Title	Specimen Retrieval from Biorepositories
SOP Code	SOP123_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 procedures for specimen retrieval and documentation. It outlines general factors that need to be considered during specimen retrieval, as well as specific steps that need to be followed to maintain the quality and integrity of the specimen.

2.0 SCOPE

This SOP outlines procedures that will ensure that retrieval will be conducted under conditions designed to safeguard the quality and integrity of the specimen.

3.0 RESPONSIBILITIES

This SOP applies to all qualified biorepository personnel and laboratory staff responsible for retrieving specimens.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 General Freezing and Thawing Considerations

Note: All attempts should be made to minimize temperature fluctuations.

5.1.1 Rate of cooling: The rate of cooling controls the size of ice crystals and how fast they are formed, which may affect cell recovery. A uniform cooling rate of 1° C per minute from ambient temperature is effective for a wide variety of cells. The steady decline of temperature can be achieved by the use of commercially available freezing devices (eg. from Nalgene) that control the rate of freezing.

5.1.2 Storage: The temperature at which frozen preparations are stored affects the length of time after which cells can be recovered in the viable state. The lower the storage temperature the longer the viable storage period.

5.1.3 Handling: In addition to temperature of storage, handling during removal from storage will affect the viability of cells and may result in degradation of cellular components. Every time an ampoule/vial is exposed to a warmer environment, even briefly, it experiences a change in temperature.

5.1.4 Reconstitution (thawing): Although slow cooling is generally best to insure cell viability, the opposite is required when thawing from the frozen state. Agitation of the vial/ampoule in a 37°C water bath is preferable, but may be detrimental to certain cell types if the process is too lengthy.

5.2 Locating Specimens in Storage

5.2.1 Create a requisition for specimen retrieval.

5.2.2 Check the requisition for accuracy, before transmitting to the biorepository .

5.2.3 Locate specimens to be retrieved on the inventory system.

5.3 Specimen Retrieval

5.3.1 Locate and pull specimens listed on the requisition, at the biorepository storage.

5.3.2 Maintain proper temperature of the specimens, according to specimen type. Collect retrieved frozen vials into pre-chilled metal racks on dry ice for sorting. Take care to minimize exposure of the ‘source’ storage box or tower to ambient temperatures.

5.3.3 Confirm that specimens on the requisition are accounted for in the freezer or storage container.

5.3.4 If missing or incorrect, file a deviation report and attempt to find the samples.

5.3.5 Place retrieved samples in appropriate container or boxes, and label as required for shipping or storage.

5.4 Documentation of Retrieval

5.4.1 Use a check list to record all steps, as required.

5.4.2 Make changes to the inventory system, as needed. If material is released, indicate where the sample was shipped. If processed, indicate derivative generated.

5.4.3 If applicable, keep records on number of times specimens may have been thawed and refrozen.

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

CTRNET Standard Operating Procedures, Canadian Tissue Repository Network

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP123_01	01-Aug-2012	Original version
SOP123_02	04-Jan-2016	Updated references. Removed OTRN logo.