Title	Tissue Collection and Transportation to Pathology
SOP Code	SOP113_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 standardized procedures for biorepositories for processing of tumour tissue collection, and transportation from the operating room (OR) to the pathology lab. This SOP does not describe detailed safety procedures for handling Human Biological Materials (HBMs).

2.0 SCOPE

This procedure ensures that tissue samples will be collected from participants in a safe, timely, and efficient manner, while eliminating the risks of contamination and maintaining high integrity and quality.

3.0 RESPONSIBILITIES

This procedure applies to all biorepository personnel responsible for collecting tissue from the participant.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 General Considerations

5.1.1 The scientific utility of the data obtained from the analysis of tissues is directly related to the quality of the tissue specimen.

5.1.2 Cellular and molecular integrity are most affected by factors such as specimen and tissue type, conditions of tissue hypoxia, method of preservation, conditions of storage, pre-excision hypoxia and tissue product extraction methods. The following factors must be the focus of the process to obtain and maintain tissue with suitable integrity for innovative research:

- Minimizing the time the tissue is subjected to hypoxic conditions, as this initiates the cell death mechanisms and subsequent degradation process.
- Use of agents or treatments to inactivate degrading enzymes for preserving nucleic acid integrity
- Preservation of tissue as fresh frozen, if the intended use is for nucleic acid analysis.
- Storage of frozen tissue and products at appropriate temperatures especially if storage is for longer periods of time.
- Avoiding contamination with surrounding histological distinct tissue or co-processed samples if the product is intended for studies involving nucleic acid amplification.

5.1.3 Note: Never place tissue intended for banking as a fresh frozen specimen in formalin.

5.2 Transporting Tissue from the OR to Pathology Lab

5.2.1 Collect only tumour tissue that is surplus to clinical needs and diagnosis for the biorepository.

5.2.2 Encourage the Operating Room (OR) staff to notify the pathologist or designate about the time of ischemia (when blood vessels were clamped).

5.2.3 Immediately after being notified by the OR team (or personnel responsible for identifying specimen availability) that a potentially bankable specimen will be available, the person responsible for obtaining the sample from the operating room must arrange to transport it to the pathology lab (or designated repository lab) in a manner optimal for preservation of cellular and molecular integrity.

5.2.4 Transport the tissue from the Operating Room to the Pathology Lab, using a rapid specimen transport protocol. Recommend that the tissue be transported on ice.

5.2.5 Prepare tissue collection kits in advance, if possible. Store kits as appropriate for contents.

5.2.6 Ensure that no more than 30 minutes elapses between the time of biopsy/resection and time of freezing of a given sample. If, due to practical considerations, the elapsed time is greater, records must clearly document the actual time period.

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
SOP113_01	01-Sep-2012	Original version