

<b>CTRNet Standard Operating Procedure Tissue Collection and Transportation to Pathology</b>			
SOP Number:	8.3.001	Version	e1.0
Supersedes:	SR 001.001	Effective Date	09 Jan 08
Subject:	Tissue Collection and Transportation to Pathology	Category	Material Handling and Documentation

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## REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
LP 002.001	2005	JdSH	CTRNet Generic SOP for Collection and Processing of Tumour Tissue
8.3.001	2008	JdSH	Revised to cover tissue collection and transportation from OR to Pathology.

## 1.0 PURPOSE

The purpose of this document is to outline standardized procedures for CTRNet repositories to follow during the process of tumour tissue collection and transportation from the operating room (OR) to the pathology lab. Tissue samples are collected from patients that have given their consent to participate in the tumour repository program only if there is tissue in excess to that required for pathological assessment and diagnosis.

## 2.0 SCOPE

The Standard Operating Procedure (SOP) describes how tissues should be collected and transported. The SOP does not cover detailed safety procedures for handling Human Biological Materials (HBMs) and it is recommended that personnel follow institutional biosafety guidelines.

### 3.0 REFERENCE TO OTHER POLICIES AND SOPS

1. CTRNet Policy: POL 005.001 Records and Documentation
2. CTRNet Policy: POL 002.001 Ethics
3. CTRNet Policy: POL 004.001 Privacy and Security
4. CTRNet Policy: POL 007.001 Material and Information Handling Policy
5. CTRNet Generic Procedure: LP 002.001 CTRNet Generic SOP for Collection and Processing of Tumour Tissue 2005
6. CTRNet SOP: 8.1.002 Biohazardous Material Waste Management

### 4.0 ROLES AND RESPONSIBILITY

The policy applies to all personnel from CTRNet member repositories who are responsible for collecting tissue from the consented participant.

<b>Tumour Bank Personnel</b>	<b>Responsibility/Role</b>	<b>Site Specific Personnel and Contact Information</b>
Tumour Bank Coordinator/Nurse	Obtain Patient Consent	
Operating Room Nurse	Notifies Pathologist Lab prior to tumor resection.	
Pathologist	Diagnosis of Tissue Malignancy, grossing of tissue and resection of excess tumour tissue for the bank	
Pathology Assistant	Assists with resection and transportation of tissue. May communicate with Lab technician.	
Lab Technician	Transportation of tumour tissue and processing	
Porter	Transport of tumour tissue from the OR to the Pathology lab	

## 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)
Container with ice	
Appropriate container for resected tissue (Petri Dishes)	
Markers and pens	
Clean Forceps	
Cold Saline for rinsing tissue if needed	
Clean Scalpels for trimming tissue	
Tissue Collection kits (Tubes containing cold culture media or Phosphate Buffered Saline)	
Gloves worn to protect personnel handling tissue	
Sufficient appropriate labels (see SOP # 8.1.001) for collection tubes and Tissue Collection/Processing Worksheets	
Tissue Collection/Processing Worksheets (see Appendix 1 for sample form)	
Sufficient appropriate labels (see SOP # 8.1.001) for collection tubes and Tissue Collection/Processing Worksheets	
Tissue Collection/Processing Worksheets (see Appendix 1 for sample form)	Site specific Name of form and version #

## 6.0 DEFINITIONS

**Encoded samples:** Samples or data that have a coded identification to protect the confidentiality of the individual during routine use, but it is possible for the repository to break the code and thus identify the individual from whom they were obtained.

**Cryopreservation:** A process for storing biological material at very low temperatures.

**Human Biological Material:** All biological material of human origin, including organs, tissues, bodily fluids, teeth, hair and nails, and substances extracted from such material such as DNA and RNA.

**Tissue Hypoxia:** This generally refers to the lack of oxygen in the tissue caused by surgical resection of the tumour. The loss of the blood supply to the tumour results in the failure to deliver oxygen and glucose to the tissue. Hypoxia induces a cascade of molecular and biochemical events in the tissue.

## **7.0 PROCEDURES**

This procedure is intended to ensure that tissue samples will be collected from consented participants in a safe, timely and efficient manner while eliminating the risks of contamination. To facilitate the use of innovative genomic and proteomic techniques, banked tissue that has been adequately processed is vital to obtaining products with high integrity and quality.

### **7.1 Tissue Collection - General Considerations.**

1. The scientific utility of the data obtained from the analysis of tissues is directly related to the quality of the tissue specimen.
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.
3. At this stage, never place tissue intended for banking as a fresh frozen specimen in formalin.

### **7.2 Transporting of Tissue from the OR to Pathology Lab**

1. Take tumour tissue that is surplus to clinical needs and diagnosis (only tissue deemed surplus by the Pathologist or delegate is considered bankable).
2. It is recommended that the Operating Room (OR) staff notifies the pathologist or designate about the time of ischemia (when blood vessels were clamped).
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

should arrange to transport it to the pathology lab (or designated repository lab) in a manner optimal for preservation of cellular and molecular integrity.

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. Prepare tissue collection kits in advance if possible. Store kits as appropriate for contents (CTRNet Policy 007.001 Material and Information Handling).
6. No more than 30 minutes should elapse 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 what the actual time period is.

Processing/preservation of tissue samples can be found in SOP #s: 8.3.002, 8.3.003, 8.3.004 and 8.3.005.

## **8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES**

1. Declaration of Helsinki. <http://ohsr.od.nih.gov/helsinki.php3>  
<http://www.wma.net/e/policy/b3.htm>
2. 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>
3. Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series. [http://www.mrc.ac.uk/pdf-tissue\\_guide\\_fin.pdf](http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf)
4. 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>
5. National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol. I: Report and recommendations of the National Bioethics Advisory Committee. August 1999. <http://bioethics.georgetown.edu/nbac/hbm.pdf>
6. US National Biospecimen Network Blueprint [http://www.ndoc.org/about\\_ndc/reports/NBN\\_comment.asp](http://www.ndoc.org/about_ndc/reports/NBN_comment.asp)
7. Jewell, S. et al. Analysis of the Molecular Quality of Human Tissues, an experience from the Cooperative Human Tissue Network. Am. J. Clin. Pathol. 2002;118:733-741.

## Appendix A. Sample Forms

The Tissue Collection/Harvesting Worksheet can be customized by specific sites to capture information relevant to the site. The following may be used as a guide for relevant sets of information to record:

### Tissue Collection and Transportation

Collection Site	
Date Tumour is resected	
Time Tumour is resected	
Date Tumour Sample Received by Pathology Lab	
Time Sample is Received by Pathology Lab	
Name of Person Transporting Tissue	
Was sample transported on ice?	YES NO
Pathologist (Name)	
Additional Collection Notes:	

### Sample Information

Label (Unique identifier)	Tissue type	Was matching normal available and taken?	Tumour size	Tissue Observations

### Tissue Harvesting

**Harvested by:** Technicians name

**Time Frozen: Very Important to record this time**

Indicate if Tissue was taken for:

#### 1. Fresh Frozen Collection.

Label (identifier)	Snap Frozen by	Date Frozen	Time Frozen	Sample Size	Storage location

#### 2. Frozen in OCT

Label (identifier)	Snap Frozen by	Date Frozen	Time Frozen	Sample Size	Storage location

**3. Formalin Fixed.** Yes No Date: Storage Location:

**4. Stored in another form (eg. In RNAlater®)** Yes No  
Date: Storage Location: