UGANDA NATIONAL COUNCIL
FOR SCIENCE & TECHNOLOGY

THE REPUBLIC OF UGANDA

NATIONAL GUIDELINES FOR USE OF ANIMALS IN RESEARCH AND TEACHING



JANUARY 2021

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Document Errors

Readers who detect errors of omission or commission are invited to send corrections and suggestions to UNCST by email at info@uncst.go.ug.

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PREAMBLE

Uganda National Council for Science and Technology (UNCST) is mandated by the UNCST Act 1990 (Cap 209) to develop and implement strategies for integrating Science and Technology (S&T) into the national development process. Some of the key responsibilities of UNCST is to provide advice to the 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 charge the UNCST with the responsibility to act as a clearing house for information on research and experimental developments taking place in scientific institutions, centres and other enterprises and on the potential applications of their results in the country.

The Council appointed a multidisciplinary National Taskforce (NTF) to lead the process of developing the National Guidelines for Use of Animals in Research and Teaching. The NTF was inaugurated on 8th November 2018 to lead the process of developing these guidelines. The NTF reviewed and consulted existing national and international guidelines and relevant regulatory frameworks: Animal (Prevention of Cruelty) Act 1957, Section (11) and (12); UNCST National Guidelines for Research Involving Humans as Research Participants; The Council for International Organization for Medical Sciences (CIOMS); the International Council for Animal Laboratory Science (ICLAS; The Guide for the Care and Use of Laboratory Animals; Directive 2010/63/EU on the Protection of Animals Used for Scientific Purposes; Terrestrial Animal Health Code 2018 and Aquatic Animal Health Code 2019 among others.

The development of these guidelines was informed by the aspirations in the UN Sustainable Development Goals 2030, the Africa Agenda 2063, Science Technology and Innovation Strategy for Africa (STISA) 2024, East African Community Science, Technology and Innovation Strategy (STI), Uganda Vision 2040 and National Development Plan (NDP) III 2020/21 –2024/25. These guidelines shall apply to the conduct of research and teaching involving animals in Uganda.

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FOREWORD

Globally, it is recognised that many medical advances, including development of VACCINES, MEDICINES And treatment agents have been made possible through the use of animals in research. Animals are used in research to ensure the safety, efficacy and effectiveness of drugs and other pharmaceutical products as well as understanding the biology of different body systems for the benefit of humans, animals and the environment. Animals are commonly utilized for teaching purposes in different academic institutions at different levels of learning and must be treated humanely and their welfare needs provided.

The Uganda National Council for Science and Technology by virtue of its mandate of research oversight as accorded by the UNCST Act 1990 (Cap 209) has developed National Guidelines for use of Animals in Research and Teaching. The purpose of these guidelines is to regulate the use of animals in research and teaching to promote ethical standards for scientific purposes. The guidelines will go a long way in facilitating research and teaching institutions to ensure proper care and use of animals.

The guidelines were developed through a consultative process that involved the relevant stakeholders and shall be used to promote ethical and scientific best practices in animal care and use. These guidelines shall also serve as a resource for stakeholders involved in research and teaching.

Dr. THERESA SENGOOBA

Chairperson, Uganda National Council for Science and Technology Board

PREFACE

Uganda National Council for Science and Technology is mandated to facilitate and coordinate the development and implementation of policies and strategies for integrating Science and Technology (S&T) into the national development process. To achieve this, UNCST has developed and implemented several guidelines to promote ethical conduct of research. The guidelines for use of animals in research aim at promoting best practices of scientific integrity and ethical standards in animal research. These guidelines were developed in line with the existing regulatory frameworks

The guidelines were formulated to provide researchers, Institutional Animal Care and Use Committees (IACUCs), facility managers, sponsors and funders, teaching institutions and animal care staff with information that will facilitate in improving both the care given to animals and the manner in which research procedures are carried out. The refinement of these guidelines is a continuous process, intended to take care of new advances in use of animals in research and teaching.

Uganda National Council for Science and Technology is grateful to all the stakeholders who were involved in the development of this document. We highly value your ongoing support and look forward to continued collaboration as we promote ethical research in Uganda.

MARTIN PATRICK ONGOL (PhD)

For: Executive Secretary, Uganda National Council for Science and Technology

ACKNOWLEDGEMENT

Uganda National Council for Science and Technology acknowledges the contribution of the following Ministries, Departments and Agencies of Government and Non-Governmental Organizations that assigned technical personnel to the development of the guidelines: Ministry of Science, Technology and Innovation (MoSTI), Ministry of Agriculture, Animal Industry and Fisheries (MAAIF), National Drug Authority (NDA), Uganda Wildlife Authority (UWA), National Animal Genetic Resource Center and Data Bank (NAGRC&DB), National Agricultural Research Organization (NARO), International Livestock Research Institute (ILRI), Makerere University College of Veterinary Medicine, Animal Resources and Biosecurity (COVAB), Makerere University College of Health Sciences (CHS), Makerere University College of Humanities and Social Sciences (CHUSS), Uganda Veterinary Board(UVB), Uganda Veterinary Association(UVA), Conservation Through Public Health (CTPH) and Conservation and Ecosystem Health Alliance (CEHA).

Uganda National Council for Science and Technology also recognizes the supplementary financial support from MAAIF, NDA, Makerere University Walter Reed Project (MUWRP), Makerere University Infectious Diseases Institute(IDI), ILRI, NARO and NAGRC&DB. Sincere appreciation is extended to all those that contributed towards the successful development of these guidelines. UNCST is particularly thankful to the members of the NTF for their honorary contribution of time and technical expertise in the development of the guidelines.

GLOSSARY

Activity: Any action or group of actions undertaken that involves the care and use of animals, including, acquisition, transport, breeding, housing and husbandry of those animals.

Adverse Event: Any untoward change in health that occurs in an animal used in a trial while receiving the intervention or within a pre specified period after the intervention has been completed.

Animal: Any live non-human vertebrate and invertebrate including fish, amphibians, reptiles, birds, arthropods, and mammals (encompassing domestic animals, purpose-bred and wild animals), used in research and teaching.

Animal Attendant: Any person involved in the care (acquisition, transportation and husbandry) of animals used in research and teaching.

Animal Biological Material: Animal substances including but not limited to blood, urine, fecal matter, saliva, semen, eggs, fetuses, hair/feathers, nail clippings/claws, skin and any other associated bio-products obtained from dead or living animals involved in research.

Animal Biological Product: Any product derived from animals, including blood products, vaccines, antisera, antibodies and cell lines.

Animal Biosecurity: any measure undertaken to reduce the chances of introduction or spread of infectious disease agents or poisonous material into or out of an animal facility by people, animal, equipment, vehicles, etc.

Animal Care and Use Program: The activities conducted by and at an institution, that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management and oversight, occupational health and safety, IACUC functions, and animal facility design and management.

Animal Ethics Committees: Committees constituted in accordance with the national guidelines on use of animals in research and teaching.

Animal Facility: Refers to housing and accommodation structures appropriate to species under study that meet physical, physiological and behavioral needs.

Animal Owner: An individual, group of persons or institution that legitimately owns and derives benefits from animals to be used in research and teaching.

Animal Use: The proper care, use and humane treatment of animals produced for or used in research and teaching.

Animal Welfare: Refers to the living conditions of an animal being able to stay healthy, comfortable, well-nourished and express normal or innate behaviors.

Attending Veterinarian: A veterinary surgeon responsible for the health and well-being of all animals used at the institution.

Biological Field Station: Research stations located within a designated and specific ecological zone quite often targeting a unique species.

Biosafety: The measures and practices implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release.

Biosecurity: The measures aimed at protection, control and accountability to prevent the loss, theft, misuse, diversion, unauthorized access, retention, transfer or intentional release of biological agents and toxins and related resources.

Biotechnology: Is any technique that uses living organisms or substances there from to make or modify a product, improve plant or animal breeds, or micro-organisms for specific purposes.

Community Trial: Is a planned study that involves administering an intervention within a group of animals in their natural/routine setting in order to assess its effect.

Endangered Species: Is a species that is very likely to become extinct in the near future.

Facility Manager: Person responsible for the overall management of the animal care personnel and the facility.

Facility: Any place where animals are kept, held or housed including, but not limited to, yards, paddocks, tanks, ponds, buildings, cages, pens and containers.

Farm Biosecurity: Refers to strategies and management practices that lessen biological risk.

Field Trial: Is a systematic study of pharmaceutical products or medical devices in animal research subjects 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.

Funding Agency: Is an organization that provides funding for the conduct of a given project.

Genetic Modification (of animals): The use of any technique for the alteration of genes or other genetic material, but does not include sexual reproduction, homologous recombination or other techniques.

Investigational Product: Is a product (drug, device or biologic) described in the protocol that will be evaluated in the study.

Livestock: Refers to domestic animals including cattle, sheep, goats, pigs, poultry, horses, donkeys, camels, bees, silkworms and rabbits mainly kept for food.

Minimal Risk: Is the probability and magnitude of harm or discomfort anticipated in the proposed research and not greater in/and of themselves than those ordinarily encountered in the daily lives of the animal populations or during the performance of the routine physical or psychological examinations or tests.

Principal Investigator: Is the main researcher overseeing or conducting a research project.

Protected Area: An area that is clearly defined in geographical space, recognized, dedicated and managed, through legal or other effective means, to achieve the long-term conservation of nature with associated ecosystem services and cultural values.

Reduction: Methods that minimize animal use and enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals there by reducing the future use of animals.

Refinement: Improvements to scientific procedures and husbandry that minimize actual or potential pain, suffering, distress or lasting harm and or improve animal welfare where the use of animals is unavoidable.

Replacement: Methods that avoid or substitute the use of animals in procedures where they would otherwise have been used.

Research: Is a systematic investigation, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Risk: Is an adverse event or negative consequence due to a specific intervention, disease or condition.

Scientific Purposes: Are activities conducted with the aim of acquiring, developing or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, creation and breeding of a new animal line, diagnosis, product testing and the production of biological products.

Scientist: A person who has studied science and whose job is to teach or do research in science.

Serious Adverse Event: Is an incident that leads to significant injury or illness, unrelieved pain or distress, or the death of an animal under study.

Sponsor: One or more designated individuals or institutions, legally responsible for committing resources for use and disposition throughout the research period.

Teaching: Any action or group of actions undertaken with the aim of achieving a scientific purpose for imparting or demonstrating knowledge or techniques to achieve an educational outcome.

Veterinarian: A qualified person in Veterinary Medicine registered by a Veterinary Statutory Body in Uganda.

Wildlife: Any free-living animal of native or introduced species, including those that are captive, bred and those captured from free-living populations.

ACRONYMS

AC	Accreditation Committee
AE	Adverse Effect
AEC	Animal Ethics Committee
BCFs	Budongo Conservation Field Station
CBD	Convention on Biological Diversity
CHS	College of Health Sciences
CHUSS	College of Humanities and Social sciences
CIOMS	Council for International Organization for Medical Sciences
CITES	Convention on International Trade in Endangered Species
Co-PI	Co- Principal Investigator
COVAB	College of Veterinary Medicine, Animal Resources and Biosecurity
CTPH	Conservation Through Public Health
CV	Curriculum Vitae
DNA	Deoxyribonucleic Acid
DSMB	Data Safety and Monitoring Board
EU	European Union
IACUC	Institutional Animal Care and Use Committee
IBCs	Institutional Biosafety Committees
ICLAS	International Council for Animal Laboratory Sciences
ILAR	Institute for Laboratory Animal Research
ILRI	International Livestock Research Institute
IO	Institutional Officer
IUCN	International Union for Conservation of Nature and Natural Resources
IVP	Investigational Veterinary Products
MAAIF	Ministry of Agriculture, Animal Industry and Fisheries
MDAs	Ministries, Departments and Agencies
MOH	Ministry of Health
MoSTI	Ministry of Science, Technology and Innovation
MTA	Material Transfer Agreement
MUWRP	Makerere University Walter Reed Project
NAGRC&DB	National Animal Genetic Resource Centre and Data Bank
NC3Rs	National Centre for Replacement, Refinement and Reductions

NDA	National Drug Authority
NDPA	National Drug Policy and Authority Act
NEMA	National Environment Management Authority
NFA	National Forestry Authority
NHPs	Non-Human Primates
NRCs	National Research Councils
NTF	National Task Force
OHSP	Occupational Health and Safety Program
OIE	World Organization for Animal Health
PI	Principal Investigator
PPE	Personal Protective Equipment
R&D	Research and Development
RH	Relative Humidity
S&T	Science and Technology
SAE	Serious Adverse Event
SCs	Scientific Committees
SDGs	Sustainable Development Goals
SOPs	Standard Operating Procedures
STISA	Science, Technology and Innovation Strategy for Africa
UNCST	Uganda National Council for Science and Technology
UNHRO	Uganda National Health Research Organization
UWA	Uganda Wildlife Authority
UWEC	Uganda Wildlife Conservation Education Centre
WHO	World Health Organization

1.0 GENERAL PROVISION OF THE GUIDELINES

1.1 Introduction

Uganda promotes Science and Technology as one of the pillars for socio-economic development and transformation. This is achieved through a number of government agencies and ministries that include Uganda National Council of Science and Technology (UNCST), an agency of the Ministry of Science, Technology and Innovation (MoSTI). UNCST is mandated to facilitate and coordinate the development and implementation of policies and strategies for integrating Science and Technology into the National Development Process as stipulated in articles 4 (d) and 5 (d, e) of the UNCST Act 1990 (Cap 209). These articles specify UNCST's responsibilities to provide oversight for Research and Development (R&D), through a regulatory framework to promote a conducive environment for growth in research. In pursuit of this role, UNCST has developed and implemented several guidelines to promote ethical conduct of research.

The National Guidelines for Use of Animals in Research and Teaching have been developed through extensive review of other existing national and international laws and guidelines such as the Animal (Prevention of Cruelty) Act 1957,the Council for International Organization for Medical Sciences (CIOMS), the International Council for Animal Laboratory Science (ICLAS), Guide for the Care and Use of Laboratory Animals, Terrestrial Animal Health Code 2018 and Aquatic Animal Health Code 2018.

The guidelines set forth a framework for which scientists, Institutional Animal Care and Use Committees (IACUCs), facility managers, sponsors and funders, teaching institutions and animal care staff shall consider while planning to use animals in research and teaching in order to maintain the health and welfare of animals.

1.2 Rationale

Regulation and oversight of animal research is required to ensure proper care of animals, ethical conduct in all procedures, maintaining scientific integrity and ensuring reliability of data. Given the rapid growth of research in Uganda, and considering the vital role played by animals in research and advancement of scientific and medical knowledge, it is therefore important to have guidelines to ensure that such research using animals is conducted ethically. The use of these guidelines will ensure that animals used in research and teaching are handled in a humane and responsible way to prevent or minimize potential harm and pain.

1.3 Purpose

The purpose of these guidelines is to regulate use of animals in research and teaching and to promote ethical standards and welfare of animals for scientific purposes.

1.4 Scope

The guidelines cover non–human vertebrates (such as fish, amphibians, reptiles, birds and mammals including domestic animals, purpose–bred animals, wildlife, livestock, genetically altered animals) and invertebrates (such as insects, worms, snails) and their products: including all stages from half of the gestation period or being capable of independent feeding. The guidelines further encompass all aspects of the care and use of animals for scientific purposes in medicine, biology, agriculture, conservation, veterinary and other animal sciences and industry. They also extend to the use of animals in research and teaching, field trials, diagnosis, production of biological products and environmental studies.

1.5 Ethical conduct involving use of animals in research and teaching

Animal research plays a vital role in many scientific and medical advances leading to better understanding of various disease processes, and subsequent development of new products, medicines and treatments. However, some procedures may cause distress, suffering, pain, long–lasting harm, or death to animal research subjects and loss to animal owners. Therefore, the use of animals for research and teaching should: have scientific and or educational merit; benefit humans, animals or the environment; and be conducted with integrity.

1.6 Ethical considerations

All persons intending to use animals in research and teaching should ensure their proper care and use in consideration of the following guiding principles:

1. Scientific integrity
2. Animal welfare
3. Replacement, Reduction and Refinement (the 3Rs) in teaching, research protocol design and implementation
4. Responsibility
5. Responsiveness to community needs

2.0 REGULATORY OVERSIGHT

2.1 Regulatory framework

The regulation and use of animals in research and teaching is enshrined in the Animals (Prevention of Cruelty) Act 1957 (Cap 39), Sections (11) and (12) that provides for conditions and restrictions for experiments on living animals. Further, the Council as per the UNCST Act 1990 (Cap 209) Sections 4(d) and 5(d, e) is mandated to act as a clearing house of information on research and experimental development taking place in scientific institutions, centers and other enterprises and on the potential applications of their results. In executing this mandate, UNCST in liaison with the Research Secretariat in the office of the President, registers and issues research registration permits for carrying out research in Uganda.

The legal and regulatory framework under UNCST and Ministry of Agriculture, Animal Industry and Fisheries (MAAIF) provided foundation for the development of the guidelines. Researchers and teaching institutions shall be required to adhere to the developed guidelines while conducting research and teaching using animals. The UNCST requires that research protocols submitted for registration should be well written, fully developed and approved by the accredited Institutional Animal Care and Use Committee (IACUC). A research protocol should have a title and, at least sections on background and literature review, objectives, methodology, justification for the study, work plan, budget and references/ bibliography. In addition, the research protocol should have a version and date, names and brief biographical sketches of the researchers and their organization of affiliation, data collection instruments such as questionnaires, and where applicable, data ownership and sharing plans, community engagement plans and informed consent documents.

2.2 Roles of other Ministries, Departments and Agencies (MDAs)

In execution of its mandate of oversight for research and development in Uganda, UNCST recognizes the functions and roles of other national regulatory agencies. The roles and functions of different agencies are briefly described to guide scientists to meet all requirements before use of animals in research and teaching.

2.2.1 Ministry of Agriculture, Animal Industry and Fisheries (MAAIF)

The Ministry of Agriculture, Animal Industry and Fisheries (MAAIF) is mandated to promote animal health and welfare as per the Animals (Prevention of Cruelty) Act 1957 (Cap 39), and therefore clearance for use of animals for research purposes should be done in consultation with MAAIF. Researchers intending to carry out field

trials on Investigational Veterinary Products (IVP) for use in or on animals are required to obtain administrative clearance from the Commissioner for Animal Health prior to submitting their research protocols to the IACUC, UNCST and the National Drug Authority (NDA).

2.2.2 National Drug Authority (NDA)

National Drug Authority regulates safety, quality, efficacy, handling and use of drugs or drug related products in research in animals. This is provided for in Section (40) of the National Drug Policy and Authority Act (NDPA) 2000 (Chapter 206). Statutory Instrument No. (30) and No. (32) NDPA (conduct of clinical trials) regulations 2014 and NDPA (conduct of ectoparasiticides field trials) regulations 2014 respectively provide for the procedure to be followed by an applicant who wishes to conduct field trials in Uganda. Research protocols for field veterinary trials shall be submitted and approved by accredited IACUC and UNCST before a certificate of trial is issued by NDA.

2.2.3 Research in Protected Areas

Researchers intending to carry out research in protected areas such as wildlife conservation areas, reserves, biological field stations, forest reserves, museums, antiquities and monuments or other conservation sites under the jurisdiction of Uganda Wildlife Authority (UWA), National Forestry Authority (NFA), National Environmental Management Authority (NEMA), Uganda Wildlife Education Center (UWEC), Budongo Conservation Field Station (BCFS) or any other relevant authorized lead agency/organization are required to obtain administrative clearance/access permits from these agencies prior to submitting their research protocols to IACUC and then to UNCST for registration and final clearance.

2.3 Research clearing process

The scientists intending to conduct research in Uganda shall follow the following process for approval:

1. Seek administrative clearance from the Commissioner for Animal Health and or other relevant agencies and organisations.
2. Scientists intending to use animal genetic materials shall obtain clearance from National Animal Genetic Resources Centre and Data Bank (NAGRC&DB) as per sections 4, 5, 7 and 8 of the Animal Breeding Act (2001). Additionally, sample of all genetic materials, imported or locally produced, shall be submitted to the NAGRC&DB national animal genetic repository center and laboratory for evaluation and future reference, as per section 9 of the Animal Breeding Act (2001).

3. Submit a research protocol to IACUC for scientific, ethical review and approval.
4. Submit an approved protocol to UNCST for final clearance and research permit.

Note[1]: A researcher intending to conduct a field trial shall obtain a field trial certificate from NDA.

3.0 ESTABLISHMENT AND FUNCTIONS OF INSTITUTIONAL ANIMAL CARE AND USE COMMITTEES

3.1 Introduction

Institutional Animal Care and Use Committees (IACUCs), also referred to as Animal Ethics Committees (AECs), are essential components of the Animal Care and Use Program (ACUP) that should be established by institutions owning and caring for animals used for the purpose of research and teaching. The primary function of IACUCs is to conduct initial and continuing review of research protocols with the aim of protecting the welfare of animals and ensuring scientific soundness of a research study. The goal of each IACUC is to ensure the humane care and responsible use of animals in research and teaching in compliance with the National guidelines and regulations. The Accreditation Committee (AC) established by UNCST shall accredit all IACUCs. In case an institution cannot set up an IACUC, it shall rely on an accredited IACUC for another institution to review their research protocols.

3.2 Establishment of IACUCs

An institution that wishes to establish an IACUC shall apply for accreditation from UNCST, with assurance that the institution shall comply with the requirements set forth in these guidelines. The assurance shall at minimum include:

a. A statement of principles for protecting the welfare and ensuring humane care of the animals involved in research and teaching conducted at or sponsored by the institution. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself.
b. Assurance of availability of adequate resources; finances, staff, office and meeting space to support the IACUC's operations.
c. A list of IACUC members appointed by the head of the institution or her/his designee. Name, qualifications, profession, specialty, institution of affiliation and their designation on the IACUC should identify the members.
d. Written Standard Operating Procedures (SOPs) for the IACUC.
e. At least 60% of the membership shall not be affiliated to the Institution.

The Accreditation Committee (AC) shall review an institution's application, based on the established guidelines and will issue a certificate of accreditation valid for a period of three years. An IACUC may apply for renewal of accreditation. Guidelines for accreditation of IACUCs are obtainable from the UNCST offices or website.

3.3 Composition of an IACUC

Each IACUC 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 institution. The IACUC members shall be sufficiently qualified through experience, expertise and diversity including gender, equity, cultural backgrounds and sensitivity to social issues in the community.

a. Each IACUC shall include at least;
    i. a registered veterinarian
    ii. a bio-physical scientist
    iii. a social-scientist
    iv. one layperson from the community
b. No IACUC member shall participate in the IACUC's initial or continuing review of any study in which such a member has a conflict of interest, except to provide information as may be requested by the IACUC.
c. Each IACUC member shall take at least one course in research ethics within three months of appointment to an IACUC, and thereafter, should undergo continued research ethics training at least once every two years.
d. An IACUC 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 IACUC. These individuals do not vote at IACUC meetings.
e. A member shall serve for a term of three (3) years renewable upon satisfactory performance.
f. A person shall not serve as a member in more than two IACUCs concurrently.

3.4 Responsibilities of IACUCs

IACUCs act as independent reviewers and shall be responsible for the oversight of the entire Institutional Animal Care and Use Program, including animal acquisition, transport, breeding, husbandry and care, restraint, clinical procedures, euthanasia and safe disposal. While performing their duties, members shall:

a. Ensure maintenance of ethical standards of practice in research and teaching.
b. Ensure protection of animals and animal owners from harm or exploitation.
c. Ensure the welfare and humane care of animals.
d. Provide assurance to the public of the protection of the welfare of animals.
e. Keep records of all IACUC operations.

3.5 Functions of IACUCs

IACUCs shall perform the following functions:

a. Evaluate and approve protocols for use of animals in research and teaching.
b. Monitor the care and use of animals in approved protocols to establish compliance with approval conditions.
c. Inspect any facilities or areas where animals are kept or used including breeding establishments for compliance of welfare aspects.
d. Investigate suspected/reported non-compliance or misconduct or refer cases of non-compliance or misconduct to regulatory bodies as may be appropriate.
e. Suspend or withdraw approval for the approved protocol in cases of established Non-compliance.
f. Ensure that sick animals receive appropriate treatment and or are terminated or euthanized to address the welfare concerns.

3.6 Review Mechanisms

Each IACUC must have written Standard Operating Procedures (SOPs) to be followed in their review mechanism. The following are the minimum requirements for IACUC review process:

3.6.1 General Requirements

a. The IACUC Quorum to review the proposed research protocol shall be at least 50%+1 of the members including at least one veterinarian. Quorum should always be maintained during the meeting and at voting.
b. A simple majority of the members present at the meeting shall approve a research protocol.
c. An IACUC shall meet as often as possible, but at least once every three months.
d. An IACUC shall notify researchers in writing about the outcome of the review of the researchers' study protocol within 14 calendar days from the date of review. In case the IACUC does not approve a research protocol, it shall communicate its decision with reasons in writing.
e. An IACUC 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.
f. An IACUC shall have a plan for onsite monitoring of approved studies and facilities.

3.6.2 Types of review

a. Regular review

It is a review process that occurs during an ordinary scheduled IACUC meeting and such a meeting shall satisfy all quorum requirements for a review meeting.

b. Fast track review

It is a review process conducted during an extra ordinary IACUC convened meeting at the request of the researcher. Such a meeting should satisfy quorum requirements of a review meeting. Reasons for a fast-track review may be due to an emergency or when timing is of great essence for the study commencement. The review process should be well documented by the IACUC. It is upon the discretion of the IACUC to either accept or reject the request.

c. Expedited Review

The IACUC may use an expedited review process for research involving no more than minimal risk or for minor changes in previously approved research protocols within one year of approval. Minor changes include such changes as addition of a collaborator or a small change in the number of animal research subjects, or spelling corrections. Major changes include, but are not limited to, significant changes in the research methodology or a change in procedures for research animals. Expedited review process may also be applied to annual renewal of studies, in which the only outstanding activity is data analysis and report writing. Each IACUC shall develop SOPs to define eligibility for expedited review.

1. Expedited review may be done by the IACUC chairperson plus one or two designated IACUC members and does not mean quick review. The review should be done within 21 calendar days. In reviewing a research protocol, reviewers may exercise all of the authority of the IACUC except that they may not disapprove the protocol.
2. Each IACUC shall present all expedited review decisions at the next regular review meeting for ratification.
3. The Accreditation Committee (AC) shall restrict or choose not to authorize an IACUC to continue conducting expedited reviews if it is determined that the IACUC is abusing the process.

d. Exemption from further IACUC Review

Exemption from further review applies where an IACUC initially reviews a given study and it does not require continued review. These studies include the use of publicly available unlinked data that does not identify the source.

3.7 Review of Collaborative Research Projects

Collaborative research projects are projects that involve more than one institution locally and or internationally. When conducting collaborative research projects, each participating institution is responsible for safeguarding welfare of research animals and for complying with these guidelines. This involves securing IACUC approvals in both the local and the foreign institution prior to registration of the study with UNCST. Where desirable, participating institutions in a collaborative research project may have a joint review arrangement for that particular research project.

The local IACUC overseeing an international collaborative research project is the IACUC of record and its decision shall be final. An international collaborative research project shall have a Co-Principal Investigator (Co-PI) in Uganda, who must be employed at and or affiliated to a recognized local institution that is relevant to the area of the proposed research. This local Co-PI shall be qualified, competent, corresponding investigator, actively participate and supervise the research study. Researchers, sponsors and collaborators are encouraged to build, develop or strengthen local capacity for the proposed research in order to fulfill the intended project objectives and achieve community benefits.

3.8 IACUC Review

a. A Scientist shall submit his/her research protocol to the IACUC of his/her institution of primary affiliation. However, for compelling justifiable reasons, the researcher may request UNCST for permission to submit his/her research protocol to another accredited IACUC other than the IACUC of his/her institution of primary affiliation.
b. Where the institution of primary affiliation does not have an IACUC, the researcher is free to choose any of the accredited IACUC to review their research protocols.
c. Where a research protocol to be implemented in Uganda, has been approved by an accredited IACUC in Uganda, such approved protocol shall not undergo additional ethical review by another IACUC in Uganda. However, an institution where the research is to be conducted shall grant administrative clearance by the head of the institution for the study to be conducted in the institution even if that institution has an IACUC. The clearance shall specify the conditions under which the research is to be conducted at the institution, including any research costs such as bench and or other administrative fees associated with the conduct of the research at the institution.
d. The approving IACUC has the primary responsibility for monitoring approved studies regardless of where they are conducted. However, where the implementing institution has an IACUC, the approving IACUC may, at their discretion, assign the monitoring role to the IACUC of the implementing institution guided by the pre agreed modalities for study monitoring.

3.9 Powers of IACUCs

The IACUC shall have authority to suspend and or withdraw approval for research that is not being conducted in accordance with the IACUC's approved protocol or that has been associated with unexpected serious harm to research animals, animal owners, society, environment or that contravenes these guidelines. Suspension or withdrawal of approval shall include a written statement of the reasons for the IACUC's action and shall be reported promptly to the researcher(s), study host institution, UNCST and other relevant regulatory agencies. The IACUC shall suspend research if the researcher;

1. Has implemented major changes in the research protocol without prior notification and approval of the IACUC.
2. Does not follow specific procedures or requirements in the protocol approved by the IACUC.

3.10 IACUC records

IACUCs shall prepare and maintain adequate documentation of their operations, including:

a. Written Standard Operating Procedures.
b. Filed copies of all research protocols submitted, scientific evaluations that accompany the research protocols, approved consent documents, progress reports submitted by researchers, and reports of injuries to research animals. The IACUC records shall be kept for at least five (5) years after completion of the research study.
c. Minutes of IACUC meetings, shall be in sufficient detail to show attendance, members absent with apology, declaration of conflicts of interests where applicable, actions taken by the IACUC and the vote on these actions including number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research protocol and a written summary of the discussion of controversial issues and their resolutions.
d. Copies of confidentiality agreements, Curriculum Vitaes (CVs) and training records of members.
e. Records of continuing review activities.
f. Copies of all correspondence between the IACUC and the researchers.
g. Copies of final research reports from the researchers

All records shall be accessible for inspection by authorized representatives of UNCST.

3.11 Basic Ethical Considerations for Approval of Research Protocols

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

a. The methods used are scientifically valid and practically feasible. The research protocol has a clear scientific question and objective, is designed using acceptable scientific principles, methods and reliable practices; and where applicable has statistical power to test the study hypothesis.
b. Appropriate justification for the use of animals where there is no relevant alternatives and appropriate application of the principle of humane experimental technique (3Rs) and reflected in the protocol design.
c. The protocol has scientific or educational merit, and has potential benefit for humans, animals and or the environment.
d. The research protocol demonstrates value in terms of new knowledge added and improvement in human and or animal health and welfare, animal management, production, or to obtain and establish significant information relevant to the understanding, maintenance or improvement of the natural environment.
e. The protocol involves the minimum number of animals required to obtain valid data.
f. Informed consent will be sought from individual animal owner(s) or their authorized representative(s).
g. Informed consent process will be appropriately documented in accordance with the provisions of these guidelines.
h. Risks to research animals are minimized by using procedures that are consistent with sound research design and which do not unnecessarily expose the animals and the animal owners to risk. Risks, if any, are reasonable in relation to anticipated benefits to the research subjects, and the knowledge that will be gained. The IACUC shall perform a risk–benefit assessment, to ensure that the likely benefits of the study outweigh the risks to the animals and animal owners.
i. Where appropriate, there is a provision for involvement of the human community in the research process right from inception to post research period.
j. Detailed plan for appropriate sedation, analgesia and or anesthesia as may be required.
l. Description and rationale for anticipated or selected endpoint criteria.
m. Criteria and process for timely intervention, removal of animals from the study, or euthanasia if painful or stressful outcomes are anticipated.
n. Approved method of euthanasia or disposition of animals.
o. Adequacy of training and experience of personnel listed on the protocol for procedures listed in the protocol.

p. Plans for management of hazardous materials and provision of a safe working environment.

3.12 Requirements for submission to IACUC

All IACUCs shall develop detailed SOPs for submission of protocols and other requirements. However, at the minimum, the requirements should include:

a. A complete research protocol with a protocol version number and date.
b. Evidence/plan for acquisition of animals, husbandry and end point procedures.
c. Study instruments e.g. questionnaires, case report forms, and other data collection tools/forms.
e. Samples of trial drugs/devices and or other appropriate interventions.
f. Informed consent documents.
g. Evidence that the researcher is appropriately qualified, experienced and, where applicable, licensed, and has adequate facilities for safe and efficient conduct of research.
h. Evidence/plan of Good Clinical Practice (GCP) training for the researcher and study team.
i. A plan for disseminating research findings to the community in which research was carried out and other relevant stakeholders in Uganda.

3.13 Obligations of an IACUC

The IACUC is obliged to;

a. Conduct initial and continuing/periodic review of research protocols, including site monitoring visits.
b. Review research protocols in a timely manner but in any case, not more than 60 calendar days from the date of receipt of a research protocol. In the case of annual continuing review, the IACUC 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 IACUC review of the research protocol.
d. Respond to any allegations of ethical violations in a research protocol approved or rejected by the IACUC.
e. Monitor institutional animal care and use programs including inspecting animal facilities.
f. Evaluate institutional compliance to the relevant national guidelines for animal research.
g. Report non-compliance and suspensions to the relevant regulatory bodies.

h. Liaise with other IACUCs within and outside the country for better performance of its functions.
i. Prepare annual reports of IACUC performance to the Accreditation Committee (AC) at UNCST.
k. Report to the UNCST and other relevant regulatory bodies any protocol that is rejected by the IACUC with clear reasons for rejection.

3.14 Appeals/Arbitration

A researcher who is dissatisfied with the IACUC's decision may appeal to UNCST within 20 calendar days after receiving the IACUC's verdict. Where two or more IACUCs disagree over interpretation of these guidelines or administrative or ethical issues in respect of a given protocol or IACUC's operation, the aggrieved IACUCs shall approach UNCST for arbitration.

In all cases of appeal, the decision of UNCST shall be final.

4.0 OVERSIGHT BY OTHER COMMITTEES

Besides IACUCs, there are several other committees involved in research regulation in the country. These committees do not perform the role of the IACUC, neither do they substitute the role of IACUC. It is recommended for researchers to submit their protocols to relevant committees for review and improvement prior to submission to IACUC.

4.1 Scientific Committees

4.2 Establishment

Scientific Committees (SCs) are set up within institutions as an internal review mechanism for research protocols. Where such committees formally exist, they should approve research protocols prior to submission to an IACUC. SCs shall be comprised of at least three experts. SCs shall have SOPs to guide their function. The SOPs shall specify 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. Methods 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 institutions. In addition, they shall not use information submitted in research protocols under their consideration for their own research projects or personal gain.

4.2.1 Functions

The primary function of a SC is to review and evaluate all scientific aspects of research project with emphasis on accuracy of the science, 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 and statistical methods of the study. The SC should maintain communication between the various departments within the institution and IACUCs.

Research protocols involving hazardous and genetically modified materials shall undergo biosafety review by a recognized Institutional Biosafety Committee, and where applicable the National Biosafety Committee or other relevant committees or lead agencies.

4.3 The National Biosafety Committee

The National Biosafety Committee (NBC) is the national technical reference point for biotechnology and biosafety issues/matters under the UNCST. The NBC provides technical advice on biosafety and maintains links with biotechnology institutions through Institutional Biosafety Committees (IBCs). The NBC reviews biosafety and biotechnology research protocols involving especially high–risk category organisms and controlled laboratory and field experiments and recommends the appropriate type of containment facility. The committee approves and monitors deliberate release of genetically engineered organisms.

4.4 Institutional Biosafety Committee

4.4.1 Establishment

Institutional Biosafety Committees (IBCs) are established by institutions that undertake research on potentially hazardous substances of physical, chemical, biological, or any other nature and genetically modified organisms. Any institution 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 submit the research protocol to the IBC before submitting to the IACUC. 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 institutions. In addition, they shall not use information submitted in the research protocol under their consideration for their own research projects or personal gain.

4.4.2 Functions

The IBC's function is to minimize potential animal, 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 IACUC and UNCST of any research with potentially hazardous substances in their institutions.
b. Conduct biosafety review of research protocols 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 institution 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.

4.5 Data Safety and Monitoring Boards

4.5.1 Establishment

A Data Safety and Monitoring Board (DSMB) is an independent group of experts established by study sponsors or PIs to review safety data during a clinical and field trial. It is to ensure that a study is conducted, and data are handled in accordance with provisions of the research protocol. The DSMB monitors adverse events and safety data. A DSMB shall be established before the commencement of a clinical and field trial and its composition submitted to the IACUC during protocol review and approval process. All clinical and field trial Phases (I, II, III and IV) 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 at least three persons including a veterinarian with competence in the research field of the trial and a biostatistician. In addition, the membership of the DSMB shall include: individuals knowledgeable in the processes of conducting the trial, and with adequate medical, pharmaceutical, scientific, and or ethics qualifications as well as clinical or field trial experience. The qualifications most appropriate for a specific DSMB will depend on the nature of the trial and the intervention.

4.5.2 Functions

Functions of DSMBs are to;

a. Ensure safety of study subjects;
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 the following to the sponsor(s) or PI of the trial concerns:

a. Over differences in serious adverse events between study arms.
b. Over serious social harms.
c. About the conduct of the trial.
d. About data integrity.

Recommendation to terminate or continue the trial based on safety and interim data;
The DSMB shall determine before the commencement of the study, the following:

a. Mode and timeframe 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 sponsor.

5.0 ANIMAL WELFARE

According to OIE, animal welfare refers to how an animal copes with the conditions in which it lives. An animal is in a good state of welfare if it is healthy, comfortable, well–nourished and able to express normal or innate behaviors, can achieve successful biological function, respond to and cope with potentially adverse conditions and diseases. The OIE further recognizes that the use of animals in agriculture, research and education makes a major contribution to the wellbeing of people and acknowledges the critical relationship between animal health and animal welfare.

The welfare of animals is inherently embedded in five freedoms of animals listed as follows;

1. Freedom from thirst, hunger and malnutrition
2. Freedom from physical and thermal discomfort
3. Freedom from pain, injury or disease
4. Freedom from fear and distress
5. Freedom to express normal patterns of behavior

The welfare of animals used for scientific purposes must be considered in terms of the cumulative effects of an animal's lifetime experience. At all stages of care and use of an animal, measures shall be taken to ensure that the animal's environment and management are appropriate for the species and the individual animal. The care and management of animals shall be based on the current best practices.

5.1 Acquisition of Animals

Animals for use in research and teaching shall be acquired either through breeding, purchased from certified/accredited breeding facilities for laboratory animals, farms of livestock or wildlife in captive facilities. The scientist shall ensure that the sources and or transporters of these animals meet the animal welfare standards or requirements as stipulated in the Animals Prevention of Cruelty Act 1957 (Cap 39). The animals selected for a procedure shall be of appropriate species and quality (appropriate age, health, fertility, demeanor, gait, specific pathogen free, and physically complete) and the minimum number required for obtaining valid results. Individuals using animals for research and teaching are expected to undertake due considerations for the 3Rs while determining appropriate numbers of animals to be used for the proposed study. Where applicable, alternative methods other than use of animals such as mathematical models, computer simulation, and in vitro biological systems shall be considered. For acquisition of animals, animal owners will be provided with information on the number and category of animals needed, the duration and purpose before commencement of the study. This information shall be provided for in the owner's consent form.

5.1.1 Husbandry

Animals should be fed palatable, uncontaminated diets that meet their nutritional and behavioral needs at least daily, unless otherwise required in the approved protocol.

a. Feeds should be appropriately stored in an area that is kept clean, easily sanitized, and held at appropriate temperature and humidity (recommended less than 21 C and below 50% RH).
b. Open bags of feeds should be stored in vermin–proof containers.
c. Minimize introduction of disease, parasites, vermin and chemical contaminants.
d. Stocks should be rotated so that oldest feeds are used first.
e. Animal feeders should be located to allow easy access and to minimize contamination with urine and fecal material.
f. When group housed, there should be enough space and feeding points to minimize competition and ensure access for all animals.
g. Animals should have access to potable, uncontaminated drinking water.
h. Watering devices should be checked frequently to ensure appropriate maintenance, cleanliness and operation.
i. Sanitation program should aim to maintain sufficiently clean and dry bedding, adequate air quality and clean cage surfaces.
j. The frequency and intensity of cleaning and disinfection should depend on what is necessary to provide a healthy environment for the animal.
k. Soiled bedding should be removed and replaced with fresh materials as often as necessary to keep the animals clean and dry and to keep ammonia levels low. The frequency of bedding change depends on species, number and size of animals; type and size of enclosure, temperature and humidity, type of ventilation, urinary and fecal output, wetness of bedding, and experimental conditions.
l. All areas of the animal facility i.e. animal rooms, storage spaces, procedure rooms, should be cleaned regularly and disinfected as appropriate.

m. Conventional, biological and hazardous waste should be removed and disposed of regularly and safely.
n. Waste containers should be leak–proof and equipped with tight–fitting lids.
o. Hazardous wastes must be rendered safe by sterilization, containment or other appropriate means before removal from the facility.
p. Pest control program; The animal facility should have a program to prevent, control or eliminate the presence of or infestation by pests. A regularly scheduled and documented program of control and monitoring should be implemented.

5.2 Animal Facilities

Research and teaching using animal subjects requires specialized facilities that ensure and maintain animal welfare. Such facilities require appropriate structures designed for particular species under the study. Facility information including the location shall be provided as part of the submission to the IACUC.

5.3 Housing

All animals shall be housed under conditions that provide sufficient space as well as supplementary structures and resources required to meet physical, physiological and behavioral needs. The type of facility used must meet the appropriate macro and micro-environment requirements of the housed animal.

a. Social animals should be housed in stable pairs or groups unless they must be housed alone for experimental reasons (should be justified in protocol) or because they are socially incompatible.
b. The primary enclosure should be secure to prevent escape and made of durable, nontoxic material. Animals should have adequate bedding material for species-specific behavior and to absorb urine and feces and or structures for resting and sleeping.
c. Monitoring and documentation of daily environmental parameters such as temperature, humidity, ventilation, air quality, illumination, noise and vibration. Animals should be housed within temperature and humidity ranges appropriate for the species.
d. Space size of primary enclosure should be appropriate for different species
e. Ventilation should provide appropriate air quality and a stable environment.
f. Lighting should be diffused throughout an animal holding area and provide sufficient illumination for the animals' well-being, good housekeeping practices, adequate animal inspection and safe working conditions for personnel.
g. Noise control should be considered in facility design and operation.
h. Noisy animals, such as dogs, swine, goats, and nonhuman primates should be housed away from quieter animals such as rodents and rabbits.

5.3.1 Disaster planning and Emergency Preparedness

Research and teaching facilities must have a disaster plan. The plan should define the actions necessary to prevent animal pain, distress and deaths due to loss of daily functional systems. The plan should identify essential personnel who have been trained in advance in its implementation.

5.4 Occupational Health and Safety Program

An institution must establish and maintain an Occupational Health and Safety Program (OHSP) as an essential part of the overall animal care and use program. The OHSP should focus on maintaining a safe and healthy workplace. It should include prevention strategies, identification of hazards and assessment of risk associated with those hazards, provision of the appropriate Personal Protective Equipment (PPE) for employees and safety equipment. The use of good personal hygiene will help to reduce the possibility of occupational injury and cross contamination. A program of medical evaluation and preventive medicine should be developed and implemented. A pre-employment health evaluation and or health history should be obtained to assess potential risks for individual employees.

Zoonosis surveillance should be part of the program. Personnel should be instructed to notify their supervisors of potential or known exposures and of suspected health hazards and illnesses. All personnel should know the clear procedures in place for reporting all accidents, bites, scratches and allergic reactions. Medical care should be readily available.

5.5 Transportation and Reassignment

5.5.1 Transport

The transport of an animal constitutes an unnatural situation for the animal and is likely to cause such animal some degree of stress. High levels of stress may increase metabolic rates, hazardous behavior, chances of injuries and susceptibility to diseases. For reasons of animal welfare, animal transport shall be quick, efficient and strive to avoid as much stress as possible to the animal. The transport of animals (from within or outside the country) shall be well planned, well prepared and effectively executed with required permits. Individuals using animals for research and teaching shall ensure that obligations of species-specific transportation of animals are met, means of transport are appropriate (including vehicle marking and labelling), persons accompanying animals are trained and competent for the purpose, and loading and offloading facilities are in place at the source and destination respectively.

5.5.2 Reassignment

Inter - institutional collaborations involving animal use shall be based on a formal written understanding (a contract, memorandum of understanding, or agreement) which specifies responsibility for offsite animal care, use and ownership, IACUC shall require researchers to submit copies of their contracts or agreements for review and oversight.

Transfer of animals from one IACUC–approved research facility shall require approval by the IACUC. An approved reassignment of animals shall become effective on the date of the transfer, and all animal related costs to cater for animal care, identifying cards, and inventories are changed to reflect this reassignment. Transporting of animals to research laboratories, procedural, or testing areas outside of an animal facility shall follow the appropriate procedures.

5.6 Animal Health

Healthy, well cared animals are a prerequisite for good quality research and teaching. The structure of the Veterinary Care Program (VCP), including the number of qualified and licensed veterinarians, shall be appropriate to fulfill the program's requirements, which will vary by institution, species used and the nature of research and teaching. To be effective in providing clinical care, the veterinarian shall be familiar with the species and various uses of animals in the institutional research and teaching programs and have access to records. The Principal Investigator/institutions shall;

a. Employ a designated/attending registered and licensed veterinarian for the study to attend to aspects of animal health.
b. Develop SOPs for timely and accurate methods of communication of any abnormalities in or concerns about animal health, behavior, and well–being.
c. Communicate recurrent or significant problems involving animal health to the IACUC with a notification to UNCST, and all treatments and outcomes shall be documented.
d. Put in place procedures to provide for emergency veterinary care both during and outside of regularly scheduled hours. Such procedures shall enable animal care and research staff to make timely reports of animal injury, illness, or death.
e. Ensure that a veterinarian is involved in establishing, reviewing, and overseeing medical and animal use records, since records are a key element of the veterinary care program and are considered critical for documenting animal well–being as well as tracking animal care and use. All those involved in animal care and use shall comply with national laws and regulations regarding human and veterinary drugs and treatments. Drug records and storage procedures shall be reviewed during facility inspections by the IACUC, UNCST and NDA.
f. Continually and thoroughly assess surgical outcomes to ensure that appropriate procedures are followed, and timely corrective changes are instituted through continuing communication among technical staff, investigators, veterinarians, and the IACUC.
g. Put in place measures to ensure that risks associated with infectious agents and biohazardous materials are minimized through the application of sound biosafety and biosecurity concepts and practices.

5.7 Pain and Distress Management

Animals used in research and teaching can experience pain and distress during housing and study procedures. It is ethical and a legal obligation of all personnel involved in the animal care and conducting of study procedures to reduce, minimize or eliminate pain and distress in animals used for research and teaching. It is the responsibility of the PI to provide SOPs for pain and distress management to IACUC and at a minimum the SOPs should address;

i. Procedures for distinguishing pain and distress in animals from their normal state.
ii. Criteria for relieving or minimizing pain and distress appropriately.
iii. Criteria of establishing humane endpoints.

5.8 Humane Endpoint

Humane endpoint refers to one or more pre-determined physiological or behavioral signs that define the point at which an animal in pain and or distress is terminated, minimized or reduced by taking actions such as terminating a painful procedure or giving treatment to relieve pain and or distress or euthanizing the animal. Humane endpoints function as an alternative to experimental endpoint and provide scientists with an alternative way to refine the study. The establishment of a humane endpoint prior to start of a study allows prevention of unnecessary pain and distress while ensuring accurate and timely data collection. The PI shall define the endpoint in the protocol prior to its submission to an IACUC. The protocol shall specify the following:

a. A precise definition of the humane endpoint(s), including specific assessment criteria.
b. The frequency of animal observation and assessment.
c. Training of personnel responsible for observation and assessment.
d. Action(s) taken when an animal reaches a humane endpoint.

5.9 Euthanasia

Euthansia as one of the humane endpoints is used in these guidelines to describe ending the life of an individual animal in a way that minimizes or eliminates pain and distress. Euthanasia shall be performed by the designated veterinarian or under his supervision. Anticipated euthanasia should be accurately described in the protocol appropriate for the species under the study. The Veterinarian performing the Euthanasia shall have the following duties;

a. Humane disposition of the animal by inducing death should be taken into consideration as part of the welfare of the animal.

b. Use humane techniques appropriate for the species to induce the most rapid, painless and distress–free death possible.

c. Supervise disposal of the euthanized animals

6.0 MANAGEMENT OF ADVERSE EVENTS

An adverse event is any untoward change in health that occurs in an animal used in a trial while receiving the intervention or within a pre specified period after the intervention has been completed. Studies involving animal subjects may be associated with adverse events. Scientists are expected to appropriately identify, manage and report such events when they occur to the IACUC of record.

6.1 Categories of Adverse Events

a. Serious Adverse Event: Is an event, which results in:
   i. A significant injury or illness.
   ii. An unrelieved pain or distress.
   ii. A significant or persistent incapacity.
   iv. A congenital anomaly or birth defect.
   v. An important veterinary condition in the opinion of the researcher.
   vi. Hospitalization or prolongation of existing hospitalization.
   vii. Death of an animal under study.

b. Non–Serious Adverse Event: Any adverse occurrence that does not meet the definition of a serious adverse event.

c. Unexpected event
   i. An event that may have an impact on the welfare of animals and was not foreseen in the approved protocol. This may result from different causes, including but not limited to;
   ii. Unexpected effects following a procedure or treatment that were not expected.
   iii. Unexpected effects in a larger number of animals than predicted during the planning of the protocol, based on the number of animals used, not the number approved for the study.
   iv. Severe pain or distress than was not predicted during the planning of the protocol.
   v. Power failures, inclement weather, emergency situations or other factors external to the protocol that have an impact on the welfare of the animals.
   vi. Death of an animal, or group of animals, that was not expected (e.g. during surgery or anesthesia, or after a procedure or treatment).

6.2 Management of Serious Adverse Events and Unexpected Events

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

6.3 Reporting Serious Adverse Events and Unexpected Events

All serious adverse events and unexpected events shall be reported to the IACUC. Reporting requirements specifically include:

a. All serious adverse events regardless of relationship to the intervention.
b. All unexpected events of greater than moderate severity regardless of relationship to the intervention.
c. All serious adverse events and unexpected events must be reported to the local IACUC as soon as possible and in any case no later than seven (7) calendar days of becoming aware of the event.
d. 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 IACUC.
e. All other reportable adverse events should be reported to the IACUC as soon as possible and in any case not later than fourteen (14) calendar days. These include:
    i. When criteria for stopping or pausing a study as stipulated in the protocol are met.
    ii. 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, vaccines and DNA-based compounds. The manager of the animal research facility shall co-sign the incident report or submit an independent incident report to the IACUC. The extended follow up and monitoring period shall be determined by the IACUC on a case by case basis, usually a minimum of two years.

6.4 Protocol Violations and Deviations

Protocol violations and deviations refer to any change in the stated procedure, activity or any provision of the protocol without prior approval except for those interventions required to save an animal's life when in danger. A change in the protocol may be minor (protocol deviation) or major (protocol violation). Violations significantly impact the quality and completeness of the informed consent, animal subject safety and welfare, and the quality of data. Where any of these occur, the researcher shall notify the IACUC.

All events associated with protocol violations and deviations regardless of severity and relationship to the intervention should be reported to the IACUC as soon as possible and in any case not later than fourteen (14) calendar days.

6.5 Format of reporting events

All reportable events including serious adverse events, adverse events, unexpected events protocol violations and deviations should contain the following information:

a. Title of the study.
b. Name of researcher.
c. Institution of affiliation.
d. Date of report.
e. Date(s) when events, violation(s) or deviation(s) occurred.
f. Brief description of what happened.
g. Any effect on the study.
h. Any adverse events arising from the violation or deviation.
i. Management and follow up of adverse events, violation(s) or deviation(s) and steps to avoid recurrence. Notification to the IACUC and where applicable the collaborating institution's IACUC and any other regulatory bodies should be made by the researcher within the specified timelines.

7.0 RESPONSIBILITIES OF SCIENTISTS, FUNDING AGENCIES, SPONSORS AND INSTITUTIONS

7.1 Scientist

The scientist is responsible for the overall conduct and adherence to research standards approved in the protocol. The scientist has an obligation to treat the animals humanely and to consider their welfare as an essential factor when planning and conducting research. Specifically, a scientist shall;

a. Ensure that the study protocol is fully developed and complete.
b. Demonstrate ownership (e.g. by signing the protocol) of the study protocol and ensure that the protocol is strictly followed at project implementation.
c. Submit a full protocol to an accredited IACUC for review and approval prior to study implementation.
d. Don't implement amendments in the study protocol without prior approval of the IACUC, except when necessary to eliminate an apparent immediate hazard or danger to research subjects.
e. Promptly investigate all Serious Adverse Events (SAEs) and take appropriate actions to ensure safety of all research subjects. The SAEs and actions taken shall be reported promptly to the IACUC, sponsors and other relevant research regulators within the specified timelines.
f. Provide adequate care for animal research subjects in accordance with sections 5. 0 and 6.0 of these guidelines.
g. Engage the relevant stakeholders to provide animal research subjects with an intervention that has been proven to be effective where applicable.
h. Inform, in writing, the IACUC, UNCST and other relevant national authorities about early termination of the study and the reasons for the termination.
i. Maintain adequate documentation of all study procedures and data.
j. Ensure a functional quality assurance system for proper conduct of the study in order to preserve integrity of the data.
k. Ensure appropriate and timely feedback on the study process and findings.
l. Take all reasonable steps to engage with the relevant community and stakeholders where applicable.
m. Have adequate time to implement/supervise the study protocol and should be reasonably present and active at the study site.
n. Ensure valid and recognized research ethics training of the research team prior to commencement of the study; and thereafter, have a refresher course at least once every two years. Student supervisors at training institutions are similarly required to take basic research ethics courses.

o. Ensure Protocol specific training is conducted for the research team before commencement of data collection.
p. Be sufficiently qualified and competent to carry out the study, and shall, where necessary, have the appropriate professional license to practice. Field trials shall be supervised by a competent and appropriately qualified veterinary surgeon. Where need be, a work permit shall be obtained for foreigners.
q. Be accountable for the animal welfare and overall facets of the care and use of animals as approved by the IACUC.
r. Ensure that the standard of animal care and use by all other persons involved in the study are compatible with the level of competence of each person and the responsibilities they are given.
s. Have a legal and ethical responsibility to ensure that animals on a study are handled using medical and surgical techniques, which are consistent with the principles of good practice and scientific knowledge in the discipline of laboratory and veterinary medicine.
t. Ensure that there is an in-house veterinarian who oversees all the health components of the animal in the study including responding to adverse events.
u. Not begin experiments before written IACUC approval is obtained and must adhere to any requirements of the IACUC.
v. For studies involving animal species which are not otherwise readily available, the scientist shall obtain the animals and hold them for adaptation prior to formal IACUC approval, provided that their research use does not commence until approval is given.
w. Inform the IACUC and UNCST when each study is completed.
x. Not submit a study protocol that is under review by one IACUC to another IACUC.
y. Appropriately document proof of safe destruction for investigational products and trial related materials.
z. Provide a detailed plan for the humane end point and or reallocation of the research animal subjects at the end of the study.
z. Submit end of study report to IACUC, UNCTS and NDA plus others where it applies.

Note: Where the study has both animal and human subjects the researcher shall submit the protocol to both an IACUC and Research Ethics Committee for review and approval.

7.2 Sponsor

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

Specifically, the sponsor shall:

a. Approve the final study report whether the study has been completed or not.
b. Cause the timely reporting and management of adverse events.
c. Be responsible for compensation or indemnity in the event of study related injuries, disability or death in accordance with applicable Ugandan laws and regulations.
d. The sponsor shall indemnify the scientist against claims that arise during or from the study except claims that are a result of malpractice or negligence of the scientist.

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

a. Provide the IACUC and all other regulatory authorities a description and a sample of the investigational or comparator drugs/devices.
b. Provide all relevant documents pertaining investigational drugs and devices.
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 labelling of investigational product(s). The investigational and comparator products must be labelled in conformity with the research protocol and the labelling must state that the product is for investigational purposes only.
f. Maintain a system for the disposal of unused investigational product and document the process.

7.3 Host Institution

The scientist's institution of affiliation and institutions that use animals for research and teaching shall supervise and monitor activities of the scientists at the institution. Specifically, the institution shall;

a. Establish, and or designate a functional IACUC(s) to review their study protocols in accordance with the provisions of these guidelines.
b. Ensure that they have qualified and competent, and where necessary, licensed scientists to carry out the studies at the institution.
c. Facilitate smooth implementation of studies conducted at the institution, and dissemination of findings.

d. Take measures to train and mentor the institution's staff in skills necessary to achieve the institution's research development goals. Such training should include regular courses in responsible conduct of research and research ethics.
e. Take appropriate disciplinary action against scientists for non–compliance with these guidelines. This shall include establishment of institutional mechanisms (Office of Research Integrity) for monitoring, investigating and disciplining of cases for alleged scientific misconduct in animal research.
f. Ensure through the IACUC, that all scientific studies and teaching activities that involve the use of animals comply with relevant guidelines and regulations.
g. Provide each IACUC with facilities, resources and mandate to fulfil its functions and operations as set out in Section 3.0 of these guidelines.
h. Establish an Animal Care and Use Program.
i. Refer to the appropriate IACUC for comment on all matters that might affect animal welfare in the institution.
j. Have an internal review annually and an external review every three years of the operation of each IACUC.
k. Respond effectively to recommendations from each IACUC to ensure that the acquisition of animals, and the facilities for the housing, care, use and disposal of animals are appropriate to the maintenance of the health and wellbeing of the animals.
l. Following an investigation by and upon the advice of the IACUC.
m. Provide all relevant staff members with details of the institution's policy on the care and use of animals, confidentiality, freedom of information, legislation, legal requirements and commercial considerations.
n. Provide staff members with information on potential disease hazards from their work with animals and engage in pro–active and preventative measures (for example, periodical examinations of persons working with animals), provide vaccinations where and when appropriate (for example, rabies, tetanus, tuberculosis, brucellosis, hepatitis A and B), and provide staff members and researchers with PPEs where and when appropriate.
o. Establish mechanisms to respond to enquiries or complaints concerning the use of animals within the institution and ensure that staff members are able to voice concerns without jeopardizing their employment.
p. Establish grievance procedures for IACUC members and scientists who are dissatisfied with the IACUC's procedures or decisions.
q. Develop and implement guidelines for animal care and use within the institution, including those, which ensure that emergencies are detected promptly and are dealt with effectively.
r. Ensure that there is an adequate number of staff members competent and trained to care for the animals.

s. Ensure that relevant veterinary services are available and that there is access to diagnostic services.
t. Ensure that sufficient funds and resources are available to meet the financial needs of laboratory animal facilities for the proper care of animals and the management of the institutional animal facility.

Note: In case the funder happens to be the sponsor then they assume the roles of the sponsor listed above. However, if the funder is independent of the sponsor then such funding should be explicitly acknowledged within the protocol.

8.0 INFORMED CONSENT PROCESS

8.1 General Requirement for Informed Consent Process

Animal used in research and teaching are incapable of protecting their own interests, hence the need to obtain informed consent from the animal owners including farmers, breeders and institutions. Except as provided elsewhere in these guidelines, no individual using animals in research and teaching shall involve animals in a study unless they have obtained informed consent from the relevant individuals and institutions that own the animals. A scientist shall seek such consent only after ascertaining that the prospective animal owner or institution has adequate understanding of the relevant facts and consequences of participation in the research and teaching.

The IACUC may require the scientist to administer a comprehension test (or test of understanding) to ensure that the animal owners have acquired adequate understanding of the relevant facts and the consequences of participation of their animals. Consent shall be carried out under circumstances that provide the prospective animal' owner or their representative, sufficient opportunity to consider whether or not to allow participation of their animals. In addition, the scientist should minimize coercion or undue influence.

The information that is given to the animal' owner or their representative, whether it is conveyed orally, in writing or otherwise, shall be in a language and form understandable to the animal owner or their representative. No informed consent, whether oral or written, shall include any exculpatory language through which the animal' owner or representative is:

a. Made to waive or appear to waive any of their concerns.
b. Appears to release the scientist, sponsor, institution, or its agents from liability.

The scientist as well as the IACUC shall ensure continued adequacy of the informed consent process, and re-consent animal owners if there are changes in the conditions or procedures of the study or if new information becomes available that could affect the animal owners' willingness to continue in the study.

8.2 Key components of the Informed Consent Form

The information to be included in the informed consent form, which is provided to each potential animal owner, shall include the following:

a. A statement that this is a study rather than provision of veterinary care; that the study involves research and or teaching; an explanation about the study; the estimated length of time that the animal will take in the study; a description of the study procedures, and identification of any other procedures that are experimental.

b. A description of any reasonably foreseeable risks or discomforts that the animal may experience.
c. A description of the benefits to the animal or community that may reasonably be expected to result from the study.
d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the animal.
e. A statement about compensation and veterinary treatment available if injury occurs and, what they consist of and where further information may be obtained.
f. Names and contact details of individual(s) who should be contacted at any time in case of questions about the study, and animal welfare. The individual(s) should be able to communicate in a language understandable by the animal owners or should be able to promptly secure the services of an interpreter to assist in responding to questions raised by the animal owners.
g. A statement that participation is voluntary, that refusal to participate will not result in a penalty or a loss of benefits to which the animal owner is otherwise entitled, and that the animal owner may discontinue participation at any time without penalty or loss of benefits to which the animal owner is otherwise entitled.
h. Where applicable, a statement of how the study will provide veterinary services to the animals.
i. The nature, form and extent of compensation for loss of production, injury or death of the animal. This compensation could be in form of pre-paid insurance cover.
j. A brief description of sponsors of the study and the institution of affiliation for the scientists.
k. A statement that animal owners will get feedback on findings and progress of the study, and that any new information that affects the study or data that has veterinary relevance (including incidental findings) will be made available to animal owners and or their veterinary care providers.
l. Where necessary, provision for a witness at appropriate specific stages of the informed consent process, for example, in the case of illiterate animal owners.
m. A statement that the study has been approved by an accredited Ugandan based IACUC.

Any of the following shall be provided to the animal owner, 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 animal or to the embryo or fetus if the animal is or may become pregnant, and that the risk is currently unforeseeable.

b. An explanation of circumstances under which the scientist may terminate the animal's participation, whether or not the owner consents to such termination.
c. An explanation of any additional costs to the animal owner that may result from his or her participation in the study.
d. A statement explaining the consequences of the animal owner's decision to withdraw from the study. The study animal may be withdrawn at any time without further notice. However, animal owners should be provided with a description of the procedures that are to be followed in order to give notice of their animals' withdrawal.
e. A statement that significant new findings obtained during the course of the study, whether by the scientist or others that may relate to the animal owners' willingness to continue his or her participation, shall be provided to the animal owner in a timely manner.
f. The approximate number of animals to be involved in the study.
g. Whether, when, how and for how long any of the products or interventions proven by the study to be safe and effective will be made available to the animal owners 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 biological 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.

8.3 Documentation of Informed Consent Process:

a. The scientist shall document the informed consent process. In addition, and except as provided in these guidelines, animal owners or their representatives shall sign/ mark/thumbprint an informed consent form approved by an accredited IACUC. The person obtaining the consent, and where applicable, the animal owners' witness shall also sign the form. Where the use of signed consent forms is not feasible, alternative viable methods should be employed. A copy of the signed consent form shall be offered to the animal owner or his/her representative.
b. The animal owner or their representative must be given sufficient time to read the consent form before signing or placing his or her thumbprint on the form indicating that he/she has read and understood and agrees to participate in the study.
c. The consent form shall be read to illiterate animal owners.
d. 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.
d. The IACUC reserve the right to determine when verbal informed consent may be appropriate and acceptable.

8.4 Waiver of Requirement for Informed Consent

An IACUC may waive some of or all the requirements for the scientist to obtain informed consent from the animal owner of a particular study when it is practically impossible to conduct the study without a waiver. For example, using stored biological materials collected during routine surveillance and when obtaining consent might cause the animal owner to change their behavior on how they handle the animals.

9.0 VULNERABILITIES IN ANIMAL RESEARCH AND TEACHING

9.1 Special considerations:

Animals, as well as other biological creatures, share a susceptibility to pain, illness, disease, and death, or what is defined as "inherent vulnerability". The concept of vulnerability is deployed in bioethics to, amongst other things, identify and remedy harm to research subjects. All animals are regarded vulnerable and scientists should take due consideration and care for animals involved in research and teaching.

9.2 Endangered species

Special consideration is made for endangered species as per the: International Union for Conservation of Nature and Natural Resources (IUCN), Convention on Biological Diversity (CBD), Convention on International Trade in Endangered Species (CITES), the World Heritage Convention and Ramsar Convention on Wetlands. Special permits shall be obtained by individuals intending to undertake studies in endangered species including import/export of biological materials from endangered species.

Use of Non-Human Primates (NHP) in experimental studies is restricted and banned in some species like chimpanzees. Specific guidelines exist for scientists intending to conduct studies involving NHPs. Consequently, the use of NHPs is strictly controlled and the purposes for which they can be used requires rigorous scientific justification. Therefore, the use of non-human primates shall be permitted only in those biomedical areas essential for the benefit of the NHPs and human beings, for which no other alternative replacement methods are available. For the purpose of this guideline, we refer to the National Centre for Replacement, Refinement and Reductions of Animals in Research (NC3Rs)

10.0 COMMUNITY ENGAGEMENT

10.1 Introduction

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 institutions, with the goal of shaping research collectively. Engagement activities shall aim at creating meaningful participation and partnerships between scientist and the animal owners. Community engagement process shall be spelt out in the protocol guided by principles of mutual understanding, respect, integrity and transparency.

Scientist shall make reasonable effort to involve community stakeholders in the study process, where appropriate, right from the inception of study ideas to post study period. Community stakeholders may include individuals and groups that are ultimately representing the interests of institutions and people who would own animals to be recruited as research subjects plus any others who are locally affected by the study. Involvement of community stakeholders shall not override the rights of animal owners to consent voluntarily for participation of their animals in the study.

10.2 Community Engagement Practices

Scientist are encouraged to identify community stakeholders early enough during project conception and design. It is important to consult with the identified stakeholders to get their input or participation in the study process. Such consultation involves obtaining prior agreement from community gatekeepers such as local leaders, local administration officials and heads of institutions where research or teaching is to be undertaken. The consultation with community stakeholders shall be undertaken prior to seeking approvals from the relevant IACUC and other relevant regulatory authorities. It is important for the scientist to note that, consultations with community stakeholders shall not end after approval of research by the IACUC and agreement with community stakeholders is not a substitute to the IACUC process. Community engagement shall be an ongoing process until completion of research. Scientists 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, study participation and ownership. Scientists shall develop plans for providing feedback on the study results and outcomes of the process to facilitate monitoring. These plans shall be shared with the IACUC.

11.0 ANIMAL BIOLOGICAL MATERIALS

Animal materials refer to any specimens collected from animals. These may include but not limited to blood, milk, eggs, fat, flesh, urine, hair, skin scrapping, semen, nail clippings/claws, fetuses and fecal matter.

11.1 Acquisition and handling

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

11.2 Storage and Future Use

A separate informed consent form shall be used for samples, which are collected with the intention of being stored for use in future studies. This consent form, 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 of the animal owner or his property, 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 scientist or IACUC.

After explaining the need to store the samples, the owner of the animal or sample owner shall be given the option to choose whether the sample should or should not be stored for future studies. A Ugandan scientist shall be included as Co-PI in all future studies using the animal materials collected from Uganda. Any future research study on such samples is subject to review by an IACUC. Where identifiable (traceable) samples have been collected, for example, as part of routine surveillance, emergency procedures, laboratory quality control, notifiable diseases and testing, without the prior intention of conducting research on the samples, samples sources shall be traced to provide consent for use of the samples in research.

11.3 Ownership

Samples shall be held in trust, on behalf of the animal owner (or sample source), by a duly registered or recognized institution in Uganda. The institution entrusted with custodianship of the samples shall have the authority to decide on the transfer, storage and future use of the samples taking into consideration the impact on the animal owners.

11.4 Exchange/Transfer of Animal Materials/Specimen for Research and Teaching Purposes

When it is necessary to transfer samples for storage or other uses from one institution to another within the country and abroad, the provider institution/laboratory holding the samples on behalf of sample sources shall negotiate an appropriate contract with the recipient institution. This contract shall be in the form of a Materials Transfer Agreement (MTA).

In order to justify transfer of animal materials abroad, scientists, sponsors and collaborators shall demonstrate that in–country capacity to perform certain types of investigations/testing does not exist or is inadequate. Samples may be transferred for quality assurance and laboratory reference purposes. scientists, sponsors and collaborators are encouraged to build, develop or strengthen local capacity for any investigative testing to fulfill the objectives of the proposed study. All exchanges and transfers (including importation and exportation) of materials for research purposes shall require clearance from UNCST, except for exchange of animal materials between institutions within the country. UNCST shall maintain a repository of all MTAs. Applications for permission to exchange or transfer animal materials for research purposes shall be made to UNCST after review and approval by an IACUC. The application must be accompanied by a MTA.

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

a. **Parties:** The MTA must give an introduction of the study and also carefully list parties and their addresses. The MTA is signed only by authorized representatives of each 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 shall fully describe the intended use of the materials. The recipient shall 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 shall be mentioned. The users cited must agree to abide by the terms and conditions of the MTA. Transfer to third parties not mentioned in the MTA is prohibited without written consent of the provider institution or their assignees.
e. **Location:** The place (full address) where the materials are to be transferred, used and or stored shall be indicated.

f. **Period of use of material:** A date for termination of use of the materials may be set to avoid indefinite use of the materials by the recipient institution. This date may be extended by written mutual consent of the parties. At the termination date, the provider institution may ask for the return of the materials or their destruction. It should be noted that terminating use of the materials does not render null and void other provisions of the MTA. It should be mentioned if the materials would be stored for future unknown uses.

g. **Disposal of materials:** A disposal plan for the materials must be described in the MTA, including methods to be used. Disposal of materials must be sufficiently documented.

h. **Restrictions:** If there are specific restrictions for the recipient institution, they shall be described. Specific restrictions may include; (i) to be used for one purpose and not the other; (ii) to be used in a specific site or country only or to be used strictly under the laws of a specific country. It shall, however, be noted that any study to be conducted in future using stored samples of animal origin will be subject to review and approval by an IACUC in the provider's country.

i. **Ownership of derivatives:** The provider institution shall clearly state whether the recipient institution can own any derivatives of the materials developed over time. The provider institution may allow the recipient institution to retain the derivatives without any restrictions.

j. **Ownership of the products:** The MTA must state who owns any new products developed using the materials. If nothing is stated about this in the MTA, the provider institution automatically assumes ownership.

k. **Commercialization rights:** The MTA shall include directions for handling commercialized products, including sharing of any royalties. The parties shall include a clause, which allows them to negotiate a separate MTA should the need for commercialization arise.

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

m. **Publication:** The provider institution may require the recipient institution to publish or not to publish the data obtained from the materials under specified conditions.

n. **Citation requirements:** If the provider institution allows any publication, it may be agreed that the provider institution is acknowledged as the provider of the materials.

o. **Governing law:** The MTA shall state the governing law. Such laws may be the laws of the provider's or both the provider's and recipient's country. The MTA shall be prepared taking into consideration the governing laws of the provider's and recipient's countries.

p. **Responsibilities:** The recipient institution is responsible for the proper handling and use of the materials.

q. **Liability:** The recipient or both the provider and recipient shall be accountable for any misuse or consequences of use of the materials. Parties must agree on such liabilities.

r. **Warranty:** The MTA should explain that the provider is giving the materials "as is" and does not promise that materials 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.

u. **Termination of MTA:** The MTA may be terminated by either party providing a written notice in an agreed timeframe. Parties must, however, make provisions for benefit sharing of any accruing or anticipated benefit at the point of termination.

When preparing MTAs, scientists shall take note of the levels of approval. UNCST liaises with MAAIF, UWA and NFA or any other agency to grant MTA permits pertaining to animal material exchange, transfer or acquisition. If, for example, the animal material is to be used together with a material governed by a separate MTA, care shall be taken under such circumstances to avoid granting two or more parties conflicting rights to the same material or product.

Before negotiating a MTA, parties correspond to reach consensus on particular issues regarding the material. Such correspondences, which include, for example, signed implementing letters indicating consent or willingness to exchange, transfer or acquire the material and utilization of facilities where results will be analyzed from. These may be attached as annexes to the MTA.

Use of animal materials by third parties should be permitted by the IACUC that initially permitted exchange, transfer or acquisition of the materials.

11.5 Exchange/Transfer of Animal Material and Specimen

The following are the required steps for the exchange or transfer of materials for research purposes within or out of the country:

a. The research study that involves the exchange or transfer of animal materials shall first be registered by UNCST.
b. The applicant shall be a legal resident of Uganda and be affiliated to a locally registered and recognized institution in country
d. A request for exchange or transfer of animal materials and specimen shall be made in writing to the Executive Secretary of UNCST.
e. Any MTA and any other document related to the exchange or transfer of animal materials shall accompany the request for the exchange or transfer of the materials.
f. The applicant shall receive feedback from UNCST on the status of his/her request within ten (10) working days from the date of submitting the request. 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 animal materials and specimen.

12.0 COLLABORATIVE RESEARCH

Collaborative research involves researchers working together to achieve a common goal of producing new scientific knowledge. This can be inter or multi institutions, local or international. Collaborative research should be conducted in accordance with the following principles of research partnership: researchers decide on objectives together, build mutual trust, share information and development works, share responsibility, create transparency, monitor and evaluate the collaboration, disseminate the results, apply the results, share profits equitably, increase research capacity and build on the achievements.

Improving local research capacity should be a priority throughout the research activities and this can be done through enhancing infrastructure, equipment, personnel, technology transfer, exchange programs as well as data and information sharing. Researchers, institutions, sponsors and collaborators are encouraged to build, develop and strengthen local capacity in collaborative research. During international collaborative research Ugandan scientists shall be included as Co-Principal Investigators.

13.0 DATA OWNERSHIP SHARING AND RESULTS DISSEMINATION

13.1 Data Ownership

Data ownership and associated intellectual property rights shall be discussed and agreed upon by collaborating partners at the inception of a research study within the context of investigator's institutional regulations/provisions. Collaborating research partners shall negotiate data ownership and use in accordance with the host institution's data use and ownership policies and any other existing regulatory frameworks. Ownership of data shall be clearly stated in the research protocol or collaborative research agreements, which shall be reviewed by the IACUC and registered with UNCST.

The institution of affiliation will own the primary research results generated from all research, development, and related activities conducted under its jurisdiction. If the PI on a study leaves the initial research institution and wishes to take original data to his/her new institution, this can only be achieved with approval of the authorised representative of the initial institution and the sponsor. Where this requirement has not been met, the original data will remain at the institution and the PI may take a copy of that data, assuming no sponsor restrictions exist.

13.2 Data Sharing

Initiatives for sharing research data are opportunities to increase the pace of knowledge discovery and scientific progress. The recurrent use of research data has the potential to avoid duplication of datasets and to bring new views from multiple analysis of the same dataset. Collaborating research partners shall agree on appropriate data access and user rights before commencement of a given study. Researchers shall have in place mechanisms for maintaining confidentiality of the owners' facility where research animal/subjects will be obtained. A collaborating research partner shall not transfer data to a third party without the written consent of the other partner. Local researchers shall have unrestricted access rights to datasets collected through a collaborative research project.

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.

13.3 Results Dissemination

Scientists shall, as appropriate, make all reasonable efforts to share findings of research with the host institution, relevant regulators, key stakeholders and communities in which the study was conducted. Scientist shall describe in the protocol, plans for results dissemination and ensure its execution. In addition, scientists shall make appropriate arrangements to engage the appropriate agencies and when the results are ready, develop policy briefs (if applicable) which together with results from other studies should guide policy or guideline development. It is strongly encouraged that study findings be published through open access journals.

14.0 ETHNOMEDICINE

Scientists intending to use herbal remedies as well as complementary and alternative veterinary remedies in animal research shall provide as much as possible information regarding proof of safety, efficacy and quality of the products. These guidelines shall apply to herbal remedies and or other products from natural sources in their crude form with medicinal claims when formulated in a pharmaceutical dosage form and are intended to be part of the list of medicines used for therapeutic, preventive, or diagnostic interventions. Researchers intending to use herbal remedies shall follow the same guidelines for clinical/field trials as stipulated in the NDPA Act 2000.

15.0 PENALTIES FOR NON-COMPLIANCE

Non-compliance refers to the conduct of research that is inconsistent with the requirements or determinations of the IACUC, UNCST, MAAIF, NDA or an allegation of such non-compliance.

Non-compliance with these guidelines may be identified by any person, IACUC, UNCST, MAAIF, NDA and all other stakeholders. Non-compliance shall be documented wherever it is identified. UNCST shall subsequently communicate non-compliance to the affected IACUC, researcher's institution of affiliation and other relevant authorities as appropriate.

UNCST will require the IACUC or the scientist's institution 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 MAAIF, NDA and any other institutions such as UWA, 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 institution.
d. Withholding approval of new studies to be conducted at the institution.
e. Disciplinary action by relevant professional bodies for cases of suspected negligence and malpractice.
f. Disqualifying an IACUC that has failed to take adequate measures to ensure compliance with these guidelines or that repeatedly fails to comply with these guidelines.
g. Recommend re training of the IACUC, the investigator and his/her team or both.

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3. The Animal Welfare Act, http://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf

4. Title 9 Code of Federal Regulations Subchapter A, "Animal Welfare", Parts 1-3 (AWA), (viewable at http://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf

5. The Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), (viewable at http://grants.nih.gov/grants/olaw/references/phspol.htm

6. Preclinical studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration should be conducted in accordance with Title 21 Code of Federal Regulations Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies Viewable at http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr58_99.html

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NATIONAL GUIDELINES FOR USE OF ANIMALS IN RESEARCH AND TEACHING

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