Title	**Labelling and Tracking Biospecimens for Clinical Trials**
SOP Code	SOP201_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 process for labelling and tracking biospecimens during processing, storage, and distribution.

2.0 SCOPE

Biospecimens obtained from consented participants must be appropriately labelled and tracked to eliminate the risks of inadequate biospecimen identification and loss. A tracking and inventory system should be place to ensure that a biospecimen can be located at any time during processing, storage, and distribution.

3.0 RESPONSIBILITIES

This SOP applies to clinical research personnel involved in labelling and tracking biospecimens for research. Roles and responsibilities may vary at specific sites.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Labelling of Samples

Note: Follow this procedure, unless otherwise instructed by the Sponsor.

5.1.1 Label all level of receptacles containing human biospecimens or products, from the smallest unit (cryovial, histological slide, or filter) to the large storage units, with a patient-specific label.

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 off 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 or pencil, thermal-transfer printer). Consider using computer-printed labels to eliminate problems that arise due to variations in handwriting and/or misreading of labels. If possible, use a bar-coded labelling system that also includes eye-readable biospecimen identification on the label.

5.1.4 Include only information on the label that is compliant with applicable privacy legislation, such as protocol number, study ID, sample type, and time point. Do not include patient identifying information, such as medical record number on the label.

5.1.5 Ensure that the information is specific enough so that the encoded information (e.g., unique identifier or accession number) can be associated with the biospecimen in the inventory system, and on the corresponding study requisition.

5.1.6 Optional: If there is sufficient space on the label, include additional information such as date of collection and time of collection. Include only static information.

5.2 Tracking and Inventory System

5.2.1 Record the assigned unique identifier, such as the accession number or bar-code from each biospecimen at the time of collection or receipt.

5.2.2 Generate a unique identifier for each freezer, refrigerator, or storage cabinet. Establish numbering for shelves, racks, and boxes, as well as each location within the storage receptacle, as applicable.

5.2.3 Update the inventory or tracking system with information collected on the study requisitions, such as date of collection, time of collection, sample type, number and volume of aliquots, time of fixation, time and place of storage, etc. It is best practice to also include information regarding method and time of specimen processing, shipping information, and deviations from processing or storage procedures.

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
SOP201_01	01-Sep-2012	Original version