

Title	Biospecimen Facility Maintenance and Security
SOP Code	SOP002_01
Effective Date	01-Sep-2012

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy

1.0 PURPOSE

This Standard Operating Procedure (SOP) outlines elements and features that should be in place to provide a safe, secure, and efficient environment for the repository employees as well as processes that should be in place to provide appropriate and optimal storage conditions of biospecimens.

2.0 SCOPE

An efficient biospecimen storage facility should have elements in place to provide a safe, secure, and efficient work environment. Biospecimens are a precious and delicate resource and each site should maintain their storage facilities and equipment to provide safekeeping and optimal conditions for maintaining specimen quality until shipment to a central laboratory. Furthermore, each site should follow the applicable regulations, guidelines and legislation (such as Occupational Health and Safety Guidelines)

3.0 RESPONSIBILITIES

This SOP applies to clinical research and biorepository personnel involved in biospecimen management. Roles and responsibilities may vary at specific sites

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Facility Security

- 5.1.1 Provide sufficient space in the facility for equipment, material being stored, and personnel.
- 5.1.2 Control entry to the facility, use physical, electronic, and/or procedural controls to limit access to restricted and sensitive areas of the facility.
- 5.1.3 Limit access to facilities to only appropriate personnel and authorized staff.
- 5.1.4 Educate and train personnel about security and emergency procedures.
- 5.1.5 Issue personnel with visible identification and controlled access method
Upon termination of employment, personnel must surrender all identification and access method as required by site.
- 5.1.6 Report lost or stolen access methods. Deactivate these methods immediately and issue new methods as appropriate.
- 5.1.7 Review and keep up-to-date access rights for the facility. Remove access for individuals that no longer need access.
- 5.1.8 Grant access to authorized visitors or authorized third party personnel.
- 5.1.9 Post emergency contact information for responsible individuals and key personnel in a prominent location within the facility.
- 5.1.10 Designate a responsible individual (including designated back-up) to assess and follow up on a security breach as necessary.

5.2 Temperature

- 5.2.1 Provide a suitable heating system to maintain ambient temperature approximately 18 - 22°C to prevent freezing of water and drain lines.
- 5.2.2 Provide a suitable cooling and ventilation system to maintain ambient temperature approximately 18 - 22°C to prevent overheating of heat-generating electronic and mechanical equipment, such as freezers and refrigerators.

5.3 Air Flow

- 5.3.1 Provide adequate ventilation and air flow to ensure safety when using biohazardous materials or hazardous chemicals.
- 5.3.2 Ensure conditions of humidity to prevent fungal growth in the storage area of the repository.
- 5.3.3 Ensure adequate air circulation around freezers and refrigeration units to prevent excessive moisture and condensation.
- 5.3.4 Provide adequate ventilation to ensure that sufficient oxygen levels are maintained in areas where dry ice or liquid nitrogen is used.

5.4 Lighting

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

5.5 Security Systems for Fire

- 5.5.1 Ensure that the fire prevention system is compliant with all codes and regulations.

5.6 Electrical Power Supply

- 5.6.1 Ensure that alarm systems are in place to alert personnel that primary power supply has been interrupted.
- 5.6.2 Post a 24-hour contact list in the lab with names of facility personnel that are responsible for responding to the power emergency.

5.7 Back-up Power System

- 5.7.1 Ensure that a power generation system is in place to deal with loss of commercial power.
- 5.7.2 Protect electronic systems, computers, incubators, refrigerators, and freezers with an uninterruptible power supply.

5.7.3 Ensure that back-up power equipment is clearly visible and easily identified.

5.8 Transfer into Back-up Storage Equipment

5.8.1 Provide adequate back-up capacity for low temperature units such as freezers and refrigerators in anticipation of equipment failure.

5.8.2 Ensure that an alternative storage unit, equal to at least the capacity of the largest storage unit, is available and maintained at operating temperature at all times.

5.8.3 Ensure that alarm systems are operational and monitored on back-up equipment.

5.8.4 Train personnel in processes ensuring rapid transfer of biospecimens to back-up units when the need arises. Alert appropriate personnel that a biospecimen transfer has been performed.

5.8.5 Document biospecimen transfer to a back-up unit. Record details of storage pattern to ensure return to the correct location when the corrective action has been taken.

5.9 General Equipment Maintenance

5.9.1 Routinely inspect equipment for cleanliness, sanitation, malfunctions, possible contamination, and proper calibration.

5.9.2 Establish a system for maintenance and repair of storage equipment and supporting systems.

5.9.3 Establish a preventive maintenance program for all operations and facility systems. Perform maintenance at intervals as per manufacturer's recommendations.

5.9.4 Calibrate all automated, mechanical, and electronic equipment according to established procedure, or as recommended by the manufacturer.

5.9.5 Allow only authorized maintenance personnel to carry out repairs and services to equipment.

5.9.6 Keep records of all maintenance and repairs.

5.10 Cryogenic Freezers Maintenance

- 5.10.1 Maintain an adequate supply of liquid nitrogen to fill cryogenic freezers or containers.
- 5.10.2 Monitor all liquid nitrogen containers to ensure that the optimal vapour phase is maintained.
- 5.10.3 Utilize a centralized alarm system to monitor liquid nitrogen levels where feasible. If a centralized alarm system is not feasible, ensure an alternate method is carried out at appropriate intervals to detect temperature deviations and take timely corrective action.
- 5.10.4 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.
- 5.10.5 Post a 24-hour emergency contact list with multiple personnel that can be contacted in case of freezer malfunction.
- 5.10.6 Review list (at least once annually) and modify to reflect changes in personnel or contact information.
- 5.10.7 Number all freezers so that they can be easily identified in case of an emergency.
- 5.10.8 Avoid temperature fluctuations. Advise personnel to minimize the number of times the freezer is opened within a given time.
- 5.10.9 Remove only one rack or box at a time.

5.11 Mechanical Freezer Maintenance

- 5.11.1 Mechanical freezers used in the facility may be in the -20° to -150°C range. Because they are run on commercial power sources, ensure that adequate back-up power is available in case of emergency situations.
- 5.11.2 Ensure that the freezers have an alarm system in place.
- 5.11.3 Establish alarm set-points to permit sufficient time for corrective action before damage to the collection occurs. This will permit a range for warming that occurs during operational variation.
- 5.11.4 Ensure that the alarm is functional, both for temperature variation and electrical power supply interruption.

- 5.11.5 Post a 24-hour emergency contact list with multiple personnel that can be contacted in case of freezer malfunction.
- 5.11.6 Review list (at least once annually), and modify to reflect changes in personnel or contact information.
- 5.11.7 Number all freezers, so that they can be easily identified in case of an emergency.
- 5.11.8 Avoid temperature fluctuations. Advise personnel to minimize the number of times the freezer is opened within a given time.
- 5.11.9 Remove only one rack or box at a time.
- 5.11.10 It is optimal to have mechanical freezers that require manual defrost. Defrost these units at regular intervals (based on usage and frost build up).
- 5.11.11 Train personnel in defrost procedures, ensuring rapid transfer and correct storage of biospecimens to back-up units.

5.12 Refrigerator Maintenance

- 5.12.1 Maintain refrigerators between 2° - 8° C.
- 5.12.2 Monitor high and low set-points.

6.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

2011 NCI Best Practices for Specimen Resources. Office of Biorepositories and Biospecimen Research, National Cancer Institute, Bethesda, MD.
<http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf>

ISBER Best Practices for repositories: Collection, storage, retrieval and distribution of biological materials for research. Cell Preservation Technology 6(1), 3-58, 2008 <http://www.isber.org/Pubs/BestPractices2008.pdf>



CTRNET Standard Operating Procedures, Canadian Tumour Repository Network,
<http://www.ctrnet.ca/operating-procedures>



7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP002_01	01-Sep-2012	Original version