Title	Inventory Verification
SOP Code	SOP004_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) describes the process for inventory verification. It outlines process validation steps to be followed to check that the correct storage locations have been entered in the inventory system. The SOP does not cover detailed safety procedures for handling Human Biological Materials (HBMs) or hazardous chemicals.

2.0 SCOPE

The primary purpose of the inventory system is to track inventory within a storage facility at the site. As part of a Quality Assurance system, inventory verification should be conducted to confirm that the appropriate specimens are in the correct freezer locations. This will validate that procedures are working to ensure sample traceability.

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 Personnel and Training

5.1.1 Assign personnel qualified by training and education to conduct the verification.

5.1.2 Ensure that the assigned personnel have authority to access the inventory system and storage facility.

5.2 Inventory Verification

5.2.1 Conduct inventory verification on a periodic basis (at least annually).

5.2.2 Conduct specimen selection for inventory verification on a random basis.

5.2.3 Conduct the check on 1% percent of the new specimens collected since the last time inventory verification was performed.

5.2.4 Access the inventory system using appropriate passwords and security measures.

5.2.5 Look up the storage location of the randomly chosen specimens in the inventory system.

5.2.6 Access the storage facility.

5.2.7 Use appropriate safety and security precautions for accessing the storage facility and handling biospecimens.

5.2.8 Remove specimens from storage receptacle and verify the label information matches the specimen information recorded in the inventory system.

5.2.9 Minimize time that specimens are handled or removed from required storage conditions.

5.2.10 Use dry ice to keep specimens frozen, if the process takes longer than anticipated.

5.2.11 Return specimens to the designated storage spot and ensure that storage equipment reaches optimally set temperatures.

5.2.12 Lock and secure the storage facility.

5.2.13 Record the date and details of the check in the inventory system.

5.2.14 If a specimen is missing or does not match recorded inventory information, change the inventory system to reflect the actual information. File a deviation report and investigate the reason for the deviation. Apply and document the corrective and preventive action.

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
SOP004_01	01-Sep-2012	Original version