

a. Indigenous knowledge of the community shall be recognized. There shall be mechanisms to share benefits equitably. This may include support to the community to conserve their traditional knowledge and genetic resources.

b. There shall be considerations for protecting intellectual property or traditional knowledge in accordance with the relevant laws in Uganda.

c. Research protocols shall explain certain terminologies that may be unique to the indigenous languages of the community where the research is to be conducted.

d. The study team involved in traditional and complementary medicine research shall include the traditional knowledge holder and trained scientists.

e. There shall be mechanisms for access and benefit sharing through establishment of memoranda of understanding (MoUs) and/or research collaborative agreements.

WHO Guidelines for methodologies on research and evaluation of traditional medicine shall be utilised in development of research protocols and their review.

13.0 GENETICS AND GENOMICS RESEARCH (GGR)

13.1 Introduction

Genomics is the study of the total or part of the genetic or epigenetic sequence information of organisms and attempts to understand the structure and function of these sequences and of downstream biological products. Genomics in health examines the molecular mechanisms and the interplay of this molecular information and health interventions and environmental factors in disease.

Genomics is distinct from genetics. While genetics is the study of heredity, genomics is defined as the study of genes and their functions, and related techniques. The main difference between genomics and genetics is that genetics scrutinizes the functioning and composition of the single gene whereas genomics addresses all genes and the inter-relationships to identify their combined influence on the growth and development of the organism.

13.2 Regulation

Research involving germline editing and species hybridization among humans shall not be carried out in Uganda.

Submission of raw sequence datasets into public databases shall meet the requirements of the DPPA (2019).

13.3 Requirements, Procedures and Guidelines for Conduct of Genetics and Genomics Research

The following requirements and procedures shall apply in the conduct and regulation of genetics and genomics research in Uganda. Review shall be undertaken by a REC and/or NBC, IACUC, UNCST and where applicable the NDA.

13.3.1 Informed Consent for GGR

There shall be a separate informed consent and documentation where GGR is a component within a main study. In addition to the general elements of an ICF this shall include specific components such as return of results and incidental findings, fair benefit sharing, genetic counseling and extending informed consent to family and community on a case-by-case basis to be determined by the REC.

In case of return of results, the consent shall involve obtaining consent at recruitment as well as re-consenting at the time of returning results. All interpretable and verified results or results with a meaning including incidental findings whether actionable/beneficial shall be returned. The participants shall be given options to consent i.e. tiered consent for return of interpretable and verified results. With participant's consent, participant's family and/or other third parties may be given an opportunity to participate in the consent process including disclosure of findings and return of results.

The vocabulary and language shall be understandable by the study participants and comprehension shall be objectively assessed and documented. This shall include candid declaration of the risks and benefits associated with the testing.

13.3.2 Genetic Counseling

Genetic counseling refers to guidance relating to genetic and genomic research that is provided to participants and/or community by healthcare personnel trained in genetic counseling.

The healthcare personnel trained in genetic counseling might provide information about how a genetic result of research and/or condition could affect a participant and/or community and/or interpret genetic tests designed to help estimate the risk of a disease. The counselor conveys information to address the concerns of the participant and/or community, helps them make an informed decision about their medical situation and provides psychological counseling to help them adapt to their condition or risk.

Genetic counseling shall include:

a. Appropriately trained personnel in genetic counseling.

b. Clear Standard Operating Procedures.

c. A risk management plan associated with the study.

d. Clear documentation of the counseling process.

e. Assessment using an understanding tool for comprehension of the genetic counseling process with a minimum pass mark of 80%.

13.3.3 Genetic Testing

Genetic testing is a medical process that involves analyzing an individual's DNA to identify genetic variations, mutations, or alterations that may indicate a predisposition to certain health conditions, diseases, or traits. Genetic tests shall be undertaken in accredited laboratories. In addition, there shall be evidence of appropriately trained and qualified personnel.

13.3.4 Return of Results

For results that have a potential to affect a community, community consultation shall be done in consultation with the CAB, REC and UNCST before disseminating the results.
When sharing genetic results with family and community (where applicabl, the following shall be considered:

a. Potential social, economic and psychological risk and their implications.

b. Legal implications of extending or not extending feedback.

c. Use of appropriate strategies to share information.

13.3.5 Privacy and Confidentiality

Despite all efforts to protect privacy and confidentiality of participants in genetics and genomics research, complete anonymization of an individual's research results can be challenging. However, the following mechanisms designed to ensure confidentiality of participants shall be adhered to:

a. A description of how privacy and confidentiality shall be maintained both during and after the study.

b. Limitation of sharing feedback to non-participants.

c. Ensure anonymization and de-identification.

d. Restricted access to participants' genetic and genomic information. Information concerning the participant's health shall only be disclosed with consent, except when required by law, when done in public interest or on court order. The institution shall ensure that the health service provider does not disclose any participants' information. Disclosure to third parties is justifiable in any of the following cases.

e. Referral and management of a participant.

f. For protection of the health of others or the public.

13.3.6 Commercialization and benefit sharing

There shall be appropriate community consultation before embarking on the GGR due to the potential benefits and commercialization.

The benefit sharing plan shall include but not limited to the following:

a. Informed consent provisions about benefit sharing.

b. Mutually agreed terms between the relevant community and the research institution.

c. Materials Transfer Agreement between the provider institution and the recipient institution as stipulated in section 14.4(k) under Exchange/ Transfer of Human Materials for Research Purposes. These shall be approved by the REC and UNCST.

13.4 Pathogen genetics and genomics

Pathogen Genetics: Is the process of identification, and tracking of pathogen species, subspecies, strains, clones, and genes of interest by means of molecular technology and evolutionary biology; and evaluation of the impact of a pathogen's genetic diversity on its relevant medical properties such as pathogenicity or drug resistance.

Phylogenetics is the branch of pathogen genetics that involves the study of evolutionary relationships among organisms or genes. Phylogenetics is a well- established scientific discipline, but one that is more commonly used to study viral dynamics within populations of organisms, rather than to suggest direct virological links between specific individuals.

Research in pathogen genetics and genomics shall follow the same provisions on genetics and genomic research.

13.5 Stigma and Risk Determination

Research may involve groups of people suffering from conditions associated with stigma or outlawed behaviors, phenotypes or lifestyles. The reporting of genomic research results involving such groups has the

potential to aggravate existing stigma, marginalization, or penalties for individuals belonging to these groups. Researchers shall consider the role that community engagement could play in managing some of the stigma-related risks that may arise.

a. Principal Investigators/sponsors shall relay to the RECs, IACUCs and community representatives information regarding any likely risk that secondary use of samples and data could cause to individuals or groups.

b. Where concerns about stigma are linked to sharing of genomic materials and samples, researchers shall liaise with relevant stakeholders (including RECs/ IACUC and community representatives) to discuss the appropriateness of data and sample sharing, and secondary use.

c. Where there are concerns about potential harm and to the extent possible, investigators from the countries and/or institutions where samples were collected shall be involved in secondary research studies to ensure appropriate interpretation of research results, capacity building, and potential translation of pertinent research findings into health policy and clinical practice.

d. Researchers shall always be mindful of how communities and population groups are described and identified in research publications and be aware that some descriptions could be perceived to be prejudiced or stigmatizing. Where possible, and where there is an identified risk that research could increase stigma, the researchers shall consider possibilities to obscure the group identity, for instance by only referring to the broader population that the community is part of, or by not naming locations for sample collection.

14.0 HUMAN MATERIALS

Human materials are a vital resource for advancing scientific knowledge and medical research. They provide the basis for understanding human biology, diagnosing diseases, and developing new treatments. However, their use requires a careful balance of scientific ambition with ethical responsibility, ensuring respect for the individuals who provide these invaluable resources through public health surveillance, research, post-mortem and clinical care. These materials include but not limited to: blood, urine, stool, saliva, hair, nail clippings, skin, genetic material (DNA and RNA) , cerebrospinal fluid, biopsies and reproductive materials (eggs, sperm, embryos) and any other associated bio-products obtained from human research participants or patients or healthy persons.

14.1 Acquisition

Any person who collects human materials shall ensure that informed consent has been obtained from the sample sources, including consent for storage for possible uses in future. Collection of samples shall follow acceptable standard procedures. 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 Biobanking Guidelines- January 2021.

14.2 Storage and Future Use

A separate informed consent form shall be used for human materials, which are collected with the intention of being stored and used in future studies. The consent form, which is separate from the one used for enrollment of research participants into the study, shall include the following components: purpose of sample storage, nature and quantities of samples to be stored, place where samples will be stored specifying the full address, duration of storage, measures to protect confidentiality, policies that will govern use of the samples in future research, potential risks and benefits of storing samples for future research, the right to withdraw consent for identifiable samples and data and any other information deemed necessary by the researcher or REC. After explaining the need to store the samples, the research participant shall be given the option to choose whether his/her sample shall or shall not be stored for future studies. A Ugandan scientist shall be included as a co-investigator in all future studies using the human materials collected from Uganda.

Use of samples by third parties' written consent shall be obtained from the provider organization, local PI or their assignees and approval from the REC of record.

A research participant shall not be penalized for his/her refusal to store the samples. Research participants reserve the right to withdraw their samples from storage if the samples are linked. Any future research study on such samples is subject to review by a REC and final registration at the UNCST.

Where samples have been collected, for example, as part of routine surveillance, emergency procedures, laboratory quality control, notifiable diseases, routine counseling and testing, etc. without the prior intention of conducting research on the samples, the following may be done:

a. Sample sources and or their representatives shall be traced to provide consent for use of the samples in research.

b. Waiver of consent with a clear justification shall be sought from the REC.

14.3 Ownership

While institutions typically hold custodianship of donated materials, sample sources own the samples. Sample sources may withdraw their samples if the samples are linked. Samples shall be held in trust on behalf of the sample sources by a duly registered and recognized organization in Uganda. The organization entrusted with custodianship of the samples shall have the authority to decide use, transfer, storage and future use of the samples taking into consideration the rights and welfare of the research participants.

14.4 Exchange/Transfer of Human Materials for Research Purposes

When it is necessary to transfer samples for storage or other uses from one organization to another within the country and abroad, the provider organization holding

the samples on behalf of sample sources shall negotiate a contract with the recipient organization. This contract shall be in the form of a Materials Transfer Agreement (MTA). To justify transfer of human materials abroad, researchers, sponsors and collaborators shall demonstrate that in-country capacity to perform certain types of investigations/ testing does not exist or is inadequate. Samples may be transferred for quality assurance, laboratory reference purposes and training to build local capacity.

Researchers, sponsors and collaborators are encouraged to build, develop or strengthen local capacity for any investigative testing to fulfil the objectives of the proposed research.

Exchange and transfer of materials for research purposes from within and outside Uganda including exchange between institutions within the country shall require an MTA. The MTA shall be reviewed and approved by the REC and final clearance and approval shall be sought from UNCST.

The following principles shall guide material transfers:

a. Quality of bio specimens
b. Respect of autonomy of research participants
c. Protection of research participants' privacy and confidentiality
d. Appropriate policies for bio specimen use
e. Scientifically sound research purpose

As a guide, the MTA shall include the following clauses:

a. Parties

The MTA must carefully list provider and recipient parties and their addresses. The MTA is signed only by legally authorized head of the institution or delegated officer. Effective date of the MTA must be indicated.

b. Description of materials

The materials being transferred/ exchanged must be fully described, including a description of derivative products, if any. Quantities must be specified and appropriately packaged.

c. Purpose and usage

The recipient shall fully describe the intended use of the materials. The recipient shall specify the intended research purposes. Materials shall not be transferred for commercial purposes.

d. User(s)

Authorized users of the materials shall be mentioned. The users cited must agree to abide by the terms and conditions of the MTA. Transfer to third parties not mentioned in the MTA is prohibited without written consent of the provider organization, local PI or their assignees and approval from the REC of record.

e. Location

The place (full address) where materials are to be transferred, used and/or stored shall be indicated.

f. Period of use of material(s)

A date for termination of use of the material(s) may be set to avoid indefinite use of the material by the recipient organization. This date may be extended by written mutual consent of the parties. At the termination date, the provider organization may ask for the return of the material or its destruction. It shall be noted that terminating use of the material does not render null and void other provisions of the MTA. It shall be mentioned if the material would be stored for future unknown uses. The approval for storage of human materials for future use shall be up to 5 years from expiry of the UNCST clearance and approval. Status report shall be provided at the end of 5 years and if there is need for continued use or storage of human materials beyond the specified time shall require further approval from the REC in Uganda and UNCST.

g. Disposal of material

A disposal plan for the materials must be described in the MTA, including methods of disposal. Disposal of material must be sufficiently documented. The destruction process shall follow applicable standards and guidelines.

h. Restrictions

If there are specific restrictions for the recipient organization, they shall be described. Specific restrictions may, for example, include: to be used for one purpose and not the other; to be used in a specific site or country only or to be used strictly under the laws of a specific country. It shall, however, be noted that any research study to be conducted in future using stored samples of human origin will be subject to review and approval by a REC in the provider's country.

i. Ownership of derivatives

The provider organization shall clearly state whether the recipient organization is allowed to own any derivatives of the material developed over time. The provider organization may allow the recipient organization to retain the derivatives without any stipulations.

j. Ownership of the product

The MTA must state who owns any new products discovered using the material. If nothing is stated about this in the MTA, the provider organization automatically assumes ownership.

k. Commercialization and Benefit sharing

The MTA shall include procedures for handling commercialization of products, including sharing of any loyalties. The parties may wish to include a clause, which allows them to negotiate a separate MTA should the need for commercialization arise. Negotiations for commercialization and benefit sharing should be initiated before conduct of study.

l. Technology transfer

The MTA shall state clearly what technologies would be transferred to the provider organization or country. Other collateral benefits to the provider organization such as building infrastructure, training and provision of certain services may be included.

m. Publication and Citation Requirements

The provider and recipient scientists shall agree on modalities for publication of the research findings and the provider organization shall be appropriately acknowledged.

n. Governing law

The MTA shall refer to the governing laws of the provider's and recipient's country or both.

o. Responsibilities

The recipient and provider organization are responsible for the proper handling and use of the material.

p. Liability

Both parties are accountable for any misuse or consequences of use of the material and must agree on liability.

q. Warranty

The MTA shall state that the provider is giving the material "as is" and does not promise that material will perform in any specific way.

r. Amendment

The MTA shall have a clause which states that it may be amended at any time by written mutual consent of the parties.

s. Termination of MTA

The MTA may be terminated by either party providing a written notice in an agreed time frame. Parties must, however, make provisions for benefit-sharing of any accruing or anticipated future benefit at the point of termination. Evidence of the destruction of samples shall be submitted to UNCST once samples are destroyed.

t. Dispute resolution

The MTA shall have a clause on how and where disputes shall be resolved and managed.

When preparing MTAs, care shall be taken not to contravene provisions of other existing agreements pertaining to the human material in question. If, for example, the human material is to be used together with material governed by a separate MTA, care shall be taken under such circumstances to avoid granting two or more parties conflicting rights to the same material or product. Usually before negotiating an MTA, parties correspond by mail to reach consensus on particular issues regarding the material. Such correspondences,

which include, for example, signed letters indicating consent or willingness to exchange, transfer or acquire the material, may be attached as annexes to the MTA.

Where parties have a memorandum of understanding (MoU) to exchange, transfer or acquire human materials within a given research programme over a specified period of time, the MTA shall be prepared within the framework of the existing MoU. The MoU usually does not specify details of the human materials, but allows in principle, the exchange, transfer or acquisition of the human materials.

14.5 Procedure for Exchange/Transfer of Human Materials for Research Purposes

The following are the necessary steps for the exchange or transfer of materials for research purposes within and outside the country:

a. The research study that involves the exchange or transfer of human material shall first be registered by UNCST.

b. The applicant must be a legal resident of Uganda and must be affiliated to a locally registered organization in Uganda.

c. A request for exchange or transfer of human material shall be made in writing to the Executive Secretary of UNCST.

d. The MTA and any other document related to the exchange or transfer of human material shall accompany the request for the exchange or transfer of the material.

e. The applicant shall receive feedback from UNCST on the status of his/her request within fourteen (14) calendar days from the date of submitting the request in (c) above. The feedback may be an approval/ clearance, reject/ disapproval or comments to improve the quality of the application for the exchange or transfer of the human material.

14.6 Return of results and disclosure of (un) solicited findings.

Medical findings resulting from use of biological materials and related data whether unsolicited or not, can be returned to the participant. The research protocol and sample informed consent process must clearly stipulate whether return of information derived from analysis of the materials is fore seen.

Participants shall have the option to receive their results if they wish. The information given to the participant shall clearly state that providing individual diagnoses is not the purpose of the biobank or future research study, to prevent false reassurance of donors by the absence of unsolicited findings.

14.7 Approval and Use of stored human materials

Approval of storage human materials shall be for a duration of 5 years beyond which the PI shall submit a report of the stored materials and a request for approval for continued storage. The participant's decision concerning duration of storage should be upheld in all decisions.

14.7.1 Minimum requirements for the 5-year report

a. Study title

b. Investigator

c. Storage location

d. Number of samples in storage

e. Description of preservation methods

f. Analysis done

g. Preliminary results

h. Planned activities

i. Status of REC approval (copy of current REC approval)

15.0 BIO BANK

15.1 Introduction

A Biobank also referred to as a biorepository is a collection of biological materials and, the associated data and information stored in an organized system, for a population or a subset of a population. A biobank collects, processes, stores, and distributes bio specimens to support future scientific investigation. It can contain or manage specimens from animals, humans, and many living organisms.

The approval for storage of biological materials for bio banking shall be up to 5 years from expiry of the UNCST clearance and approval of the study. A status report shall be provided by the investigator at the end of 5 years. If there is need for continued use or storage in accordance with the participant storage consent and the MTA, further approval shall be required from the REC and UNCST.

15.2 Establishment

The establishment of a Biobank shall be initiated by any legally recognized organization which shall act as the custodian on behalf of the donors who are the owners of the biological materials and bio data. Bio-banks shall be accredited by UNCST in reference to the National Banking Guidelines for Research 2021.

The custodian organization shall ensure that a biobank has:

a. Evidence of operation as a legal entity,

b. A clearly defined protocol and scope,

c. Standard Operating Procedures, defining ethical requirements, technical, quality management, information technology, safety and biosecurity requirements,

d. A business plan with evidence of resources in place,

e. A sustainability plan,

f. Governance structure of the biobank,

g. Evidence of proficiently trained and competent personnel,

h. A contingency plan e.g. covering natural disasters and relocation of the biobank,

i. Provision for equitable access by various stakeholders,

j. Certification of the building/infrastructure suitability by Ministry of Works and Urban Planning and Development or the applicable relevant authorities,

k. Evidence of Environmental Impact Assessment by the National Environment Management Authority (NEMA) ,

l. Clearance from the Institutional Biosafety Committee,

m. Have risk assessment plan for the biobank,

n. Have all administrative requirements according to the accreditation committee of the UNCST.

15.3 Standard Operating Procedures (SOPs) for Biobanks

The Bio bank must have SOPs which shall comprise of the following elements:

a. How authorization from the sample donors is/was obtained.

b. How the donors can retract this authorization.

c. Circumstances in which sample donors need to be re-contacted.

d. A procedure for determining whether unsolicited findings shall be disclosed, and if so, how they shall be managed.

e. How the quality of the bio specimens is controlled.

f. How confidentiality of the link between biological specimens and personal identifiers of the donors is maintained.

g. Who may have access to the bio specimens for future research, and under what circumstances.

h. Which body may review research protocols for future use of the bio specimens.

i. Appropriate mechanisms for keeping donors informed of research outcomes.

j. How participatory engagement with patient groups or the wider community is organized.

k. To which other sources of personal information the results of analyses on biological specimens may be linked.

l. In broad terms, which types of research will be pursued. Which types of research will be excluded or included only after contacting the donor for consent.

m. To whom any benefits from the research are expected to accrue.

n. How the rights and welfare of individuals from whom the bio specimens were collected are not adversely affected. All governance systems shall follow the principle of accountability and shall maintain good stewardship of stored biological specimens and related data. None of the regulations concerning the storage, use and the final fate of biological samples shall contradict or overrule conditions originally stated in the informed consent documents and agreed to by research participants.

16.0 RESEARCH DATA

16.1 Introduction

Data protection and privacy has been of public concern especially since computer and communication technologies emerged in the 1970s.

16.2 Privacy and confidentiality of data

Under section 20(1) of the Uganda Data Privacy and Protection Act-2019 (DPPA) , a data controller, data collector or data processor shall secure the integrity of personal data in the possession or control of a data controller, data processor or data collector by adopting appropriate, reasonable, technical and organizational measures to prevent loss, damage, or unauthorized destruction and unlawful access to or unauthorized processing of personal data.

Researchers shall have in place mechanisms for ensuring safety, privacy, confidentiality and proper disposal of research data including electronic domains such as anonymization delinking and/or strict custody of delinked identifiers

16.3 Data Storage

Section 18(1) of the DPPA states that a person who collects personal data shall not retain the data for a period longer than is necessary to achieve the purpose for which the data are collected and processed. Researchers shall ensure that research records from which the data have been obtained are available at the research site for a specified period after completion of the research study as follows; at least 20 years for clinical trial studies and at least 5 years for any other type of study. This shall include hard and or electronic copies. Mechanism of backup shall be stated in the protocol. A local server in-country shall be used for storage and backup of the data.

16.4 Source document disposal

Data shall be disposed of in a way that protects confidentiality of the participants. Disposal can be in form of delinking, deleting or destruction. Documents must be disposed of in a way that prevents reconstruction in an intelligible form. Request for disposal shall be submitted to the REC for approval with a notification to UNCST prior to disposal of data.

16.5 Digital technologies and electronic records

The emergence of new technologies and sources of data, such as social media, mobile phone data, satellite imagery, and Artificial Intelligence (AI) are increasingly used in research. This has both opportunities for improved data migration, protection and policymaking but may create risks for loss of privacy, confidentiality and data security. Utilization of electronic data requires safe guards and compliance with national laws and policies.

Minimum requirements for the establishment of research E-Systems shall follow the components stipulated in Annex1.

16.6 Artificial Intelligence in research

Artificial intelligence (AI) refers to systems that display intelligent behavior by analyzing their environment and taking actions with some degree of autonomy to achieve specific goals. AI-based systems can be purely software-based, acting in the virtual world (e.g. voice assistants, image analysis software, search engines, speech and face recognition systems). AI can also be embedded in hardware devices (e.g. advanced robots, autonomous cars, drones or Internet of Things applications).

AI can also be defined as a computer program's capacity to execute tasks associated with human intelligence such as adaptation, sensory understanding and interaction. This is the ability to analyze quantities and sources of data. It links data, finds patterns and yields outcomes across domains.

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.

The Principal Investigator shall provide administrative clearance from the national body responsible for information systems and data protection prior to submission to the REC, IACUC, and/or NBC and final registration and clearance by the UNCST.

16.7 Open databases

Open data refers to data that can be freely used and shared by anyone for any purpose, under strict principles of privacy and confidentiality, when appropriate. The main ethical issues to be considered in the protocol are:

a. participant autonomy,

b. privacy and confidentiality,

c. commercialization rights,

d. community harm,

e. purpose and intended use, and equity.

Submission shall be made to the REC, IACUC, and/or NBC, and final registration and clearance by the UNCST.

16.8 Digital migration

Digital migration means the conversion of digital information from an existing format to another format that maintains the content, context, and structure of a record. The main ethical issues to be considered in the protocol are; privacy and confidentiality, iownership and iidata safety and security. Appropriate backup shall be put in place for data storage in-country.

Exchange of data shall be negotiated between provider and recipient institutions using appropriate Data Transfer and Use Agreements (DTAs) approved by the REC/IACUCs and the UNCST. The providing institution is the primary custodian for all data collected. The providing institution in Uganda shall always be appropriately acknowledged in publication and dissemination of results.

17.0 PARTNERSHIPS AND COLLABORATION

17.1 Introduction

Researchers shall ensure that there is equitable partnerships and collaborations. All MoUs, MTAs, DTAs and research collaborative agreements shall be signed off only by legally authorized head of the institution or delegated officer.

17.2 Benefits in research

In cases where there are expectations of tangible benefits that will accrue to an identifiable group, a benefit sharing arrangement shall be discussed and agreed to by the relevant stakeholders. Fair benefit sharing is the action of giving (or measures taken to ensure that) a portion of advantages/profits arising from utilization of research findings, associated traditional knowledge, and subsequent applications and commercialization, in an equitable manner to the individuals, institutions or communities identified as having contributed to resource management, research and development, and/or commercialization, in order to achieve justice.

Feedback of study results to research participants is expected in all types of research. Representatives of local communities shall be involved in discussions regarding this benefit. Where there are no expectations of tangible benefits arising as a result of research, researchers shall explore other ways in which they may confer benefits to research participants and their communities. These could take the form of social recognition, support for local infrastructure, feasible ancillary care for diseases discovered in the course of a study and capacity building.

In all cases and to the extent possible, researchers shall clearly articulate expected benefits associated with research, and consider how research participants and their communities are likely to partake of such benefits. This involves ensuring that no unrealistic expectations are raised, especially about monetary benefits.

17.3 Data Ownership

Research participants are sample sources and own their data. Institutions are custodians of data and can negotiate its use. Collaborating research partners shall negotiate data ownership and use in accordance with the institution of affiliation's data use and ownership policies. Ownership of data shall be clearly stated in the research protocol and DTAs which shall be reviewed and approved by the REC, or IACUCs and UNCST.

17.3.1 Elements of Data Transfer and Use Agreements

The elements of a DTA shall include:

a. User(s) ,
b. Purpose,
c. Description of data,
d. Restrictions,
e. Publication rights,
f. Ownership,
g. Privacy and Confidentiality,
h. Security of data,
i. Data Collection, management and Processing
j. Methods of data sharing,
k. Period of use,
l. Governing Laws,
m. Warranty,
n. Costs,
o. Amendments, and
p. Termination of the DTA.

17.3.2 Data Sharing, Access and Use

Collaborating research partners shall agree on appropriate data access, sharing and use rights before commencement of the study. A collaborating research partner shall not transfer data to a third party without the written consent of the other partner. Researchers shall have mechanisms for ensuring privacy and confidentiality as stated in the DPPA. A copy of the data sets shall be available for access by the local institution.

18.0 CAPACITY BUILDING

It is of key importance that research programs include appropriate capacity building for either one or more of the following: human resource development, financial management, grant administration, infrastructure and technology transfer.

Plans should provide for study members involved in different aspects of research such as sample processing, data generation and analysis, and preparation of manuscripts for publication, in which they shall be granted co-authorship.

For new and emerging technologies, therapeutics and designs, efforts shall be made for infrastructural capacity enhancement and professional development by the institution of affiliation. This shall be provided for in the protocol.

19.0 COMMUNITY ENGAGEMENT

19.1 Introduction

Researchers shall make reasonable effort to involve community stakeholders in the research process, where appropriate, right from the inception of research to post research period. Community stakeholders may include individuals and groups that are ultimately representing the interests of people who would be recruited to or who participate in research as research participants, as well as others who are locally affected by the study. Engaging with the community is a process of building transparent, meaningful, collaborative, and mutually beneficial relationships with interested and/or affected individuals, groups of individuals, or organizations, with the goal of shaping research collectively. Involvement of community stakeholders shall not override the rights of individuals to consent voluntarily for participation in a research study.

19.2 Principles of Community Engagement

The following principles are useful for effective community engagement:

a. Mutual Respect

Respect among stakeholders is key to communicating effectively, fostering trust, and developing partnerships to achieve shared goals. Respect is demonstrated when stakeholders communicate and act in ways that value and honor each other's perspectives and realities. This respect includes respect for local values, cultures, and perspectives as well as respect for the scientific process.

b. Mutual understanding

A common understanding about objectives and how to achieve them is essential to effective partnerships among stakeholders. Researchers shall understand the norms, practices, and beliefs of relevant local cultures, and local social stances, as well as diverse community stakeholder perspectives, priorities, and research needs. This informs the design of the study so that it is culturally appropriate.

c. Mutual Trust

Community engagement shall aim at building, strengthening, and sustaining trust between researchers and communities. An open, truthful, and active community engagement is critical for building and maintaining trust among stakeholders. The success of an individual research program as well as the sustainability of conducting research in communities depends on mutual trust between communities and researchers.

d. Integrity

Researchers shall strive for the highest standards of scientific and ethical conduct of research. This is vital for achieving scientific goals and maximizing benefit to the community and society.

e. Transparency

Transparency about research includes ensuring that stakeholders receive open, honest, and understandable information about the objectives and processes of research. Transparency means ensuring that feedback from a broad range of stakeholders is acknowledged and addressed. It also includes ensuring that stakeholders are clear on their respective roles and responsibilities, the constituents they represent, and the extent to which their input may influence research-related decisions.

f. Accountability

Accountability is fundamental in sustaining relationships built in trust and mutual respect. Community engagement is one of the strategies for ensuring that stakeholders in research take responsibility for their decisions and actions (or inactions). Research funders, sponsors, researchers, research regulators, research ethics committees, among others are accountable to the society at large for conducting scientifically valid and ethical research. They also ensure that funding is adequate to enable optimal engagement between research teams and other stakeholders. Researchers shall put in place strategies for improving research participants' and communities' participation in the research process.

19.3 Community Engagement Practices

Researchers are encouraged to identify community stakeholders early enough during study conception and design. It is important to consult with the identified stakeholders to get their input or participation in the research process. Such consultation involves obtaining prior agreement from community gatekeepers such as local chiefs, local administration officials or heads of organizations where research is to be undertaken. Such consultations with community stakeholders shall be undertaken prior to seeking approvals from relevant RECs and other relevant regulatory authorities. This does not mean that consultations with community stakeholders shall end after approval of research by the REC, neither shall agreement with community stakeholders be taken as a substitute to the REC process; but rather community engagement is an ongoing process.

19.4 Approaches to community engagement

Researchers may engage with the community in a variety of innovative ways, which broadly include, but not limited to, community education to improve research literacy, community dialogues to promote understanding, research participation and ownership. Community engagement approaches include, but are not limited to engaging the following:

a. Formative consultations
b. Existing community structures and groups
c. Community leaders
d. Community events
e. Mass media
f. Community Advisory Boards (CABs)

Researchers' choice of the approaches for community engagement shall consider the fact that not every approach can be relevant for every research. Hence, researchers shall consider the following for whichever approach(es) they choose:

a. Nature of the research, for example, if participation in the research may lead to stigma and discrimination, then it may not be relevant to use mass media and any other approach that may compromise participants' privacy and confidentiality.
b. The characteristics of the target community/ population e.g. , age, literacy levels, reading culture, gender, culture and religion.
c. The goals of community engagement in the particular research study.
d. The cost implications to both the researchers and the community, for example, using Internet-mediated communication may impose costs on the community. Researchers need to consider the magnitude of the costs and how they will be covered.
e. Privacy and confidentiality issues, including the venue and number of participants attending the meetings, and their frequency including cyber security.
f. Local/community power dynamics which can potentially affect the success of research and uptake of results. Although a community is defined by a common identity among its members, researchers shall take into account religious, social and cultural norms
g. Potential misconceptions about the research that may be left unaddressed and or unresolved.
h. Potential perceptions of sectarianism and discriminatory tendencies. For example, use of social and cultural institutions.
i. The language to be used shall be relevant to the target community.
j. Accessibility and ability to effectively and sustainably use the selected community engagement approach.
k. Timing of activities e.g., when targeting rural communities there is need to take into consideration the seasons and the times of the day.
l. Appropriate feedback mechanisms. Where required these shall be accessible, convenient, affordable, and secure.
m. Risks of transmission of infection.
n. Applicable national laws, regulations, and policies

19.5 Community Engagement Plan

Researchers shall develop a detailed clear community engagement plan the approaches and activities that will be employed to that effect. The plan should also include providing feedback on the research results, the outcomes of the research process and shall be shared with the RECs, IACUCs and UNCST.

A community engagement plan helps researchers design and implement activities in a systematic manner. It also provides a point of reference for those involved, evidence and, or criteria against which to monitor, evaluate and improve the quality of the engagement.

19.5.1 Minimum Elements of a Community Engagement Plan

The minimum elements of a community engagement plan shall include:

a. Goal and objectives.

b. Key community stakeholders.

c. Research team responsible for community engagement.

d. Approach(es) justification for selecting them; activities and mode of their implementation.

e. Annual work plan and budget.

f. Communication strategy for engagement.

g. An evaluation plan for the community engagement activities.

h. Plan for identification, mitigation, documentation and addressing risks, conflicts as well as grievances resulting from community engagement efforts.

i. Where applicable monitoring efforts for long term follow up shall be provided.

20.0 RESEARCH INTEGRITY

20.1 Introduction

Research Integrity refers to the use of honest and verifiable methods that can be trusted by other people, involving adoption of generally acceptable methods in proposing, performing, and evaluating research, including reporting research results while focusing on adherence to guidelines and commonly accepted professional codes or norms.

Integrity in research is fundamental in the advancement of knowledge and maintenance of trust in scientific findings. It involves adherence to the ethical principles and professional standards essential for responsible practice of research. Integrity of research is based on the following core values: honesty, accuracy, accountability, transparency, fairness, efficiency, objectivity, respect, reliability and good stewardship.

20.2 Types of research misconduct and other unacceptable practices

Research misconduct undermines the credibility of scientific work and can have serious consequences for the individuals involved and the broader scientific community. Types of research conduct include:

a. Fabrication is making up data or results entirely. This can be done by inventing data points, manipulating images, or falsifying research materials.

b. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

c. Plagiarism is using someone else's ideas, words, or results without giving them proper credit. This can be done intentionally or unintentionally.

Types of misbehavior:

a. Salami slicing is publishing a single study in multiple publications to create the appearance of more research than was actually done.

b. Duplicate publication is publishing the same research findings in multiple publications without proper disclosure. This is a violation of a journal's publication ethics policies.

c. Authorship issues which include ghost authorship (where someone who made significant contributions to the research is not listed as an author), gift authorship (where someone who did not contribute to the research is listed as an author), and honorary authorship (where someone is listed as an author as a courtesy but did not contribute to the research).

d. Conflicts of interest arise when a researcher's personal or financial interests could influence their research. Researchers are required to disclose any conflicts of interest to their research institution and to the journals where they publish their work.

e. Improper data collection or analysis can include using faulty methods, failing to get proper consent from research participants, or mishandling data. This can lead to unreliable or invalid research findings.

f. Violation of research regulations which includes failing to get the necessary approvals for human or animal research, or failing to follow safety protocols according to institutional, national, and international regulations.

g. Data management issues which include poor data storage practices leading to loss or corruption of data that compromises its integrity and not sharing data as required by funding bodies or journals.

20.3 Identification of Research integrity issues

This shall be the responsibility of all stakeholders. These include researchers, institutional administrators, Institutional Committee (IC) , research communities, research participants or any other interested party.

20.4 Reporting mechanisms

a. One shall report to the relevant department or institution. This could include the , host institution and/or institution of affiliation, regulatory agencies such as UNCST, NDA, UNHRO, UNBS, UWA, NFA, and where applicable the data Protection and Privacy Office.

b. If one deems that the institution is unable to handle the nature or source of the allegation or is unable to reliably report to his or her institution, or the institution is unable to handle, a report shall be made to UNCST.

c. All allegations will be treated with fairness, sensitivity and respect. The UNCST shall acknowledge receipt of the allegation within five (5) working days and will advise the complainant about the procedure of handling research misconduct issues. While the UNCST will endeavor to comply with all the timelines outlined in this procedure, these may be extended in exceptional circumstances.

Non-reporting of research integrity issues is research misconduct.

20.5 Management mechanisms

One shall lodge a complaint with the responsible officer at the department or institution and the institution shall handle the matter as follows:

a. Inquiry: Institution initiates an inquiry to discover/ confirm whether there is a genuine case.

b. Investigation: If the department or institution finds that there is a case to answer, an investigation shall be done within 60 working days from the date of report of the complaint. After the investigation is done the institution shall provide a report to the parties involved.

c. Reporting to regulatory agencies: If the person is aggrieved by the institution, they shall appeal to the UNCST. The UNCST together with relevant regulatory bodies shall expeditiously investigate the complaint and make appropriate decisions.

d. Restoration of reputation: Practical efforts shall be taken by either the institution or UNCST to protect the position and reputation of any complainant, witness or committee member and to counter potential or actual retaliation actions against the complaints.

e. Disciplinary actions: in case of violation, the institution shall take relevant disciplinary actions such as; warning, reprimanding, retraction of published materials, suspension from grants and/or research practice and dismissal from the institution.

f. Any behavior that constitutes criminal conduct shall be referred to the relevant criminal justice systems.

All research institutions shall have in place a research integrity policy that provides a framework for compliance and designation of a research integrity officer in accordance with international and national applicable standards. Institutions shall submit reports of all cases handled at institutional level as well as refer cases not adjudged to the UNCST.

20.6 Responsible Conduct of Research

Responsible conduct of research (RCR) is the application of established scientific, professional norms and ethical principles in the performance of all activities related to scientific research and optimization of responsible behavior and integrity.

Responsible Conduct of Research is essential for maintaining the integrity and credibility of scientific work. It encompasses a wide range of practices, from ethical planning and data management to honest reporting and ethical treatment of research subjects. Researchers, institutions, and funding bodies must collaborate to promote and uphold these standards to ensure that scientific research is conducted in an ethical, transparent, and responsible manner.

21.0 END OF STUDY OBLIGATIONS

21.1 Introduction

This section provides for guidance on end of study obligations by the Principal Investigator, Sponsor and National Regulatory Agencies.

The following shall be required:

a. Protocol shall have provision on the end of study process.

b. The SOP for study closure.

c. A budgetary provision for end of study.

d. End of research study report: When procedures in the protocol have been completed for all participants including the follow up period. This is the time data collection ceases, and the research team focuses on data analysis and publication.

e. A close out report includes end of research study activities, destruction of specimen and unused products (where applicable with supervision of relevant authorities and publications from the study.

f. Administrative handling of transition from study to routine institutional care.

22.0 POST RESEARCH RESPONSIBILITIES

22.1 Introduction

This section provides guidance on Post Research Responsibilities (PRR) and applies to all research.

These are a broad set of requirements beyond study close out:

a. Post-research availability means availing any intervention, product developed, or knowledge generated, for the population or community in which the research is carried out, and to assist in building local research capacity.

b. Post-trial access is the process of availing an intervention proven effective after study closure to trial participants or communities.

c. Post research care encompasses a broad array of responsibilities. These include arranging clinical care or social services after completion of research, referral to appropriate follow-up care in the health-care sector or to another study, or provision of alternative interventions to the investigational medication, and other types of support to ensure smooth transition from research to health-care sectors.

PRR shall be considered at the conception of the research study and a dedicated section on this shall be part of the research protocol.

22.2 Approaches to PRR

The approaches to PRR include:

a. Review of the protocol including the PPR plan by REC/IACUC/NBC and appropriate national regulatory agencies and Ministries.

b. Development of an appropriate Community engagement on PRR in accordance to the National Community Engagement Guidelines.

c. Submission of a specific report on PRR to REC/IACUC/NBC and UNCST by the investigator.

d. Evaluation of findings, knowledge and technology transfer, translation and innovation with a possibility of policy integration by the National Regulatory Agencies and relevant ministries.

22.3 Responsibilities of stakeholders.

i. Researchers shall;

a. Submit research protocols with PRR plans;

b. Ensure that PRR plans are explained during the informed consent process;

c. Publish positive, negative as well as inconclusive results.

ii. Sponsors

The sponsor is responsible for providing the necessary financial support for implementation of the research study, including post research obligations. Specifically, the sponsor shall ensure that what was agreed upon is implemented.

iii. Researcher's Institution of Affiliation

These shall ensure that collaborative agreements are well negotiated and signed by authorized signatories to ensure that post research responsibilities are adequately adhered. They shall specifically ensure:

a. Relevant study agreements and MoUs are negotiated.

b. Archival of PRR reports on activities.

c. Participate in settling legal claims where appropriate.

d. In collaboration with other partners, arrange access to interventions that have been proven to be effective.

iv. Institutions where research is conducted/research sites (host institutions).

These shall ensure that:

a. Transition plans from research to post research implementation are developed.

b. Relevant monitoring plans for the post research management practices are developed and implemented.

v. Research Communities

These communities shall:

a. Participate in the information sharing between research institutions and study communities e.g CABs.

b. Be empowered to negotiate benefit sharing plans including appropriate agreements on matters related to patents, royalties and Intellectual property rights.

vi. Research regulators

These shall ensure that PRR plans are incorporated in the research protocols and ICFs and ensure monitoring of PRR implementation.

vii. Local government

These shall:

a. Demand public accountability and responsibility.

b. Ensure all sector policies are followed during implementation of the PRR.

c. Negotiate for access to beneficial investigational products.

d. Ensure continued provision of services to the population.

e. Where appropriate follow up administrative issues relevant to the PRR.

viii. Ministries, Departments, Agencies, and Policy makers

These shall:

a. Provide leadership including monitoring during implementation of PRR plans.

b. Ensure that the general population gets access to products that have been approved for market.

c. Ensure that study results are fed into policy development strategies.

23.0 RESULTS DISSEMINATION

Researchers shall make reasonable efforts to share findings of research with the host organization, research participants, key stakeholders and communities in which research was done. Researchers shall describe in the protocol plans for research results dissemination and ensure its execution.

Researchers shall be sensitive about the ethical implications of the research results and take appropriate measures to protect research participants and their communities. This shall include notifying the UNCST on planned dissemination activities.

24.0 PENALTIES FOR NON-COMPLIANCE

Non-compliance with these guidelines may be identified by research regulators: REC/IACUC, NBC UNCST, UNHRO, NDA and/or other stakeholders. Non- compliance shall be documented whenever it is identified.

UNCST shall subsequently communicate non-compliance to the responsible REC, researcher's organization of affiliation and other relevant authorities as appropriate. UNCST will require the REC or the researcher's organization of affiliation to respond to this communication within a specified period. The response shall specify any corrective actions that shall be made to achieve compliance with these guidelines. UNCST in collaboration with UNHRO and NDA, where necessary, may schedule an audit to confirm the adequacy of corrective actions taken.

Non-compliance with these guidelines may lead to:

a. Revocation of research approval for a study found to be non-compliant.

b. Withdrawal of research registration permits of researcher(s) involved in repeated non-compliance.

c. Retraction of journal publications.

d. Suspension or eventual termination of ongoing studies at the site or organization.

e. Withholding approval of new studies to be conducted at the organization.

f. Disciplinary action by relevant professional bodies for cases of suspected negligence and malpractice.

g. Suspension from service on any ethics body or committee.

h. Banned from research for a period determined by UNCST.

i. Disqualification of a REC that has failed to take adequate measures to ensure compliance with these guidelines or that repeatedly fails to comply with these guidelines.

j. Withdrawal of data in case of plagiarism, falsification, fabrication, gross non-compliance or obtaining data without ethical approval. A researcher shall face penalties for falsification, fabrication, and gross non-compliance in studies.

Referral to the National Information Technology Authority - Uganda (NITA) as provided for under the DPPA in case of breach of privacy and confidentiality.

25.0 GLOSSARY

Adolescent: WHO defines an adolescent as a person between ages 10- 19years.

Adverse event is any untoward occurrence in a participant in a study participating in an interventional study. The event may or may not be casually related to the intervention.

Assent means a child's affirmative agreement to participate in a research study. Failure to object does not constitute assent.

Biological agents include bacteria, viruses, fungi, other microorganisms and their associated toxins. They have the ability to adversely affect human health in a variety of ways, ranging from relatively mild, allergic reactions to serious medical conditions—even death. For the purposes of this guideline it will also refer to larger organisms and vectors that may impact on human health whether in the diagnosis, prevention and, or treatment of human diseases.

Child is a person below the age of eighteen years.

Clinical trial is a systematic study of pharmaceutical product or medical devices in human research participants in order to discover or to verify the beneficial or adverse effects, to identify any adverse reaction in the investigational product, and/or to study the absorption, distribution, metabolism, and excretion of the product with the objective of ascertaining its safety and efficacy.

Conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.

Co-principal investigator is responsible for coordination of all study related activities within the country.

Data protection is the systematic application of a set of institutional, technical and physical safeguards that preserve the right to privacy with respect to the collection, storage, use and disclosure of personal data.

Data subjects are individuals that can be directly or indirectly identified by the reference to a specific factor or factors. Such factors may include a name, an identification number, material circumstances and physical, mental, cultural, and economic or social characteristics.

Documentation are records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a research, the factors affecting research, and the actions taken.

Essential Documents: Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

Fetus means the product of conception from the time of implantation as indicated by any of the presumptive signs of pregnancy, including missed menses or a medically accepted pregnancy test, until a determination is made, following expulsion or extraction of the fetus, that it is viable.

Gene editing means a method or technology for making specific changes to the DNA of a cell or organism.

Guardian means a person recognized as a guardian under the children's Act.

Humans as a Research Participant: means a living or dead individual about whom an investigator conducting research obtains data or samples through intervention or interaction with the individual or their information.

Institution/Organization means an entity or agency, whether public or private, legally recognized in Uganda.

Interventional study means any experiment or study on one or more persons, which involves administration of a test product/ article, drug, treatment, procedure, or device, psychological interventions, social behavioral interventions, or economic interventions.

Invasive intervention devices are devices which, in whole or in part, penetrates inside the human body either through a body orifice or through the surface of the body.

Investigational product or study product is any pharmaceutical product or medical device or placebo being tested or being used as a reference in a clinical trial.

Lay person from the community refers to an individual whose primary background is not in scientific research involving human participant, and who is capable of sharing his/her insights about the community from which participants are likely to be drawn. A person who does not have expert knowledge of a particular subject.

Local Investigator/Researcher is an individual who is employed by an organization in Uganda, who is qualified by training and has experience as an appropriate expert who conducts a research study.

Medical camp refers to the out of hospital routine arrangement where health personnel usually from different institutions organise to examine, screen, treat and where possible refer patients.

Medical device is any device that has a therapeutic, prophylactic, or diagnostic use or is intended to modify physiological functions and is attached, implanted, or inserted for use in humans.

Medical tourism refers to people traveling from a country other than their own to obtain medical treatment.

Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical, dental, or psychological examination of healthy persons.

Parent means the biological mother or father or adoptive mother or father of a child.

Parental responsibility means all rights,
duties, powers, responsibilities and authority which by law a parent of a child has in relation to the child.

Pharmaceutical product is any substance or combination of substances that has a therapeutic, prophylactic, or diagnostic use or is intended to modify physiological functions and is presented in a dosage form suitable for administration to humans.

Peoples involved in illegal activities are persons who are involved in acts committed in violation of law where the consequence of conviction by a court is punishment.

Permission means the agreement of the parent(s) or guardian(s) to the participation of their child in the research study.

Pregnancy refers to the time period from confirmation of implantation through any of the presumptive signs of pregnancy including, for instance, missed menses or a medically accepted pregnancy test, until expulsion or extraction of the fetus.

Personal data is any information relating to an identified or identifiable data subject that is recorded by electronic means or on paper.

Post Research Responsibilities is a broad set of potential responsibilities when an individual has completed trial participation or at the conclusion of a clinical trial, including but not restricted to continued access. Post research responsibilities may also include, for instance, communicating the results of aggregate (summary) and/or individual results to participants, transitioning research participants to other venues for obtaining, clinical care and treatment, provision of counseling, environmental protection and/or the obligation to provide benefits to the community and country in which the clinical trials were conducted.

Potential Participants is a person identified for research up to a point of enrollment.

Principal Investigator/Researcher is the main researcher overseeing or conducting a research study. Such an individual is qualified by training and has experience as an expert in conducting a research study, and where appropriate, under whose immediate direction the investigational agent under investigation is administered or dispensed. When a team of individuals conducts an investigation, the responsible leader of the team is a Principal investigator.

Prisoner means any individual who is involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil provision or ruling, individuals detained in other facilities by virtue of statutes or commitment procedures, which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending a final disposition of their case.

Protocol Deviation: Any divergence from the REC approved study protocol or procedures that has no potential for major impact on the participants' right, safety or wellbeing.

Protocol Violation: Any divergence from the REC approved study protocol or procedures that has potential for major impact on the participants' right, safety or wellbeing.

Public facilities: means services provided by the government to its citizens. These can include infrastructure such as schools, hospitals, training institutes.

Research means any type of systematic investigation, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research institution refers to a registered institution or organization that carries out studies in Uganda.

Research involving humans as research participants is defined as a systematic investigation involving persons, and directed to the advancement of knowledge, that cannot be regarded as an element in established practices or social practices and that involves either physical or psychological intervention or assessment, or generation, storage, and analysis of information referable to identifiable individuals and communities.

Research involving humans as research participants also includes research on any material obtained from a research participant, whether the participant is still living or has died.

Representative means a person who has been authorized by the participant or law to act on behalf of a participant. This authorization must be documented, and the participant must be in state of mind to do so.

Research integrity means an active adherence to the ethical principles and professional standards essential for the responsible practice of research.

Researcher means a person who engages in the methodical and systematic investigation of hypotheses with the goal of contributing to new knowledge.

Research permit refers to the approval letter provided by the UNCST.

Serious adverse event is an adverse event associated with death, hospital admission, prolongation of a hospitalization, persistent or significant disability or incapacity, or otherwise life-threatening condition in connection with a clinical trial.

Source Documents; Original documents, data, and records (e.g. , hospital records, clinical and office charts, laboratory notes, memoranda, participants' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, photographic negatives, microfilm or magnetic media, x-rays, participants files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

Social harm non-medical adverse consequences of study participation for example, difficulties in personal relationships; Stigma or discrimination from family or community.

Standard of care is the health care package provided for by national policies.

Street children and orphans are persons who have not yet attained the legal age of majority under the applicable law and have no identifiable parent or guardian or have been abandoned by their parent(s) or guardian (s), are in wards of government or governmental entity, institution, organization, ministry, department, or subunit thereof, or are under the care of any governmental entity, institution, organization, ministry, department or subunit thereof.

Suspected Unexpected Serious Adverse Reaction refers to an adverse event that occurs in a clinical trial subject, which is assessed by the sponsor and/ or study investigator as being unexpected, serious and as having a reasonable possibility of a causal relationship with the study drug. Reports of these reactions are subject to expedited submission to health authorities.

Viable means being able, after spontaneous or induced delivery, to survive, given the benefit of available medical therapy, to the point of independently maintaining heartbeat and respiration. If a fetus is viable after delivery, it is a premature infant.

Vulnerability refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities or being a junior or subordinate member of a hierarchical group.

26.0 ANNEX I:

ANNEX I: GUIDANCE ON ESTABLISHMENT OF RESEARCH E-SYSTEMS

The following procedures and controls shall be employed to ensure the authenticity, integrity, and confidentiality of electronic records/binders in compliance with the 21 CFR Part 11 requirement and other applicable guidance regulatory frameworks.

Procedure/control measure	Requirement met		Notes – description of control measure in place
	Yes	No	
Validation of systems to ensure accuracy, reliability, consistent intended performance,and the ability to discern invalid or altered records.	☐	☐	Yes, the system allows detection of invalidated and altered data/ records
The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons shall contact the institution if there are any questions regarding the ability of the institution to perform such review and copying of the electronic records.	☐	☐	Yes, this is possible.
Protection of records to enable their accurate and ready retrieval throughout the records retention period.	☐	☐	The system sends notifications for any changes made. Version history also prevents loss of data
Limiting system access to authorized individuals.	☐	☐	Yes, the system allows granting of access permissions
Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	☐	☐	Through version history feature of the Electronic Binder, changes can be tracked.

Procedure/control measure	Requirement met Yes	No	Notes – description of control measure in place
Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	☐	☐	
Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	☐	☐	The system uses roles to authorize users.
Use of device (e.g. , terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	☐	☐	● Roles are configured to regulate data input ● You must have an approved account to use the system
Determination that persons who develop, maintain, or use electronic record/ electronic signature systems have the education, training, and experience to perform their assigned tasks.	☐	☐	Yes, these are recruited through an HR recruitment process
The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	☐	☐	Have the following Policies in place ● E-signature Policy ● Data protection policy ● Account management policy

ANNEX II: MATERIAL TRANSFER TEMPLATE

PARTIES

This agreement is made and entered into by and between:
("PROVIDER) whose address and principal place of business is **<<Insert site Name, full address, Country>>, (the "PROVIDER SITE")**

AND

<<Insert name of the Central Lab>>, with offices located at ……<<Insert location and address>> ("RECIPIENT" representing the interests of Insert Sponsor name, having it's registered office <<at … >>, <<insert country>> (the "SPONSOR") on the other part.

OR (If there are no multiple labs) <<RECIPIENT) , with offices located at **<<Insert location and address>> ("RECIPIENT SITE) "**

WHEREAS, the PROVIDER is conducting <<Insert study Title >>Protocol number<<.
WHEREAS, the parties have agreed that the PROVIDER will research materials collected in the course of the Study (the "BIOLOGICAL/CHEMICAL MATERIAL" OR "MATERIALS" as defined below) for analysis to RECIPIENT.

WHEREAS, RECIPIENT has selected various services providers (the "RECIPIENT'S DESIGNEES" as defined below) who will perform the analyses of the BIOLOGICAL/CHEMICAL MATERIAL. (If applicable)
WHEREAS, BIOLOGICAL/CHEMICAL MATERIAL will be shipped directly by PROVIDER to RECIPIENT'S DESIGNEES and shipping frequency and quantity of other Biological/Chemical Material will be coordinated by <<Insert Lab Name>>, who will store, track and forward samples to RECIPIENT's DESIGNEES, <<Add all applicable Labs with full address indicated>> (If applicable)

RECITALS:

A. **The PROVIDER SITE** is a healthcare facility, and is handling confidential **MATERIALS** and data associated with the sample collection for study… (Indicate study title). Protocol number<<Insert Protocol number>> (the "Study") , on behalf of the sponsor of the study, **<<Insert sponsor name>> (THE "SPONSOR").**

B. The **RECIPIENT** is a laboratory company designated by the **SPONSOR and/or PROVIDER** to conduct research into or with the **MATERIALS** for the purpose of scientific research for the **STUDY**, that being the testing and preliminary validation of current version of the Protocol.

C. This agreement sets out the terms that the parties agree are to apply to the use of MATERIALS by the **RECIPIENT.**

IT IS AGREED BETWEEN PARTIES THE FOLLOWING:

1. DEFINITIONS

Agreement means this material transfer agreement and all its annexes
Custodian means a person or entity entrusted by the Donor with safeguarding and protecting the Materials.
Materials means the **Materials** described in accordance with the agreement signed between Supplier and Recipient, Supplier will provide Recipient the samples and associated information ("Material(s) ").

Purpose and usage means the conduct of the Research as described in Study protocol and the patient information and consent form signed by Study Participants. The conditions for use by the **RECIPIENT** are fully described in the patient information and consent form and in accordance with the Laboratory Agreement.

Research means the research program under which the **Material** is going to be used is described in the Study protocol and patient information and consent form.

1.1 **Results** means all information and tangible objects arising from the **Recipient's** use of the **Materials**. **Third party** means any entity or person other than the parties who have signed off on this agreement

2. SUPPLY OF THE MATERIALS

The **Provider** agrees to provide the **Recipient** with the **Materials** (Generic description of materials should be provided i.e.. Serum, Swabs. etc.) in the quantity and in the packaging, and by the mode of transport, set out in the template table in Annexure A.

2.1 The **Provider** warrants that it has obtained all authorizations to supply the **Materials** and in particular that a separate patient information and consent form has been signed by each study participant from whom **Materials** will be used.

2.2 The **Recipient** acknowledges that the **Materials** have been collected by the **Provider** and contain information, which may be confidential in nature, and are of considerable research value. The **Recipient** undertakes to take due care of the **MATERIALS** as provided in the agreement and applicable laws and regulations.

3. DESCRIPTION OF SAMPLES

The materials being transferred/exchanged must be fully described, including a description of derivative products, if any. Quantities must be specified and appropriately packaged. **(Detailed description in Annex A)**

4. USE OF THE MATERIALS

4.1 The Recipient agrees to keep the Materials secure and confidential that will be used in development of the Research and the Study only. For materials being transferred for future use, materials shall be used for related research areas as prescribed in the Informed Consent for Storage for future use signed by the participant.

4.2 Neither the Results nor the **Materials** will be identified with participant's name or any other directly identifying particulars. All biomarker **Materials** will be coded using labels with a unique code number. Only the Study doctor and designated Study site staff working for **Provider** will have the ability to link this code to the participant. The analysis Results will only be linked to this code.

4.3 The materials stated in section 2.1 will be sent to the Recipient for analysis, interpretation, and reporting results back to **PROVIDER** and **SPONSOR**. The confidentiality of the information provided to the **Recipient** will be maintained by **Recipient** and its staff members.

4.4 The **Recipient** must not, without the prior written permission of the Provider sell, loan, or otherwise provide any **Material** to any third party; or use the **Materials** for any purpose other than the Purpose stated in section.

4.5 Both parties must ensure that its use of the **Material** complies with all relevant laws, codes of practice and ethical principles.

5. TRANSFER TO 3RD PARTY

Transfer to 3rd parties after approval of the MTA shall not be done without approval of the provider institution in Uganda and the regulatory body; Uganda National Council for Science and Technology (UNCST)

4.1 Additional testing to additional laboratories (If applicable)

The Material will be sent to the Recipient's address mentioned above from which they will be transferred to the addresses listed below for a period of ……. and shall be returned in accordance with the Laboratory Agreement between the Recipient and

PROVIDER and the SPONSOR (If applicable). (Clearance letters from the laboratories are attached in Annex 2)

Storing, tracking and onward shipping as may be necessary, to the following testing entities:

Name of the Lab	Full address of the Lab	Name and contact of responsible officer	Name of specimen	Quantity of specimen

6. RESTRICTIONS

(Describe any specific restrictions if any for the recipient organization. Examples of restrictions maybe: to be used for one purpose and not the other: to be used in a specific site or country only or to be used strictly under the laws of a specific site or country only or to be used strictly under the laws of a specific country. It should, however, be noted that any research project to be conducted in future using stored samples will be subject to review and approval by a Research Ethics Committee (REC) and approval by UNCST. **(If no restrictions, indicate N/A).** All restrictions and obligations relate to MATERIAL, and to any replicated forms of MATERIAL. Reference to MATERIAL herein is therefore intended to include all such forms of MATERIALS

7. DISPOSAL OF MATERIAL:

Describe a disposal plan for the material, including methods of disposal. This should include aspects of section 4.1

8. TIME PERIODS:

Indicate period of use of the material

9. INTELLECTUAL PROPERTY

Intellectual property will be dealt with through relevant laws related to the applicable protocol and underlying third party agreements in so far as there are any. (It should be noted that there could be monetary benefits from research i.e.

1. Monetary Benefits e.g. royalties, milestone payments, licensing fees of a drug or device;
2. Non-monetary benefits e.g. technology transfer, enhancement of research skills, sharing research results, research partnerships, access to scientific information)

9.1 OWNERSHIP OF PRODUCTS

9.2 OWNERSHIP OF DERIVATIVES

9.3 AUTHORSHIP AND PUBLICATION

Publications are subject to the underlying collaboration agreement between the Provider and Sponsor, applicable laws and approval of the Sponsor.

9.4 COMMERCIALIZATION RIGHTS (INCLUDING FAIR BENEFIT SHARING)

9.5 TECHNOLOGY TRANSFER

9.6 COMPLETION REQUIREMENTS:

Participants may withdraw their consent at any time. If withdrawal of consent occurs, the SPONSOR, the Study doctor and/or the **Provider** should not continue to use data and/or samples nor disclose any information collected before the date of withdrawal. However, once analysis has been done, data collected may be used provided participants have consented to such use after they have withdrawn their consent.

LIABILITY

The **Provider** gives no warranty that the **Materials** are fit for the Purpose, or that they have any qualities or characteristics. The **Recipient** acknowledges that the **Materials** are experimental in nature and that the speculative nature of scientific research is such that it is unreasonable to expect the **Provider** to give any assurances to the Recipient as to the performance of the **Material**.

9.7 WARRANTY

9.8 GENERAL

c. The Recipient warrants that the Research shall be conducted solely in accordance with the Laboratory Agreement, Material Transfer Agreement and approved protocol.

d. The Provider warrants that to the best of its knowledge all information provided to the Recipient with the Material is accurate and complete.

e. If any provision of this agreement is unenforceable or invalid for any reason, the relevant provision will be deemed to be modified to the extent necessary to remedy such unenforceability or invalidity or, if this is not possible, then such provision will be severed from this agreement, without affecting the enforceability or validity of any other provision of the agreement.

f. This agreement is governed by the Laws of Uganda and shall be subject to the exclusive interpretation of the Uganda Courts.

g. The Recipient shall ensure that its use, maintenance and disposition of the Material will be conducted in strict accordance with all appropriate local, national and international laws, as well as guidelines and regulations.

h. The Provider prior to the transfer of such human research samples origin will be obtained from the UNCST and the patient information and consent form which describe how the Materials will be handled and stored.

9.9 AMENDMENT

9.10 TERMINATION

9.11 CONFLICT MANAGEMENT

EXECUTED as an AGREEMENT

<<Indicate Name of the Central Laboratory/Institution>> (Recipient Authorized signatory)

Name:. . . . . .

Title:. . . . . .

Date:. . . . . .

Signature. . . . . .

<<Insert Details for Additional Central Labs/ institutions if applicable (add more signature Blocks as applicable>>
<<Insert Sponsor Name>> (Where applicable)

Name:. . . . . .

Title:. . . . . .

Date:. . . . . .

Signature. . . . . .

<Insert Institution/Site Name >> (Provider Authorized signatory)

Name:. . . . . .

Title:. . . . . .

Date:. . . . . ..

Signature. . . . . .

<<Insert PI's Name>> (Witness)

Name:. . . . . .

Title:. . . . . .

Date:. . . . . .

Signature. . . . . .

Material /Type of Sample	Test	Quantity / Vial of sample	Estimated total number of samples to be shipped for duration of trial	Packaging material /derivative used	Shipment condition	Destination

ANNEX III: DATA TRANSFER AGREEMENT TEMPLATE

a. This Data Transfer Agreement for Research Organizations Here-In-After referred to as the "Agreement") Between. . . . . of P. O Box. . . . . (here-in-after referred to as the "PROVIDER") ;

and . . . . . of P. O Box. . . . . (here-in-after referred to as "a person" or the "RECIPIENT").

made this. . . . . Day of . . . . . .

b. PROVIDER and RECIPIENT may each be referred to as a "Party" or collectively as "Parties" to this Agreement. This preamble shall be a definitive part of this Agreement.

c. WHEREAS under this Agreement it is agreed that DATA of medical research may be transferred between Parties to this Agreement only through the conditions stipulated in this Agreement;

d. WHEREAS the PROVIDER retains all ownership rights on DATA procured from the study;

e. WHEREAS under this Agreement it is agreed that the DATA to be transferred pursuant to this Agreement are only those to be used for academic or research purposes;

f. WHEREAS it is hereby agreed that no transfer to third parties is allowed, except for academic or research purposes where RECIPIENT has secured the written consent of the PROVIDER;

g. WHEREAS it is hereby agreed that the RECIPIENT shall cooperate with the PROVIDER to facilitate capacity building in DATA management and analysis;

h. AND WHEREAS the parties to the Agreement undertake to be bound by any lawful order or instruction, as they will be from time to time be obliged to do by the Permit-Issuing Organization.

i. NOW THEREFORE in consideration of the mutual benefits to be derived and the representations, conditions and promises herein contained,the PARTIES HEREBY AGREE AS FOLLOWS:

ARTICLE I

DEFINITIONS AND RULES OF INTERPRETATION

1.1 Definitions

a. "Agreement" means this "DATA Transfer Agreement for Researchers/Organizations" between the Parties.

b. "Data" in this context refers to facts, observations, or any information generated and documented (numerical, descriptive or visuaas specified in Annex I, which forms part of this agreement.

c. "Permit" means approvals, authorization, notifications, concessions, acknowledgments, licenses, permits or similar items required to be obtained from UNCST.

d. "Provider" means a person or organization providing the original DATA.

e. "Recipient" means a person or organization to which the original DATA is transferred.

f. "The Law" means any applicable laws of Uganda or the RECIPIENT country when there is a lacuna in the laws of Uganda.

g. "Confidential Matter" means information that is PROVIDER's proprietary and confidential information. Such CONFIDENTIAL MATTER shall not include any item of information, data, that: (a) is within the public domain prior to the time of the disclosure by the PROVIDER to the Receiving Party or thereafter becomes within the public domain other than as a result of disclosure by the RECIPIENT or any of its representatives in violation of this Agreement;

h. (b) was, on or before the date of disclosure in the possession of the RECIPIENT; (c) is acquired by the RECIPIENT from a third party not under an obligation of confidentiality; (d) is hereafter independently developed by the RECIPIENT, without reference to the information received from the PROVIDER; or (e) the PROVIDER expressly authorizes the RECIPIENT to disclose.

1.2 Rules of Interpretation In this Agreement:

a. The headings are for convenience only and shall not be considered in interpreting this Agreement;

b. The singular includes the plural and vice versa;

c. The obligations on part of the PROVIDER or RECIPIENT shall be interpreted to apply to the conduct and responsibilities of the PROVIDER Investigator or RECIPIENT Investigator, respectively.

ARTICLE II

GUIDING PRINCIPLES FOR DATA TRANSFER AGREEMENTS

a. This Agreement shall be linked to a project that has been registered and approved by the Uganda National Council for Science and Technology (UNCST). The need to transfer DATA shall be stipulated in an approved protocol or subsequent amendment.

b. Signing of this Agreement shall be mandatory for all research involving foreign researchers, and this shall be declared in a research application for a research permit. This Agreement shall also be mandatory for local researchers collaborating with foreigners, before sending/transferring DATA for research. This Agreement applies also to local researchers when using DATA from individuals and/or communities.

ARTICLE III

TRANSFER OF THE DATA

1.1 DATA to be transferred

Subject to the terms and conditions of this Agreement, the PROVIDER agrees to transfer the DATA and the RECIPIENT agrees to receive the DATA as identified in Annex I.

1.2 Obligation of the RECIPIENT

It is hereby agreed that the following conditions to the Agreement shall be binding on the RECIPIENT:

a. The RECIPIENT agrees to use, store or dispose of the DATA in compliance with the Uganda Data protection and Privacy Act 2019 and the specific guidance on data as per the National Guidelines for Research Involving Humans as Research Participants.

b. The DATA shall remain the property of the PROVIDER and PROVIDER hereby consents to the Data being made available as a service to the research community.

c. The RECIPIENT shall use the DATA for teaching or academic research purposes only.

d. Except as previously approved by the UNCST, and with the written consent of the PROVIDER, the RECIPIENT shall not transfer or distribute the DATA to a third party.

e. The RECIPIENT shall acknowledge the source of the DATA in any publications reporting use of it.

f. Subject to Article V of this Agreement, the RECIPIENT shall be liable for damages which may arise from RECIPIENT's use, storage and disposal of the DATA.

g. The RECIPIENT and the RECIPIENT Investigator shall sign two copies of this Agreement and return one signed copy to the PROVIDER. The PROVIDER shall then transfer the DATA.

h. The RECIPIENT shall provide the PROVIDER with a manuscript of any proposed publication or presentation resulting from the study using the DATA at least thirty (30) days prior to submission thereof for publication or presentation.

i. The PROVIDER reserves the right to review any such manuscript and to require the removal of CONFIDENTIAL MATTER in order to protect its proprietary rights and interests. PROVIDER shall notify RECIPIENT in writing within a thirty (30) day period concerning the removal of CONFIDENTIAL MATTER and to suggest editorial modifications in the manuscript.

1.3 Obligation of the PROVIDER

It is hereby agreed that the following conditions to the Agreement shall be binding on the PROVIDER;

a. The PROVIDER agrees to transfer, store or dispose of the DATA in compliance with all applicable laws

b. The PROVIDER shall immediately transfer the DATA upon receipt of one of the two copies duly signed by the RECIPIENT.

c. Subject to availability, the PROVIDER may agree to make the DATA available under a separate agreement with other scientists (at least those at nonprofit organizations or government agencies) who wish to replicate the RECIPIENT Investigator's scientific research).

d. Subject to Article V of this agreement, the PROVIDER shall be liable for all liabilities for damages which may arise from PROVIDER's use, storage and disposal of the DATA.

ARTICLE IV

COSTS AND PAYMENT ARRANGEMENTS

The DATA shall be provided at no cost.

ARTICLE V

WARRANTIES

Any DATA transferred pursuant to this Agreement is understood to be experimental in nature. The PROVIDER and RECIPIENT MAKE NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

ARTICLE VI

LEGAL TITLE TO DATA TRANSFERRED AND BENEFIT SHARING

Legal title to the DATA transferred shall be unaffected by this Agreement or the transfer of any Material hereunder. (i). As between the PROVIDER and the RECIPIENT, the PROVIDER shall be the sole owner of all rights and the title to the DATA transferred including existing intellectual property rights. (ii). The PROVIDER and RECIPIENT shall discuss the sharing of benefits arising from use of the DATA in accordance with the contributions of the Parties.

ARTICLE VII

PERMITS, LICENSES AND APPROVALS

e. Prior to commencement of this Agreement, PROVIDER and RECIPIENT shall, at their own expense:

a. Make or cause to be made all necessary prerequisite applications and shall diligently pursue all such applications and shall use all reasonable efforts to maintain the consents in effect once obtained and;

b. Give all required notices and allow all required inspections under all consents obtained in connection with that transfer. The information supplied in the applications shall be complete and accurate and shall satisfy the substantive and procedural requirements of the applicable laws of Uganda or of the other country where the DATA is transferred.

ARTICLE VIII

NON-EXCLUSIVE LICENSE

The transfer of the DATA constitutes a nonexclusive license to use the DATA solely for academic and research purposes only. The transfer of DATA does not grant the RECIPIENT any additional rights in the DATA other than specifically set forth in this Agreement.

ARTICLE IX

AMENDMENTS

This Agreement may be amended by mutual written Agreement of the Parties, which shall enter into force on the date agreed by both Parties.

ARTICLE X

TERMINATION

Termination of this Agreement is accomplished:

a. Immediately upon mutual written consent of both Parties;

b. Unilaterally by either Party with sixty (60) days' written notice to the other Party; or

c. Upon 30 days' written notice of a Party's contravention of law; and

d. As stated in Article XI

ARTICLE XI

APPLICABLE LAW, SEVERABILITY

The Parties recognize and agree that this Agreement is a contract and not an International agreement, that International Law is not applicable to this Agreement, and that International Law does not govern the interpretation of the provisions of this Agreement. Any dispute arising under this Agreement which is not disposed of by agreement between the Investigators shall be submitted jointly to the Authorized signatories of this Agreement. A joint decision of the Authorized signatories or their designees shall be the disposition of such dispute. If the Parties cannot reach a joint decision, either Party may terminate this Agreement immediately.

The Parties hereby consent to the jurisdiction of the Republic of Uganda for any action, suit or proceeding arising out of or relating to this letter agreement brought against the Republic of Uganda; and to the jurisdiction of the courts of the RECIPIENT Government for any action brought against the RECIPIENT Government or any of its agencies.

This Agreement is effective when signed by all Parties and approved by the UNCST. The Authorized Officials executing this Agreement certify that they are the legal representatives of their respective organizations, authorized to sign on behalf of their respective organizations for the purpose of binding the said organizations to the terms of this Agreement, for the transfer specified above.

ARTICLE XII

NOTICE

All notices pertaining to or required by this Agreement shall be in writing, shall be signed by an authorized representative and shall be delivered to the addresses indicated on the signature page for each Party.

ARTICAL XIII

NON APPLICABILITY OF THIS AGREEMENT TO EXISTING OR FUTURE AGREEMENTS

The terms of this Agreement are not intended to and do not affect any other existing or future agreements between the Parties.

IN WITNESS WHEREOF the PARTIES hereto have signed this Agreement in the presence of the witnesses and at the places and on the dates set opposite their respective signatures.

EXECUTED as an AGREEMENT

<<Indicate Name of the Central Laboratory/Institution>> (Recipient Authorized signatory)

Name:. . . . . .

Title:. . . . . .

Date:. . . . . .

Signature:. . . . . .

<<Insert Details for Additional Central Labs/ institutions if applicable (add more signature Blocks as applicable>>
<<Insert Sponsor Name>> (Where applicable)

Name:. . . . . .

Title:. . . . . .

Date:. . . . . .

Signature:. . . . . .

<Insert Institution/Site Name >> (Provider Authorized signatory)

Name:. . . . . .

Title:. . . . . .

Date:. . . . . .

Signature:. . . . . .

<<Insert PI's Name>> (Witness)

Name:. . . . . .

Title:. . . . . .

Date:. . . . . .

Signature:. . . . . .

ANNEX I

Description of Information to be transferred under this Agreement: (DTA)

No 1.
No 2.
No 3.

ANNEX IV: ITEMS TO BE CONSIDERED FOR INCLUSION IN A PROTOCOL

Include the items relevant to the study/protocol in question

1. Title of the research study;
2. A summary of the proposed research in lay/non-technical language;
3. A clear statement of the justification for the research study, its significance in development and in meeting the needs of the country /population in which the research is carried out;
4. The investigators` views of the ethical issues and considerations raised by the research study and, if appropriate, how it is proposed to deal with them;
5. Summary of all previous studies on the topic, including unpublished studies known to the investigators and sponsors, and information on previously published research on the topic, including the nature, extent and relevance of animal studies and other preclinical and clinical studies (where applicable);
6. A statement that the principles set out in these guidelines will be implemented;
7. An account of previous submissions of the protocol for ethical review and their outcome;
8. A brief description of the site(s) where the research is to be conducted, including information about the adequacy of facilities for the safe and appropriate conduct of the research, and relevant demographic and epidemiological information about the site, country or region concerned;
9. Name and address of the sponsor;
10. Names, addresses, institutional affiliations, qualifications and experience of the principal investigator and other investigators
11. The objectives of the research study, its hypotheses or research questions, its assumptions, and its variables ;
12. A detailed description of the design of the study. In the case of controlled clinical trials the description should include, but not be limited to, whether assignment to treatment groups; will be randomized (including the method of randomization), and whether the study will be blinded (single blind, double blind), or open;
13. The number of research participants needed to achieve the study objective, and how this was statistically determined;
14. The criteria for inclusion or exclusion of potential participants, and justification for the exclusion of any groups on the basis of age, sex, social or economic factors, or for other reasons
15. The justification for involving as research participants children or adolescents, persons who are unable to give informed consent or vulnerable persons or groups, and a description of special measures to minimize risks to such persons ;
16. The process of recruitment, e.g. advertisements, and the steps to be taken to protect privacy and confidentiality during recruitment ;
17. Description and explanation of all interventions (the method of treatment administration, including route of administration, dose, dose interval and treatment period for investigational and comparator products used);
18. Plans and justification for withdrawing or withholding standard therapies in the course of the research, including any resulting risks to persons ;
19. Any other treatment that may be given or permitted, or contraindicated, during the study;

20. Clinical and laboratory tests and other tests that are to be carried out;
21. Samples of the standardized case-report forms to be used, the methods of recording therapeutic response (description and evaluation of methods and frequency of measurement), the follow-up procedures, and, if applicable, the measures proposed to determine the extent of compliance of persons with the treatment;
22. Rules or criteria according to which participants may be removed from the study or clinical trial, or (in a multi-centre study) a centre may be discontinued, or the study may be terminated;
23. Methods of recording and reporting adverse events or reactions, and provisions for dealing with complications ;
24. The known or foreseen risks of adverse reactions, including the risks attached to each proposed intervention and to any drug, vaccine or procedure to be tested;
25. The potential individual benefits of the research to participants and to others ;
26. The expected benefits of the research to the population, including new knowledge that the study might generate ;
27. For research carrying more than minimal risk of physical injury, details of plans, including insurance coverage, to provide treatment for such injury, including the funding of treatment, and to provide compensation for research-related disability or death;
28. Provision for continued access to study interventions that have demonstrated significant benefit, indicating its modalities, the parties involved in continued care and the organization responsible for paying for it, and for how long it will continue ;
29. For research on pregnant women, a plan, if appropriate, for monitoring the outcome of the pregnancy with regard to both the health of the woman and the short-term and long-term health of the child ;
30. The means proposed to obtain individual informed consent and the procedure planned to communicate information to prospective participants, including the name and position of the person responsible for obtaining consent ;
31. When a prospective participant is not capable of informed consent, satisfactory assurance that permission will be obtained from a duly authorized person, or, in the case of a child who is sufficiently mature to understand the implications of informed consent but has not reached the legal age of consent, that knowing agreement, or assent, will be obtained, as well as the permission of a parent, or a legal guardian or other duly authorized representative ;
32. An account of compensation and incentives to prospective participants to participate, such as offers of cash payments, gifts, or free services or facilities, and of any financial obligations assumed by the participants, such as payment for medical services;
33. Plans and procedures, and the persons responsible, for communicating to participants information arising from the study (on harm or benefit, for example), or from other research on the same topic, that could affect participants' willingness to continue in the study ;
34. Plans to inform participants about the results of the study;
35. The provisions for protecting the confidentiality of personal data, and respecting the privacy of persons, including the precautions that are in place to prevent disclosure of the results of a participants' genetic tests to immediate family relatives without the consent of the participants;
36. Information about how the code, if any, for the persons' identity is established, where it will be kept and when, how and by whom it can be broken in the event of an emergency ;
37. Any foreseen further uses of personal data or biological materials ;
38. A description of the plans for statistical analysis of the study, including plans for interim analyses, if any, and criteria for prematurely terminating the study as a whole if necessary;

39. Plans for monitoring the continuing safety of drugs or other interventions administered for purposes of the study and, if appropriate, the appointment for this purpose of an independent data and safety monitoring board;

40. A list of the references cited in the protocol;

41. The source and amount of funding of the research: the organization that is sponsoring the research and a detailed account of the sponsor's financial commitments to the research institution, the investigators, the research participants, and, when relevant, the community;

42. The arrangements for dealing with financial or other conflicts of interest that might affect the judgement of investigators or other research personnel: informing the institutional conflict-of-interest committee of such conflicts of interest; the communication by that committee of the pertinent details of the information to the ethical review committee; and the transmission by that committee to the research participants of the parts of the information that it decides should be passed on to them;

43. For research that is to be carried out in the country, contribution that the sponsor will make to capacity-building for scientific and ethical review and for research in country, and the assurance that the capacity-building objectives are in keeping with the values and expectations of the participants and their communities;

44. The research protocol or documents sent to the research ethics committee should include a description of the plan for (continuecommunity engagement, and present resources allocated for the community engagement activities. This documentation must clarify what has been and will be done, when and by whom to ensure that the community is clearly mapped and defined and can be proactively engaged throughout the research to ensure that the research is relevant to the community and is accepted. The community should participate, when feasible, in the actual discussion and preparation of the research protocol and documents;

45. Particularly in the case of an industrial sponsor, a contract stipulating who possesses the right to publish the results of the study, and a mandatory obligation to prepare with, and submit to, the principal investigators the draft of the text reporting the results ;

46. In the case of a negative outcome, an assurance that the results will be made available, as appropriate, through publication or by reporting to the National Regulatory Agencies;

47. Plans for publication of research results by maintaining confidentiality during and after the study and publishing the resulting data in a manner that is respectful of the interests of all concerned; and

48. A statement that any proven evidence of falsification of data will be dealt with in accordance with the applicable laws and guidelines.

NATIONAL GUIDELINES FOR RESEARCH INVOLVING HUMANS AS RESEARCH PARTICIPANTS

Contact Information
Uganda National Council for Science and Technology
Plot 6 Kimera Road, Ntinda
P.O. Box 6884, Kampala, Uganda |
Tel: +256 414 705 500 | E-mail: info@uncst.co.ug |
Facebook: UNCST
Website: www.uncst.go.ug

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