INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

MAKERERE UNIVERSITY
COLLEGE OF HEALTH SCIENCES

POLICY

TITLE: **EDUCATION AND TRAINING POLICY**		**PAGE 1 of 9**
POL #: **IBRH$_3$AU-POL-005**	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

Adequate knowledge of the IBRH3AU and H3Africa consortium processes, related regulations and guidelines (e.g. ISBER best practices) is essential to safeguarding the interests of the patient, achieving program goals and compliance, data and biospecimen integrity and overall quality assurance at levels. Personnel by their position descriptions must understand the responsibilities of the biorepository as the "custodian" of biospecimen for research purposes and be appropriately qualified by education, training and experience to perform these tasks in an efficient, professional and ethical manner. The Integrated Biorepository of H3Africa Uganda is committed to promoting and educating personnel to achieve adherence to high ethical standards and practices in the reception, processing, storage, retrieval and distribution of biospecimens for research purposes.

2. PURPOSE

The purpose of this IBRH3AU policy is to outline general principles that shall be used in all situations to ensure that personnel working at the IBH3AU are adequately educated and trained to perform their tasks.

3. SCOPE

This policy describes recommendations for areas and material that shall be the focus of any educational or training process to ensure that ethical and operational standards are maintained at the IBRH3AU

4. RESPONSIBILITY

This policy applies to IBRH3AU personnel involved in all aspects of the IBRH3AU program. The Principal Investigator/Scientific director is ultimately responsible for the IBRH3AU specific staff training, as well as ensuring that he/she has adequately-trained staff to carry out the processes of the program. The administrative and technical IBRH3AU replace personnel have a professional responsibility to obtain and maintain the knowledge and skill sets necessary to perform their relevant duties.

5. POLICIES

5.1 Learning is a dynamic process. All IBRH3AU staff shall be qualified by education, training and experience to assume their responsibility for the proper conduct of the program.

5.2 It is optimal that all those involved in biorepository operations have necessary skills and knowledge and a clear understanding of the processes and policies that define the running of a compliant, efficient and successful biorepository program.

5.3 It is important that the personnel have a clear understanding of their role within the organization and have access to the appropriate level of information to support their decisions and actions.

5.4 A three weeks course in biorepositing at the University of Luxembourg shall be provided to new staff and annually to old/current staff have not previously received such training and for experienced staff who need to keep current with new development, new methods, updated equipment or software and evolving regulatory requirements.

5.5 Training shall be designed to meet the needs of the staff in biorepository operations. The scope, detail and content of the training shall reflect the particular responsibilities of each individual.

5.6 Training shall be designed to include general issues such as:

5.6.1 Human Research Subject Protection (HRSP)
5.6.2 International Air Transport Association certificate
5.6.3 ISBER best practices
5.6.4 GCP/GCLP

5.7 Training shall be designed to include **site-specific** issues that may include:
5.7.1 Facility security and procedures
5.7.2 Occupational health and safety
5.7.3 Technical procedures and processes relevant to operations of the biorepository
5.7.4 Formal course in biorepository science and management at the University of Luxembourg

5.8 The IBRH3AU will consider implementing procedures by which they can assess and evaluate whether or not the personnel have achieved the learning outcomes of the training component through regular appraisal/ competency assessment.

5.9 Tools used for training such as policies or standard operating procedures (SOPs) shall be updated in a timely manner so as to accurately reflect current practice.

5.10 Staff shall be mandated to keep current in their area of expertise. This could include attending relevant seminars, conferences, continuing education courses and keeping professional certification updated

5.11 Introduction to Organization and Personnel

Laboratory management and staff share the responsibility of thorough documentation of the structure of the organization and the respective job descriptions and qualifications, as well as an ongoing documentation of an individual's professional experience, training, and skill-assessment. This ensures an employee's ability to adequately and safely perform his/her job.

5.12 Standards for Organization and Personnel

5.12.1 **Documentation***:* The biorepository shall have the following documents stored appropriately and readily available to authorized personnel, as appropriate:

5.12.2 **Personnel policies** must be available that address such topics as orientation, training, continuing education requirements, performance evaluations, benefits, discipline, dress codes, holidays, security, termination, and attendance. These policies detail employer and employee responsibilities as they relate to continued employment, employee and employer legal requirements, and protections.

5.12.3 **Organizational and/or departmental policies** that describe how personnel can communicate existing issues which may affect quality of testing or safety of personnel must be available to ensure a non-retaliatory environment that encourages communication vital to the integrity of the study and the institution.

5.12.4 **Job descriptions** that define qualifications and delegation of duties for all positions within the laboratory must be available to staff and other appropriate individuals

5.12.5 **Personnel files** must be available to appropriate individuals that include a summary of the following items as they relate to each employee:

a. Orientation and training
b. Experience
c. Education
d. Applicable licensure/certification (if required)
e. Competency assessments
f. Continuing education records
g. Curriculum Vitae
h. Safety training
i. Attendance at job-related workshops and seminars; s*ee Appendix* for an example of a Training Attendance Log.

Note: Personnel files must be readily available only to authorized personnel such as Scientific Director/Principal Investigator, Biorepository Coordinator, Biorepository Manager, Quality Manager and regulatory bodies/auditors.

5.12.6 **Organizational chart(s)** that represent the formal reporting and communication relationships that exist among personnel and management and between the main laboratory unit and satellite units, as applicable, must be available. These charts ensure the staff understands communication path options and requirements.

5.12.7 **Staff education and evaluations***:* Managerial and technical personnel engaged in the conduct of laboratory testing related to clinical research must have the education, training, and experience commensurate with their assigned functions.

5.12.8 **Job-specific Training, Education and Assessments**

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

5.12.8.2 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.

5.12.8.3 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.

5.12.8.4 A clinical laboratory continuing education program that is adequate to meet the needs of all personnel must be documented, and evidence of ongoing adherence by all laboratory personnel must be readily available. This documentation should include scheduling information such as how frequently personnel should attend a given course, the type of courses required, and the number of educational sessions personnel are required to attend over a given time period. Examples of training include, but are not limited to, topics such as blood-borne pathogens, shipping of dangerous goods based on International Air Transportation Association (IATA) regulations, and laboratory safety.

5.12.9 **GCLP Training**

5.12.9.1 At this time, GCLP training is not a DAIDS requirement. However, it is recommended that all laboratory personnel receive training in GCLP. The frequency of this training must be sufficient to ensure that employees remain familiar with the GCLP requirements applicable to them.

5.12.10 **Performance Evaluations**

5.12.11 Annual performance evaluations must be given to all laboratory personnel. These evaluations compare the employee's overall performance of job responsibilities, duties, and tasks as outlined in the job description. These evaluations often take into consideration many aspects of job performance in addition to technical competency, such as quality of interpersonal communication, attendance, and behavioral expectations.

5.12.12 **Staff numbers***:* The laboratory must employ an adequate number of qualified personnel to perform all of the functions associated with the volume and complexity of tasks and testing performed within the laboratory. The number of employees needed for optimal laboratory operations is determined by upper management in consultation with staff; this number is adjusted based on the scope and amount of workload.

5.12.13 **Staff identification**: If signatures, initials, or codes are used as staff identifiers on any laboratory documentation, a documented list that links these identifiers to a printed name must be in place. Changes in staff signatures, initials, or codes, as well as identifiers for new staff must be immediately recorded in the laboratory's documented list. The laboratory's documented list should be a "controlled version" document that must be updated when applicable changes described occur in the laboratory. Signature logs should be archived so that those individuals who performed trial testing throughout the length of a trial may be identified. As an example, staff signatures, initials, or codes included in results from assays should be traceable to printed names available in the laboratory.

6. ATTACHMENTS

6.1 Training log; refer to **IBRH3AU-FORM-009**

7. REFERENCES

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

7.2 International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8. http://www.ich.org/products/guidelines.html

7.3 Office for Protection from Research Risks, US Department of Health and Human Services, Tips on Informed Consent. http://www.hhs.gov/ohrp/policy/ictips.html

7.4 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

7.5 USA Food and Drug Administration FDA Code of Federal Regulations, Title 21, Part 50: Protection of Human Subjects. http://www.fda.gov/oc/gcp/default.htm or http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

8 REVISION HISTORY

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

ANNEX 1: DOCUMENTATION OF SUGGESTED CHANGES TO THIS POLICY

CLAUSE	SUGGESTION	BY	DATE