Title	Archival Tissue Request and Release for Clinical Trials
SOP Code	SOP206_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) describes the processes of requesting and releasing archival tissue material, to ensure that access and release of tissue specimens is ethical and efficient. The SOP does not cover detailed safety procedures for handling Human Biological Materials (HBMs) or hazardous chemicals.

2.0 SCOPE

Clinical trials often include a requirement for collection of archival tumour tissue from previous diagnostic biopsies or surgical resection. Archival tissue specimens are collected from participants that have been through the informed consent process. This includes ethical, legal, and practical considerations that arise in the process of releasing tissue samples from the 'custodian' to the researchers requesting specimens for clinical trials.

3.0 RESPONSIBILITIES

This SOP applies to clinical research personnel involved in requesting and collecting archival tissue for research. Roles and responsibilities may vary at specific sites.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Archival Tissue Request and Release

5.1.1 Communicate with the originating institution, outlining the following:

- Qualified/Principal Investigator name and contact information
- Title and description of research project
- Tissue requirements for blocks or slides
- Participant's name
- Participant's date of birth
- Surgical specimen required
- Destination and designated recipient of material

5.1.2 Provide additional information, if required by the originating hospital, e.g., signed Informed Consent Form, Research Ethics Board approval letter, etc.

5.1.3 Upon receipt of archival tissue, match the surgical specimen number on the archival material to the corresponding pathology report, to ensure that the correct tissue was received.

5.1.4 Store specimens in the biospecimen facility at room temperature, in boxes labelled with the study protocol number, until shipment or analysis is conducted.

5.1.5 Return any tissue blocks to the originating institution, after the tissue analysis is complete.

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
SOP206_01	01-Sep-2012	Original version