



National Guidelines for Research involving Humans as Research Participants

July 2014



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Uganda National Council for Science and Technology
Kampala - Uganda

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These guidelines are prepared by Uganda National Council for Science and Technology (UNCST).

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Preface

The purpose of research is to generate or contribute to knowledge that could benefit present and future generations. People who volunteer as research participants bear the burden of research in order to bring about the future benefit. It is necessary, therefore, to ensure that people who bear the burden of research also benefit in some way or that their rights and welfare are not compromised during the research process. These Guidelines establish a system 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 2007 National Guidelines for Research involving Humans as Research Participants. The revisions were in keeping with changing conditions and new information and practices in the field of research ethics. The revised Guidelines, therefore, reflect consensus among research stakeholders on norms and standards, which should 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 plan and conduct and/or participate in research following 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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Acronyms

ACREC Accreditation Committee for Research Ethics Committees in Uganda

CAB Community Advisory Board

CV Curriculum Vitae

DSMB Data and Safety Monitoring Board

IBC institutional Biosafety Committee

MTA Material Transfer Agreement

NDA National Drug Authority

R&D Research and Development

REC Research Ethics Committee

S&T Science and Technology

SAE Serious Adverse Event

SC Scientific Committee

SOP Standard Operating Procedures

UCG Uganda Clinical Guidelines

UNCST Uganda National Council for Science and Technology

UNHRO Uganda National Health Research Organization

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 projects involving humans as research participants in Uganda has more than quadrupled 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 uncontrolled, involve exposing research participants to a spectrum of risks. These guidelines provide a national system or framework for harnessing the benefits of research while ensuring that rights, interests, values and welfare of research participants are protected.

1.2 Rationale

Research is conducted for the benefit of society. It is important to have in place a system that promotes beneficial research and guards against unethical research. Research has inherent burdens, which individuals and communities who volunteer as research participants bear in order to bring about a future benefit. Individuals and communities should 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 or after the research.

1.3 Objectives

The overall objective of these guidelines is to establish a coherent regulatory framework for conduct of research involving humans without compromising their rights and welfare.

Specifically, these guidelines are to:

- a. Provide mechanisms for protecting rights and welfare of research participants;
- b. Provide ethical standards and procedures for conduct of research involving humans as research participants;
- c. Ensure that researchers take into account social and cultural values of participating communities.

1.4 General Policy

Research and development including scientific investigations involving humans as research participants shall be conducted for the benefit of communities in Uganda and abroad without causing unnecessary harm or inconvenience, and shall not compromise rights and welfare of research participants.

1.5 Scope of Application

The aforementioned general policy and other provisions of these guidelines apply to (1) all research involving humans as research participants in Uganda, including research in humanities and social sciences, biomedical science and traditional and complementary medicine, (2) research conducted in or by public, private, inter-governmental and non-governmental organizations, and by individuals or groups, and (3) research conducted in a foreign country on human materials collected from Uganda.

2.0 RIGHTS AND WELFARE OF RESEARCH PARTICIPANTS

2.1 Research Involving Humans as Research Participants

Research involving humans as research participants includes:

- a. Clinical investigations, that is, any experiment or study on one or more persons, which involves a test product/article, whether a drug, treatment, procedure, or device;
- b. Social-behavioral studies, which involve interaction with or observation of people;
- c. Basic scientific research to study biology of persons or organs and specimens thereof;
- d. Systematic collection, storage and analysis of data on humans.

2.2 Rights and Welfare of Human Research Participants and their Communities

Research should be conducted in a manner that does not violate rights and welfare of human research participants and their communities.

2.2.1 Human Research Participants have a right to, *inter alia*:

- a. Participate in research or not, or withdraw at any time without penalty;
- b. Be respected, including the right of their autonomy, culture, beliefs and values;
- c. Information about the research (it is important to ensure that information is communicated in understandable language, format and in a conducive environment at all stages of the research);

- d. Protection against research related injuries, harm, exploitation, and any other forms of abuse;
- e. Privacy and confidentiality of their participation, during and after the research;
- f. The standard of health care that is established nationally;
- g. Treatment and management of research related injuries;
- h. Reimbursement for costs associated with their participation in the research.

2.2.2 Research should aim at improving the welfare of research participants and their communities. This can be attained through:

- a. Ensuring adequate welfare for research participants, including compensation for inconveniences and time;
- b. Provision of health (ancillary) care beyond research related care;
- c. Provision of collateral¹ benefits to research communities;
- d. Provision of good client care during study investigations and procedures;
- e. Taking measures to ensure easy access by the community to the test drug/device, if proven beneficial.

2.3 Principles of Research Ethics

In order to protect rights and welfare of human research participants, research should be conducted in accordance with four basic research ethics principles, namely: respect

¹ These may include benefits that are related to but not directly linked to the research project.

for persons, beneficence, non-maleficence and justice. It is generally observed that these principles guide the conscientious preparation of proposals for scientific studies. They may be expressed differently and given different moral weight in different settings, and their application may lead to different decisions or courses of action in those particular settings.

These principles are briefly described as follows:

- a. Respect for persons incorporates at least two fundamental ethical considerations, namely: respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination; and protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.
- b. Beneficence refers to the ethical obligation to maximize benefits and to minimize harms. That is to say, risks of harm by research should be reasonably justified by expected benefits, research design should be scientifically acceptable, and researchers should be competent to conduct research and to safeguard rights and welfare of research participants.
- c. Non-maleficence (i.e. to do no harm) prescribes that researchers should 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 done first at the organizational 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 research. UNCST liaises with the Research Secretariat in the office of the President on national security issues in respect of research conducted in Uganda. An additional requirement with regard to clinical trials is for the researcher to obtain a certificate from the National Drug Authority (NDA) in respect of a trial drug/device preferably prior to review of the research protocol (or proposal) by a REC and registration of the protocol with UNCST.

The mandates of UNCST, UNHRO and NDA with respect to oversight of research are briefly mentioned below.

3.2 Oversight by Uganda National Council for Science and Technology

UNCST is a semi-autonomous government agency established in 1990 (CAP 209 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 government of Uganda on policy matters necessary for advancing S&T and, 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 clearinghouse 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 cooperation with and co-ordinate all scientific and technological activities of persons, institutions, sectors and organizations”.

In executing this mandate, UNCST as one-stop point, 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 registers² and issues research registration permits for the purpose of carrying out research in Uganda. The research registration permit is to facilitate conduct of research in the country, and covers the entire duration of the research project. All persons intending to carry out research in Uganda shall register their research activities with UNCST and obtain a UNCST research registration permit. Under normal circumstances, the registration process is accomplished within 14 working days.

Research project proposals submitted to UNCST for registration should be well written and fully developed. A research proposal should have a title and, at least, sections on background to the study, objectives, methodology, significance/justification for the study, work plan, budget and references/bibliography. In addition, the research project proposal should have a version and date, names and brief biographical sketches of the researchers and their organizations of affiliation, data collection instruments such as questionnaires, and where applicable, informed consent documents.

² The registration is for oversight in accordance with the UNCST Act, and may involve additional review of a research proposal by specialized/ethics committees, task forces or expert review.

3.3 Oversight by National Drug Authority

NDA regulates safety, quality, efficacy, handling and use of drugs or drug related products and devices in research. Part IV, section 40 of the National Drug Policy and Authority Act (Chapter 206) states that, with respect to clinical trials: a) the authority may issue a certificate to any person for the purpose of carrying out clinical trials in respect of a drug that may be specified in the certificate, and b) no person may carry out any clinical trial in respect of any drug unless he or she is in possession of a certificate issued under subsection (1).

It is the responsibility of each trial sponsor and/or researcher to obtain such authorization certificate for all experimental drugs/devices, irrespective of whether the drug/device has previously been licensed for use in humans or not. Researchers must file a copy of the NDA certificate authorizing the importation and/or use of the trial drug/device in Uganda with the relevant REC and UNCST. NDA shall also verify the continued use and eventual disposal of unused trial drug/device.

The researcher shall, *inter alia*, provide the following information about the drug/device to NDA:

- a. Investigator's brochure;
- b. A description of the drug/device (physical characteristics);
- c. Dosage form of the drug/device;
- d. Composition (complete formula);
- e. Active ingredients;
- f. Other ingredients (adjuncts, excipients, preservatives, colour, flavour etc);
- g. Pack size (weight or volume);
- h. Quality control processes done;
- i. Certificate of analysis;
- j. Batch release certificate;
- k. Stability studies done on the drug/device;
- l. Authorisation of the clinical trial from the country of origin;
- m. Good Manufacturing Practice certificate of plant from which drug/device was manufactured;
- n. Containers in which products is packaged;
- o. Labelling; and
- p. Relevant published literature on the drug/device.

3.4 Oversight by 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 National Health Strategic Plan." In executing this function, UNHRO collaborates with UNCST to register all research protocols related to health. This registration process is done centrally at UNCST.

3.5 Oversight by Research Ethics Committees

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 projects, with the aim of protecting rights and

welfare of human research participants. RECs operating in Uganda must be accredited by an Accreditation Committee for Research Ethics Committees based at UNCST. RECs have a special role of monitoring research activities to ensure compliance with scientific and ethical requirements in accordance with these guidelines. Operations of RECs are described in detail in Section 4.0 below.

3.6 Oversight by Other Committees

Besides RECs, there are a number of other committees that are involved in one way or another in the research process. These committees include:

3.6.1 Scientific Committees

3.6.1.1 Establishment

Scientific Committees (SCs) are sometimes set up within organizations as an internal review mechanism for research proposals. Where such committees formally exist, they should approve research protocols prior to submission to a REC.

SCs should be comprised of at least three experts. They should have standard operating procedures (SOPs) to guide their functions. The SOPs should specify, at least, the following:

- a. Format of research protocol to be submitted for review;
- b. Frequency of SC 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. ways of communicating decisions (with reasons for every decision made clearly stated in writing).

Members of SCs shall protect confidentiality of all information given to them in the course of their work, and sign confidentiality agreements with their organizations. In addition, they shall not use information supplied in research proposals under their consideration for their own research projects or personal gain.

3.6.1.2 Functions

The primary function of a SC is to review and evaluate all scientific aspects of research projects with emphasis on suitability, relevance and feasibility of the study. Specific issues that shall be scrutinized by the SC include, but are not necessarily restricted to: study design, objectives of the study, methodology, appropriate controls, statistical methods, and feasibility of the study.

The SC shall also build lines of communication between the various departments within the organization and RECs;

3.6.2 Data and Safety Monitoring Boards

3.6.2.1 Establishment

A Data and Safety Monitoring Board (DSMB) is an independent group of experts established by study sponsors to review safety data during a clinical trial. It is to ensure that a study is conducted and data are handled in accordance with provisions of the research protocol. The DSMB also monitors adverse events and safety data. A DSMB shall be established before the commencement of a clinical trial and its composition submitted to the REC for record purposes.

All Phase I, Phase II, and Phase III clinical trials conducted in Uganda should have a safety monitoring plan and a DSMB. Other interventional studies, such as community trials, may be required to set up DSMBs on a case by case basis.

A DSMB shall comprise of at least three persons including a clinician with competence in the research field of the trial and a biostatistician.

In general, membership of the DSMB shall include:

- a. Individuals knowledgeable in the processes of conducting the trial, including requirements for research protocol amendments;
- b. Individuals with adequate medical, pharmaceutical, scientific, and/or ethics qualifications and clinical trial experience. The qualifications most appropriate for a specific DSMB will depend on the nature of the clinical trial and of the product under investigation.

3.6.2.2 Functions

Functions of a DSMB are to:

- a. Ensure safety of study participants;
- b. Preserve the integrity and credibility of the trial;
- c. Ensure availability of definitive and reliable results in a timely manner;
- d. Make decisions related to safety, based on the submitted results and adverse event reports and recommend whether the study should continue or not.

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

- a. Any concerns over differences in serious adverse events between study arms;

- b. Any serious social harms;
 - c. Any concerns about the conduct of the trial;
 - d. Any concerns about data integrity;
 - e. Whether the study should be terminated or continued based on safety and interim data;
- The DSMB shall determine before the commencement of the study, the following:

- 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 at hand (where there may be concern, the DSMB may choose to review data more frequently);
- d. Channels of communication with the study and the REC.

3.6.3 Community Advisory Boards

3.6.3.1 Establishment

Community Advisory Boards (CABs) are established by the researcher. A CAB facilitates dialogue between the community and the researcher team.

CAB members are identified from communities where research is to be undertaken. The CAB's role and expectations should be clearly stated in their terms of reference. Members of a CAB may include, but are not limited to, the following:

- a. Individuals with understanding of local laws, cultural values and gender issues;
- b. Peer leaders;
- c. Religious leaders;
- d. Representatives of the study population;
- e. Media;
- f. Professionals who understand research or science issues;
- g. Community leaders.

3.6.3.2 Functions

The primary function of a CAB is to assist researchers understand and incorporate community concerns into their research activities. This happens through different ways like advising on issues central to the informed consent process, achieving successful volunteer recruitment and retention, among others.

Responsibilities of CABs may vary according to the study location, size, and other factors, but generally, they are to:

- a. Provide information on traditional beliefs and needs of the study population and their concerns regarding the research project;
- b. Provide input into the design of the research protocol as appropriate including the informed consent process;
- c. Advise on effective methods for disseminating information about the research project and its outcomes;
- d. Provide advice and support regarding recruitment and retention of research participants including considerations of gender.

3.6.4 Institutional Biosafety Committees

3.6.4.1 Establishment

Institutional Biosafety Committees (IBCs) are established by organizations that undertake research on potentially hazardous substances of a physical, chemical, biological, or any other nature. Any organization involved in or planning to conduct research with potentially hazardous substances is required to set up or designate a competent IBC. Each IBC once formed shall consist of a biosafety officer and at least three other officers with appropriate expertise. The IBC shall be certified by UNCST.

It is the responsibility of the researcher to notify and provide the IBC with the research proposal involving potentially hazardous substances of a physical, chemical, biological, or any other nature.

Members of the IBC shall protect confidentiality of all information given to them in the course of their work, and shall sign confidentiality agreements with their organizations. In addition, they shall not use information supplied in the research proposals under their consideration for their own research projects or personal gain.

3.6.4.2 Functions

The IBC's function is to minimize potential human and environmental harm that may be associated with research on or with potentially hazardous substances such as pathogens, radioactive material and applications of biotechnology, especially recombinant DNA techniques and processes.

Specifically, IBCs shall:

- a. Notify the REC and UNCST of any research with potentially hazardous substances in their organizations;
- b. Conduct biosafety review of research proposals on potentially hazardous substances;
- c. Ensure provision of suitable and safe storage and disposal facilities for all materials involved in work with potentially hazardous substances;
- d. Ensure that all appropriate technical personnel of the organization have adequate training in biosafety;
- e. Establish a health-monitoring plan for all high-risk personnel involved in application, use and production of potentially hazardous substances.

4.0. ESTABLISHMENT AND FUNCTIONS OF RESEARCH ETHICS COMMITTEES

4.1 Introduction

RECs are established in or by an organization to conduct initial and continuing review of research projects with the primary goal of protecting rights and welfare of research participants. All organizations in Uganda 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 projects, provided the REC is accredited by the Accreditation Committee for RECs in Uganda (ACREC) based at UNCST.

4.2 Establishment

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 of research conducted at or sponsored by the organization. This may include an appropriate existing code, declaration, or statement of ethical 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 should be identified by name, qualifications, profession,

specialty, organization of affiliation and representative capacity in REC.

- d. Written standard operating procedures for the REC;

The ACREC 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 by the ACREC. Guidelines for accreditation of RECs are obtainable from the UNCST offices or website.

4.3 Composition of a REC

- a. Each REC shall be composed of at least five (5) members, with varying backgrounds to ensure balanced and adequate review of research activities commonly conducted by the organization. The REC shall be sufficiently qualified through the experience, expertise and diversity of its members, including consideration of gender, cultural backgrounds and sensitivity to social issues in the community in which research participants are drawn.
- b. 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 nonscientific areas.
- c. Each REC shall include at least one member who is not affiliated with the organization and who is not part of the immediate family of a person who is affiliated with the organization.
- d. Each REC shall include at least one lay³ person from the community.

³ "Lay person from the community" refers to an individual whose primary background is not in scientific research involving human participants, and who is capable of sharing his/her insights about the community from which participants are likely to be drawn.

- e. No REC member may participate in the REC's initial or continuing review of any project in which the member has a conflict of interest, except to provide information as may be requested by the REC.
- f. Each REC member shall take at least one course in human research protection within one year of appointment to an REC, and thereafter, should undergo continued research ethics education at least once every two years.
- g. A REC may, at its discretion, invite individuals with competence in special areas to assist in the review of protocols, which require expertise beyond, or in addition to that available in the REC. These individuals do not vote at REC meetings.
- h. Membership in any REC shall not exceed a term of three years. After serving for three years, a member is eligible for reappointment.
- i. A person may not serve as a member in more than two RECs concurrently.
- j. REC members must guard against any tendencies of unethical conduct on their own part, for example, they must protect the confidentiality of research projects, documents and discussions; a REC member shall not appropriate the submitted proposal for his or her own use; and REC members shall not compel researchers to submit to unnecessary repetition of review.
- k. RECs have a special responsibility to determine whether the objectives of a research project are responsive to the health needs and priorities of the proposed study population in particular and of Uganda in general. The ability to judge

the ethical acceptability of various aspects of a research proposal requires a thorough understanding of a community's customs and traditions. The REC, therefore, must have competent members or consulting persons with such understanding.

4. 4 Functions

RECs act as independent reviewers of any proposed study on human research participants, to ensure ethical conduct of research, and that participant's rights and welfare are not violated. Therefore, the major responsibility of RECs is to safeguard the rights, safety, and welfare of research participants. It is important for RECs to review the scientific soundness of the research proposals. In view of this, the functions of any REC in Uganda shall be to:

- a. Maintain ethical 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; and
- e. Ensure adherence to ethical conduct of research protocols approved by the REC;

4. 5 Review Mechanisms

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

4.5.1 General Requirements

- a. REC shall review proposed research at convened meetings at which at least fifty percent (50%) of the members of the REC are present, including at least one lay member. Quorum should be maintained at all times during the meeting and at voting.
- b. In order for the research project to be approved, it shall receive the approval of a simple majority of those members present at the meeting. The only exception to this procedure shall be in the case of expedited review as provided in Section 4.5.2;
- c. A REC shall meet as often as possible, but at least once every three months;
- d. A REC shall notify researchers in writing about the outcome of review of the researchers' project within 14 calendar days from the date of review. In case the REC does not approve a research activity, it shall include in its written notification reasons for its disapproval.
- e. A REC shall conduct continuing review of research covered by these guidelines 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 Expedited Review

- a. The REC may use an expedited review process for research involving no more than minimal risk or for minor changes in previously approved research protocols during a period of one year or less for which approval is given. Minor changes include such changes as addition of a collaborator or a small change in the number of research participants, or spelling corrections. Expedited review process

may also be applied to annual renewal of studies, in which the only outstanding activity is data analysis and report writing. Major changes include, but are not limited to, significant changes in the research methodology or a change in procedures for research participants. Each REC shall develop standard operating procedures to define eligibility for expedited review.

- b. Expedited review may be done by the REC chairperson and/or one or more REC members he/she designates, and should typically be done within 21 calendar days. In reviewing the research, the reviewers may exercise all of the authority of the REC except that the reviewers may not disapprove the research.
- c. Each REC shall present all expedited review decisions at the next full REC meeting for ratification.
- d. The ACREC may restrict or choose not to authorize a REC to conduct expedited review when it is determined that the REC is abusing the process.

4.5.3 Exemption from REC Review

The following categories of research are exempt from REC review:

- a. Use of publicly available unlinked data that does not identify individuals or communities;
- b. Emergency use of a test article provided that such emergency use is reported to the REC within seven calendar days. Any subsequent use of the test article at the organization is subject to REC approval.

If a researcher believes that his/her research project would satisfy the requirements for exemption by REC review, the researcher

shall apply to the REC for his/her study to be exempt from REC review. The REC shall review the application to ensure that the proposed study satisfies requirements for exemption from REC review, and will, thereafter, grant exemption.

4.5.4 Review of Collaborative Research Projects

- a. Collaborative research projects are projects that involve more than one organization locally and internationally. When conducting collaborative research projects, each participating organization is responsible for safeguarding rights and welfare of research participants and for complying with these guidelines. This involves securing REC approvals in both the local and foreign organization prior to registration of the study by UNCST. Where desirable participating organizations in a collaborative research project may have a joint review arrangement for that particular research project.
- b. The local REC overseeing an international collaborative research project is the REC of record in view of its better understanding of cultural sensitivities of the population in which the proposed research is to be conducted. It is also better placed to monitor compliance with these guidelines in the course of a study.
- c. An international collaborative research project should have a co-principal investigator in Uganda, who must be employed at and/or affiliated to a recognized local organization that is relevant to the area of the proposed research. The co-principal investigator should be qualified and competent and should actively participate in and/or supervise the research project.

4.5.5 Multiple REC Review

- a. As a general rule, a researcher shall submit his/her research protocol to the REC of his/her organization of primary affiliation. However, for compelling justifiable reasons, the researcher may request UNCST for permission to submit his/her research protocol to another accredited REC other than the REC of his/her organization of primary affiliation.
- b. Where the organization of primary affiliation does not have a REC, the researcher is free to choose any of the accredited REC to review their research protocols.
- c. Where a research protocol, which is to be implemented in Uganda, has been approved by an accredited REC in Uganda, such approved protocol shall not undergo additional ethical review by another REC in Uganda. However, an organization where the research is to be conducted shall grant administrative clearance for the study to be conducted in the organization even if that organization has a REC. 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 any research costs such as bench or other administrative fees associated with the conduct of the research at the organization, which the researcher should pay.
- d. The approving REC has the primary responsibility for monitoring approved studies regardless of where they are conducted. However, where the implementing organization has a REC, the approving REC may, at their discretion, assign the monitoring role to the REC of the

implementing organization. The approving REC and the REC of the implementing organization shall agree on modalities for study monitoring.

4.5.6 REC Suspension or Termination of Approved Research

- a. A REC shall have authority to halt, suspend or terminate 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 these guidelines. The REC may suspend research when, for instance:
 - i. It finds that the researcher has implemented major changes in the research protocol without prior approval of the REC,
 - ii. When the researcher has failed to follow specific procedures or requirements enunciated by the REC in its initial review of the research protocol, or
 - iii. When there is unexpected serious harm to research participants including, but not limited to, serious physical injury or death.
- b. Any suspension or termination of approval shall include a written statement of the reasons for the REC's action and shall be reported promptly to the researcher(s), appropriate organizational officials, UNCST and other relevant regulatory agencies.

4.6 REC Records

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

- a. Detailed written standard operating procedures.

- b. Copies of all research proposals reviewed, scientific evaluations that accompany the proposals, approved consent documents, progress reports submitted by researchers, reports of injuries to research participants, etc. These records shall be kept for at least five (5) years after completion of the research project.
- c. Minutes of REC meetings, which shall be in sufficient detail to show attendance at the meetings, conflicts of interests declared, actions taken by the REC and the vote on these actions including number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, and a written summary of discussions of controversial issues and their resolution.
- d. Copies of confidentiality agreements, CVs and training records of members.
- e. Records of continuing review activities.
- f. Copies of all correspondence between the REC and researchers.
- g. Statements of significant new findings provided to research participants.

All records shall be accessible for inspection and copying by authorized representatives of UNCST and other authorized agencies.

4.7 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 project has a clear scientific objective, is designed using acceptable scientific

- principles, methods and reliable practices; and, where applicable, has sufficient power to definitely test the study hypothesis.
- b. The research project demonstrates value in terms of new knowledge added and probably improvement in health care provision and general social wellbeing. There should be foreseeable benefits to the individuals and community that is going to be studied, and risks should be minimized.
 - c. Risks to research participants are minimized by using procedures that are consistent with sound research design and which do not unnecessarily expose research participants to risk. Risks, if any, are reasonable in relation to anticipated benefits to the research participants, and the knowledge that will be gained. Risks may include psychological, mental, social, physical and economic harms. Benefits may include such aspects as medical care and treatment. Benefits also include those that accrue to the wider community such as capacity building or enhancement of social amenities.
 - d. The selection of research participants is fair and equitable. In making this assessment the REC shall take into account the purposes of the research and the setting in which the research will be conducted. It should be particularly cognizant of special challenges associated with research on vulnerable populations.
 - e. Informed consent will be sought from each individual prospective research participant or the individual participant's authorized representative. Informed consent process will be appropriately documented in accordance with the provisions of these guidelines.
 - f. There are adequate provisions to protect privacy of research participants and to maintain confidentiality of personal identifiable information.
 - g. Additional safeguards have been included in the study to protect vulnerable groups.
 - h. Where appropriate, there should 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 study population specific.

4.8 Requirements for Submission to REC

All RECs shall develop detailed standard operating procedures for submission of protocols and other requirements. However, at the minimum, the requirements should include:

- a. A complete research protocol with version and date.
- b. Study instruments e.g. questionnaires, case report forms, videos, flip charts and other data collection tools/forms.
- c. Samples of trial drugs/devices.
- d. Informed consent documents.
- e. Evidence that the researcher is appropriately qualified, experienced and, where applicable, licensed, and has adequate facilities for safe and efficient conduct of research.
- f. A plan for disseminating research findings to the community in which research was carried out and other authorized authorities in Uganda.

4.9 Obligations of a REC

The REC is obliged to:

- a. Conduct initial and continuing/periodic review of research projects, including site monitoring visits.
- b. Review research protocols in a timely manner but in any case within 60 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.
- c. Communicate outcome of the review within 14 calendar days from the date of REC review of the research protocol.
- d. Respond to any allegations of ethical violations in research projects approved or rejected by the REC.

- e. Liaise with other RECs within and outside the country for better carrying out of its functions.
- f. Prepare annual reports of REC performance to the ACREC at UNCST.

4.10 Appeals/Arbitration

A researcher who is dissatisfied with the REC's decision may appeal to UNCST within 30 calendar days after receiving the REC's decisions.

Where two or more RECs disagree over interpretation of these guidelines or administrative or ethical issues in respect of a given protocol or REC's operation, the aggrieved RECs shall approach UNCST for arbitration.

5.0 INFORMED CONSENT PROCESS

5.1 Introduction

Respect for persons requires that research participants be given the opportunity to make choices about what should be done to them. 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 should be adequate, clearly understood by the research participant with decision making capacity and the research participant should voluntarily decide whether or not to participate.

5.2 General Requirements for Informed Consent Process

Except as provided elsewhere in these guidelines, no researcher shall involve an individual person 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 may not consent for participation of community members in research without the individual research 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. For certain types of research, the REC may require the researcher to administer a comprehension test (or test of understanding) to 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 coercion or 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 the 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 researcher as well as the REC shall ensure continued adequacy of the informed consent process, and re-consent research participants if there are changes in the conditions or procedures of the research project or if new information becomes available that could affect the research participant's willingness to continue in the research project.

5.3 Key Components of the Informed Consent Form

5.3.1 The information to be included 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; that the study involves research; an explanation about the research project; the estimated duration the research participant will take in the research project; a description of the study procedures, and identification of any other procedures that are experimental.

- b. A description of any reasonably foreseeable risks or discomforts that the research participant may experience.
 - c. A description of the benefits to the research participant or to others that may reasonably be expected to result from the research project.
 - d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the research participant.
 - e. A statement describing the extent, if any, to which privacy and confidentiality of the research participant will be maintained.
 - f. A statement about compensation and medical treatment available if injury occurs and, what they consist of and where further information may be obtained.
 - g. Names and contact details of individual(s) who should be contacted at any time in case of questions about the research project, the research participants' rights and welfare. The individual(s) should be able to communicate in a language understandable by the research participant or should be able to promptly secure the services of an interpreter to assist in responding to the research participant's questions.
 - h. 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.
 - i. Where applicable, a statement of how the researcher will provide medical services to the research participant.
 - j. The nature, form and extent of compensation for study participation, e.g. reimbursement for transport, time and meals.
 - k. A brief description of sponsors of the research project and the organizational affiliation of the researchers.
 - l. A statement that research participants will get feedback on findings and progress of the study, and that any new information that affects the study or data that has clinical relevance to research participants (including incidental findings) will be made available to research participants and/or their health care providers.
 - m. Where necessary, provision for a witness at appropriate specific stages of the informed consent process, for example, in the case of illiterate, mentally incapacitated or physically handicapped research participants.
 - n. A statement that the study has been approved by an accredited Ugandan based REC.
- 5.3.2 Any of the following shall be provided to the research participant, whenever appropriate, 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. An explanation of circumstances under which the researcher may terminate the research participant's participation, whether or not the research participant consents to such termination.

- c. An explanation of any additional costs to the research participant that may result from his or her participation in the research project.
- d. A statement explaining the consequences of a research participant's decision to withdraw from the research project. Research participants may withdraw at any time without further notice. However, research participants' should be provided with a description of the procedures that are to be followed in order to give notice of their withdrawal.
- e. A statement that significant new findings that are made during the course of the study, whether by the researchers or others that may relate to the research participant's willingness to continue his or her participation, shall be provided to the research participant in a timely manner.
- f. The approximate number of individuals participating in the research study.
- g. Whether, when, how and for how long any of the products or interventions proven by the research project 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.
- h. With regards to research involving the collection of human materials, an explanation should be provided on how specimens will be managed at the end of the study. If the samples will be stored for future use, separate consent should be obtained (See section on storage of human materials).

5.4 Documentation of Informed Consent Process

The researcher shall document the informed consent process. In addition, and except as provided in section 5.5 below, research participants or their representative shall sign/mark/thumbprint an informed consent form approved by a REC. The person obtaining the consent, and where applicable, the research participant's witness shall also sign the form. Where the use of signed consent forms is not feasible, alternative viable methods should be employed. A copy shall be offered to the research participant or the research participant's representative.

The research participant or the research participant's representative must be given sufficient time to read the consent form before the research participant or the research participant's representative signs the form or places his or her thumbprint on the form indicating that he or she has read and understood and agrees to participate in the study. The consent form may be read to illiterate research participants.

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. However, verbal consent must be documented. RECs reserve the right to determine when verbal informed consent may be appropriate and acceptable.

5.5 Waiver of Requirement for Informed Consent

A REC may waive some of, or all of the requirements for the researcher to obtain informed consent and/or a signed /thumb printed consent form for some or all of the research participants of a particular study if the REC determines that:

- a. The research project carries no more than minimal risk, that is, risk that is no more than the risks encountered in normal daily life in a stable society;
- b. The research project could not practicably 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. The only record linking the research participant and the research project would be the informed consent form and the risk to the research participant would be potential harm resulting from a breach of confidentiality;
- e. The research participant presents in an emergency situation and informed consent cannot be reasonably obtained from the individual or his/her representative.

5.6 Assent

Assent to participate in research shall be obtained from all children eight (8) years of age and above, and from all persons incapable of self-determination. A child's assent is obtained after parental/guardian's consent. The child's assent or dissent takes precedence over the parent's or guardian's consent. Assent for all other persons incapable of self-determination is obtained after consent from their representatives.

5.7 Informed Consent by Pregnant Women

For research involving pregnant women, informed consent should be obtained from both the mother and father of the embryos

and fetuses. 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 whereabouts are unknown; (iii) the father is not reasonably available; or (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 Informed Consent by Mature and Emancipated Minors

Mature minors are individuals 14-17 years of age who have drug or alcohol dependency or a sexually transmitted infection; while emancipated minors are individuals below the age of majority who are pregnant, married, have a child or cater for their own livelihood. Mature and emancipated minors may independently provide informed consent to participate in research if:

- a. In the view of the REC the research is not objectionable to parents or guardians (established by the REC with evidence from the community);
- b. The research protocols include clear justification for targeting mature and emancipated minors as participants; and a clear justification for not involving parents or guardians in the consent process.

6.0 CARE FOR RESEARCH PARTICIPANTS

6.1 Care and Treatment for Research Participants

A care package for research participants should be stated before initiation of a research project. Care and treatment for research participants should be provided with the ideal aim of providing the best proven intervention and, at the least, should be in accordance with the current Uganda Clinical Guidelines and other national health guidelines and standards. In the absence of these national health 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 should be negotiated before initiation of the study. Sponsors are encouraged, but not obliged, to provide care for concurrent illnesses not associated with the research project. However, researchers and sponsors are obliged to manage serious adverse events related to the study (including paying for associated costs thereof) until they are fully resolved or stabilized. Researchers should provide relevant follow up procedures for research participants for an appropriate period of time after the trial.

6.2 Care for Research Participants in Control Groups

Research participants in a control group of a research project of a diagnostic, therapeutic, or preventive intervention should receive a proven intervention or as may be determined with reference to the applicable national health standards. Sponsors may, where possible, provide care and treatment beyond what is

recommended in the national health guidelines taking into consideration sustainability issues.

In certain circumstances, and as may be advised by a REC, a placebo or no intervention may be used in the control group where:

- a. Based on knowledge that is currently available, a proven intervention does not exist.
- 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 has been demonstrated to be superior, the sponsor(s) shall promptly offer to research participants in the control arm the intervention free of charge. However, sponsors are encouraged but not obliged to provide lifelong care and treatment for chronic and relapsing illnesses.

6.3 Care for Research Related Injuries

The sponsor should provide care until complete cure or stabilization of a research related injury. The injured research participant shall be given the best care available within the country for the research related injury. Research participants shall not be required to waive their legal rights for redress in courts of law.

6.4 Referral of Research Participants

The researcher shall undertake to 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 should be adequately documented and all referral guidelines should be adhered to as stipulated in national guidelines on referral. Furthermore, researchers should have prior arrangements with the referral facility to receive referred patients. Research participants should always be informed of all 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.

6.5 Compensation for Research Related Injury

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 project;
- b. **Probably:** When injury is most likely explained by participation in a research project but when no definite proof of causality is evident;
- c. **Possibly:** When explanation for injury is equally due to participation in a research project or other cause;
- d. **Unlikely:** When injury is more likely explained by another cause other than participation in a research project;

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

Subject to applicable laws in Uganda, research participants shall be entitled to compensation when injury is classified as “Probably” or “Definitely” related to their participation in a research project. Sponsors shall ensure that research participants who suffer injury as a result of their participation in a research project are entitled to free medical treatment for such injury and to such financial or other assistance as would compensate them equitably for any resultant impairment, disability or handicap. 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.

The sponsor and researcher shall put in place a mechanism for compensating research related injury at the commencement of a study. The mechanism, which may include, *inter alia*, insurance and medical care, should be acceptable to the REC. The REC, research participant and/or researcher may initiate the compensation process. The REC, sponsor and researcher shall agree on an appropriate mechanism for arbitration.

6.6 Compensation for Participation in Research

Research participants shall be fairly compensated for inconveniences, time spent and expenses incurred in taking part in a study such as travel costs, refreshments, meals, and any other compensation deemed appropriate by the REC. Research participants may also receive free medical services.

The compensation or medical services shall not be out of proportion as to induce prospective research participants to consent to participate in the research against their better judgment.

6.7 Incentives for Research Participation

Incentives to research participants for their participation in research projects shall not be considered a research benefit, but a recruitment incentive, and should not present undue inducement to potential research participants.

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

7.1 Researcher

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

- a. Ensure that the research protocol is fully developed and complete.
- b. Demonstrate ownership (e.g. by signing the protocol) of the research protocol, and ensure that the protocol is strictly followed at project implementation.
- c. Not implement changes/amendments in the research protocol without 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 appropriate 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.
- g. Advise, in writing, the REC, UNCST and other relevant national authorities about early termination of the study and the reasons for the termination.
- h. Ensure good documentation of all study procedures and data.
- i. Put in place a quality assurance system for proper conduct of the study in order to preserve integrity of the data.
- j. Ensure appropriate and timely feedback on the research process and findings.
- k. Take all reasonable steps to engage with the community.
- l. Have adequate time to implement/supervise the research protocol, and should be reasonably present and active at the study site.
- m. Take, together with his/her research team, a recognized research ethics course or equivalent within three years prior to commencement of the study; and thereafter, have a refresher course at least once every three years. Student supervisors at training organizations are similarly encouraged to take basic research ethics courses.
- n. Be sufficiently qualified and competent to carry out the research project, and shall, where necessary, have the appropriate professional license to practice. Clinical trials shall be supervised by a competent and appropriately qualified physician or other health care professional.

7.2 Sponsor

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

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

- b. Cause the timely reporting and management of adverse events.
- c. Be responsible for compensation or indemnity in the event of research-related injuries, disability, or death, in accordance with applicable Ugandan laws and regulations.

7.2.2 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/ devices;
- b. Provide a dossier (research protocol and investigator’s Brochure);
- c. Ensure that the investigational product and any comparator products are of appropriate 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 labeling of the investigational product(s) or medical device. The investigational and comparator products must be labeled in conformity with the research protocol and the labeling 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 characteristics so that, if necessary, an independent laboratory may check the product for quality control or bio-equivalence.

7.3 Researcher's Organization of Affiliation

The researcher’s organization of affiliation shall supervise and monitor research activities of the researcher(s) at the organization. Specifically, the organization shall:

- a. Establish, and/or designate a functional 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 should include regular courses in responsible conduct of research and research ethics;
- e. Take appropriate disciplinary action against researchers for non-compliance with these guidelines.

8.0 VULNERABLE GROUPS AND INDIVIDUALS

8.1 Introduction

Some groups or individuals are relatively (or absolutely) incapable of protecting their own interests. They may have insufficient power, intelligence, 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 consent or decline consent. These include, but are not limited to, children, mature and emancipated minors, street children, prisoners, the homeless, refugees, adults staying on the street, internally displaced persons, substance abusers, handicapped (mentally and physically), armed forces, terminally ill and pregnant women. 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 individuals, shall specify how they will address particular vulnerabilities.

8.2 Additional Protection for Vulnerable Populations

8.2.1 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;
 - c. Inadequate protection of human rights;
 - d. Discrimination on the basis of health status;
 - e. Limited availability of health care and treatment options;
 - f. Communities in acute disaster and disease epidemics;
- 8.2.2 In order to protect vulnerable communities, RECs should ensure that:**
- a. Selection of communities is justified by the research goals;
 - b. Research is responsive to needs and priorities of the community in which it is to be conducted;
 - c. With respect to pregnant women and fetuses, appropriate studies on animals and non-pregnant individuals have been completed.
- 8.2.3 For all vulnerable groups and individuals,**
- a. Research can only be conducted in this group and individuals if the objectives of the research project cannot be addressed using non-vulnerable groups and individuals.
 - b. Risk of participating in research is justified by anticipated benefits;
 - c. The intervention or procedure presents experiences that are commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
 - d. The intervention or procedure is likely to yield generalizable knowledge about the group or individual's disorder or condition that is of vital importance for the understanding or amelioration of that disorder or condition;
 - e. RECs may co-opt a person knowledgeable about and has experience working with the vulnerable group and individuals.

9.0 MANAGEMENT OF SERIOUS ADVERSE EVENTS

9.1 Introduction

The researcher shall identify, manage and promptly report serious adverse events to the REC. This shall not apply to events that are observed among participants who are in observational studies in which no health related intervention is being administered.

9.2 Defining Seriousness of Adverse Events and Unexpected Events

9.2.1 *A serious adverse event is an event, which:*

- a. Results in death;
- b. Is life threatening;
- c. Requires in 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.

9.2.2 *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.

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

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

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

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

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

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

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

9.3 Management of Serious Adverse Events and Unexpected Events

- a. The research protocol shall clearly state how the researcher will identify, manage and report serious adverse events and unexpected events.
- b. The site facilities must be adequate and appropriately licensed for patient care. Where a patient cannot be adequately treated at the site, the researcher shall refer the patient to more advanced or specialized facilities for better management.
- c. The researcher shall properly document occurrence of serious adverse events or unexpected events using a standard format acceptable to the REC.

9.4 Reporting Serious Adverse Events and Unexpected Events

All serious adverse events and unexpected events shall be reported to the REC. 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.

All serious adverse events and unexpected events must be reported to the local REC 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 the serious adverse event and unexpected event should be submitted within seven (7) *calendar* days from the date it is reported to the REC.

All other reportable adverse events should be reported to the REC as soon as possible and in any case not later than fourteen (14) *calendar* days. These include:

- a. All events associated with protocol violations regardless of severity and relationship to the intervention;
- b. When criteria for stopping or pausing a study as stipulated in the protocol are met;
- c. Any event mandated by regulatory authorities;
- d. Any event stipulated in the protocol as reportable to the regulatory bodies.

Certain categories of interventions with potential long term effects may require extended follow up and monitoring for serious adverse events. This may include investigations involving 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, but may usually be for a minimum of two years.

9.5 Protocol Violations and Deviations

Any change in the stated procedure, activity or any provision of the protocol without prior approval except for the purposes of intervening when a person's life is in danger constitutes a protocol violation or deviation. Violations tend to be more serious than deviations. When any of these occur, the researcher shall notify the REC.

The report should contain the following information:

- a. Title of the study,
- b. Name of researcher,
- c. Organizational affiliation,
- d. Date of report,
- e. Date(s) when violation occurred,
- f. Brief description of what happened,
- g. Any effect on the study,
- h. Any adverse events arising from the violation,
- i. Management and follow up of violation and steps to avoid recurrence of the violation.

Notification to the REC and where applicable the collaborating organization's REC or any other regulatory bodies should be made by the researcher within seven (7) *calendar* days of becoming aware of the event.

10.0 HUMAN MATERIALS

Human materials are substances including, but not limited to, blood, urine, stool, saliva, hair, nail clippings, skin, and any other associated bio-products obtained from human research participants or patients or healthy persons.

10.1 Acquisition

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

10.2 Storage and Future Use

A separate informed consent form shall be used for samples, 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, quantities of samples to be stored, place where samples will be stored, 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 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 should or should not be stored for future studies. A Ugandan scientist shall be included as co-investigator in all future studies using the human materials collected from Uganda. 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.

Where identifiable 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, sample sources shall be traced to provide consent for use of the samples in research.

10.3 Ownership

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 rights and welfare of the research participants.

10.4 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 an appropriate contract with the recipient organization. This contract shall be in the form of a Materials Transfer Agreement (MTA).

In order to justify transfer of human materials abroad, researchers, sponsors and collaborators

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

All exchanges and transfers (including importation and exportation) of materials for research purposes shall require clearance from UNCST, except for exchange of human materials between organizations within the country. UNCST shall maintain a depository of all MTAs. Applications for permission to exchange or transfer human materials for research purposes shall be made to UNCST. The application must be accompanied by a MTA.

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

a. Parties

The MTA must carefully list parties and their addresses. The MTA is signed only by authorized representatives of the party. 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 should fully describe the intended use of the materials. The recipient should also specify whether

the materials would be used for research purposes only or for commercial applications or both.

d. User(s)

Authorized users of the materials should 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 or their assignees.

e. Location

The place (full address) where material is to be transferred, used and or stored should be indicated.

f. Period of use of material

A date for termination of use of the material 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 should be noted that terminating use of the material does not render null and void other provisions of the MTA. It should be mentioned if the material would be stored for future unknown uses.

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.

h. Restrictions

If there are specific restrictions for the recipient organization, they should 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 should, however, be noted that any research project 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 should 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 through the use of the material. If nothing is stated about this in the MTA, the provider organization automatically assumes ownership.

k. Commercialisation rights

The MTA should include directions for handling commercializable products, including sharing of any royalties. The parties may wish to include a clause, which allows them to negotiate a separate MTA should the need for commercialization arise.

l. Technology transfer

The MTA should 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

The provider organization may require the recipient organization to publish or not to publish the data obtained from the material under specified conditions.

n. Citation requirements

If the provider organization allows any publication, it may be agreed that the provider organization is acknowledged as the provider of the material.

o. Governing law

The MTA should state the governing law. Such laws may be the laws of the provider's and recipient's country or both. Whatever the case may be, the MTA should be prepared taking into consideration the governing laws of the provider's and recipient's countries.

p. Responsibilities

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

q. Liability

The recipient or both the provider and recipient are accountable for any misuse or consequences of use of the material. Parties must agree on liability.

r. Warranty

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

s. *Amendment*

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

t. *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.

When preparing MTAs care should 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 a material governed by a separate MTA, care should be taken under such circumstances to avoid granting two or more parties conflicting rights to the same material or product.

Usually before negotiating a 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 should be prepared within the framework of the 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.

10.5 Procedure for Exchange/Transfer of Human Materials Abroad or From Abroad for Research Purposes

The following are the necessary steps for the exchange or transfer of materials for research purposes abroad or from abroad:

- a. The research project 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 be affiliated to a locally registered and recognized 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. A 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.

11.0 DATA OWNERSHIP, SHARING AND RESULTS DISSEMINATION

11.1 Data Ownership

Data ownership and associated intellectual property rights shall be discussed and agreed upon by collaborating partners at the inception of a research project. Collaborating research partners shall negotiate data ownership and use in accordance with the host organization's data use and ownership policies. Ownership of data shall be clearly stated in the research protocol or collaborative research agreements, which shall be reviewed by the REC and registered with UNCST.

11.2 Data Sharing

- a. Collaborating research partners shall agree on appropriate data access and use rights before commencement of the study. Researchers shall have in place mechanisms for maintaining confidentiality of research participants and their communities.
- b. A collaborating research partner shall not transfer data to a third party without the written consent of the other partner.

- c. Local researchers shall have unrestricted access rights to data sets collected through a collaborative research project.
- d. Researchers shall ensure that research records from which the data has been obtained are available at the research site for at least five years after completion of the research project. Electronic records are acceptable.

11.3 Results Dissemination

- a. Researchers shall, as appropriate, make all reasonable efforts to share findings of research with the host organization, research participants, key stakeholders and communities in which research was done.
- b. Researchers shall describe in the protocol plans for research results dissemination and ensure its execution.
- c. Researchers shall be sensitive about the ethical implications of the research results, and take appropriate measures to protect research participants and their communities.

12.0 COMMUNITY ENGAGEMENT

12.1 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 or affected individuals, groups of individuals, or organizations, with the ultimate goal of shaping research collectively. Involvement of community stakeholders shall not override the rights of individuals to consent voluntarily for participation in a research project.

12.2 Principles of Community Engagement

The following principles⁴ are useful for effective community engagement:

a) 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 honour 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 should 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) Integrity

Researchers should strive for the highest standards of scientific and ethical integrity in the conduct of their research. This is vital for achieving scientific goals and maximizing benefit to the community and society. Researchers should, therefore, adhere to sound scientific processes and appropriately weigh and address ethical issues in their study.

d) 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, if any, they each represent; and the extent to which their input may influence research-related decisions.

12.3 Community Engagement Practices

Researchers are encouraged to identify community stakeholders early enough during project conception and design. It is important

⁴ Adapted from Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials 2011

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 should be undertaken prior to seeking approvals from relevant RECs and other relevant regulatory authorities. This does not mean that consultations with community stakeholders should end after approval of research by the REC, neither should agreement with community stakeholders be

taken as a substitute to the REC process; rather community engagement is to be treated as an ongoing process until completion of research.

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. Normally, researchers should develop plans for providing feedback on the research results and outcomes of the research process. These plans should be shared with the RECs.

13.0 TRADITIONAL AND COMPLEMENTARY MEDICINE RESEARCH

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

Additional considerations are:

- a. Indigenous knowledge of the community should be recognized. There should
- b. be mechanisms to share equitably the benefits, which may arise out of the utilization of the knowledge in research. This may include support to the community to conserve their traditional knowledge and genetic resources.
- b. There should be considerations for protecting intellectual property or traditional knowledge in accordance with the relevant laws in Uganda.
- c. Research protocols should 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.

14.0 PENALTIES FOR NON-COMPLIANCE

Non-compliance with these guidelines may be identified by any person, REC, UNCST, UNHRO, NDA and all other stakeholders. Non-compliance shall be documented wherever it is identified.

UNCST shall subsequently communicate non-compliance to the affected 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 should 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. Withdrawing research registration permits of researchers involved in repeated non-compliance;
- c. Suspension and eventual termination of ongoing studies at the site or organization;
- d. Withholding approval of new studies to be conducted at the organization;
- e. Disciplinary action by relevant professional bodies for cases of suspected negligence and malpractice;
- f. Disqualifying a REC that has failed to take adequate measures to ensure compliance with these guidelines or that repeatedly fails to comply with these guidelines.

GLOSSARY

Adverse event is any untoward medical occurrence in a participant in a clinical trial who has been administered a pharmaceutical product or a medical device. The event may or may not be casually related to the treatment or procedure.

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

Child is a person below the age of eighteen years.

Clinical trial is a systematic study of pharmaceutical products 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.

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.

Guardian means a person having parental responsibility for a child.

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

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.

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 project.

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.

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.

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

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.

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.

Principal Investigator/Researcher is the main researcher overseeing or conducting a research project. Such an individual is qualified by training and has experience as an appropriate 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.

Research involving humans as research participants is defined as any study involving persons, and directed to the advancement of biomedical or other knowledge, that cannot be regarded as an element in established clinical management, public health or social practices and that involves either physical or psychological intervention or assessment, or generation, storage, and analysis of records containing biomedical or other 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.

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

Research participant means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

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

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.

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.

Viable means being able, after spontaneous or induced delivery, to survive, given the benefit of available medical therapy, to the point of independently maintaining heart beat 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.

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