

CTRNet Standard Operating Procedure Physical Security at Tumour Bank			
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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
FS 002.001	2005	JdSh	Original
4.1.001 e1.0	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 manage the safekeeping of Human Biological Materials (HBMs) in their custody. HBMs are a precious and delicate resource and each repository should use basic security systems to provide a protective environment for the resource they control.

2.0 SCOPE

This standard operating procedure (SOP) outlines general elements and features that should be in place to provide a safe and efficient environment for the repository employees. It also covers physical security of the material (tissue and information) stored in the repository

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 RESPONSIBILITY

The policy applies to all personnel from CTRNet member repositories who work at the repository site or are the responsible custodians of the collection within the bank.

Tumour Bank Personnel	Responsibility/Role	Site Specific Personnel and Contact Information
Lab Technicians	Maintaining Security at Bank	
Bank Director	Maintaining Security at Bank	
Bank Manager/Coordinator	Maintaining Security at Bank	

5.0 MATERIALS, EQUIPMENT AND FORMS

Items 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)
Emergency Contact Lists	
Maintenance Documentation	

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 (HBM): 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 facility should employ fundamental security systems to protect the collection. An efficient tumour repository should be designed and have elements in place to provide a safe, secure and efficient work environment. Measures should also be taken to protect expensive and specialized equipment at the facility.

7.1 Facilities - General Procedures for Maintaining Security

1. Provide sufficient and secure space in the repository for equipment, material being stored and personnel employed.
2. Provide basic security systems to ensure safekeeping of the collection. Monitor the systems adequately to allow for prompt response to any breach in security.
3. Designate a responsible individual (including designated back-up) to take necessary action in case of a security breach.
4. Post emergency contact information for responsible individuals and key personnel in a prominent location within the repository.
5. Provide personnel with education and training about security and emergency procedures to ensure an appropriate response to any security breach that may occur.

7.2 Facilities - Temperature

1. Provide a suitable heating system to maintain ambient temperature to prevent freezing of water and drain lines.
2. When needed provide suitable cooling to maintain adequate ambient temperature for electronic and mechanical equipment.

7.3 Facilities – Air Flow

1. Provide adequate ventilation and air flow to ensure safety when using biohazardous materials or hazardous chemicals.

7.4 Facilities - Lighting

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 repository.
2. Provide back-up lighting for emergency situations.

7.5 Security Systems for Fire

1. Ensure that the fire prevention system is compliant with the codes and regulations in effect.

7.6 Facilities – Limiting Access.

1. Define and create physical barriers around repository resources to prevent physical intrusion.
2. Lock all doors and control entry to repository facilities.
3. Limit access to repository facilities to appropriate personnel and authorized staff.
4. Use physical, electronic and/or procedural controls to limit access to restricted and sensitive areas of the repository.
5. Issue personnel with visible identification and controlled access keys. Upon termination of employment, make personnel surrender all identification and access keys.
6. Report lost or stolen access cards, deactivate these cards immediately and issue a new card as appropriate.
7. Review and keep up-to-date access rights, remove access for individuals that no longer need access.
8. Grant restricted access to authorized visitors or third party personnel.

7.7 Facilities – Back-up Power System

1. Have a power generation system in place to deal with loss of commercial power.
2. Keep a sufficient fuel supply for the emergency power generation system to ensure to provide emergency power for a minimum of 48-72 hours.
3. Protect electronic systems, computers and freezers by an uninterruptible power supply.
4. Have appropriate procedures in place to test the back-up power generation system for reliable function (as per manufacturer's instructions).

7.8 Facilities – Equipment Security

1. Protect equipment as needed to reduce risk of unauthorized access to data and HBMs stored in the repository and to protect from loss and damage.
2. Maintain equipment correctly to ensure continued availability and integrity.
3. Allow only authorized maintenance personnel to carry out repairs and services to facilities equipment.

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

9.0 APPENDICES

None