


Maintenance of Sample Storage Facility and Equipment

CTRNet Standard Operating Procedure Maintenance of Sample Storage Facility and Equipment			
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Approved By:	CTRNet Management Group (CMG)		01-May-2012
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1.0 PURPOSE

Tumour biobanks or biobanks 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 biobank. HBMs are a precious resource and each biobank 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 CTRNET SOPS OR POLICIES

Note: When adopting this SOP for local use please reference CTRNet.

3.1 CTRNet Policy: POL 2 Ethics

3.2 CTRNet Policy: POL 4 Privacy and Security

3.3 CTRNet Policy: POL 7 Material and Information Handling Policy

4.0 ROLES AND RESPONSIBILITIES

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

Tumour Biobank Personnel	Responsibility/Role
Laboratory Technician/Technologist	Responding to alarms and checking that maintenance procedures are carried out.
Biobank Director, Manager, and/or Coordinator	Responding to alarms, overseeing that maintenance procedures are carried out and updating lists and procedures.

Maintenance of Sample Storage Facility and Equipment

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.

Materials and Equipment	Materials and Equipment (Site Specific)
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

See the CTRNet Program Glossary: <http://www.ctrnet.ca/glossary>

7.0 PROCEDURES

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

7.1 Storage Facility – Temperature

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

7.2 Storage Facility – Air Flow

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

7.3 Storage Facility - Lighting

- 7.3.1 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 biobank. Lighting should be of correct intensity to facilitate accurate reading of labels for proper storage and retrieval of samples.
- 7.3.2 Ensure back-up lighting for emergency situations.

Maintenance of Sample Storage Facility and Equipment

7.4 Storage Facility – Back-up Capacity

- 7.4.1 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.
- 7.4.2 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.
- 7.4.3 Train personnel in processes ensuring rapid transfer of HBMs to back-up units when the need arises.
- 7.4.4 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

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

7.6 Storage Equipment – Cryogenic Freezers

- 7.6.1 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.
- 7.6.2 Monitor all liquid nitrogen containers to ensure that the optimal vapour phase is maintained.
- 7.6.3 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.
- 7.6.4 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.
- 7.6.5 Post a 24-hour emergency contact list with multiple personnel that can be contacted in case of freezer malfunction.
- 7.6.6 Review list (at least once annually) and modify to reflect changes in personnel or contact information.
- 7.6.7 Number all freezers so that they can be easily identified in case of an emergency.
- 7.6.8 Avoid temperature fluctuations. Advise personnel to minimize the number of times the freezer is opened within a given time.
- 7.6.9 Only one rack or box should be removed at a time.

Maintenance of Sample Storage Facility and Equipment

7.7 Storage Equipment – Mechanical Freezers

- 7.7.1 Mechanical freezers used in the biobank may be in -20° C 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.
- 7.7.2 Ensure that the freezers have an alarm system in place.
- 7.7.3 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.
- 7.7.4 Ensure that the alarm is functional both for temperature variation and electrical power supply interruption.
- 7.7.5 Post a 24-hour emergency contact list with multiple personnel that can be contacted in case of freezer malfunction.
- 7.7.6 Review list (at least once annually) and modify to reflect changes in personnel or contact information.
- 7.7.7 Number all freezers so that they can be easily identified in case of an emergency.
- 7.7.8 Do not leave freezer doors open for more than 2 minutes.
- 7.7.9 Only one rack or box should be removed at a time.
- 7.7.10 It is optimal to have mechanical freezers that are not self-defrost. Monitor freezers for buildup of frost around doors and storage units that could prevent normal operation or inhibit proper sealing of freezer doors.
- 7.7.11 At regular intervals (based on usage and frost buildup) these units should be defrosted. Have adequate back-up capacity at the correct temperature for these occasions.
- 7.7.12 Train personnel in defrost procedures ensuring rapid transfer of HBMs to back-up units.

7.8 Storage Equipment – Refrigerators

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

7.9 Storage Facilities for Tissue Blocks

- 7.9.1 There is no international standard for the storage of tissue blocks or cut tissue section. Options may include the following:
 - a) Room temperature storage in a well-ventilated and air-conditioned area to avoid fluctuations in temperature from season to season.
 - b) Refrigerated environment where temperatures are maintained between 2° and 8° C. This could be a refrigerator or a cold room. Care should be taken to ensure a low level of humidity.
 - c) Cut sections may be stored in appropriate slide boxes, vacuum packed, or paraffin dipped. The storage method chosen should be validated for the recovery of common antigens using immunohistochemistry (IHC) techniques.
 - d) A second site for storage should be identified in the event that an emergency impacts on the safe storage in the primary location. Duplicate Tissue Micro Arrays (TMAs) should be stored in separate locations.

Maintenance of Sample Storage Facility and Equipment

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.1 Tri-Council Policy Statement 2; 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, December 2010.

<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-epct2/Default/>

8.2 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/Search/search.asp?zoom_query=best+practices+for+repositories

8.3 US National Biospecimen Network Blueprint

<http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp>

9.0 APPENDICES

None

10.0 REVISION HISTORY

SOP Number	Date revised	Author	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
4.1.006 e1.0	May 2012	CMG	<ul style="list-style-type: none"> • Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates • Updated SOP references • Section 1: Deleted “delicate” • Section 4: Deleted Bank Director and responsibility/role. • Added 7.9 a, b, c, and d.