

CTRNet Standard Operating Procedure Labeling and Tracking Materials			
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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions

1.0 PURPOSE

The purpose of this CTRNet Standard Operating Procedure (SOP) is to outline general procedures that can be used by repositories to ensure that labeling and tracking are maintained with essential standards to prevent loss of samples due to inadequate identifying information.

2.0 SCOPE

The Standard Operating Procedure (SOP) describes how samples are labeled and tracked.

3.0 REFERENCE TO OTHER POLICIES AND SOPS

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

4.0 ROLES AND RESPONSIBILITY

The policy applies to all personnel from CTRNet member repositories that are responsible for obtaining, processing storing and tracking human biological samples in the tumor bank.

Tumour Bank Personnel	Responsibility/Role	Site Specific Personnel and Contact Information
Consent Nurse	Obtain Patient Consent	
Phlebotomist/ Venipuncture nurse	Draw Blood from patient and read and understand product inserts	
Lab Technician	Transport and Process blood	
Tissue Bank Manager/Director	Responsible for Operation and Quality Assurance at a tumour bank	

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)
Appropriate Labels such as Cryogenic Thermal Transfer-Tags	
Computerized Inventory system	

6.0 DEFINITIONS

Audit Trail: Documentation that allows reconstruction of the course of events that occurred before, during and after the conduct of a collection, storage and release of a tumour sample and associated information.

7.0 PROCEDURES

This procedure is intended to ensure that samples obtained from consented participants are appropriately identified and tracked to eliminate the risks of sample misidentification and loss.

7.1 Labeling of Samples

1. Label all level of receptacles containing human biological samples or products, from the smallest unit (cryovial, histological slide, or filter) to the large storage units.
2. Make sure that each label used adheres tightly to the receptacle under all projected storage conditions. Do not use labels that will come out in liquid nitrogen or under specific conditions of heat or cold used for processing or storage.
3. Make sure the printing on the labels is resistant to all common laboratory solvents and water. (e.g., use a cryomarker, cold-resistant label, waterproof/solvent-proof pen, thermal-transfer printer)
4. Test adherence of labels to containers as well as different types of marking ink under different storage conditions before implementing the labelling method for routine use.
5. Only include information on the label that is compliant with applicable privacy legislation. Do not include patient identifying information. Identifying information such as health insurance number, etc. must not be on the label.
6. However, the information should be specific enough so that the encoded information (e.g., unique identifier or tracking number assigned by tumour bank) can be associated with the sample in the database.
7. If there is sufficient space on the label, additional information may be included. Only include static information. Caution: Inclusion of dynamic information will cause relabeling.
8. Consider labelling by computer and not by hand as this will eliminate problems that arise due to variations in handwriting and misreading of labels.
9. If possible, use a bar coded labelling system utilizing a linear (one dimensional) bar code that includes human readable identification of contents.

7.2 Tracking and Inventory system

A tracking and inventory should be place to ensure that a sample can be located at any time during collection, processing, storage, and distribution. The system should be capable of linking the sample to associated patient consent, clinical and research information. It should also be designed to ensure that the sample environment is kept as stable as possible during processing, storage, sorting and shipping.

1. Assign a unique identifier such as a tracking number or bar-code to each sample at the time of collection
2. Link the same identifier to all associated clinical and scientific data for the sample.
3. Update the inventory or tracking system to reject any movement or change in the sample or data within or outside the repository.

4. Ensure that the inventory and tracking system is capable of generating a full audit trail of changes made to the database or system,
5. Control access to the computerized inventory very tightly. Define what tasks a specific tumour bank employee may perform on the system (e.g., entering data or determining specimen availability).
6. Generate a unique identifier (address) for each freezer, refrigerator, or storage cabinet. Establish numbering for shelves, racks, boxes as well as each location within the storage receptacle.
7. Use the inventory system to track sample type, date of collection, volume and size of aliquots, history of sample movement, method and time of sample processing, shipment and thaws and deviations from regular storage conditions if relevant.

8.0 APPLICABLE REFERENCE, REGULATIONS AND GUIDELINES

1. Declaration of Helsinki. <http://ohsr.od.nih.gov/helsinki.php3>
<http://www.wma.net/e/policy/b3.htm>
2. 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>
3. Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series.
http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf
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>
5. National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol. I: Report and recommendations of the National Bioethics Advisory Committee. August 1999.
<http://bioethics.georgetown.edu/nbac/hbm.pdf>
6. US National Biospecimen Network Blueprint
http://www.ndoc.org/about_ndc/reports/NBN_comment.asp