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MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

MUHAS BIOREPOSITORY POLICY AND GUIDELINES

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LIST OF ABBREVIATIONS

DNA	Deoxyribonucleic acid
DTA	Data Transfer Agreement
IRB	Institutional Review Board
MBEC	MUHAS Biorepository Executive Committee
MTA	Material Transfer Agreement
MUHAS	Muhimbili University of Health and Allied Sciences
QMS	Quality Management System
REC	Research Ethics Committee
RNA	Ribonucleic acid

1.0 INTRODUCTION

1.1. Background

Muhimbili University of Health and Allied Sciences (MUHAS) conducts a variety of health-related research including basic biomedical research, epidemiologic surveys, clinical trials and others, which require the use of biological samples. Extensive data is generated from such studies. There is an increasing demand and recognized value of biological samples with associated clinical, biomedical and public health data that has led to the establishment of biorepositories in many countries in the world. Despite the expansion of research projects and in particular those involving biological samples, there is no centralized biorepository for research samples and research data at MUHAS. The majority of investigators at the University operate in silos, each having their own mini bio-collection facilities while others have no means to store or process samples.

In line with quality practice, the collection, processing and storage, of research samples and data need to be carefully coordinated and properly organized. To this end, the MUHAS Senate, during its 57th meeting held on 14th November 2018 approved a proposal for the establishment of a University Biorepository that will be responsible for the collection, processing, storage and management of biospecimens and biodata. Several issues need to be considered carefully when establishing and maintaining repositories. These issues include what samples to collect; method of collection, transport, and storage; legal and ethical matters relating to sample collection and use; durability of analytes of interest in stored specimens; specimen quality; maintenance and sustainability of the repository.

Some repositories are created and maintained explicitly for research purposes. Others are created and maintained for non-research purposes, but may be accessed for research uses. Such repositories must conform to applicable regulations and policies, as well as the decisions made by research participants.

The purpose of the MUHAS biorepository Policy and Guidelines is to ensure that human biospecimens and/or biodata to be used for or generated from research are responsibly collected, stored, distributed and utilized, and to protect the rights of individuals who have donated human biospecimens or data to repositories. During the conduct of research, collection and management of biological samples shall be governed by the research study and not the biorepository guidelines.

The scope is to ensure that samples are kept safe and in line with the ethical approvals beyond the end of the original research.

There is a concerted effort at MUHAS to create a strong and reputable health research infrastructure that will allow the University to achieve her vision. In anticipation of a strategic national approach to standardize biorepositories, MUHAS has recognized the need to develop policy and guidelines to standardize the collection, processing and storage of biological materials and biodata across the different departments at the University.

1.2. Scope

These guidelines are intended to provide general guidance to standardized procedures for the collection, transporting, processing, storage, and sharing of biological materials (including blood, urine, DNA, RNA cells, and tissue) which can be used across different departments at MUHAS to ensure sample uniformity, quality and integrity. The guidelines will also provide guidance on the procedures to be used when scientists at MUHAS, students, and collaborators request and use the stored samples. These guidelines apply to human subject research repositories established for the purpose of storing data and/or human biospecimens for future research purposes. These guidelines do not apply to biodata and biospecimens that are collected and stored solely as part of routine clinical care or hospital procedures.

1.3. Definitions

The following definitions apply to this document:

1.3.1. Biospecimen

This term encompasses a full range of human specimen types including: Sub-cellular components such as DNA or RNA; cells or tissues from any part of the human body; organs such as liver, bladder, kidney, heart, placenta; gametes (ova and sperm); embryos and fetal tissues; stem cells; breast milk; bodily products such as teeth, hair, nail clippings, sweat, urine, feces; blood and blood fractions: plasma, serum, peripheral blood mononuclear cells (PBMC), red blood cells; saliva and buccal cells.

1.3.2. Biorepository

The storage site or mechanism by which human biospecimens are collected from various sources and stored or archived in a form designed for ease and speed of aggregation, search, and retrieval. Biorepositories include data banks, tissue banks, and registries that collect, store and distribute human tissue, specimens and/or data for use in future research projects.

1.3.3. Biobank

The Organization for Economic Co-Operation and Development (OECD)[1] defines a biobank as a collection of biological material and the associated data and information stored in an organized system, for a population or a large subset of a population. The terminologies biorepository and biobank are often used interchangeably.

1.3.4. Donor

A donor is an individual from whom a human biospecimen is derived, with their consent.

2.0 GOAL AND OBJECTIVES OF THE MUHAS BIOREPOSITORY POLICY AND GUIDELINES

2.1. Goal

The overall goal of the MUHAS Biorepository Policy Guidelines is to serve as a framework to guide the establishment, maintenance and use of a Biorepository for biospecimens and biodata collected by MUHAS faculty and students in their various research activities.

2.2. Objectives

The objectives of the MUHAS Biorepository Policy and Guidelines document are to:

i. Provide guidelines that will facilitate establishment of a state-of-the-art biorepository for the receipt, processing, storage, and distribution of biospecimens and biodata for use in health research.

[1] OECD. Guidelines on human biobanks and genetic research databases. 2009.
available at: http://www.oecd.org/sti/biotech/44054609.pdf

ii. Establish guidelines for proper maintenance of storage facilities for biospecimens and biodata.
iii. Provide guidance on proper use of stored biospecimens and biodata emanating from research conducted at MUHAS or officially acquired from collaborating institutions.
iv. Harmonize collection and storage of biospecimens and biodata in the various repositories in the University departments and research units.
v. Establish a versatile laboratory information management system for the MUHAS Biorepository
vi. Harmonize biodata use, request, and sharing with MUHAS students, researchers, and collaborators in line with other MUHAS and National data sharing policies
vii. Establish guidelines for adption of best practices from globally recognised biorepositories
viii. Build capacity for local expertise in biorepository operations

3.0 BIOREPOSITORY POLICY AND GUIDELINES

3.1 Custodianship of MUHAS Biorepository

There are several scattered mini bio-collection facilities at MUHAS that are operated by various research projects and departments. Custody of these mini-biorepositories is only evident the specific projects are operating but when they are completed the custodianship is left undefined leading to loss of research opportunities, wasted resources, and lack of research continuum. To ensure custody of biospecimens and biodata collected by researchers and students at MUHAS, the MUHAS Biorepository shall:

a) Maintain custodianship of all human biospecimens and biodata that are placed into the MUHAS biorepository after the end of research programs.
b) Ensure that if an investigator places human biospecimens into the MUHAS biorepository and subsequently leaves MUHAS, the human biospecimens remain the property of the MUHAS biorepository and may not be taken from the repository without permission from the Vice Chancellor. When samples and data are collected in the hospital as part of a research study, but the samples are used in a research project in the university, then approval for the study by both parties must be ensured.
c) Ensure continuous utilization of biodata beyond the specific project life by attracting new researchers and interested collaborations.

d) Ensure quality and worthiness of biodata for extended time beyond the project life
e) Ensure protection of human subjects whom the biodata was obtained from.

3.2 Ethical matters relating to biospecimen collection and use

Ethical issues are commonly present in many aspects of biobanking. Since biobanks deal with human samples, invading an individual autonomy or limiting self-control, provokes a number of ethical issues. The main ethical issues encountered includes: the informed consent, confidentiality, secondary use of samples and data over time, and return of results. Standard practice dictates that consent or waiver of consent is required for the collection, storage and future use of data/human biospecimens entered into an institutional biorepository. This practice may not be followed by some projects. In line with the recommended standard practice the MUHAS Biorepository shall ensure that:

a) It adheres to the World Medical Association declaration of Taipei on ethical considerations regarding health databases and biobanks[2].
b) Specimens that will be stored in a biorepository for future use have informed consent documents specific to biorepository storage.
c) Investigators conducting research that may later be of value for additional studies should address the possibility of submitting the data/human biospecimens to the MUHAS Biorepository in the initial consent.
d) Since it is often unknown what research will be performed with stored samples, donors may retain the right to withdraw authorization to use their tissue samples in the future.
e) A waiver of the requirement to obtain consent may be granted by MUHAS or other nationally recognized research Ethics Committee/IRB if all of the requirements for waiver are met.
f) Mechanisms for assuring confidentiality, privacy, and data protection should be put in place, because they are fundamental human rights which need to be protected at all time

[2] WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks. *Adopted by the 53rd WMA General Assembly, Washington, DC, , USA, October 2002, and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016.*

3.3 Storage and inventory

Proper storage and documentation of biospecimens and biodata are critical to the operation of an effective and quality biorepository. Currently at MUHAS storage of biospecimens and biodata is largely individualized to specific research projects. Because of this, it is not easy to track and ascertain the quality of stored biospecimens and data over time especially given the situation of frequent power outages and virus attack of computer programs. Establishment of a properly organized and managed centralized university biorepository would resolve these challenges. The MUHAS Biorepository shall:

a) Encourage all researchers to register and deposit their research specimens and data in the MUHAS Biorepository.
b) Require all researchers to provide all necessary information about the biospecimens and biodata deposited in the central biorepository. This includes the original tools accompanied with the biodata collected, demographic and clinical data that can be of future use.
c) Adopt laboratory information management system with demonstrated versatility in functions.
d) Put in place a computer-based inventory system to track the location and pertinent annotation of every specimen in the repository. The system should also track significant events such as sample thaws, receipt and/or processing delays, destruction, processing, transfer of the sample within the repository, and specimen distribution and return (if applicable).
e) Have trained personnel to manage the biodata, biorepository equipment, and ensuring safety and security of the data stored.
f) Clear guidelines and standard operating procedure (SoP) guiding harnessing data, storage, and record keeping.

3.4 Access to biospecimens and biodata at MUHAS Biorepository

Given the valuable use of stored biospecimens and biodata, it is essential to put in place mechanisms to safeguard their security. Access to the MUHAS Biorepository sample/data storage and inventory system should therefore be tightly controlled. Therefore:

a) The MUHAS Biorepository Executive Committee will oversee all access to repository of human biospecimens and data, as well as procedures that offer qualified investigators the opportunity to access the repository.
b) Access to biological samples and their associated data shall be tightly controlled in order to ensure the security and integrity of the biospecimens.
c) Access to a given sample shall be limited to authorized researchers with sample custody and designated biorepository staff.
d) Detailed audit trails for samples shall be maintained, including access logs compliant with MUHAS standards for electronic records and signatures.
e) Quarterly report of the biodata collected will be submitted to the Senate Research and Publications Committee (SRPC) for notification.

3.5 Implementation of a quality management system

The purpose of MUHAS Biorepository is to collect, transport, process, and store biological samples and their associated data using a procedure that is well standardized and that meets acceptable quality criteria and is provided in compliance with all necessary ethical, regulatory and statutory obligations. Therefore, it is prudent to put in place a Quality Management System (QMS) that includes Quality Assurance (QA) and Quality Control (QC) programs for the biorepository. Accordingly, the QMS for the MUHAS Biorepository should ensure that:

a) A well-trained staff should be assigned to ensure repository staff are trained to comply with quality standards and provide regular guidance and instruction to all personnel who should have a collective responsibility for assuring compliance with SOPs, policies and regulatory requirements
b) A Quality Manual is in place which has a clear quality statement and describes the roles and responsibilities of staff within and connected to the MUHAS Biorepository's operations and infrastructures in compliance with regulatory, health and safety obligations. The Quality Manual may reference all SOPs which are required to ensure that QA/QC objectives of the MUHAS Biorepository are fulfilled.

c) An appropriate Quality Standard {e.g. The International Organization for Standardization (ISO) ISO9001[3]; the Clinical and Laboratory Standards Institute (CLSI)[4]; and the Current Good Practices (cGP)} should be selected for use in order to allow for confidence and reproducibility in the MUHAS Biorepository practices.
d) Audits should be performed on a regular (quarterly, semi-annually or annually) basis or in response to a non-compliant incident, accident or a change/deviation in procedure.

3.6 Requesting data/human biospecimens from MUHAS Biorepository

Proper procedures need to be followed in the course of sharing biospecimens and biodata in order to avoid their inappropriate access and use. Accordingly, requesting data/human biospecimens from MUHAS Biorepository shall observe that:

a) All data emanating from MUHAS research shall belong to MUHAS.
b) Data Transfer Agreement (DTA) and Materials Transfer Agreement (MTA) must be executed between MUHAS and the receiving institution before an investigator outside of MUHAS receives data or human biospecimens from the MUHAS Biorepository.
c) For anonymous or coded data, a request for determination from the IRB must be submitted.
d) Request of the biodata shall be authorized by the Director of Research and Publications and Chair of the Senate upon satisfying the sharing requirements.

3.7 Cost management of the MUHAS Biorepository

Specimen collection, processing, storage and distribution are financially very demanding. It is important for a biorepository to develop a financial plan for the expected lifetime of the specimen storage and handling activities. Plans should be reviewed on a regular basis and adjusted as needed. In order for the MUHAS Biorepository to operate effectively, it is critical that it has sufficient financial support to allow for proper functioning. Use of biospecimens and biodata to generate funds exists in several institutions in the world. This practice is prone to abuse and conflicts if not properly managed and regulated. In order to ensure that any commercial use of biospecimens and data stored in the MUHAS Biorepository does not cause problems it is directed that:

[3] ISO 9000 Quality Management Systems standards
[4] CLSI: Clinical And Laboratory Standards Institute standards

a) MUHAS Biorepository should develop a business plan based on its objectives and based on known and estimated costs.
b) Human subject specimens and data stored in the MUHAS Biorepository must not be sold for profit.
c) MUHAS Biorepository may be permitted to recover the costs of providing human biospecimens (including collection, processing, storage and distribution) provided that such costs are established in accordance with this policy guideline.

3.8 Terminating storage of samples in the MUHAS Biorepository

When there is no intent by researchers to continue to maintain samples in the central University Biorepository for future research, or if the data/human biospecimens are being transferred to another repository, maintenance of the samples/data in the repository should be terminated. In order to ensure a smooth process of termination:

a) The termination request must include the reasons for termination or transfer, disposition of the data and human biospecimens.
b) The request must include details on the secure transfer, donation of human biospecimens or data as the case may be.
c) The University shall continue to store the samples provided they are of worthy quality

3.9 Destruction of biospecimens and biodata stored in the MUHAS Biorepository

Unless there is a good reason, ethical approval for storage should be limited to five years after which it is MUHAS responsibility to destroy the samples. Circumstances may also arise that may lead to decisions to destroy biospecimens and biodata. In such cases, the applicable policy for destroying biospecimens and their associated biodata will be used. The following reasons may be considered for destroying samples:

a) All identifying information has been lost.
b) Samples have been compromised by equipment failure.
c) Samples have experienced freeze-thaw cycles such that the contents have been spoiled.
d) Primary custodian has left the organization and key information regarding the specimens has been lost.
e) Required to be destroyed by consent, study design or regulation.
f) New information obtained about potential biohazards associated with the specimen.

g) When extra specimens were collected or stored in excess of the Investigator's protocol.
h) Lack of use.

MUHAS should ensure that destruction and/ or disposal of biospecimens and biodata is in line with other national and institutional policies and guidelines.

3.10 Transparent Governance structure

For efficient delivery of its responsibilities the MUHAS Biorepository should have a structure of committees and appropriately qualified personnel in relevant roles to oversee its governance. The Biorepository personnel should have clear roles, reporting lines and accountability, with documented levels of authority and responsibility associated with each role. An organizational chart of the governance structure should be made which is proposed to have the following committees:

a) The MUHAS Biorepository Executive Committee (MBEC) shall have the overall management responsibility. It will also be responsible for defining strategic objectives, monitoring progress, revising and/or adopting policies, developing a communications strategy and conducting annual review meeting to consider the QMS.
b) Laboratory Safety and Biosecurity Committee shall advise MBEC on issues related to Laboratory safety, biosafety, and security issues
c) Ethics Oversight Committee which shall be responsible for advising the MBEC on strategy, developments, and procedures relating to ethical oversight, including legal and policy issues.
d) Scientific Advisory Committee, which will provide scientific feedback to the MBEC, advise on scientific strategy and current developments.
e) Operations Committee whose role will be to support the executive committee by providing expertise in all aspects of biobanking operations, quality management and data and sample access.

3.11 Sustainability plan

To ensure continued operations without compromising quality, specific plans for five years and beyond should be developed to anticipate long term costs and revenues. MUHAS Biorepository should therefore develop and implement sustainability plan that:

a) Ensures that core activities are embedded within the University research landscape

b) Provide regular budget allocation
c) Provide institutional support
d) Establish effective cost recovery program
e) Encourage soliciting supplementary funding from grants, and research support
f) Establish membership of Biorepository website networks to provide visibility and promotion of quality in all aspects of biobanking.

4.0 DOCUMENT MANAGEMENT AND CONTROL

4.1 Responsible Office

Office for the Directorate of Research and Publications

4.2 Status of the Policy Guidelines

These are new Policy Guidelines.

4.3 Key Stakeholders

The main stakeholders of these policy guidelines are:

a) All MUHAS academic staff
b) Heads of Academic Departments
c) Deans and Directors
d) Student researchers
e) MUHAS research collaborators
f) Associated teaching hospitals

4.4 Approval and Commencement

The MUHAS Biorepository Policy Guidelines were approved by the University Council at its 57th meeting held on 7th August 2020.

4.5 Related Policies

a) MUHAS Research Policy
b) MUHAS Research Agenda
c) Data sharing policy

d) Policy and guidelines on retention and disposal of information resources and Research materials.

4.6 Related Documents

a) Biorepository SOP
b) Biorepository business plan
c) Forms and reporting tools

4.7 Next Review Date

These policy guidelines are intended to be evolutionary in nature and will be reviewed after every three years and revised in light of experience gained and developments in best practice for management of biorepositories.

4.8 Owner of the MUHAS Biorepository Policy Guidelines

The University Council shall own the MUHAS Biorepository Policy Guidelines.

4.9 Contact Person

Any queries regarding the content of these Policy Guidelines or need for further clarification should be directed to:

The DVC-ARC,
Muhimbili University of Health and Allied Sciences,
P.O. Box 65001,
9 United Nations Road, Upanga West, Dar es Salaam, Tanzania.

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