INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

MAKERERE UNIVERSITY
COLLEGE OF HEALTH SCIENCES

POLICY

TITLE: GOVERNANCE POLICY	PAGE 1 of 9

POL #: **IBRH$_3$AU-POL-001.1**	Effective Date**: 06/01/2014**	Next Rev: **DEC 2014**
Prepared by:	Reviewed by:	Approved by:
(Signature & Date) NAME: Musinguzi Henry TITLE: Lab Manager	(Signature & Date) NAME: Dr. Samuel kyobe TITLE: Coordinator	(Signature & Date) NAME: Prof Moses Joloba TITLE: Principal Investigator

VALIDATION AND RETIREMENT

	NAME	DATE
Validated by:		
Retired by:		

ACKNOWLEDGEMENT OF READING AND UNDERSTANDING

I have received and understood the training on this Policy. If I have not understood the training I have asked the trainer to retrain me to ensure that I completely understand all the requirements.

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1. INTRODUCTION

Human biological specimens have been the basis of pathological inquiry for a very long time. However, with the advancement of molecular biology and genetics insights, there has been a significant increase in the demand for properly prepared and clinically annotated biospecimens that yield valuable insights into the mechanisms and pathways of human disease. Research on biospecimens has not been always formally regulated or extensively harmonized by governing agencies. Existing guidelines for the protection of human subjects in clinical research continue to provide oversight for the use of biospecimen in basic and translational research. These guidelines have been applied to issues related to collection, processing, storage, retrieval, transfer and disposal of biospecimens and associated data. Of the many institutions now involved in biobanking, few have developed written policies, documents or protocols defining the rights and obligations of the biorepository or the participants. In that biospecimen are becoming a valuable and irreplaceable resource, and society has a growing interest and investment in the advancement of medical knowledge, consistent and coherent governance should encompass biorepositing

2. PURPOSE

The Integrated Biorepository of H3Africa Uganda is committed to the highest standards and practices in the reception, processing, storage, retrieval and distribution of human biospecimens for research purposes. The purpose of this IBRH3AU governance policy is to outline general principles that shall be implemented for good governance of the IBRH3AU biorepository to ensure that the interests of the patient and all other stakeholders are safeguarded.

3. SCOPE

This policy applies to major governance considerations that relate to the conduct of the Integrated Biorepository of H3Africa Uganda. The following principles apply to all members of IBRH3AU and a commitment to adopt a standard operating procedure (SOP) on governance.

4. RESPONSIBILITY

This policy applies to IBRH3AU management and personnel involved in all aspects of the IBRH3AU program

5. POLICIES

IBRH3AU management and personnel shall be aware that appropriate governance principles reassure biorepository stakeholders that the biorepository has processes in place to protect their interests in the use of their biospecimen and accompanying data. The following principles shall guide IBRH3AU in establishing good governance mechanisms.

5.1 Declaration of Purpose

To ensure that the Integrated Biorepository of H3Africa Uganda is governed by the overarching principles of transparency and accountability, the biorepository shall have a clearly defined purpose/mission (i.e., primary focus of research it supports in consonance with H3Africa consortium) operational scope and this shall be made publicly available.

5.2 External Governance and Accountability

Compliance with the laws, codes, agency and institutional requirements that exist in Uganda is required. These external governance elements include:

Uganda National Council of Science and Technology regulations governing the reception, processing, storage, retrieval, distribution and destruction of biospecimen and associated data for research purposes

Uganda professional codes of conduct that govern the various professionals that will be involved in operations of the Integrated Biorepository of H3Africa Uganda

Other requirements from funding agencies/organizations/foundations and host institutions comprise additional external accountability factors (e.g. annual reporting, creation of advisory and scientific boards) that shall be incorporated into the internal governance of the biorepository.

5.3 Internal Governance and Accountability

An organizational structure shall be clearly defined to encompass at a minimum the following roles and elements; leadership, management of operations, contact and access processes. This organizational structure, including identification of individual(s) who shall perform these roles shall be accepted by all those who assume a defined role and is known to all staff, and also a matter of public record.

The biorepository can choose to assign the different roles within its structure to individual(s), or committees and this shall be based on factors relating to size of the biorepository, stakeholders, and the number of anticipated users of the biorepository.

This means that as the biorepository grows more individuals or committees may be formed

This internal governance structure shall include components that perform the following roles:

5.3.1 **Leader/Director/PI Role**:

This component is responsible overall for;

5.3.1.1 Biorepository staff,

5.3.1.2 Daily operations of the biorepository

5.3.1.3 Partnership activities and funding

5.3.1.4 Reporting or accountability to institutions or agencies.

5.3.2 **Coordinator**:

5.3.2.1 Shall ensure the quality, safety and traceability of stored data and biospecimens

5.3.2.2 Monitor technical and organizational biorepository procedures

5.3.2.3 Ensure compliance with safety regulations

5.3.2.4 Ensure that resources and infrastructures are adequately stocked

5.3.2.5 Supervise infrastructure maintenance and ensure proper operation and handle requests to access,

5.3.2.6 Provide information about the biorepository in consultation with the PI

5.3.2.7 Rectify, cancel and oppose data and data use in compliance with current legislation in consultation with BAC/DAC.

5.3.2.8 Reports to the PI/Scientific director

5.3.3 **Administrator**

5.3.3.1 Supervise and justify projects

5.3.3.2 Manage biospecimen requests

5.3.3.3 Coordinator administrative tasks

5.3.3.4 Coordinator information coverage

5.3.3.5 Keep orderly files of internal biorepository documents

5.3.3.6 Provide support to quality committee.

5.3.3.7 Reports the coordinator

5.3.4 **Biorepository Lab manager:**

5.3.4.1 Shall be in charge of the IBRH3AU biorepository

5.3.4.2 Shall be responsible for representing the biorepository in proceedings and interactions with other stakeholders

5.3.4.3 Ensuring the quality, safety and traceability of data and biospecimens stored at the biorepository

5.3.4.4 Supervising activities carried out at the biorepository and ensure compliance with safety regulations.
5.3.4.5 Responsible for the development of any new techniques.
5.3.4.6 Determine the need for new features, equipment and facilities.
5.3.4.7 To identify user requirements, determine biorepository personnel training/staffing requirements and to sit on the quality committee and provide support to the quality Manager.
5.3.4.8 Reports to the coordinator.

5.3.5 **Database officer**
5.3.5.1 Shall administer the biorepository database and website
5.3.5.2 Coordinate biospecimen accessioning and shipment
5.3.5.3 Monitor biospecimen inventory
5.3.5.4 Archive management

5.3.6 **Quality Officer**
5.3.6.1 Shall direct and coordinate the development and maintenance of the Quality Management Systems.
5.3.6.2 Manage and conduct regular and focused technical audits of laboratory processes and staff training.
5.3.6.3 Evaluate quality control data to determine trends and issues.
5.3.6.4 Report audit results and trends to other members of the management committee.
5.3.6.5 Direct development of corrective action plans to address any non-conformance issues identified through quality control audits, customer complaint investigation, or accident investigation.
5.3.6.6 Provide training and guidance on corrective actions and ensure plans are implemented, followed and effective.
5.3.6.7 Review, approve and maintain the SOPS for current and new testing procedures.
5.3.6.8 Collaborate with other management committee members, plan the validation process for new certified procedures and ensure they conform to standard requirements specified by international best practices.
5.3.6.9 Evaluate completed validations for scientific validity
5.3.6.10 Oversee the equipment maintenance process required in the Quality Management Plan.
5.3.6.11 Provide technical guidance in creating, maintaining and auditing manual and electronic monitoring systems for the proper maintenance of equipment in accordance with the equipment manufacturers.
5.3.6.12 Guide and control the document control process for the biorepository ,

5.3.6.13 Provide direction on proper identification, filling, retrieval and archival processes in accordance with the quality plan and accrediting agencies.

5.3.6.14 Provide training on the biorepository's Quality Policy Statement, Safety Plan and Quality System Essentials to all biorepository staff.

5.3.7 **Risk Officer**

5.3.7.1 Shall serve as a certification officer for regulatory programs

5.3.7.2 Coordinate biorepository functions such as;

5.3.7.3 Risk management

5.3.7.4 Emergency response

5.3.7.5 Health and safety administration

In addition to the required roles listed above, the governance structure may also include other roles, performed by individual(s) with the following additional components:

5.3.8 Public/community/Participant Advisory Role: This role provides advice to the biorepository on all aspects of the biorepository, with specific emphasis on public, community concerns.

5.3.9 Ethics Advisory Role: This role provides advice and if required, oversight in the areas of law, ethics and the public's perception of the biorepository.

5.3.10 Oversight of Access Role: This component oversees the processes that govern research access and utilization of the biospecimens and data in the biorepository.

5.3.11 Scientific Advisory Role: The role provides advice to the biorepository on the scientific plan for the biorepository.

5.4 Access to the Biorepository

IBRH3AU commits to strive with the H3Africa consortium to make materials nationally or internationally available where possible to achieve harmonization of standards and operations. The principles and processes relating to access and release include the following:

5.4.1 Biospecimens are accessible through a transparent access processes relevant to and independently approved projects that have also passed ethical review.

5.4.2 Provide publicly accessible information on the biorepository.

5.4.3 Provide publically accessible information around how to contact and apply for access.

5.4.4 Provide publically accessible information on priorities for determining access and release.

5.4.5 Entertain and respond with a decision to all reasonable requests for access.

5.4.6 Provide information on their criteria and review processes, as provided in the relevant IBRH3AU policy.

5.4.7 Shall have the option, if supplies are adequate, of making biospecimens available to commercially supported projects that meet scientific and ethical criteria, on a full cost-recovery or similar basis.

***For details on biospecimen and data access refer to**:*
Biospecimen access and release procedures
Data access and release procedures

6 ATTACHMENTS

For management and governance structure refer to the links below

http://www.ibru.mak.ac.ug/management/index.php

http://www.ibru.mak.ac.ug/management/profile.php

7 REVISION HISTORY

Revision No	Effective Date	Description of Changes Made from Preceding Revision	Approved by/ Date

ANNEX 1: DOCUMENTATION OF SUGGESTED CHANGES TO THIS SOP

CLAUSE	SUGGESTION	BY	DATE