Title	Specimen Retrieval
SOP Code	SOP207_02
Effective Date	04-Jan-2016

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the process for specimen retrieval and documentation, under conditions designed to safeguard the quality and integrity of the specimen.

2.0 SCOPE

When specimens are required for laboratory work, it is necessary to retrieve previously collected specimens from local storage facilities.

3.0 RESPONSIBILITIES

This SOP applies to clinical research personnel involved in retrieving specimens for shipment. Roles and responsibilities may vary at specific sites.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 General Considerations for Frozen Specimens

5.1.1 The temperature at which frozen preparations are stored affects the length of time after which specimens can be recovered in the viable state. The lower the

storage temperature, the longer the viable storage period.

5.1.2 Handling during removal from storage will affect the viability of specimens and may result in degradation of cellular components. Every time a cryovial is exposed to a warmer environment, even briefly, it experiences a change in temperature.

5.1.3 Collect retrieved frozen cryovials into dry ice for sorting. Care must be taken to minimize exposure of the storage box to ambient temperatures.

5.2 Specimen Retrieval

5.2.1 Compile completed study requisitions for all specimens that need to be retrieved.

5.2.2 Locate the specimens to be retrieved in the inventory system, at the local storage facility.

5.2.3 Remove specimens to be retrieved from the storage unit. If specimens are missing or in an incorrect location, file a deviation report and follow up with corrective and preventive action as appropriate.

5.2.4 Place retrieved specimens in suitable containers or boxes, and label as required for transportation. Ensure that boxes are labelled with appropriate biohazard and dangerous goods labels.

5.2.5 Update the inventory system with the date the specimens were retrieved and the new location of the specimens.

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, 3rd Edition, 2012 http://www.isber.org

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP207_01	01-Aug-2012	Original version
SOP207_02	04-Jan-2016	5.2.3: Added “as appropriate” 5.2.4: Added “biohazard and dangerous goods labelling. Updated references. Removed OTRN logo.