Title	Labelling and Tracking Materials for Biorepositories
SOP Code	SOP109_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) outlines the general procedures for labeling and tracking biorepository specimens.

2.0 SCOPE

Biorepository staff must ensure that labelling and tracking are maintained with essential standards to prevent loss of samples, due to inadequate identifying information.

3.0 RESPONSIBILITIES

The policy applies to all biorepository personnel responsible for obtaining, processing storing and tracking human biological specimens in the biorepository.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Sample Labelling

5.1.1. Label all levels of receptacles containing human biological samples or products, from the smallest unit (cryovial, histological slide, or filter) to the large storage units.

5.1.2. Ensure 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.

5.1.3. Ensure that 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). Consider labelling by computer and not by hand as this will eliminate problems that arise due to variations in handwriting and misreading of labels. If possible, use a bar coded labeling system utilizing a bar code that includes readable identification of contents.

5.1.4. Include only information on the label that is compliant with applicable privacy legislation. Do not include patient identifying information. Do not write identifying information, such as medical record number on the label.

5.1.5. Ensure that information is specific enough so that the encoded information (e.g., unique identifier or tracking number assigned by biorepository) can be associated with the sample in the database.

5.1.6. Include additional information, if there is sufficient space on the label. Include only static information.

5.2 Tracking and Inventory system

5.2.1. Assign a unique identifier such as a tracking number or bar-code to each specimen at the time of collection

5.2.2. Link the same identifier to all associated clinical and scientific data for the specimen.

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

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

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

5.2.6. 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.

5.2.7. Use the inventory system to track the sample unique identifier, sample type, date of collection, volume and size of samples, history of sample movement, method and time of sample processing, shipment and thaws and deviations from regular storage conditions, if relevant.

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
SOP109_01	01-Sep-2012	Original version