INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

MAKERERE UNIVERSITY
COLLEGE OF HEALTH SCIENCES

STANDARD OPERATING PROCEDURE

TITLE: **CORRECTIVE ACTION**		**PAGE 1 of 5**
SOP #: **IBRH$_3$AU-SOP-RDM-004**	Effective Date: **09/01/2014**	Next Rev: **DEC 2014**

Prepared by:	Reviewed by:	Approved by:
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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 PURPOSE

This Standard Operating Procedure (SOP) describes the action to take in case of Non conformities.

2 SCOPE

This SOP applies to all laboratory personnel involved in all operations of the Integrated Biorepository of H3Africa Uganda

3 RESPONSIBILITIES

3.1 Laboratory Personnel are responsible for:

3.1.1 Performing the prescribed activity as detailed in this procedure

3.1.2 Abiding by all applicable Quality System requirements

3.2 Laboratory Management is responsible for:

3.2.1 Ensuring that all laboratory processes are appropriate for their intended use

3.2.2 Ensuring that all personnel involved in this process are appropriately trained

3.2.3 Ensuring that discrepancies, excursions etc, related to this process are investigated, documented and resolved in accordance with Quality system requirements.

3.2.4 Implementing the necessary precautions to ensure a safe working environment for those employees who frequent the laboratory areas for which she or he is responsible.

3.3 The Quality Assurance staff is responsible for:

3.3.1 Review of documentation and records to assess conformity of GLP/GCLP standards, external regulatory policies and ISBER best practices

4 ABBREVIATIONS

4.1 GLP Good Laboratory Practices

4.2 SOP Standard Operating Procedures

4.3 ISBER International Society of Biological and Environmental Repositories

5 MATERIALS

5.1 Black pen

5.2 Corrective action form: IBRH3AU-FORM-004

6 PROCEDURE

6.1 On the Investigation and Corrective Action Form, precisely describe the problem statement for non conformity. Provide as much detail as possible**.**

6.2 Indicate your initials and the date of documentation.

6.3 If possible state the root cause and if not contact the service provider in the case of equipment or the lab supervisor for problems with procedures who will investigate the root cause for non-conformity.

6.4 Describe the corrective action taken and document your initials and date.

6.5 Provide evidence that the corrective action was successfully implemented and completed.

6.6 Inform the lab supervisor about the corrective action taken and the lab supervisor should sign form to indicate approval and closure of the investigation.

6.7 The Quality Manager should review all investigations performed monthly to determine any reoccurring problems or issues related to lab procedures or equipment.

6.8 Any investigations that affect active study protocols should be reported to the Principal Investigator or designee.

6.9 If applicable the incidence should be reported as a deviation according to Deviation Reporting and CAPA.

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