INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

MAKERERE UNIVERSITY
COLLEGE OF HEALTH SCIENCES

STANDARD OPERATING PROCEDURE

TITLE:**BIOSPECIMEN INVENTORY VERIFICATION**		**PAGE 1 of 6**
SOP #: **IBRH$_3$AU-SOP-RDM-002**	Effective Date: **09/01/2014**	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 SOP. If I have not understood the training I have asked the trainer to retrain me to ensure that I completely understand all the requirements.

	NAME	SIGNATURE	DATE
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Table of Contents

1. INTRODUCTION

The IBRH3AU shall employ a suitable Information Management System. The primary purpose of the Information Management System is to annotate biospecimen and track the inventory within the biorepository or biorepository network. This verification procedure is designed to confirm that appropriate biorepository biospecimen are in the correct location in the storage unit as indicated by the computerized inventory system (e.g. racks, drawers, cabinets, refrigerators, freezers, liquid nitrogen tanks). It validates that procedures are working to ensure sample traceability.

2. PURPOSE

In operating a biorepository there is a responsibility to maintain and operate/safeguard the collection. The use of an Information Management System for documenting and tracking the collection is crucial. A database developed specifically for documenting and storing biospecimen information will be part of the information management system. As part of the Quality Assurance system, inventory verification shall be conducted to confirm that the appropriate data/documents are in the correct storage locations.

3. SCOPE

This standard operating procedure (SOP) covers the procedures for biospecimen inventory verification. It outlines process validation steps to be followed/checked in order to confirm that correct storage physical locations have been entered in the computerized inventory system.

4. REFERENCE TO OTHER IBRH3AU SOPS OR POLICIES

4.1 *IBRH3AU Policy: POL 003 Records and Documentation*
4.2 *IBRH3AU Policy: POL009 Material Handling*
4.3 *IBRH3AU Policy: POL 004 Information Handling*

5. ROLES AND RESPONSIBILITIES

The SOP applies to all qualified IBRH3AU biorepository personnel and laboratory staff that are responsible for entering data in the informatics system, maintaining the informatics system, storing biospecimen in freezers and refrigerators and performing inventory verification. This includes the following personnel.

Personnel	Responsibility
Laboratory Technician/Technologist, Data Entry Clerk	Responsible for storing biospecimen, entering data in the informatics system and for conducting inventory verification
Data manager	Responsible for conducting verification on informatics system
Biorepository manager	Responsible for initiating inventory verification

6. MATERIALS, EQUIPMENT AND FORMS

6.1 Inventory/Database/LIMS.
6.2 Safety equipment for handling stored biospecimen such as face shield and thermal gloves for liquid nitrogen storage containers.
6.3 Cool box with dry ice.

7. PROCEDURES

7.1 Biorepository personnel qualified by training, experience and education shall be assigned to conduct the verification.
7.2 Biorepository personnel assigned to do the verification shall have authority to access the information management system and storage facility.
7.3 Inventory verification shall be conducted every three months.
7.4 Randomly select biospecimen for inventory verification from the existing collection.
7.5 Include a percentage of new biospecimen collected since the last time inventory verification was performed.
7.6 Appropriate safety and security precautions for accessing the cryopreservation facility and handling biology biospecimen should be followed.
7.7 Remove sample from storage receptacle and verify that label matches the sample recorded in the database.
7.8 Minimize time that biospecimen are handled or removed from required storage conditions.
7.9 Ensure that the temperature is controlled during inventory verification (e.g. Use dry ice to keep sample frozen if the process takes longer than anticipated.)
7.10 Return sample to its designated storage spot and ensure that storage unit reaches optimally set temperatures.
7.11 Lock and secure unit.
7.12 Document results of inventory verification.
7.13 Identify any deviations and document any corrective actions.
7.14 If a sample is missing or incorrect or does not match recorded inventory, change inventory system to reflect the actual situation.

8. ATTACHMENTS

8.1 Corrective action log: refer to **IBRH3AU-FORM-004**

9. REFERENCES

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

9.2 International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8.

9.3 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/Search/search.asp?zoom_query=bestpractices+for+repositories

10.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