CTRNet Standard Operating Procedure Inventory Verification			
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Subject:	Inventory Verification	Category	Material Handling and Documentation

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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions

1.0 PURPOSE

In operating a tumour tissue repository there is a responsibility to maintain and operate the bank to safeguard the collection. The use of an informatics system for documenting and tracking the collection is crucial. A database developed specifically for documenting and storing sample information will be part of the informatics system. As part of the Quality Assurance system, inventory verification should is conducted to confirm that the appropriate specimens are in the correct freezer locations.

2.0 SCOPE

The SOP covers the procedures for inventory verification. It outlines process validation steps to be followed to check that the correct storage locations have been entered in the computerized inventory system. These steps may be adopted as is, or modified by specific CTRNet member repositories at their collection sites to allow for the incorporation of site-specific details, conditions, requirements and features of their informatics system.

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

1. CTRNet Policy: POL 005.001 Records and Documentation
2. CTRNet Policy: POL 007.001 Material and Information Handling
3. CTRNet Policy: POL 004.001 Privacy and Security
4. CTRNet Generic SOP: 3.1.008 Records and Documentation

4.0 ROLES AND RESPONSIBILITY

The SOP applies to all qualified tumor bank personnel and laboratory staff that are responsible for entering data in the informatics system, maintaining the informatics system, storing samples in freezers and refrigerators and performing inventory verification. This may include the following personnel:

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Lab Technician/Data Entry Clerk	Responsible for storing samples, entering data in the informatics system and for conducting inventory verification	
Tumour Bank Analyst or Pathology Coordinator	Responsible for conducting verification on informatics system	
Tumour Bank Manager	Responsible for initiating inventory verification	

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)**
Inventory Database	
Safety equipment for handling stored samples such as face shield and thermal gloves for liquid nitrogen storage containers.	
Dry Ice	
Cooled racks	

6.0 DEFINITIONS

Informatics System: Refers to software, hardware, written documents, support and training necessary to annotate, track, and distribute biospecimens within a tumor bank or repository network.

Process Validation: The process demonstrating that a specific procedure will consistently produce expected results within predetermined specifications.

Quality Assurance (QA): An integral system of management activities involving planning, implementation, documentation, assessment, and improvement to ensure that a process or item is of the type and quality needed for the project. Same as Quality Management Systems (QMS).

Traceability: The ability to locate a specimen during any step of its donation, collection, processing, testing, storage and disposition.

Tumor Bank or Repository: Regional, provincial or local repositories that coordinates the collection, processing, storage and distribution of tumour tissue and associated annotated data; normally derived from consented participants for the purpose of medical research. The term ‘bank’ and ‘repository’ is used interchangeably.

7.0 PROCEDURES

The primary purpose of the informatics system is to annotate and track inventory within a tumor bank or repository network. This verification procedure is designed to confirm that appropriate repository samples are in the correct freezer locations as indicated by the computerized inventory system. It validates that procedures are working to ensure sample traceability.

7.1 Verification procedures – personnel and timing

1. Assign tumour bank personnel qualified by training and education to conduct the verification.

2. Ensure that the assigned tumour bank personnel have authority access to the informatics system and storage facility.

7.2 Verification of inventory

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

2. Conduct sample selection for inventory verification on a random basis.

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

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

5. Look up the storage location of the randomly chosen sample in the inventory system/database.

6. Access the storage facility.

7. Use appropriate safety and security precautions for accessing the cryopreservation facility and handling biology samples.

8. Remove sample from storage receptacle and verify that label matches the sample recorded in the database.

9. Minimize time that samples are handled or removed from required storage conditions.

10. Use dry ice to keep sample frozen if the process takes longer than anticipated.

11. Return sample to its designated storage spot and ensure that storage equipment reaches optimally set temperatures.

12. Lock and secure facility

13. Record details of check in a QA system.

14. If sample is missing or incorrect (does not match recorded inventory) Then change inventory system to reflect the actual situation.

15. File a deviation report.

16. Investigate the reason for the deviation.

17. Make and document corrective action.

8.0 APPLICABLE REFERENCES, REGULATONS AND GUIDELINES

1. Declaration of Helsinki. http://ohsr.od.nih.gov/helsinki.php3 http://www.wma.net/e/policy/b3.htm
2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8. http://www.ich.org http://www.ich.org/UrlGrpServer.jser?@_ID=276&@_TEMPLATE=254
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials. Division 5. Canada Gazette Part II, Vol. 135, No. 13, June 7, 2001 Section C.05.010 Sponsor Obligations http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/food_drug_reg_amend_1024_gcp_tc_e.html
4. 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
5. 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
6. US National Biospecimen Network Blueprint http://www.ndoc.org/about_ndc/reports/NBN_comment.asp

