CTRNet Standard Operating Procedure Sample Retrieval			
SOP Number:	8.3.011	Version	e1.0
Supersedes:	SR 001.001	Effective Date	09 Jan 08
Subject:	Sample Retrieval	Category	Material Handling and Documentation

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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary

1.0 PURPOSE

During the operation of a tumour bank it will be necessary to retrieve samples from freezers for distribution or processing. These procedures deal mainly of retrieval of frozen samples but many points may be applicable to samples stored in other conditions and in other equipment. The purpose of this SOP is to outline procedures that will ensure that retrieval will be conducted under conditions designed to safeguard the quality and integrity of the sample.

2.0 SCOPE

The SOP covers the procedures for sample retrieval and documentation. It outlines general factors that need to be considered during sample retrieval as well as specific steps that need to be followed to maintain the quality of the sample. These steps may be adopted as is, or modified by specific CTRNet member repositories at their collection and storage sites to allow for the incorporation of site-specific details, conditions, requirements and features of their informatics and storage systems.

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3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

1. CTRNet Policy: POL 005.001 Records and Documentation
2. CTRNet Policy: POL 007.001 Material and Information Handling
4. CTRNet SOP: 3.1.006 Records and Documentation

4.0 ROLES AND RESPONSIBILITY

The SOP applies to all qualified tumor bank personnel and laboratory staff that are responsible for retrieving samples. This may include the following personnel:

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Lab Technician or Pathology coordinator	Responsible for storing samples and entering data in the informatics system and retrieving samples.	

5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the site-specific task or procedure.

Materials and Equipment	**Materials and Equipment (Site-Specific)**
Inventory Database	
Safety equipment for handling stored samples (such as face mask and thermal gloves for handling liquid nitrogen)	
Pens, Markers etc	
Ice	
Dry Ice	

6.0 DEFINITIONS

Informatics System: Refers to software, hardware, written documents, support and training necessary to annotate, track, and distribute biospecimens within a tumor bank or repository network.

Sample: A single unit containing material derived from one specimen.

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Specimen: A specific tissue, blood sample etc. taken from a single donor at a specific time.

Storage: Maintenance of specimens for future use.

Retrieval: The removal or recovery of a specimen from its storage location.

Tumor Bank or Repository: Regional, provincial or local repositories that coordinates the collection, processing, storage and distribution of tumour tissue and associated annotated data; normally derived from consented participants for the purpose of medical research. The term 'bank' and 'repository' is used interchangeably.

7.0 PROCEDURES

Sample retrieval requires that the sample be removed from its stable storage environment. Any variation in storage conditions can have a serious effect on the viability of the specimen (if relevant) or cellular and molecular quality of the sample. This retrieval procedure is designed to ensure that the retrieval process maintains the molecular and cellular integrity of the sample. The anticipated use for the samples may determine the best practice to be observed.

7.1 Retrieval - General freezing and thawing considerations

This may be more relevant for retrieval of cell lines however; all attempts should be made to minimize temperature fluctuations.

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.

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.

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.

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.

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7.2 Retrieval – Locating Specimens in storage

1. Create a requisition for sample retrieval.

2. Before transmitting to the repository check the requisition for accuracy.

3. Locate specimens to be retrieved on the inventory system.

7.3 Retrieval – Sample Retrieval

1. At the storage of the repository locate and pull specimens listed on the requisition.

2. Maintain proper temperature of the specimens according to specimen type. Retrieved frozen vials should be collected into pre-chilled metal racks on dry ice for sorting. Care must be taken to minimise exposure of the 'source' storage box or tower to ambient temperatures.

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

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

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

7.4 Retrieval – Documentation of Retrieval

1. Use a check list to record all steps where appropriate.

2. Make changes to the inventory system where relevant. If material is released indicate where the sample was shipped to (See SOP # 9.1.004). If processed, indicate derivative generated.

3. If applicable, keep records on number times samples may have been thawed and refrozen.

8.0 APPLICABLE REFERENCCES, REGULATONS AND GUIDELINES

1. Declaration of Helsinki. http://ohsr.od.nih.gov/helsinki.php3 http://www.wma.net/e/policy/b3.htm
2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8. http://www.ich.org http://www.ich.org/UrlGrpServer.jser?@_ID=276&@_TEMPLATE=254
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials. Division 5. Canada Gazette Part II, Vol. 135, No. 13, June 7, 2001

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Section C.05.010 Sponsor Obligations http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/food_drug_reg_amend_1024_gcp_tc_e.html

4. Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, August 1998. http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm
5. Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER). http://www.isber.org
6. US National Biospecimen Network Blueprint http://www.ndoc.org/about_ndc/reports/NBN_comment.asp

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