THE REPUBLIC OF UGANDA

UGANDA NATIONAL POLICY GUIDELINES FOR BIOBANKING

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Uganda National Council for Science and Technology

in collaboration with the

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TABLE OF CONTENTS

FOREWORD

Biobanks receive, store, process, and disseminate biological specimens and associated data as needed for research and public health purposes. They play a crucial role in ensuring that quality bio-specimens are available to foster scientific research and collaborations, health care and public health purposes. Biobanks currently exist in Uganda, with most hosted in research institutions and their collaborations. However, development and expansion of the biobank network capacity locally continues to face challenges, since host institutions have to consider a series of ethical, legal and social issues, such as informed consent, benefit sharing, confidentiality, ownership, commercialization and public participation. Maintaining these biobanks and producing effective outcomes is not easy without a proper regulatory and governance framework. Researchers and public health specialists, however, continue to cite lack of access to high quality, well-identified samples as a major hindrance to their work.

The national bio-banking policy guidelines provide a framework for establishing, certification and operating of the biobanks in Uganda in health care, agriculture; horticulture, animal care, forensic, environment, aquatic sciences, wildlife and education. The benefits resulting from access to bio-specimens and associated data of biobanks underscores the urgent need for these guidelines. It is our hope that these policy guidelines will ensure that Biobanks are established for custodianship of high quality, highly valuable biological materials and data; maintain ethical standards in collection, processing, storage or inventory, disposal, use and distribution of biological material. These should also ensure that legal standards in management of Biobanks are maintained and biosafety and biosecurity standards ensured.

We commend the bio-bank governance technical working group and stakeholders that participated in the development of these policy guidelines and pledge our support to enable their implementation nationally.

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LIST OF ACRONYMS

CDC	Centers for Disease Control and Prevention
CHS	College of Health Sciences
DMM	Department of Microbiology
DNA	Deoxyribonucleic acid
GCLP	Good Clinical Laboratory Practice
IDI	Infectious Disease Institute
Mak	Makerere
MTA	Material Transfer Agreement
MUST	Mbarara University of Science and Technology
NEMA	National Environment Management Authority
NHLDS	National Health Laboratory Services and Diagnostics
QA	Quality Assurance
QC	Quality Control
REC	Research Ethics Committees
RNA	Ribonucleic acid
SOP	Standard Operating Procedure
UNCST	Uganda National Council for Science and Technology
UNHLS	Uganda National Health Laboratory Services

1.0 INTRODUCTION

Biological materials such as tissues, cells, blood, and serum play a critical role in academic research. Clinical trials and epidemiological studies have contributed for quite a long time to a better understanding of certain diseases, but the incredibly rapid pace at which biotechnology, medical research, and high quantities of phenotypic information which are constantly added to each patient's case demand that we take a step back and look at the bigger picture involved. Biological resource centres help in the storage of the materials, which contribute significantly to our understanding of genetic and environmental factors that influence disease risk, care and treatment. Additionally, these resources provide platforms for building local capacity and foster international collaborations. Uganda has seen a move by a various institutions setting up biorepositories and biobanks.

1.1. Rationale

Due to advances in scientific research and health care there is need to formulate appropriate guidance for stakeholders on handling of stored human biological materials and their associated data. This especially becomes important due to the need to both advance science and protect the rights and welfare of the donors of the materials and associated data. In principle, the rights and well-being of the participants and the common good prevail over the research interests of the custodian organization and users of the biobank.

1.2. Scope

These policy guidelines cover the acquisition, storage, sharing and use of biological materials in research and health care and associated data in health, agriculture; horticulture, animal, forensic, environment, aquatic sciences, wildlife and education. For biological materials/data collected during public health emergencies, surveillance, quality assurance, clinical care, public health and research exempt from review these guidelines shall apply. Additionally, these guidelines shall apply to research in all training institutions.

These National Biobanking Policy guidelines give guidance on establishment, governance, management, operation, access, use, and discontinuation of human biobanks and bio databases based on the ethical principles of respect for persons, beneficence and justice, community engagement and Non-maleficence. The biobank should be operated throughout its existence with integrity, transparency, accountability and respect for principles of ethics.

These policy guidelines define a Biobank as a collection of biological material and associated biodata stored in an organized system that are raw materials for the advancement of research in human health and biotechnology. Biobanks typically:

a) Collect and store biological materials that are annotated not only with medical, but often also epidemiological data, agricultural, horticulture, animal, forensic, environment, aquatic sciences, wildlife and education;
b) Are not static projects, since biological materials and data are usually collected on a continuous or long-term basis;
c) Are associated with current and/or future research projects or routine patient care at the time of specimen collection;
d) Apply coding or anonymization to guarantee donor privacy but have, under specific conditions provisions that participants remain re-identifiable in order to provide clinically relevant information back to the donor;
e) Include established governance structures and procedures that serve to protect donors' rights, competing priorities and stakeholder interests
f) Cater for biosafety and biosecurity concerns

These policy guidelines are applicable to Biobanks, Bio-repositories, gene banks and biological databases. The term bio-database refers to biological specimen associated data, and related information which include information collected in the establishment of the database and information that is obtained through routine patient care or research on the material held (e.g. personal, clinical, genetic, biochemical or phenotypic information).

This includes but is not restricted to biobanks:

a) established within public or private institutions, and/or international collaborations
b) established using biological samples and/or information obtained from research subjects /communities within the Republic of Uganda
c) Biological materials imported into the country

1.3. Goal

To establish a coherent regulatory frame work for establishment, operation and accreditation of the biobanks.

1.4. Objectives

a) To ensure that Biobanks are established for custodianship of high quality, highly valuable biological materials and data.
b) To maintain legal standards in management of Biobanks.
c) To maintain ethical standards in collection, processing, storage or inventory, disposal, use and distribution of biological material.
d) To maintain Biosafety and Biosecurity standards in collection, processing, storage or inventory, disposal, use and distribution of biological material.

2.0 ESTABLISHMENT AND CERTIFICATION OF BIOBANKS

2.1. Establishment of biobanks

The establishment of a Biobank shall be initiated by any legally recognized organization which shall act as the custodian on behalf of the donors of the biological materials who are the owners of specimen and bio data. The custodian organizations shall ensure that a bio bank has;

a) Evidence of operation as a legal entity;
b) A clearly defined protocol and scope;
c) Standard Operating Procedures, defining ethical requirements, technical, quality management, information technology, safety and biosecurity requirements;
d) A business plan with evidence of resources in place;
e) A sustainability plan;
f) Governance structure of the biobank;
g) Evidence of proficiency trained and competent personnel;
h) A contingency plan e.g covering natural disasters, relocation of the biobank;
i) Provision for equitable access by various stakeholders;
j) Certification of the building/infrastructure suitability by the National Environment Management Authority (NEMA);
k) Approval from Institutional Biosafety Committee;
l) Have risk assessment and risk management plan for the biobank;
m) Meet at least 80% of all administrative and technical biobank requirements listed in the national bio-bank certification checklist (See annex 1).

The certification of biobank by the national biobank certification committee under UNCST and NHLSD (Formally UNHLS) will involve an assessment process following a standardized

checklist (see annex 1) to evaluate the level of compliance to applicable standards and to implement ways to continuously improve.

When establishing a biobank, the custodian should carry out consultations with stakeholders, which includes relevant participants, Research Ethics Committees (RECs) and regulatory bodies. The Biobank should describe and document the nature of the biological materials and their sources. Biological materials shall include but not limited to; human and non-human tissues, organs, blood, plasma, sputum, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, breast milk, fecal matter, bones, urine and saliva. Other biological specimen may include isolated or cultured microorganisms/pathogens of human origin, vectors of human pathogens, environmental samples, plant and animal products.

2.2. Regulatory oversight of biobanks

2.2.1. Roles and Responsibilities of UNCST

The Biobanks for research will be certified by a specialized committee established by the UNCST to serve the regulatory oversight. This committee will offer independent scientific, and ethical oversight to ensure compliance to laws, ethical, regulatory guidelines, policies and procedures.

2.2.2. Roles and Responsibilities of NHLSD (Formally UNHLS)

Establishment of biobanks for non-research by a specialized committee established by the UNHLS to serve the regulatory oversight. This committee ensure compliance of the biobanks to the laws, ethical, regulatory guidelines, policies and procedures.

2.3. Biobanks governance structure

Every biobank shall have a governance structure in place responsible for management and oversight roles and responsibilities.

During the establishment of a biobank, governance systems should be defined to take into account the biobank's scope and the context in which it operates. There should be an established organogram and terms of reference for each position. The governance structure should:

a) Have an executive committee or steering group. The responsibilities of this committee may include overall management, defining strategic objectives, monitoring progress, revising and/or adopting policies, and developing a communications strategy. This

committee may also conduct an regular performance review meeting to evaluate performance of biobanking activities.

b) Have a Governance structure that has a diverse composition including but not limited to: scientists, legal personnel, social scientists, ethicists, biosecurity specialists and community representatives
c) Have a sample/data access committee that reviews applications, access and retrieval of biological materials and/ or associated data
d) Have self-audits to ensure compliance to National and International Standards, laws, regulations, ethical, regulatory guidelines, policies and procedures
e) Have mechanisms to avoid breach of privacy and confidentiality
f) Have reporting mechanisms in compliance or otherwise on bio banking in accordance to relevant institutions or regulatory agencies' requirements
g) Have clear definitions of roles and responsibilities and chain of reporting
h) Have the Governance and management activities subjected to independent auditing by the NHLSD (Formally UNHLS) and UNCST to ensure compliance to laws, ethical, regulatory guidelines, policies and procedures.
i) A biobank quality manager, who is responsible for the QMS and for periodic review of all SOPs, and has overall responsibility for assurance (QA).
j) A data steward, who is responsible for data protection and privacy.

2.3.1. Roles of Institutional Biosafety Committee (IBC)

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

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

Objectives of the IBC

a) To protect all bio-bank personnel, other users and environment from potential exposure to biological agents.
b) To prevent an intentional release of biological materials from loss, theft and or misuse.
c) To promote occupation health and safety programs at bio-bank working environment.
d) Comply with all legal requirements applicable to Biorisk management processes.
e) To enhance monitoring and evaluation of Biorisk management program.

Functions of IBC

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

Specifically, IBCs shall;

a) To conduct biosafety and biosecurity risk assessments at inception;
b) Document the all the hazards and categorized;
c) List the risk groups of the pathogens available based national/international requirement;
d) Advise on the mitigations methods;
e) To conduct continuous evaluation of the Bio-bank;
    - When there is a change in procedures
    - When a new biological agent is introduced
    - Modification of the biobank infrastructure
f) Advise on the emergency procedures in the event of occurrence or an incident;
g) Conduct biosafety review of research proposals on potentially hazardous substances;
h) Conduct initial and periodic risk assessment of the of the biobank using a structured risk assessment checklist (Annex 2);
i) Conduct periodic biosafety and biosecurity audits of the biobank;
j) Develop relevant biosafety and biosecurity documentations for the biobank;
k) Follow up on the after audits biobank action plans to ensure compliance according to the national and international requirements;

l) Provide guidance or supervise on the operation of pathogen asset control system) such as establishment of an electronic application system used to account or control biological agent stocks).

2.3.2. Roles of the Biobank Custodian

a) The bio bank custodian shall ensure compliance with the relevant policies, procedures and protocols. Ensure that the bio bank protocols and procedures have been subjected to approval by UNCST and UNHLS respectively.

b) Have amendments to the policies and procedures subjected to ethical review and approval.

c) Have in place mechanisms for re-consenting when there are changes that affect the scope of the consent or a consent waiver in circumstances where re-consenting is not possible.

d) The biobank custodian shall ensure easy public access of bio bank related documents, governance, management and oversight documents. This information should include:

- Ethical and Regulatory approval records;
- Roles and responsibilities as stipulated in the governance, management and oversight structures;
- Application procedures for access, review and authorizations;
- Summary of the biological materials and associated bio-data except where there are biosecurity reasons;
- Key elements of the applicable laws, ethical, regulatory guidelines, policies and procedures; and
- Annual reports of compliance to laws, ethical, regulatory guidelines, policies and procedures

e) Ensure that stakeholders, including the general community and researchers, are consulted to formulate criteria for prioritizing applications for access to the samples.

f) Ensure information is publicly available on the research projects for which samples and data are accessed, and the results of these projects.

3.0 SAMPLE ACQUISITION

Prior to obtaining biological materials from sample sources the following should be obtained or in place;

3.1. Community engagement

Reasonable effort to involve community stakeholders in collection and storage of biological materials shall be made. Community stakeholders may include individuals and groups that are ultimately representing the interests of people whose samples or those of their subjects (animals) are being stored. Engaging with the community is a process of building transparent, meaningful, collaborative, and mutually beneficial relationships with interested or affected individuals, groups of individuals, or organizations.

The bio bank shall require an appropriate community engagement process before receipt and transfer of biological materials /data. At a minimum community engagement shall include but not limited to documented evidence of; consulting gate keepers of the community; organizing community meetings and involvement of Community Advisory Boards.

3.2. Informed Consent

Documented proof of adequate informed consent for biological material and data donation shall be provided. This shall include; a separate consent document for storage for future use and separate consent document for genetic research where applicable.

Informed Consent Process

All biological materials/data obtained during research, clinical care, public health interventions and surveillance require evidence of documented informed consent from the sample donor or their representative. Each Biobank shall have a documentation of the informed consent status for each bio-specimen. Additionally, procedures for obtaining informed consent and protecting the privacy of identifiable human research participants and confidentiality of data and procedures to follow in the case of withdrawal of consent shall be clearly described.

During the clinical care process, public health interventions and surveillance the researcher will document the process of having obtained informed consent from the samples donors. The laboratory request form should have adequate basic information for the participant to make a decision.

For clinical care, the laboratory form should be in triplicate with copies given to the sample donor, laboratory and custodians of the Bio bank. The biobank custodian shall ensure that there are available policies, protocols and procedures in place on the, collection/reception, labeling, registration, processing, storage, tracking, retrieval, dissemination, use, auditing, sharing and certified safe destruction of samples and/or data.

3.3. Regulatory approval

Evidence of approval of the protocol by UNCST or NHLSD (Formally UNHLS) where applicable

3.4. Material Transfer Agreement

All samples to be stored in the bio bank should be accompanied with an MTA between the custodian institution and the bio bank.

3.5. Data Transfer Agreement

Data sharing shall be established between the participating partners with the mutually agreed position documented in a Data Transfer Agreement.

3.6. Manual of Operating Procedures

An operating Manual shall specifically include, but not limited to, SOPs and other documents regarding the following:

a) *Informed consent;* each Biobank shall have a documentation of the informed consent status for each bio-specimen.

b) *Equipment monitoring, calibration, maintenance and repair;* each Biobank shall have procedures to routinely monitor equipment that are used for bio-specimen storage or preparation. This includes ensuring that equipment is accurately calibrated, that operational settings are routinely recorded, and that scheduled maintenance and repairs are documented. Equipment SOPs and records shall also cover associated backup and emergency notification systems.

c) *Control of Bio-specimen collection supplies (Disposables and Reagents*); a biobank shall have a procedure to ensure that consumable supplies and reagents used for collection, processing, and storage conform to required standards. This includes ensuring purchased supplies are approved, and acquired from approved suppliers, meet defined material specifications, and are in good condition for use.

d) *Bio-specimen Identification and Labelling Conventions*; a biobank shall define policies and procedures for labelling and coding bio-specimens and linking or delinking bio-specimens to other data sets and patient informed consent according to national and international standards. However, there should be a documented mechanism for return of useful results.

e) *Bio-specimen collection and processing methods;* a biobank shall establish procedures of bio-specimen collection (including chain of custody), handling, processing, and preservation for each bio-specimen type. Bio-specimen collection and processing should always include the recording of personnel names, dates, and times to accurately record these potential sources of pre-analytic variation.

f) *Storage and retrieval; a* biobank shall define procedures for the storage and retrieval including processes for adding new bio-specimens, withdrawing bio-specimens, responding to and filling requests, and final disposition of bio-specimens.

g) *Shipping and Receiving*; a biobank shall have defined procedures and policies for the packaging and transport at ambient temperature and frozen bio-specimens to ensure bio-specimen integrity and safety. This includes packaging specifications to maintain appropriate temperature conditions; wet ice, dry ice, and liquid nitrogen handling; shipment temperature monitoring; shipment regulations for hazardous materials; shipment logs; delivery notifications; confirmation of delivery; shipment feedback mechanisms; and MTAs or other appropriate agreements to cover transfers.

h) *Laboratory Tests performed in-house including Bio-specimen Quality Control Testing;* each bio-specimen resource should have SOPs governing standardized in-house testing procedures and should document the results in associated quality records. This includes tests to assess and control bio-specimen quality, such as confirmation of histopathology diagnosis, nucleic acid integrity, or biomarker expression.

i) *Bio-specimen Data Collection and Management (Informatics);* each bio-specimen resource should have policies for managing records and procedures defining data access, data collection methods, reporting, data QC, and standardized medical terminology

j) *Biosafety;* each bio-specimen resource should have policies and procedures covering biosafety, including reporting staff injuries, spillage as well as standard precautions for blood borne pathogens, personal protection equipment, hazardous material handling, and disposal of medical waste and other biohazardous materials.

k) *Training;* each bio-specimen resource should have policies and procedures for training of all staff members. Such training should be documented and have mechanisms to manage corrective actions; to resolve inventory and shipment discrepancies; to monitor all sample storage; and to manage power outages, emergencies, and natural disasters.

l) *Security;* security SOPs and policies should include information on points of contact and designated backup personnel, including names and emergency contact numbers. There should be documented policies and procedures to manage corrective actions; to resolve inventory and shipment discrepancies; to monitor all sample storage; and to manage power outages, emergencies, and natural disasters.

4.0 QUALITY ASSURANCE

All biological specimen and associated data shall be subject to quality assurance measures according to national and international standards at every stage of its processing including acquisition, collection, labeling, registration, processing, storage, tracking, retrieval, dissemination, use and destruction in order to ensure high standards of quality in all biobank holdings.

The participant confidentiality shall be assured through all quality assurance processes such as; sample tracking and audit trails The biological bio-specimens shall be maintained through a system that allows all samples, data and any other information to be tracked according to the Biobank SOPs.

In general, biobanks should implement systems that specify QA for sample collection, processing, storage, shipment, and disposition. Such systems are essential for maintaining a fit-for-purpose biobank. The ISO 20387:2018 standard currently referred to by biobanks, which provide general requirements for the competence and for the QMS, respectively.

Biobanks should have appropriate QA and QC programmes with respect to equipment maintenance and repair, staff training, data management and record-keeping, and

adherence to principles of good laboratory practice. All biobank operations must be subject to regular audits. The timing, scope, and outcome of these audits should be documented.

4.1. Biobank standard operating procedures (SOPs)

Biobanks should develop, document, and regularly update policies and procedures in a standardized written format incorporated into an SOP manual that is readily available to all laboratory personnel. The SOP manual is a key part of the overall QMS of the biobank, is important to the success of biobanking, and is a major contributor to the development of biomedical practice worldwide.

The SOP manual should specifically include:

a) Procedures for obtaining informed consent and withdrawal of consent from participants;
b) Records management policies, including access control, a backup system, clinical annotation, and document maintenance and archiving;
c) Policies and procedures for specimen handling, including supplies, methods, and equipment;
d) Laboratory procedures for specimen processing (e.g. collection, transportation, processing, aliquoting, tests, storage, and QC);
e) Procedures for sharing and transferring specimens (access policy, MTA); procedures for a business model and cost recovery, when applicable;
f) Policies and procedures for shipping and receiving specimens;
g) QA and QC policies and procedures for supplies, equipment, instruments, reagents, labels, and processes used in sample retrieval and processing;
h) Procedures for security in biobank facilities;
i) Policies and procedures related to emergencies and safety, including reporting of staff injuries and exposure to potential pathogens;
j) Policies and procedures for the investigation, documentation, and reporting of accidents, errors, complaints, and adverse events;
k) Policies, procedures, and schedules for equipment inspection, maintenance, repair, and calibration;
l) Emergency procedures in case of failure of a refrigerator, freezer, or LN2 tank;
m) Procedures for disposal of medical waste and other hazardous waste; and
n) Policies and procedures describing the requirements of recruitment and training programmes for biobank staff.

4.2.Protection of biological specimen and associated data

Processing, handling and storage of biological specimen and associated data shall be conducted in a manner that protects the privacy of the participants and the confidentiality of their biological specimen and associated data.

The custodian organization shall ensure that;

a) Data contained within the biobank databases are protected in accordance with domestic law
b) A combination of mechanisms such as secure storage of samples and data, coding, Data anonymization and data pseudonymisation are implemented to ensure privacy and confidentiality
c) The biobank is established, managed and governed in such a way as to prevent any inappropriate or unauthorized access to or use of participants' biological specimen and associated data.
d) Policies and procedures shall be documented to safeguard the privacy and confidentiality of participants, samples and data, especially those that may allow, directly or indirectly, the identification of the participants.
e) Quality control and assurance measures shall be in place to ensure, security and confidentiality during collection, storage, handling, distribution and destruction of the samples and data.
f) Adequate infrastructure with controlled access to the biobank should be put in place.

4.3.Access to biobank samples and data

The biobank custodian shall ensure that there are available institutional policies, protocols and procedures in place governing access to all biological materials and associated data.

Policies on access shall include but not limited to the following:

a) Requirements for accessing biological materials and associated data
b) Circumstances under which they provide access to biological specimen and associated data to third parties including restrictions to unlimited access requirements for the return or destruction of biological specimens and data provided to third parties at the completion of their research

c) Prohibitions to sample access for usage as well as physical access should be given by provision of subcategorization of authorization to access of some of the samples within the institution

d) Institutional Biobank access and fee policies. Transfer, access and use of biological specimen and associated data shall be consistent with the terms of participation and respect the privacy of the participants and their communities' confidentiality of the samples and data, and ensure good safety and laboratory methods.

4.4. Access Control Provisions

a) The biobank custodian shall ensure that access to and use of biological material and data are in line with established protocols that are consistent with informed consent with respect to privacy and confidentiality.

b) The biobank should provide relevant information about the types of activities and specimen held within the biobank framework using its resources whether biological materials and data will be made available to the public for public accountability.

c) The biobank custodians shall ensure that samples and associated data access requests and distribution are consistent with the informed consent provided by the sample donor and the existing data and material transfer policy of the biobank.

d) The biobank should provide to researchers' biological materials and data that is anonymized. However, in exceptional circumstances, it may be in the donor's interest that the researcher has access to non-coded or non-anonymized materials or data with participant's consent. For example, this may be the case for research involving rare diseases.

e) The biobank should have procedures in place by which participants should be directly contacted by researchers, clinicians, public health specialist who have accessed their biological materials and data from the biobank for the returned significant findings.

f) The biobank should not grant access to or disclose participants' biological materials or data to third parties e.g. insurers, Employers, law enforcement agencies or other civil-law agencies, for non-research purposes, except when required by law and surveillance purposes.

g) Biobank material and data access applications shall be reviewed by existing biobank sample access committee to ensure that the proposed uses are scientifically and ethically appropriate and consistent with applicable policies, frameworks and legislation.
h) The biobank should have their access policies readily available for sample donors, communities, clinicians, researchers and third parties to ensure transparency.
i) The biobank should have policies in regards to access to its resources and services ensuring that these are applied in a fair and transparent manner without prohibiting the use of the material and data.
j) Where biological materials and data are to be released to third parties by the biobank, consideration should be given to the implications for the custodianship of any data derived from the analysis of such material that relates directly to participants (e.g. genotype data derived from DNA), particularly where such data can be linked to significant amounts of phenotypic data about the same participant. Such issues should be addressed in the material transfer agreement which governs the release of human biological materials and data from the biobank to the researchers.
k) The biobank should ensure that its governance mechanism is able to deal with problematic situations pertaining to data derived from the analysis of biological materials and other information shared with the third party.
l) The biobank should provide the quantity of materials and data consistent with that required for the research to be carried out. Hence the requesting party must provide information on what they require from the biobank, type of material and quantities.
m) Biobanks should have dedicated storage facilities that are not shared with other activities, for the safety and security of bio specimen collections.
n) Biobanks should be equipped with a system that adequately limits access to authorized staff members and protects against intrusion by unauthorized individuals.

4.5. Records management

Documentation related to sample collection, sample processing, sharing of samples (MTA and DTA), and shipment of samples (proof of shipment and delivery) must be appropriately maintained and archived in a traceable and secure manner. A backup system must be implemented to guarantee appropriate maintenance of all records. All documentation must be kept centrally and should include: quality certifications; personnel training records; completed templates of forms and

spreadsheets; documentation of biobank audits; documentation of adverse events; instrument calibration records; maintenance and repair records; signed informed consents; signed collaboration agreements; sample request forms; signed MTAs and data transfer agreements (DTAs); and shipping notes.

All hard copies of records must be archived in a secure manner, to be accessed only by authorized personnel. All stored records should be stored in a manner that provides easy access for inspection by authorized personnel. Each container, tank, freezer, refrigerator, or room-temperature storage cabinet should have a unique identifier. The hierarchy of each storage unit should be clearly defined, to enable stored samples to be located easily. A convention should be established for numbering shelves, racks, and boxes as well as each location within the container. An IT solution can provide a centralized system to maintain traceable records of samples. Where possible, hard copies of records should be scanned into an IT system to provide a backup. All records should be archived for a period in line with institutional or local regulations, where they exist. Where there are no such regulations, the biobank should decide the period for record retention depending on the type of record. Records pertaining to samples that no longer exist may be destroyed if the records are considered to no longer be valuable. Records pertaining to samples that were withdrawn should be destroyed in a secure manner. Records pertaining to instruments may be destroyed once the instrument has been retired. The destruction of records should be carried out in a manner in line with the security requirements of the record.

5.0 Specimen transportation and shipment

The transportation and shipping of bio-specimens shall be conducted according to national and international standards. These standard, are applicable to any mode of transport, are based on the recommendations of the international committee recommendations for the Transport of Dangerous Goods, under the United Nations Economic and Social Council.

6.0 Biosafety and biosecurity

The primary, basic requirement of a biobank is general safety. This includes protection of people and of the environment against biological and chemical hazards. The management of these risks should be based on a general implementation of a precautionary principle similar to those used in laboratories and clinical settings, and should be embodied in a general safety management plan.

6.1. Biosafety

Biobanks must follow established national and international standards and guidelines in relation to chemical, physical, and electrical safety. The use of liquid gases such as liquid nitrogen (LN2) for cryopreservation poses a serious source of hazard. Where LN2 refrigeration is used, an adequate supply of refrigerant must be maintained. The supply maintained on-site should be at least 20% more than the normal refill use, to allow for emergency situations. Handling LN2 has serious safety implications. Skin contact with LN2 can cause severe frostbite. Oxygen-level sensors should always be used when LN2 containers are used in a biobank. LN2 expands to 650 times its original volume at room temperature, causing a form of explosion hazard if evaporation is restricted. Storage areas must be well ventilated. Plastic and glass containers can easily explode if liquid is trapped when the container is removed from the LN2. Protective safety equipment must be worn when handling LN2. Heavy gloves, a face shield, and a protective garment should always be worn Protective shoes are also recommended. Safety notices and protocols must be clearly displayed in the biobank area. Appropriate training on the risks of LN2, including safe handling and means of protection, must be given to personnel before they work in a biobank, and should be repeated on a regular basis.

There are also risks associated with the use of chemical fixatives and solvents used in tissue processing. In addition, electrical safety is an important concern. Freezers must be properly wired to adequate sources of electrical supply, and grounded. Work in a biobank also entails several occupational hazards typical of the laboratory environment. These risks must be taken into account before setting up a biobank, and their prevention must be integrated into all aspects of the SOPs of the biobank.

6.2. Biosecurity

Laboratory biosecurity describes the protection of, control of, and accountability for valuable biological materials, to prevent their unauthorized access, loss, misuse, theft, or intentional release The scope of laboratory biosecurity is broadened by addressing the safekeeping of all valuable biological materials, including not only pathogens and toxins but also scientifically, historically, and economically important biological materials, such as collections and reference strains, pathogens and toxins, vaccines and other pharmaceutical products, food products, genetically modified organisms, non-pathogenic microorganisms, extraterrestrial samples, cellular

components, and genetic elements. Biosecurity can also refer to precautions that should be taken to prevent the use of pathogens or toxins for bioterrorism or biological warfare. Securing pathogens and toxins at research and diagnostic laboratories cannot prevent bioterrorism but can make it more difficult for potential terrorists to divert material from a legitimate facility so as to build a biological weapon

Laboratory biosecurity measures should be based on a comprehensive programme of accountability for valuable biological material that includes:

a) Assessment of biosecurity risks;
b) Restricted and controlled access;
c) Containment-in-containment architecture;
d) Regularly updated inventories with storage locations;
e) Identification and selection of personnel with access;
f) Plan of use of valuable biological material;
g) Clearance and approval processes; and
h) Documentation of internal and external transfers within and between facilities and of any inactivation and/or disposal of the material.

Institutional laboratory biosecurity protocols should include how to handle breaches in laboratory biosecurity, including:

a) Incident notification;
b) Reporting protocols;
c) Investigation reports; and
d) Recommendations and remedies.

Adoption of these security requirements is important for biobanks that store pathogenic or toxic bio-specimens.

6.3. Facility and Infrastructure

The biobank infrastructure and storage system depend on the type of material being stored, the required storage conditions, the anticipated period of storage, the intended use of the materials, and the resources available for purchasing the storage equipment. The storage infrastructure also depends on the available resources and support to the biobank. The storage system is fundamental to maintaining high sample quality. The data and databases related to bio-specimen annotation,

quality, storage location, and use, including the patients' clinical and epidemiological information, are important attributes of biobank infrastructure.

7.0 QUALIFICATION, EDUCATION AND TRAINING

The bio bank shall ensure that all personnel are competent with knowledge and skills to run a bio bank. The Human resource in the Biobank shall be qualified by training and experience to carry out its mandate.

a) The custodian should be knowledgeable in biological laboratory sciences
b) The biobank custodian shall ensure that personnel have the appropriate professional qualifications that meet recognized standards, underpinned by experience, skills, up-to-date knowledge, education and training and are assigned responsibilities commensurate with their capabilities.
c) The biobank custodian shall develop and implement periodic employee training programs. Training should form an integral part of the biobank certification system. Technical staff of the biobank shall be responsible for the implementation of policies and procedures
d) GCLP shall be required of the personnel working in the biobank every two years.

8.0 OWNERSHIP AND CUSTODIANSHIP, BENEFIT SHARING AND INTELLECTUAL PROPERTY

6.1. Ownership and Custodianship

Sample donors own the samples which are kept in trust by the Primary source institution (where the sample is collected and/ or where the primary interaction with the donor takes place in a duly registered and recognized organization in Uganda.). Whether to link or de-link samples will be determined by the sample donors during the informed consent process which shall be appropriately documented. Samples donors may withdraw their samples if the samples are linked. The Primary source institution shall have the authority to decide use, transfer, storage and future use of the samples taking into consideration rights and welfare of the sample donor. The Biobank has full custody of the specimen as per the MTA drawn between the parties.

6.2. Intellectual Property

Intellectual Property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce. These include; markers

for developing assays and guides for identifying new potential targets for drugs, therapeutics, and diagnostics. Intellectual Property rights grant the owner of the work exclusive rights to exploit and benefit from his/her creation.

Patenting of technology suitable for subsequent private investment should lead to the development of products that address public needs without impeding research or the rights and welfare of the sample donors.

The biobank and primary source institution should define an intellectual property policy and aspects of this policy should be defined in the MTA.

The primary source institution shall ensure the following;

a) The primary source institution shall ensure there are available policies and procedures on benefit sharing in line with applicable national policies, regulations and laws;
b) Benefits from IP are shared in different ways and should be pre-negotiated these include the; financial benefits, information, licensing, or transferring of technology or materials;
c) The derivatives from the donors' biological material shall be taken as new products and should be considered as Intellectual Property;
d) The biobank shall ensure that they are acknowledgement in publications, presentations;
e) Sample donor institutions and communities' acknowledgement in publications, presentations and where relevant.

9.0 DISCONTINUATION OF THE BIOBANK AND DISPOSAL OF MATERIALS AND DATA.

7.1. Discontinuation of a bank

The operators of the biobank should plan for its possible discontinuation and should have a suitably detailed policy setting out the manner in which the donor biological materials and data that it holds will be dealt with in the event of its discontinuation.

Where a biobank of scientific value can no longer be supported by its current operators, efforts should be made to transfer the biological materials and data to another biobank or another entity. Once a biobank is no longer required or is no longer of scientific value and it has been determined that it will be discontinued, the biological materials should be disposed of in an appropriate manner, consistent with the principles of consent, privacy and confidentiality.

The biobank's discontinuation plan should include details for the transfer or destruction of the biological materials and data. Where the discontinuation of the biobank results from insolvency, the operators should be aware that under applicable insolvency law the liquidator may be permitted or required to sell the assets of the biobank to commercial buyers, subject to any constraints in the participants' consent or under the law. The operators should consider what steps should be taken to provide for this and make information available to participants. For the human biological biobanks, one shall only sell movable assets and not the samples under custody. The biobank's policy on the destruction and disposal of biological materials and data should take into consideration cultural heritage and/or religious beliefs known or disclosed by the participants, and/or their communities.

The operators of the biobank should ensure that all information and data it holds is destroyed in a manner not permitting its recovery in accordance with the state of the art and technology. The operators of the biobank should dispose of biological materials in accordance with national and international legislation and regulation applicable to the disposal of biological materials and bio-hazardous waste. A biobank should document the destruction of any specimens, and monitoring specimen destruction due to compromised quality as part of quality management for the repository. Biobanks should document disposition of specimens or collections through destruction or transfer to a new custodian and retain the documents in the archival records of the repository.

Before a Biobank is terminated the following shall be done;

a) One-year notice to all stakeholders is provided;
b) SOPs for the safe transfer of the samples are in place;
c) Documented justification for closure is available;
d) Audit report by the IBC is available

7.2. Disposal of materials and data

Before disposal of materials and data following shall be done;

a) Audit report by the IBC
b) Material and data destruction certificate

10.0 DISASTER PREPAREDNESS AND RECOVERY PLANNING FOR BIOBANK

Biobanks should have a written disaster recovery plan in place for responding to a wide variety of emergency situations for business continuity. The plan should cover a wide range of natural and man-made disasters, which must be categorized with their various effects on the biobanks' ability to carry out its essential functions. Assessment of likelihood of various types of disasters e.g. chemical spills, fire, floods, power outage should be documented within the plan.

The recovery plan should be tested at least annually to ensure that it fulfills the purpose. A notification report of this shall be documented.

8.1. Biological material protection and recovery

a) Biobanks have a fundamental objective to protect every single specimen and whole collections in its custody to minimize hazards such as; spillage, contamination, floods, staff exposure while maintaining the sample integrity.
b) Biobanks should have a backup that is adequate for disaster handling and management. For example, backup freezers, power backup and data servers.
c) Duplication of specimen collections and data in distinct locations (e.g., including in different freezer units) is recommended to ensure preservation of the holding in the event of a catastrophic event.
d) The biobank should be placed on a list of "*high priority*" users for power restoration following an emergency and this shall be documented.
e) Notification of security and environmental monitoring systems should be verified on a routine basis and documented. Where possible, emergencies should be simulated to ensure proper follow-through for the established emergency plan.

8.2. Data protection and recovery

a) The biobank sample inventory should be backed by an off site server;
b) If biobank sample inventory is not housed on a local server, some consideration should be given to storing electronic inventory records on site to ensure that needed records are accessible in an emergency.

8.3. Biobank personnel

a) All biobank personnel should be trained and knowledgeable on the procedures laid out in the recovery plan.

b) The biobank should have a checklist of activities for "on call" staff to follow during an emergency. "On call" staff should be familiar with the location and operation of certain key equipment and controls (i.e., circuit boards) that may need to be checked during an emergency.

c) Emergency telephone numbers for professional assistance should be clearly posted in the biobank and accompanying administrative areas e.g., engineering or facilities personnel, power companies, fuel supply companies, transportation services.

d) SOPs of emergency plans should be available at the biobank for the relevant potential disasters identified. This should include components on preparedness, response and recovery.

11.0 COLLABORATIVE ENGAGEMENTS

The collaborative framework should be drawn at protocol development and before collection of the biological materials. This shall be in a clearly written MoU. Collaborators are required to build, develop or strengthen local capacity for any investigative testing. Collaborating institutions partners shall agree on appropriate data storage, access and use rights.

9.1. Responsibilities of stakeholders

9.1.1. Role of the sample donor

The sample donor is responsible for the following;

a) understanding and updating the Informed Consent

b) Provision of donor materials

9.1.2. Role of the research, healthcare and public institutions

a) Effective community engagement to increase public awareness and acceptability of biobank activities;

b) Appropriate documentation e.g MTAs, MoUs, ICFs, SOPs and regulatory approvals

c) Appropriate handling and safety of biological materials

d) Maintaining privacy and confidentiality of sample donors;

e) Obtaining informed consent from sample donors;

f) Dissemination of results for maximum impact;

g) Translation of results to action and policy;

h) Capacity building of research and public institutions through technical and infrastructural developments;
i) Custodianship of samples
j) Ensure sustainability of the Biobank

9.1.3. Role of the Researchers

The researcher is responsible for the overall conduct and supervision of the research project in collaboration with the biobank custodian. Specifically, the researcher shall;

a) Demonstrate ownership (e.g. by signing the protocol) of the research protocol, and ensure that the protocol is strictly followed at project implementation.
b) Not implement changes/amendments in the research protocol without prior approval of the REC, except when necessary to eliminate an apparent immediate hazard or danger to research participants.
c) Obtain adequate informed consent from research participants in accordance with the National Guidelines for Research Involving Humans as Research Participants and National Guidelines for Research Involving Animals as Research Subjects.
d) Inform the biobank, Research Ethics Committees, Institutional Animal Use and Care Committee, UNCST and other national authorities about early termination of the study, reasons for the termination and their effect on the biological materials in the biobank;
e) Ensure proper documentation of all study records, procedures in collection, processing and transportation of biological samples to the biobank;
f) Put in place a quality assurance system for proper conduct of the study in order to preserve integrity of the biological samples and associated data;
g) Ensure appropriate and timely feedback to the sample donor of the research process and findings.
h) Effective community engagement should be carried out by the researcher before recruitment of specimen donors and continuously thereafter.
i) Have adequate time to implement/ supervise the collection, processing, transportation and storage activities of the biological samples.
j) Take, together with his/her research team, a recognized research ethics course and GCP/GCLP and other relevant training within two years prior to commencement of the study; and thereafter, have a refresher course at least once every two years.

k) Be sufficiently qualified and competent to carry out the research project, and shall, where necessary, have the appropriate professional license to practice.

12.0 GLOSSARY

Anonymization	Description
Biosafety	Technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release
Biosecurity	are measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins
Bio-risk Management	A combinations of biosafety and biosecurity practices.
Biodata	The biodata includes relevant factual information about an sample donor, such as: date of birth, gender, religion, height, complexion, father's name, geographical location etc
Biological databases	This a collection of data on a given specimen that is organized so that its contents can easily be accessed, managed, and updated. They contain information gene function, structure, localization (both cellular and chromosomal), clinical effects of mutations as well as similarities of biological sequences and structures.
Biological material donation	This is material that includes and is not limited to; blood, sputum, saliva, hair, fecal matter, skin that is provided by a sample donor to the researcher or biobank custodian
Communities	This is the environment from which the sample donor is obtained. This includes the persons living with and around the sample donor
Derivatives	This is a new, original product that includes aspects of a preexisting, already copyrighted work
Disaster	This is a serious disruption occurring over a relatively short period of time, affecting the functioning of a community or a society as it causes widespread human, material, economic or environmental loss which exceeds the ability of the affected community or society to cope using its own resources
Gene Bank	This is a type of biorepository which preserve genetic material. For plants, this could be by in vitro storage, freezing cuttings from the plant, or stocking the seeds (e.g. in a seedbank). For animals, this is the freezing of sperm and eggs in zoological freezers until further need
Hazard	This is a something that is dangerous and likely to cause damage.
Publically available	This is information that has been published or broadcast for public consumption, is available on request to the public, is

Anonymization	Description
	accessible on-line or otherwise to the public, is available to the public by subscription or purchase, could be seen or heard by any casual observer,
Pseudonymisation	This is a data management and de-identification procedure by which personally identifiable information fields within a data record are replaced by one or more artificial identifiers, or pseudonyms

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ANNEXES

Annex 1: Checklist for certification of biobanks in Uganda

Part 1: General Information

Biobank Name and Address of Biobank	
Biobank custodian Name	
Biobank custodian telephone number	
Biobank custodian email address	
Name of Inspectors	
Date of Inspection	

Part 2: Checks and comments

Biobank accreditation requirements	Yes	Partial	No	N/A
Manual of Operating procedures				
There is a Manual of Operating Procedures for: a) Quality Manual b) Equipment monitoring, calibration, maintenance and repair; c) Control of Biospecimen collection supplies (Disposables and Reagents. d) Biospecimen Identification and Labelling Conventions				

Biobank accreditation requirements	Yes	Partial	No	N/A
e) Biospecimen collection and processing methods; f) Storage and retrieval; **g)** Shipping and Receiving**;** **h)** Laboratory Tests performed in-house including Biospecimen Quality Control Testing; **i)** Biospecimen Data Collection and Management (Informatics); j) Biosafety; k) Training; l) Security; m) Business plan n) Contingency plan See section 4.0 of the National Policy guidelines for biorepository				
1. There is evidence that all copies of procedures are up to date				
2. Changes in procedures are documented and communicated to staff				
3. There is restricted access to patient information				
Comments and remarks				
Regulatory procedures				
4. **There are regulatory procedures:** a) Environmental Impact assessment report approved by NEMA b) Risk assessment report approved by the Institutional Biosafety committee (IBC) c) Legal entity of the Biobank				
Comments and remarks				

Biobank accreditation requirements	Yes	Partial	No	N/A
Sample handling				
5. The Biobank maintains and tracks temperature monitoring information during transportation				
6. There is a documented chain of custody for the samples collected				
7. Is there quality assurance process for stored specimens?				
8. Is there a specimen identification procedure?				
9. Is there a system for identifying, monitoring and correcting specimen misidentification?				
10. There is documentation of the informed consent status for each bio specimen				
11. There is documentation of sample acceptance and rejection criteria for required specimen by researchers and a corrective action taken if it does not meet researchers' needs				
Comments and remarks				
Storage equipment and space				
12. The Biobank maintains and tracks environmental monitoring information during storage				
13. Is there evidence of a corrective action taken when the environmental conditions are out of range?				
14. Is there an alert system for environmental monitoring system?				
15. The Biobank has adequate storage equipments/capacity				
16. The Biobank storage equipment/space are properly labelled				
Comments and remarks				

Biobank accreditation requirements	Yes	Partial	No	N/A
Sample management				
17. The biobank captures pre-analytical variables that could impact sample integrity				
18. There are quality checks to ensure accuracy and timeliness of pre-analytic data capture				
Comments and remarks				
Sample processing				
19. The laboratory followed SOPs for activities including supplier qualification, procurement, testing				
20. Records were appropriate for the qualification and calibration of the laboratory equipment and instruments.				
21. Equipment log books were maintained				
22. Current normal ranges and values of the measures were specified.				
23. Procedures were in place for the receipt, storage and handling of certified reference materials, chemicals and reagents.				
24. No expired stock was used, and storage conditions were maintained.				
25. Procedures were followed for handling hazardous materials e.g. live viruses				
26. Test methods were verified or validated as appropriate				
Comments and remarks				
Instruments and Equipment				
27. All instruments and equipment are verified upon installation and after major maintenance procedures				
28. Preventive maintenance is performed as per relevant SOPs				

Biobank accreditation requirements	Yes	Partial	No	N/A
29. There is an Equipment inventory in place				
30. The Biobank has an Equipment service schedule				
31. The Biobank has service contracts/ agreements with Engineering companies				
32. Is there a mechanism of power back up in case of power outages (UPS, Generators, Solar systems)?				
Comments and remarks				
Biobank inventory management system				
33. Biobank has an inventory management system				
34. The Inventory management system is supported by the server				
35. The Inventory management system has safety features incorporated				
36. The Inventory management system has been verified for suitability of its intended purpose				
37. There are access levels assigned for the Inventory management system				
38. Biobank has quality checks of the location of samples & corrective action taken for those that cannot be located.				
Comments and remarks				
27. Is there evidence of proficient training of personnel in the Biobank?				
Does the Biobank store highly infectious biological materials?				
Is the Biobank accredited (ISO 20387: 2018, CAP, etc.)?				

Biobank accreditation requirements	Yes	Partial	No	N/A
Does the Biobank have a sustainability plan?				
Does the Biobank have a contingency plan?				
Are there relevant sample processing procedures with Quality control measures?				
Score (Yes- 1 points; Partial-0.5 points; No=0 points Per checklist question)				
Total Score (Yes & Partial only)				
Overall comments				

Annex 2: Risk assessment Checklist for biobanks in Uganda

BIOLOGICAL RISK ASSESSMENT CHECKLIST FOR BIOBANK

Health Facility
Name……District……Region…….

Ownership……Implementing Partner…….

Date: ……Assessor(s)……

Audit Scoring Criteria

- For each of the sections listed below, responses to all questions must be, "Yes," or "No," or "Partial" (where applicable).
- Indicate "Yes" only when all elements are satisfactorily present. Evidence of compliance should be present in a tangible and/or observable form, e.g., written material, physical items, etc.
- If the site has a written procedure but no evidence is found of consistent implementation or if there is evidence of non-adherence, then the element should be scored as "Partial."
- If the element (e.g., SOP or job aides) requires a written procedure but it is not available at the site, then the element should be scored as "No."
- When marking "Partial" or "No," provide comments for each "Partial" or "No" response.

Recombinant or Synthetic Nucleic Acids Yes ☐ No ☐

1. Select Agents Yes ☐ No ☐
2. Research animals Yes No
3. Chemical Hazards Yes No
4. Radiation Hazards Yes No
5. Dual Use Research of Concern (DURC) Yes No
6. Human Blood and Body Fluids Yes No
7. Use of High Containment Laboratories (BSL3 [E] and BSL4) Yes No
8. Import/Export or transfer of Infectious Material Yes No

Microorganisms

Risk groups	**Genus and Species**	**Strains**

Parameters to Assess		Up to standard		Comments
A. Biological Materials	Y	P	N	
1. Is the material a Select Agent?				
2. Is the biobank in possession of Tier 1 select agents and toxins?				
3. If toxin, list:				
a) LD50				
b) Name				
c) Source organism				
4. Is the material cell Culture? If yes:				
a) Provide Name ….....				
b) Origin…….				
5. Clinical Specimens?				
a) If yes, name specimen matrix (e.g. blood, sputum)……..				
6. Environmental Specimens?				
a) Sample matrix (e.g. soil, water)				
7. Is the material received from outside source? 8. What is the geographical origin of the material?				
B. Documentations				
9. Are there relevant guidelines, SOPs, or working instructions related to biobank available? (Check applicable standard for required documents)				
10. As per the license, Is there documentation for: a) procedures for inactivation of live biological agents? b) attenuated biological agents? c) Handling of live biological agents?				

Parameters to Assess		Up to standard		Comments
11. Does the biobank have inventory management policy of select biological agents?				
12. Does the biobank have a policy on the transfer of valuable/select biological materials?				
13. Does the biobank maintain and update inventory records?				
14. Does the inventory system in the biobank include detailed information regarding the location of the biological agents				
15. Are there biohazard signage at the entrance of Biobanks and storage spaces to indicate presence of biological agents without revealing the organisms?				
C. Risk Evaluations				
16. What is the infectious Dose of the biological materials?				
17. What is the case Fatality Rate?				
18. What is the incubation period?				
19. Is the biological agent airborne?				
20. Is the agent zoonotic?				
21. Vector borne?				
22. What is the Stability of the agent in the environment?				
23. Routes of transmission (check all that apply):				
a) Inhalation				
b) mucosal membrane exposure				
c) Ingestion				

Parameters to Assess		Up to standard		Comments
d) percutaneous (e.g. animal/insect bite/needle stick)				
24. Additional information: (e.g., History of (Laboratory Acquired Infection), symptoms/severity of infection)				
25. Does the biological material generate Aerosol?				
26. Does material procedures involve use of equipment below: (check all that apply): a) Centrifuge/micro-centrifuge b) Sonicator c) Aerosolization chamber d) Homogenizer e) Shaker f) Vacuum/aspirating equipment g) Cell sorters h) Pipettors i) Sharps(e.g. needles, scalpels) j) Grinding equipment k) Vortex l) Other _____				
m) Does it require inactivation before transfer?				
27. What is the Severity of the biological agent? (Negligible, Minor, Serious, Critical or Catastrophic (Virulence versus severity and pathogenicity)				
28. What is the probability of infection? (Improbable ,Remote, Occasional, Probable, Frequent				
29. What quantity is being stored? (Large Scale 10 L or greater)?				
D. Occupational Health				
30. Is there local /onsite availability of effective prophylaxis?				

Parameters to Assess		Up to standard		Comments
31. Is there local /onsite availability of effective Post Exposure prophylaxis?				
a) If yes, specify				
32. Are first-aid boxes provided at strategic locations?				
33. Is the premises maintained in a clean and orderly way?				
34. Is medical evaluation performed for workers who may be exposed to pathogens at time of employment?				
35. Is medical evaluation performed for workers post employment?				
36. Does the institution have a health policy including a provision for vaccination in place?				
37. If yes, is the policy based on a risk assessment of the hazards workers,contractors, and visitors will be exposed to?				
Personnel Training				
38. Is there a list of all trainings biobank staff received prior to working with agent(s)/material(s)?				
39. Is there a list of continuous refresher trainings?				
40. Do the trainings include specifics of: a) Equipment use				
b) Procedures performed				
c) Required biosafety, biosecurity and other safety practices?				
d) Shipments of infectious substances?				
e)GCLP training				
f) Others , specify				

Parameters to Assess		Up to standard		Comments
41. Is there a continuous training program planned for all personnel?				
Equipment (Primary barriers)				
42. Are relevant equipment for biobank available?				
43. Are the required engineering/mechanical controls (Primary barriers) in place? BSC, Ventilated animal cage, rack system, Glove box, Sealed centrifuge rotors, Safety centrifuge cups, Chemical fume hood , Other…….				
44. Are all equipment certified for safe for use?				
45. 2. Are procedures available for decontaminating equipment prior to maintenance?				
46. Are equipment maintenance records available and up to date?				
Facility (Secondary barriers)				
47. Does the biobank facility meets the national/international standards?				
48. Is there access control restriction?				
49. Does the management enforce an access control policy?				
50. Do different areas of the biobank have different levels of security? Guard force, lockable doors, Biometrics, Magnetic cards)				
51. Is the biobank located in an area with minimum traffic from unauthorized personnel?				
52. Are hands free hand washing sink and safety showers available?				

Parameters to Assess		Up to standard		Comments
Personal Protective Equipment (PPE):				
53. Are there appropriate PPEs available for use in the biobank? Please				
54. Are the follow PPEs available (Tick all that apply): a) Lab coats and aprons b) Latex Gloves c) Safety glasses or goggles d) N-95 respirator				
e) Others, specify…….				
Emergency response				
55. Does the biobank have an emergency response plan to effectively respond and control biological emergencies?				
56. If yes, does the plan cover: a) Management of biological spills?				
b) Emergency drills or exercises?				

Overall Project Risk: Low (minimal) ☐ Moderate ☐ High ☐