

<b>CTRNet Standard Operating Procedure Maintenance of Sample Storage Facility and Equipment</b>			
SOP Number:	4.1.006	Version	e1.0
Supersedes:	EM 001.001	Effective Date	09 Jan 08
Subject:	Maintenance of Sample Storage Facility and Equipment	Category	Facilities Operation and Management

Prepared By:		Jean de Sousa-Hitzler		
	Signature	Name	Title	ddMmmyy
Approved By:		Peter Geary	CEO	09 Jan 08
	Signature	Name	Title	ddMmmyy

### REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
EM 001.001	2005	JdSH	CTRNet Generic SOP for Maintenance of Sample Storage Facility and Equipment
4.1.006	2007	JdSH	Revised to make minor formatting changes and reviewed to reflect current practice at member banks

## 1.0 PURPOSE

Tumour banks or repositories are intended to store and manage the Human Biological Materials (HBMs) in their custody. Appropriate storage is a core requirement for the operation of a successful tumour repository. HBMs are a precious and delicate resource and each repository should maintain their storage facilities and equipment to provide optimal conditions for maintaining sample quality.

## 2.0 SCOPE

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

## 3.0 REFERENCE TO OTHER POLICIES AND SOPS

1. CTRNet Policy: POL 002.001 Ethics
2. CTRNet Policy: POL 004.001 Privacy and Security
3. CTRNet Policy: POL 007.001 Material and Information Handling Policy

#### 4.0 ROLES AND RESPONSIBILITY

The policy applies to all personnel from CTRNet member repositories that work at the repository site and are responsible for storing repository samples or maintaining the storage facility or equipment. This may include the following personnel:

<b>Tumour Bank Personnel</b>	<b>Responsibility/Role</b>	<b>Site Specific Personnel and Contact Information</b>
Lab Technicians	Responding to alarms and checking that maintenance procedures are carried out	
Bank Director	Responding to alarms, overseeing that maintenance procedures are carried out and updating lists and procedures	
Bank Manager/Coordinator	Responding to alarms, overseeing that maintenance procedures are carried out and updating lists and procedures	

#### 5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the site-specific task or procedure.

<b>Materials and Equipment</b>	<b>Materials and Equipment (Site Specific)</b>
Back-up power capacity	
Thermometers	
Back-up freezers and refrigerators	
Back-up lighting	
Adequate Liquid Nitrogen Supply	
Alarm systems	
Alarm system contact lists	

#### 6.0 DEFINITIONS

**Custodianship:** Responsibility for safe keeping of tissue samples and associated data and control of their use and eventual disposal in accordance with the terms of the consent given by the participant and as regulated by the Research Ethics Board. Custodianship implies some rights to decide how the samples are used and by whom, and also responsibility for safeguarding the interests of donors.

**Human Biological Material:** All biological material of human origin, including organs, tissues, bodily fluids, teeth, hair and nails, and substances extracted from such material such as DNA and RNA.

**Safety:** Processes, procedures and technologies to ensure freedom from danger or harm.

**Storage:** Maintenance of specimens for future use.

## 7.0 PROCEDURES

The storage facility (and storage equipment) is a key element in the operation of a tumour repository. Proper maintenance of the facility and equipment should be the responsibility of designated personnel.

### 7.1 Storage Facility - Temperature

1. Ensure appropriate air cooling and ventilation to maintain ambient temperatures at approximately 18 - 22° C. Freezers and refrigerators contribute heat to the environment and conditions should prevent overheating of equipment.

### 7.2 Storage Facility - Air Flow

1. Ensure conditions of humidity to prevent fungal growth in the storage area of the repository.
2. Ensure adequate air circulation around freezers and refrigeration units to prevent excessive moisture and condensation.
3. Provide adequate ventilation to ensure that sufficient oxygen levels are maintained in areas where dry ice or liquid nitrogen is used.
4. If needed, ensure filtration for air flow to prevent excessive dust in the storage facility.

### 7.3 Storage Facility - Lighting

1. Have adequate general and task lighting to ensure that the appropriate level of illumination is available to perform routine and specialized tasks undertaken at the repository. Lighting should be of correct intensity to facilitate accurate reading of labels for proper storage and retrieval of samples.
2. Ensure back-up lighting for emergency situations.

## Maintenance of Sample Storage Facility and Equipment

---

### 7.4 Storage Facility - Back-up Capacity

1. Provide adequate back-up capacity for low temperature units in anticipation of equipment failure. Have a power generation system in place to deal with loss of commercial power for at least 72 hours.
2. Extra capacity, equal to at least the capacity of the largest storage unit, and equivalent to 10% (or other percentage as specified) of the total storage capacity, must be maintained at operating temperature at all times.
3. Train personnel in processes ensuring rapid transfer of HBMs to back-up units when the need arises.
4. Document sample transfer to back-up unit, and track samples to ensure return to correct location when corrective action has been taken.

### 7.5 Equipment - General Maintenance

1. Routinely inspect equipment for cleanliness, sanitation, malfunctions, possible contamination and proper calibration (yearly calibration is sufficient for freezers).
2. Put into place a system for maintenance and repair of storage equipment and supporting systems.
3. Preventative maintenance should be in place for all operations and facility systems and should be performed at intervals as per manufacturer's recommendations.
4. Where appropriate, calibrate all automated, mechanical, electronic and other equipment according to established procedure or as recommended by the manufacturer.
5. Allow only authorized maintenance personnel to carry out repairs and services to storage equipment.

### 7.6 Storage Equipment – Cryogenic Freezers

1. Maintain an adequate supply of liquid nitrogen to fill cryogenic freezers or containers. A minimum 3-day supply should be maintained with the assumption that re-supply is available.
2. Monitor all liquid nitrogen containers to ensure that the optimal vapour phase is maintained.
3. Utilize a centralized alarm system to monitor liquid nitrogen levels where feasible. If a centralized alarm system is not feasible, ensure a security walk-through is carried out at appropriate intervals to detect temperature deviations and take timely corrective action.

## Maintenance of Sample Storage Facility and Equipment

---

4. Establish alarm set-points to permit sufficient time for corrective action before damage to the collection occurs and ensure that the alarm system is functional.
5. Post a 24 hour emergency contact list with multiple personnel that can be contacted in case of freezer malfunction.
6. Review list (at least once annually) and modify to reflect changes in personnel or contact information.
7. Number all freezers so that they can be easily identified in case of an emergency.
8. Avoid temperature fluctuations. Advise personnel to minimize the number of times the freezer is opened within a given time.
9. Only one rack or box should be removed at a time.

### 7.7 Storage Equipment – Mechanical Freezers

1. Mechanical freezers used in the repository may be in -20° to -150° C range. Because they are run on commercial power sources make sure that adequate back-up power is available in case of emergency situations.
2. Ensure that the freezers have an alarm system in place.
3. Establish alarm set-points to permit sufficient time for corrective action before damage to the collection occurs. This will permit some leeway for warming that occurs during operational variation.
4. Ensure that the alarm is functional both for temperature variation and electrical power supply interruption.
5. Post a 24 hour emergency contact list with multiple personnel that can be contacted in case of freezer malfunction.
6. Review list (at least once annually) and modify to reflect changes in personnel or contact information.
7. Number all freezers so that they can be easily identified in case of an emergency.
8. Do not leave freezer doors open for more than 2 minutes.
9. Only one rack or box should be removed at a time.
10. It is optimal to have mechanical freezers that are not self-defrost. Monitor freezers for build up of frost around doors and storage units that could prevent normal operation or inhibit proper sealing of freezer doors.
11. At regular intervals (based on usage and frost build up) these units should be defrosted. Have adequate back-up capacity at the correct temperature for these occasions.
12. Train personnel in defrost procedures ensuring rapid transfer of HBMs to back-up units.

## 7.8 Storage Equipment – Refrigerators

1. Refrigerators must be kept at temperatures between 2° - 8° C.
2. Monitor high and low set-points

## 8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

1. Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, August 1998. <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>
2. Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER). <http://www.isber.org>
3. US National Biospecimen Network Blueprint  
[http://www.ndoc.org/about\\_ndc/reports/NBN\\_comment.asp](http://www.ndoc.org/about_ndc/reports/NBN_comment.asp)

## 9.0 APPENDICES

None