INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

MAKERERE UNIVERSITY
COLLEGE OF HEALTH SCIENCES
POLICY

TITLE: **MATERIAL HANDLING POLICY**		**PAGE 1 of 7**
POL #: **IBRH$_3$AU-POL-009.1**	Effective Date: **06/01/2014**	Next Rev: **DEC 2015**
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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

Translational research, using advances in molecular biology, archived biospecimen and annotated data is pursued to aid in the elucidation of the disease process and discovery of new diagnostic and treatment modalities. A collection of stored and well-annotated biospecimens is a valuable resource, important to the research process and the value accompanying data is a determinant of value. The goal of the Integrated Biorepository of H3Africa Uganda is to standardize procedures for handling biospecimens, thus ensuring that the quality and integrity of the collection is consistently maintained at a high level.

2 PURPOSE

The purpose of this Material handling policy is to outline general principles that shall be used to ensure that biospecimens and accompanying data are handled and stored in a manner sensitive to the rights of the participant, responsible to the safety of biorepository personnel and protective of the quality and integrity of the collection.

3 SCOPE

This policy applies to the operational and practical considerations that arise in the process of receiving, handling, processing, storing, retrieval and distribution of biospecimen. The policy intends to ensure that the goals of H3Africa consortium are met and that the quality and value of the collection is maintained.

4 RESPONSIBILITY

It's the responsibility of IBRH3AU biorepository personnel involved in all operations of the biorepository. In particular, it applies to those personnel involved in receiving, processing, handling, storing, retrieving and distributing biospecimen.

5 POLICIES

The use of biospecimen and accompanying data is critical for medical research. The public and other stakeholders should have confidence that the biorepository and researchers will use and handle such biospecimen with sensitivity, responsibility and concern for maintaining the value of the collection. The following principles shall guide the IBRH3AU in receiving, processing, storing, retrieving and distributing biospecimens.

5.1 Material handling – General Considerations

IBRH3AU aims to provide users of the biorepository with standardized, high quality biological biospecimen that are readily accessible for their research needs.

5.1.1 To meet the needs of the users, biospecimen shall be received, processed, stored, retrieved and distributed in a manner that optimally maintains the biospecimen and the molecular integrity associated with them.

5.1.2 All steps shall be performed by staff that are suitably qualified and trained to perform the tasks.

5.1.3 Established standard operating procedures (SOPs) shall be in place for all procedures involved in receiving, processing, storing, retrieving and distribution of biospecimen and annotated data at the biorepository.

5.1.4 Laboratory equipment and infrastructure shall be appropriate to ensure proper reception, processing, storage, retrieval, quality control and distribution.

5.1.5 Computer/Informatics infrastructure shall be appropriate to enable biorepository to receive, store and share data in an efficient and secure method.

5.1.6 Quality Assurance (QA) procedures such as routine audits and quality control analysis shall be performed and documented to ensure that the integrity and quality of the collection is maintained.

5.2 Biospecimen Processing

5.2.1 To ensure suitability for future research, the processing of biospecimen shall be done in a manner to protect biospecimen quality.

5.2.2 Biospecimens shall be handled as being potentially bio-hazardous and laboratory staff shall take appropriate precautions when handling them.

5.2.3 Desiccation and degradation of biospecimen shall be avoided. The method of transporting biospecimen to and from the biorepository shall be standardized and documented according to IATA standards and local regulations.

5.2.4 All precautions to avoid cross-contamination of biospecimen during processing shall be employed. This shall include using fresh containers, pipette tips between specimens and between different areas of the same specimen.

5.2.5 Freezing in a cryoprotectant shall be done by suitable means.

5.2.6 Biospecimens in the collection are useless if incorrectly identified. All biospecimen shall be accurately labeled.

5.3 Biospecimen Storage and Retrieval

The storage method of the biospecimen, or derived products, affects the suitability of the sample for use in research.

5.3.1 Storage procedures shall be geared to protecting the integrity of the collection and shall allow efficient and accurate retrieval of biospecimen.

5.3.2 Frozen biospecimen shall be stored in screw-capped, plastic containers or cryovials that can be sealed. Vials shall permit appropriate labeling, prevention of contamination or biospecimen desiccation and shall withstand freezing in liquid nitrogen if necessary.

5.3.3 If mechanical or liquid nitrogen systems are used for storage of frozen biospecimen, adequate back-up capacity shall be in place to ensure that operating temperatures are maintained at all times. Events such as equipment failure or power-outage emergency shall be planned for and processes shall be in place to deal with possible emergencies.

Refer to Risk management and Disaster recovery policy IBRH$_3$AU-POL-007

5.3.4 For mechanical freezers, manual defrost feature is optimal as freeze-thaw cycles of automatic units can degrade biologic biospecimen.

5.3.5 Alarm systems shall be used to continuously monitor temperatures in the storage freezers and procedures shall be in place to permit corrective action before the temperatures fall out of range.

5.3.6 Proper procedures shall be followed for sample retrieval to ensure that proper conditions are maintained to protect the sample, and that documentation is completed to record any change in inventory.

5.3.7 Shipping and transportation procedures shall be established to ensure that containers, labels, packaging, conditions and methods are optimal for the biospecimen.

5.3.8 Tracking and auditing of biospecimen is critical. A high quality inventory shall be employed so that every sample can be tracked and audited. All records pertaining to sample retrieval, use, or removal shall be maintained to facilitate tracking, cold chain management and monitoring.

5.4 Safety Considerations

Refer to IBRH3AU Occupational Health and Safety Policy IBRH3AU POL 008

6 REFERENCES

6.1 Declaration of Helsinki. http://www.wma.net/en/30publications/10policies/b3/index.html

6.3 Human Tissue and Biological Biospecimen for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series. http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420

6.4 Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research, International Society for Biological and Environmental Repositories (ISBER) http://www.isber.org

7 REVISION HISTORY

Revision	Effective	Description of Changes Made from Preceding	Approved by/

No	Date	Revision	Date

ANNEX 1: DOCUMENTATION OF SUGGESTED CHANGES TO THIS SOP

CLAUSE	SUGGESTION	BY	DATE