| CTRNet Standard Operating Procedure<br>Inventory Verification | | | |
|---|---|---|---|
| SOP Number: | 08.01.003 | Version: | e2.0 |
| Supersedes: | 8.1.003 e1.0 | Category: | Material Handling and Documentation - General |

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|---|---|---|
| Approved By: | CTRNet Management Group (CMG) | 01-June-2012 |
| | Per: Brent Scahcter | 14-June-2012 |

## 1.0 PURPOSE

In operating a tumour biobank there is a responsibility to maintain and operate the biobank 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 be conducted to confirm that the appropriate specimens are in the correct freezer locations.

## 2.0 SCOPE

This standard operating procedure (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 biobanks 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

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

**3.1** *CTRNet Policy: POL 5 Records and Documentation*
**3.2** *CTRNet Policy: POL 7 Material and Information Handling*
**3.3** *CTRNet Policy: POL 4 Privacy and Security*
**3.4** *CTRNet Standard Operating Procedures: SOP 03.008 Document Maintenance*

## 4.0 ROLES AND RESPONSIBILITIES

The SOP applies to all qualified tumour biobank 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 Biobank Personnel** | **Responsibility/Role** |
|---|---|
| Laboratory Technician/Technologist, 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

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

## 7.0 PROCEDURES

Biobanks are encouraged to employ a suitable informatics system. The primary purpose of the informatics system is to annotate and track inventory within a tumour biobank or biobank network. This verification procedure is designed to confirm that appropriate biobank samples are in the correct location in the storage unit as indicated by the computerized inventory system (eg. cabinets, refrigerators, freezers, liquid nitrogen tanks). It validates that procedures are working to ensure sample traceability.

### 7.1 Verification Procedures – Personnel and Timing

7.1.1 Assign tumour biobank personnel qualified by training and education to conduct the verification.

7.1.2 Ensure that the assigned tumour biobank personnel have authority access to the informatics system and storage facility

### 7.2 Verification of Inventory

7.2.1 General:

7.2.1.1 Conduct inventory audit on a periodic basis (annually or as appropriate).

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

7.2.1.3 Ensure that a percentage of new samples collected are included since the last time inventory verification was performed.

7.2.2 Procedure:

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

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

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

7.2.2.4 Where appropriate, ensure that the temperature is controlled during inventory verification (Eg. Use dry ice to keep sample frozen if the process takes longer than anticipated.)

7.2.2.5 Return sample to its designated storage spot and ensure that storage unit reaches optimally set temperatures.

7.2.2.6 Lock and secure unit.

7.2.2.7 Document results of inventory verification. Identify any deviations and document any corrective actions.

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

## 8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

**8.1** Declaration of Helsinki.
http://www.wma.net/en/30publications/10policies/b3/index.html

**8.2** 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/dhp-mps/compli-conform/clini-pract-prat/reg/1024-eng.php

**8.3** 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-eptc2/Default/

**8.4** 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

**8.5** US National Biospecimen Network Blueprint
http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp

**8.6** International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8.

http://www.ich.org/products/guidelines.html

## 9.0 APPENDICES

None

## 10.0 REVISION HISTORY

| SOP Number | Date revised | Author | Summary of Revisions |
|---|---|---|---|
| 8.1.003 e1.0 | June 2012 | CMG | • Grammatical and formatting throughout<br>• Definitions removed<br>• Revision History moved to bottom<br>• Reference links updates<br>• Updated SOP references<br>• Section 7.0: Inserted first sentence.<br>• Section 7.2: Revisions to 7.2.1, 7.2.3, 7.2.6, 7.2.10, 7.2.12, and 7.2.13. |
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