INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

MAKERERE UNIVERSITY
COLLEGE OF HEALTH SCIENCES

POLICY

TITLE: **RECORDS AND DOCUMENTATION**		**PAGE 1 of 7**
POL #: **IBRH$_3$AU-POL-003.1**	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.

	NAME	SIGNATURE	DATE
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1. INTRODUCTION

Recent developments in molecular biology and genomics have essentially enhanced the value of clinically annotated biospecimen in translational research and drug discovery. Adherence to best practices in the generation and maintenance of complete and accurate documentation is important in ensuring the value and utility of resources within a biorepository. Intellectual property rights (IPR) can only be protected adequately if all records and documents are thorough, accurate and contemporaneous. The IBRH3AU is committed to promoting and educating personnel for adherence to high ethical standards and practices in the reception, processing, storage, retrieval and distribution of human biospecimens for research purposes. The generation of clear, accurate, comprehensive and retrievable records and documents is vital to biorepository compliance and success.

2. PURPOSE

The purpose of this IBRH3AU document and records policy is to outline general principles that shall be used by personnel to ensure that records and documents are maintained with common essential standards.

3. SCOPE

This policy applies to all records and documents that have to be generated and maintained as part of the operations of the IBRH3AU. The policy covers written notebooks, original paper records, true copies such as photocopies, as well as electronic records and documents

4. RESPONSIBILITY

As custodians of Human Biological Materials and associated information, IBRH3AU personnel have a responsibility to maintain complete and auditable records. This policy applies to all personnel involved in generating, maintaining and managing records and documents within the IBRH3AU program.

5. POLICIES

The use of Biospecimens and accompanying data is critical for medical research. Clear, accurate and complete records are essential to any research program. As legal custodians of the biospecimen collection, the IBRH3AU is responsible for keeping proper records. The following principles shall guide the IBRH3AU personnel in maintaining compliant records and documents.

5.1 Managing information and data

5.1.1 Confidentiality of personal information as well as data associated with biological biospecimen shall be essential.

5.1.2 Data records shall be monitored to ensure completeness and accuracy.

5.1.3 The IBRH3AU as the custodian of Biospecimens shall be responsible for keeping proper records of all uses that have been made of the material, whether by themselves or by others.

5.1.4 The IBRH3AU as the custodian of Biospecimens shall ensure that all uses have appropriate Research Ethics Board/Institutional Review Board approval, and keep copies of such approvals for easy reference.

5.1.5 When linked encoded biospecimen are provided to a third party, the custodian (IBRH3AU) shall be responsible for safe keeping of the code enabling biospecimen to be linked to individual donors.

5.2 Retaining information and data

5.2.1 Retention of accurately recorded and retrievable information, data and results are essential for the running of a biorepository and shall be retained indefinitely to be of value to translational researchers.

5.2.2 Researchers (who are leaving an establishment) and who wish to retain anonymised data/copies of data for future use must get specific permission to do so from both the biorepository and from the appropriate data access committee. Where personal data is involved, the request shall be refused unless it is clear that future use will be consistent with the terms of the consent and contract with that researcher. A material transfer agreement (MTA) shall govern this transaction.

5.3 Retention of Data in the Case of Withheld or Revoked Consent

Publication of data imposes a requirement that researchers and the biorepository retain source data or records and that the biorepository is acknowledged in the publication.

5.3.1 For cases of withheld consent, all case related information and data held (electronically or on paper) by the biorepository shall be removed or destroyed.

5.3.2 For cases of revoked consent, all case related information and data shall be limited or destroyed. Guidance of the REB/IRB shall be used in the management of case related biospecimen and data accrued, that cannot be destroyed as it may already be engaged within a research protocol. In some cases, such material may be used as anonymous donor/biospecimen without information about the clinical characteristics and with REB/IRB approval.

5.4 Notebooks and Electronic Records

5.4.1 All raw data shall be recorded and retained in laboratory notebooks or in an electronic database dedicated to that purpose.

5.4.2 Machine print-outs, questionnaires, chart recording, forms, letters, etc. shall be retained in a database dedicated to that purpose.

5.4.3 Notebook and electronic records shall be entered as soon as possible after the data is collected or generated. Recorded data shall be identified by date of the record. Subsequent modifications or additions to records shall be clearly identified and dated.

5.4.4 There shall be processes in place for quality assurance of data generated and recorded electronically.

5.4.5 Where feasible, internal annotated digitized data/images shall be recorded and retained in a "raw" or original format as well. This is especially relevant where data/images undergoing digitization are subsequently enhanced. If possible, both the original and enhanced forms shall be stored.

5.4.6 Electronic records shall be backed-up regularly

5.5 Personnel and Users Access to Information and Records

Access to data shall be given to users on a 'need to know' basis. Users shall be granted access to specific data records that they need in order to perform their duties. This access shall be removed when the activity is completed.

5.6 Transmission of Information and Data

Information from incoming sources (H3 Africa consortium members) shall be transmitted in a secure and safe manner.

Refer to: Data and Biospecimen Access and submission policy

5.7 Physical Storage of Information and Data

5.7.1 Data and records shall be stored securely and with appropriate contingency plans.

5.7.2 Data and records shall be stored in a manner to permit retrospective audit if needed.

6. REFERENCES

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

6.2 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

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

6.4 Medical Research Council, Ethics Series. Good Research Practice http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/Researchpractice/principles_guidelines/index.htm

6.5 Good Laboratory Practice for nonclinical lab studies (CFR21-Chapter1 Part 58 Subpart J(58.185, 58.190 and 58.195)

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*