INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

MAKERERE UNIVERSITY
COLLEGE OF HEALTH SCIENCES

STANDARD OPERATING PROCEDURE

TITLE: **EDUCATION AND TRAINING**		**PAGE 1 of 8**
SOP #: **IBRH$_3$AU-SOP-MGT-003.1**	Effective Date: **09/01/2014**	Next Rev: **DEC 2015**
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
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1. INTRODUCTION

Adequate knowledge of the IBRH3AU operations, related regulations and guidelines is essential to safeguarding the interests of the donor, achieving program goals, maintaining compliance, data and biospecimen integrity and overall quality assurance at the IBRH3AU. Training is designed to inform, educate, and orient new personnel and update old ones with relevant material vital to performing their duties, inform and update existing personnel with evolving requirements and procedural changes

2. PURPOSE

To outline processes and areas in which biorepository personnel need to be educated and trained in order to efficiently carry out their assigned tasks.

3. SCOPE

This SOP covers an outline for training and education of personnel at the IBRH3AU.

4. RESPONSIBILITIES

Personnel	**Responsibility**
Biorepository personnel	Clinical and technical personnel at the biorepository have a professional responsibility to obtain and maintain knowledge and skill sets necessary to perform their respective duties.
Director	The Director/coordinator/manager of the biorepository are ultimately responsible for facilitating specific staff training, as well as ensuring that staff are adequately trained to carry out the processes of the program.

5. MATERIALS

5.1 IBRH3AU Quality manual

5.2 IBRH3AU Policies

5.3 IBRH3AU Standard Operating Procedures

5.4 ISBER best practices; Third Edition

6. PROCEDURES

6.1 **Core Training Modules for Biorepository Staff**

6.1.1 IBRH3AU Policies and Standard Operating Procedures

6.1.2 ISBER best practices

6.1.3 GCP/GCLP training

6.1.4 IATA training on packaging, labeling and transportation of biological substances

6.1.5 Ethical conduct of Research. (HRSP)

6.1.6 Participant consent

6.1.7 Role of the Research Ethics Board in the approval of consent and material release process

6.1.8 Declaration of Helsinki as additional reading

6.1.9 Training in Privacy Issues

6.2 **Train in Best Practices for Record Keeping and Documentation**

6.2.1 Instruct personnel about optimal documentation and reporting practices to ensure security, integrity, and accuracy of information and data handled and generated by the biorepository Provide IBRH3AU Policy *POL 005 Records and Documentation,* and *IBRH3AU Document Maintenance SOP* **IBRH$_3$AU-SOP-RDM-003** for personnel to read and understand

6.2.2 Train in IBRH3AU SOPS

6.2.3 Design and present a core training module to provide personnel with a master list and location of IBRH3AU generic SOPs (or equivalent biorepository specific policies and SOPs)

6.2.4 Advise personnel to read and gain familiarity with the procedures relevant to their job function

6.3 **Site specific Training**

6.3.1 Occupational health and safety with specific details pertinent to the IBRH3AU

6.3.2 Physical security at the IBRH3AU

6.3.3 Relevant technical procedures applicable to personnel and operations at the sites such as derivation of tissue products

6.3.4 Maintaining records, updating inventories and databases, interfacing with IBRH3AU databases if relevant to personnel at the site

6.3.5 Design and present site-specific training module to relevant personnel so that they can perform their duties efficiently and ethically

6.3.6 Provide for them relevant site-specific policies and SOPs to read and assimilate if relevant to their job function.

6.3.7 All personnel must receive direct and detailed training for the performance of all duties and tasks that they perform.

6.3.8 Competency assessments must be conducted and recorded for all components of the employee's training and functional responsibilities upon completion of initial training. Competency must be assessed every 6 months during the first year of employment, annually thereafter, and/or as laboratory management deems necessary. Competency assessments must compare employee performance against a documented standard and clearly verify competency or lack of competency for each evaluated task.

- Examples of methods utilized to evaluate competency include, but are not limited to: direct observation of test performance, direct observation of equipment maintenance, monitoring test result production, assessment of performance of analysis on known specimens, and external proficiency testing performance.

6.3.9 Continuing education program that is adequate to meet the needs of all personnel must be documented, and evidence of ongoing adherence by all biorepository personnel must be readily available.

6.4 **Documentation of Training**

6.4.1 Once the training is complete, a written record of the completed training should be made, that includes the trainee's signature, topic covered, date of training as well as the trainer's signature.

6.4.2 Electronic signatures should be used for documentation of electronic training

6.5 **Assessment of Training**

6.5.1 At the end of a training session and on an ongoing basis, personnel should be encouraged to discuss policies and SOPs and ask for clarification if required. These discussions or sessions will provide some indication if the educational material has been "read and understood".

7. ATTACHMENTS

7.1 IBRH3AU training log: **IBRH3AU-FORM-009**

8. REFERENCES

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

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

9. 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