CTRNet Standard Operating Procedure Labeling and Tracking Materials			
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Approved By:	CTRNet Management Group (CMG)	01-May-2012
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1.0 PURPOSE

The purpose is to outline general procedures that can be used by tumour biobanks to ensure that labeling and tracking are maintained with essential standards to prevent loss of samples due to inadequate identifying information

2.0 SCOPE

This standard operating procedure (SOP) describes how samples are labeled and tracked.

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 4 Privacy and Security*
3.3 *CTRNet Policy: POL 7 Material and Information Handling*

4.0 ROLES AND RESPONSIBILITIES

This SOP applies to all personnel from CTRNet member biobanks that are responsible for obtaining, processing storing and tracking human biological samples in the tumour biobank. Applicable staff may include the following roles:

Tumour Biobank Personnel	**Responsibility/Role**
Consent Nurse	Obtain Patient Consent
Phlebotomist/ Venipuncture nurse	Draw Blood from patient and read and understand product inserts
Biobank Staff/Laboratory Technician/Technologist	Transport and Process blood
Tumour Biobank Director, Manager, or Principal Investigator	Responsible for Operation and Quality Assurance at a tumour biobank

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	
Label printer	
Label scanner	

6.0 DEFINITIONS

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

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

7.1.1 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.

7.1.2 Make sure that each label used adheres tightly to the receptacle under all projected storage conditions. Do not use labels that will come off in liquid nitrogen or under specific conditions of heat or cold used for processing or storage.

7.1.3 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).

7.1.4 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.

7.1.5 Only include information on the label that is compliant with applicable privacy legislation. Do not include patient identifying information. Identifying information such as name, date of birth, health insurance number, etc. must not be on the label.

7.1.6 However, the information should be specific enough so that the encoded information (e.g., unique identifier or tracking number assigned by tumour biobank) can be associated with the sample in the database.

7.1.7 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.

7.1.8 Consider labelling by computer and not by hand, as this will eliminate problems that arise due to variations in handwriting and misreading of labels.

7.1.9 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 system should be in 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.

7.2.1 Assign a unique identifier such as a tracking number or bar code to each sample at the time of collection.

7.2.2 Link the same identifier to all associated clinical and scientific data for the sample.

7.2.3 Update the inventory or tracking system to reject any movement or change in the sample or data within or outside the biobank.

7.2.4 Ensure that the inventory and tracking system is capable of generating a full audit trail of changes made to the database or system,

7.2.5 Control access to the computerized inventory very tightly. Define what tasks a specific tumour biobank employee may perform on the system (e.g., entering data or determining specimen availability).

7.2.6 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.

7.2.7 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 REFERENCES, REGULATIONS AND GUIDELINES

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

8.2 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/

8.3 Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics
http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420

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 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

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

9.0 APPENDICES

None

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
8.1.001 e1.0	Oct 2011	MMA	Added definitions Updated references Other minor revisions: wording and formatting
8.1.001 e1.0	Mar. 2012	SD	See comments in the above table and in SOP 07.001 e2.0. Use terminology “biobank” or “tumour biobank”.
8.1.001 e1.0	June 2012	CMG	• Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates • Updated SOP references • Section 4.0: Added “Applicable staff may include the following roles:”