



INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

**MAKERERE UNIVERSITY
COLLEGE OF HEALTH SCIENCES**

STANDARD OPERATING PROCEDURE

TITLE: INTERNAL AUDIT		PAGE 1 of 5
SOP #: IBRH ₃ AU-SOP-MGT-002.1	Effective Date: 09/01/2014	Next Rev: DEC 15
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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 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

To successfully manage quality expectations of biobanking stakeholders it's essential to have fundamental systems in place including proper Quality Management systems and processes to assess the effectiveness of this system to meet set standards and regulations and stakeholder needs and program objectives. Periodic audits shall be carried out to assess the effectiveness of quality systems.

2. PURPOSE

The purpose of this SOP is to describe who, when and what will be used to carry out an internal audit at the IBRH3AU.

3. SCOPE

This Standard Operating Procedure applies to performing an internal audit in the Integrated Biorepository of H3Africa Uganda and it describes the audit plan, with who, when, which section an internal audit shall be done, and also how to perform the audit within biorepository. This SOP shall be used in conjunction with the ISBER self assessment tool and ISBER best practices.

4. ABBREVIATIONS

4.1 QM	Quality Manager
4.2 GCLP	Good Clinical Laboratory Practice
4.3 GCP	Good Clinical Practice
4.4 ISBER	International Society for Biological and Environmental Repositories
4.5 SAR	Self Assessment Tool

5. RESPONSIBILITIES

5.1 Scientific Director/PI

5.1.1 Ensure that internal audits are carried out as stated in the audit schedule

5.2 Quality manager

5.2.1 Perform an internal audit

5.2.2 Submit/present an audit report to the biorepository management

5.3 Biorepository manager/Quality Manager

5.3.1 Implement recommendations of the audit report

5.3.2 Assign lab staff action points/recommendations for implementation

5.4 Audit tools/materials

5.4.1 ISBER Self Assessment Tool

5.4.2 SLIPTA checklist



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5.4.3 ISO 15189 standard for reference

6 PROCEDURE

6.1 Criteria, scope, frequency and methods

- 6.1.1 The internal audit shall be carried out twice every year using the ISBER self assessment tool
- 6.1.2 All biorepository areas should at least be audited within the one year cycle
- 6.1.3 A specific section can be audited as a follow up on action item implementation

6.2 Selection of auditors

- 6.2.1 Non self section audit for Lab technologist participating as auditors
- 6.2.2 At least one of the selected auditors should have had auditors training
- 6.2.3 Quality manager/designee should be the lead auditor

6.3 Audit

- 6.3.1 Access the ISBER SAT tool from the ISBER website
- 6.3.2 Answer the multiple choice questions from beginning to the end by answering YES/NO/NA and provide a comment where necessary
- 6.3.3 Submit results by clicking on the submit button at the end of the questionnaire
- 6.3.4 Print results and put a copy on file **Note:** feedback may take up to a month
- 6.3.5 For lab processes administer the WHO AFRO SLIPTA checklist
- 6.3.6 Generate the audit report
- 6.3.7 Generate a table of findings, recommendations and Non conformities
- 6.3.8 Generate action points from the non conformities table and assign to individuals to follow up
- 6.3.9 Follow-up action points to their logical conclusion



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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