



**INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA**

**MAKERERE UNIVERSITY  
COLLEGE OF HEALTH SCIENCES**

**STANDARD OPERATING PROCEDURE**

TITLE: **BIOSPECIMEN STORAGE FACILITIES AND EQUIPMENT MAINTANANCE**

PAGE 1 of 9

SOP #: **IBRH<sub>3</sub>AU-SOP-MGT-006.1**

Effective Date: **09/01/2014**

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 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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#### Table of Contents

<b>VALIDATION AND RETIREMENT.....</b>	<b>1</b>
<b>ACKNOWLEDGEMENT OF READING AND UNDERSTANDING .....</b>	<b>1</b>
<b>1 PURPOSE .....</b>	<b>3</b>
<b>2 SCOPE.....</b>	<b>3</b>
<b>3 ROLES AND RESPONSIBILITIES .....</b>	<b>3</b>
<b>4 MATERIALS, EQUIPMENT AND FORMS .....</b>	<b>3</b>
<b>5 PROCEDURES .....</b>	<b>4</b>
<b>6 ATTACHMENTS.....</b>	<b>7</b>
<b>7 REFERENCES.....</b>	<b>8</b>
<b>8 REVISION HISTORY .....</b>	<b>9</b>



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#### 1. PURPOSE

Appropriate storage is a core requirement for the operation of a successful biorepository. Biospecimen are a precious resource and the biorepository shall maintain its storage facilities and equipment to provide optimal conditions for maintaining biospecimen quality.

#### 2. SCOPE

This standard operating procedure (SOP) outlines elements and processes that shall be in place to provide appropriate and optimal storage conditions.

#### 3. ROLES AND RESPONSIBILITIES

The SOP applies to all personnel from the IBRH<sub>3</sub>AU biorepository that work at the biorepository site and are responsible for storing biorepository biospecimens or maintaining the storage facility or equipment. This may include the following personnel;

Personnel	Role/Responsibility
Lab tech	Responding to alarms and checking that maintenance procedures are carried out.
Coordinator/Manager	Responding to alarms, overseeing that maintenance procedures are carried out and updating lists and procedures.

#### 4. MATERIALS, EQUIPMENT AND FORMS

4.1 Maintenance logs

4.2 Power backup capacity

4.3 Thermometers

4.4 Back up freezers and refrigerators

4.5 Back up lab

4.6 Adequate LN<sub>2</sub> supply

4.7 Alarm systems

4.8 Alarm systems contact list



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## 5. PROCEDURES

### 5.1 Storage Facility – Temperature

- 5.1.1 Monitor and log in room temperature logs everyday (morning and evening).
- 5.1.2 Maintain appropriate air-cooling and ventilation to maintain ambient temperatures at approximately 15°C - 30°C. Freezers and refrigerators contribute heat to the environment and air conditioning (set between 16°C-30 C) prevents overheating of equipment.

### 5.2 Storage Facility – Air Flow

- 5.2.1 Conditions of humidity shall be controlled to prevent fungal growth in the storage area of the biorepository.
- 5.2.2 Ensure adequate air circulation around freezers and refrigerators to prevent excessive moisture and condensation.
- 5.2.3 Provide adequate ventilation to ensure that sufficient oxygen levels are maintained in areas where dry ice or liquid nitrogen is used.
- 5.2.4 Maintenance procedures to prevent excessive dust in the storage facility shall be carried out daily.

### 5.3 Storage Facility – Lighting

- 5.3.1 Provide adequate general and task lighting to ensure that the appropriate level of illumination is available to perform routine and specialized tasks undertaken at the biorepository.
- 5.3.2 Provide lighting of correct intensity to facilitate accurate reading of labels for proper storage and retrieval of biospecimens. The lighting system shall be connected to the power back up system.

### 5.4 Storage Facility – Back-up Capacity

- 5.4.1 Adequate back-up capacity for low temperature units should be in place in anticipation of equipment failure.
- 5.4.2 Reserve enough fuel to run the generator for up to 24 hours.
- 5.4.3 Always update the MOU with partner lab (National TB Reference Laboratory) to accommodate specimens in case of emergencies.
- 5.4.4 Maintain extra capacity, equal to at least the capacity of the largest storage unit or equivalent to 10% of the total storage capacity, maintained at operating temperature at all times.



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- 5.4.5 Train Personnel in processes ensuring rapid transfer of biospecimen to back-up units when the need arises.
- 5.4.6 Document Biospecimen transfer to back-up unit, and track biospecimens to ensure return to correct location when corrective action has been taken.

#### **5.5 Equipment – General Maintenance**

- 5.5.1 Inspected equipment daily for cleanliness, sanitation, malfunctions, possible contamination and proper calibration. Documented and maintain evidence of these actions.
- 5.5.2 A documented system for maintenance and repair of storage equipment and supporting systems.
- 5.5.3 Preventative maintenance shall be in place for all operations and facility systems and shall be performed at intervals as per manufacturer's recommendations.
- 5.5.4 All automated, mechanical, electronic and other equipment should be calibrated according to established procedure or as recommended by the manufacturer.
- 5.5.5 Only authorized maintenance personnel shall be allowed to carry out repairs and services to storage equipment.

#### **5.6 Storage Equipment – Cryogenic Freezers**

- 5.6.1 Monitor all liquid nitrogen containers weekly to ensure that the optimal vapor phase is maintained.
- 5.6.2 Automatic refill level alarms should be maintained and plugged in power.
- 5.6.3 Set all alarm points to ensure sufficient time for corrective action before damage to the collection occurs and test to ensure that the alarm system is functional.
- 5.6.4 Post a 24-hour emergency contact list with multiple personnel that can be contacted in case of malfunction.
- 5.6.5 Reviewed list periodically and modify to reflect changes in personnel or contact information.
- 5.6.6 Number equipment all so that they can be easily identified in case of an emergency.
- 5.6.7 Avoid environmental temperature fluctuations in the facility.



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5.6.8 Advice personnel to minimize the number of times the freezer is opened within a given time and only one rack or box should be removed at a time.

#### **5.7 Storage Equipment – Mechanical Freezers**

5.7.1 Set mechanical freezers used in the biorepository between -20° C to -150° C.

5.7.2 Maintain temperature probe in the freezer.

5.7.3 Test alarms for functionality of both temperature variation and electrical power supply interruption every two months.

5.7.4 A 24-hour emergency contact list with multiple personnel that can be contacted in case of freezer malfunction shall be maintained and reviewed (at least once annually) and modified to reflect changes in personnel or contact information.

5.7.5 All freezers shall be numbered so that they can be easily identified in case of an emergency.

5.7.6 Freezer doors shall not be unnecessarily opened for more than 2 minutes and only one rack or box may be removed at a time.

5.7.7 Mechanical freezers that are not self-defrost should be monitored daily for buildup of frost around doors on storage units this could prevent normal operation or inhibit proper sealing of freezer doors.

5.7.8 At regular intervals (based on usage and frost buildup) these units shall be defrosted and adequate back-up capacity shall be maintained at the correct temperature for these occasions.

5.7.9 Train Personnel defrost procedures.

#### **5.8 Storage Equipment – Refrigerators**

5.8.1 Set refrigerators temperatures between 2°C and 8°C.

5.8.2 Monitor high and low set points.

5.8.3 Log in temperatures daily.

#### **5.9 Monitoring**

5.9.1 Log in every morning and evening for freezer, fridges, room temperature, centrifuges, and daily for bio-safety cabinets and incubators.

5.9.2 Check the level of LN2 once a week.



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5.9.3 Ensure equipment are serviced every three months and document these procedures in each equipment file where each equipment has; manufacturers manual, SOP and service records.

#### **5.10 Floor**

5.10.1 The floor of the equipment facility shall be cleaned with soap and water by a facilities assistant trained in safety.

### **6. ATTACHMENTS**

**6.1 Freezer and Fridge maintenance logs IBRH3AU-FORM-010,011 and 013.**

**6.2 Centrifuge maintenance log IBRH3AU-FORM-014.**

**6.3 Biosafety cabinet maintenance log IBRH3AU-FORM-012.**

**6.4 Room temperature monitoring log IBRH3AU-FORM-007.**

**6.5 Liquid Nitrogen monitoring log IBRH3AU-FORM-003.**



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## 7. REFERENCES

- 7.1 Best Practices for Repositories I. Collection, Storage and Retrieval of Biospecimen for Research. International Society for Biological and Environmental Repositories (ISBER). [http://www.isber.org/Search/search.asp?zoom\\_query=best+practices+for+repositories](http://www.isber.org/Search/search.asp?zoom_query=best+practices+for+repositories).
- 7.2 US National Biospecimen Network Blueprint <http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp>.





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### 8 BREVISION 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