INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

MAKERERE UNIVERSITY
COLLEGE OF HEALTH SCIENCES
POLICY

TITLE: **ETHICS AND REGULATORY ISSUES**		
POL #: **IBRH$_3$AU-POL-002.1**	Effective Date: **06/01/2014**	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

1.1.1.1.1 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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2 INTRODUCTION

Biospecimens have been the basis of pathological inquiry for a very long time. However, with the advancement of molecular biology and genetic insights, scientists have greatly increased their use and demand for properly prepared and clinically annotated biospecimen that yield valuable insights into the mechanisms and pathways of human disease.

Research on human biospecimen has not been always formally regulated or extensively harmonized by governing agencies. Existing guidelines for the protection of human subjects in clinical research continue to provide oversight for the use of biospecimen in basic and translational research in general. These guidelines have been applied to dealing with issues related to collection, study, storage, transfer and disposal of biospeciemen and associated participant data. In view that biospecimen are becoming a valuable and irreplaceable resource and society's interest in the advancement of medical knowledge, this policy is intended to foster a consistent and coherent ethical framework that shall govern biospecimen use.

3 PURPOSE

The Integrated Biorepository of H3Africa Uganda is committed to promoting and educating staff for adherence to high ethical standards and practices in the reception, processing, storage, retrieval and distribution of human biospecimen and accompanying data for research purposes. This IBRH3AU policy is intended to outline general principles that shall be used in most situations to ensure that the interests of individual participants are safeguarded.

4 SCOPE

This IBRH3AU policy applies to major ethical considerations that arise in the conduct of biorepositing. The issues concern custodianship, risk, confidentiality, consent and quality of research.

5 RESPONSIBILITY

This policy applies to personnel involved in all aspects of the Integrated Biorepository of H3Africa Uganda biorepository program

6 POLICIES

The use of biospecimen and accompanying data is critical for medical research. The public and program participants should have confidence that the biorepository and researchers will use and handle such material according to recognized ethical standards. It is important to ensure that collections of biospecimens are used ethically and optimally

in research to benefit/improve the prevention, diagnosis, and treatment of illness and the promotion of health throughout society. The interests of the participants shall always take precedence over the interests of research, science and society.

6.1 Ethics Review

The following principles in areas requiring ethical consideration shall guide the Integrated Biorepository of H3Africa Uganda in maintaining and managing the resource it controls

Processes such as consent, collection, storage and proposed research shall be reviewed and approved by a legal officer qualified in research ethics (both national and international) where applicable and an appropriately constituted Research Ethics Board/Institutional Review Board to ensure that among other things the research is in line with the individual participant consent.

The standard of "minimal risk" shall be considered in the review process. The physical risks in donating biospecimen for research may be minimal, but the risk that information from research on the biospecimen and annotated data could harm the privacy and confidentiality of the participant shall be considered.

6.2 Confidentiality

Personal and medical information and research results relating to the participant and biospecimen shall always be treated as confidential. The participant shall be made aware of the type of personal and medical information that will be used by researchers, and what safeguards will be in place to protect their confidentiality and anonymity.
All members of the biorepository that have access to biospecimen and accompanying data shall sign confidentiality agreements

6.3 Commitment to maintaining confidentiality

The IBRH3AU shall maintain strict measures to protect confidentiality, and will ensure that data and biospecimens are (reversibly) anonymised, linked and stored to very high standards of security. The same protection will be extended under contract for any handling or analysis of data or biospecimens by third parties engaged to provide services necessary for developing the resource. Research users will only be given access to anonymised data and biospecimens.

6.4 Economic Factors

Economic factors may provide motivation for participants to provide biospecimens but this could compromise the quality and safety of the collection. Subjects shall not be offered or receive any financial compensation for participation in the program. Participants may be reimbursed for costs involved in participation. Biospecimen collected from participants shall be treated as gifts.

Biospecimen shall not give rise to financial gain. The biorepository shall not sell (for a profit) biospecimens that they have collected. A reasonable payment from users of the biorepository to recover cost of managing, maintaining, processing and handling the biorepository collection is however acceptable.

6.5 Custodianship of Biospecimen and Data

The biorepository shall bear responsibility for the biospecimen and data in the collection that they manage and maintain.

The biorepository shall bear responsibility for keeping proper records of all uses that have been made of the materials, by themselves. If transfer of material occurs, appropriate material transfer procedures shall be followed and documented.

The IBRH3AU as legal custodians of "Existing Collections" shall ensure that they make optimal use of the resource they control and seek the advice as guided by national standards.

Access to biospecimen and accompanying data shall be through a documented and approved procedure

Refer to: ***Biospecimen Access and Release policy and procedures***
Data Access and Release policy
Material Transfer Agreement

6.6 Commercialization and Intellectual Property Issues

The development of new drug therapies and diagnostics to a point where they can be made available to universally benefit society is very dependent on commercial involvement. Access by the commercial sector to biospecimen within the biorepository shall be facilitated if consistent with the goals of the biorepository. However, no one commercial enterprise shall be given exclusive rights of access to the collection, Use of the biological biospecimens will have to be carefully coordinated and controlled because

they are limited and depletable . Individual participants shall be informed in the consent process, that biospecimens or their products may be used by academic researchers as well as researchers in the commercial sector and that they will not be entitled to a share of the profits that may ensue from research. Disclosure that there is the possibility or intent to commercialize research might help alleviate ethical concerns that participants are not aware of intended uses of their biospecimen.

Intellectual property (IP) rights arising from research using human biospecimens may be sold or licensed in the same way as other IP rights. Before allowing access to biospecimens by either academic or commercial sector researchers, the biorepository/custodian of the biospecimen and data shall make clear (by contractual agreement) its policies on ownership of Intellectual Property rights.

6.7 **Genetic Testing**

The ability to study biospecimen stored in the biorepository and to generate information about genetic disease and susceptibility to disease has raised concerns over risk to participants associated with discrimination and stigmatization. Privacy of research results shall never be breeched, as the consequences for the participant are likely to be social, economic and psychological.

Much as genetic information generated from research is of unknown or uncertain predictive value. Results may not be disclosed to the participant or added to medical records unless consent is obtained through an approved procedure. The biorepository may facilitate this process
Instead, the overall findings and implications of results that derive from IBRH3AU will be made available to the wider community so that they can influence public health strategies (including, where appropriate, the introduction of screening for newly discovered risk factors).

If consent is sought, then appropriate counseling must be made available to the participants.
During this counseling, participants shall be advised of the potential risks and implications of genetic information (e.g. on family members, relationships, employment, and insurance).

6.8 Ongoing Engagement with Stakeholders

Regular communication will be important to inform participants of general findings from research based on the resource and to encourage continued participation. The IBRH3AU will, therefore, look for a variety of ways to facilitate communicating with (including listening to) participants, the general public, research users and the scientific community.

A variety of media, such as websites, help lines, newsletters, and public meetings will be used to inform stakeholders about the development and use of the resource, and of ways to contact the IBRH3AU Biorepository (including, for example, how to withdraw). Systems will be put in place to allow stakeholders to indicate how, and whether, they would like to receive such information.

The IBRH3AU Biorepository shall maintain procedures for responding in a timely fashion to any enquiries or complaints.

6.9 Legal issues

The integrated Biorepository of H3Africa Uganda will be the legal custodian of the database and the biospecimen collection. Such ownership conveys certain rights, such as the right to take legal action against unauthorized use or abuse of the database or biospecimens, and the right to destroy the biospecimens. Participants will not have property rights in the biospecimens.

6.10 Security

A wide variety of measures will be taken to ensure the security of data, biospecimens, the database and the information technology system in general. These include staff training and confidentiality pledges, physical and electronic controls on access to data, cyber security, and physical security. This should prevent identifiable information from being used inadvertently or deliberately for any purpose other than approved research

When using this policy
REFER TO: ***IBRH3AU Material and Information Handling Policy 004***
IBRH3AU Records and Documentation policy 003

7 REFERENCES

7.1 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

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

7.3 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 SOP

CLAUSE	SUGGESTION	BY	DATE