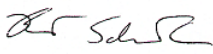


Solid Tissue - Tissue Collection and Transportation

CTRNet Standard Operating Procedure Tissue Collection and Transportation			
SOP Number:	08.03.001	Version:	e2.0
Supersedes:	8.3.001 e1.0	Category:	Material Handling and Documentation – Solid Tissue
Approved By:	CTRNet Management Group (CMG)	01-June-2012	
	Per: Brent Schacter 	26-June-2012	

1.0 PURPOSE

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

2.0 SCOPE

This 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 CTRNET SOPS OR POLICIES

Note: When adopting this SOP for local use please reference CTRNet.

- 3.1 CTRNet Policy: POL 5 Records and Documentation
- 3.2 CTRNet Policy: POL 2 Ethics
- 3.3 CTRNet Policy: POL 4 Privacy and Security
- 3.4 CTRNet Policy: POL 7 Material and Information Handling
- 3.5 CTRNet Standard Operating Procedure: SOP 08.01.002 Biohazardous Material Waste Management

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4.0 ROLES AND RESPONSIBILITIES

The SOP applies to all personnel from CTRNet member biobanks responsible for collecting tissue from the consented participant. Applicable staff may include the following roles:

Tumour Biobank Personnel	Responsibility/Role
Tumour Biobank Coordinator/Nurse	Obtain Patient Consent
Operating Room Nurse	Notifies Pathologist and Laboratory prior to tumour resection.
Pathologist	Diagnosis of Tissue Malignancy, grossing of tissue and resection of excess tumour tissue for the biobank.
Pathology Assistant	Assists with resection, harvesting and transportation of tissue and performs tasks delegated by the pathologist. May communicate with Laboratory Technician/Technologist.
Laboratory Technician/Technologist	Transportation of tumour tissue, harvesting, processing and storage.
Porter	Transport of tumour tissue from the operating room to the Pathology Laboratory

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 <i>SOP # 08.01.001</i>) for collection tubes and Tissue Collection/Processing Worksheets	
Tissue Collection/Harvesting Worksheets (see Appendix A for sample form)	Site specific Name of form and version #

6.0 DEFINITIONS

See the CTRNet Program Glossary: <http://www.ctrnet.ca/glossary>

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

- 7.1.1 The scientific utility of the data obtained from the analysis of tissues is directly related to the quality of the tissue specimen.
- 7.1.2 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:
 - a. Minimizing the time the tissue is subjected to hypoxic conditions, as this initiates the cell death mechanisms and subsequent degradation process.
 - b. Use of agents or treatments to inactivate degrading enzymes for preserving nucleic acid integrity.
 - c. Preservation of tissue as fresh frozen, if the intended use is for nucleic acid analysis.
 - d. Storage of frozen tissue and products at appropriate temperatures especially if storage is for longer periods of time.
 - e. Avoiding contamination with surrounding histological distinct tissue or co-processed samples if the product is intended for studies involving nucleic acid amplification.
- 7.1.3 At this stage, never place tissue intended for banking as a fresh frozen specimen in formalin.

7.2 Transporting of Tissue from the Operating Room to the Pathology Laboratory

- 7.2.1 Take tumour tissue that is surplus to clinical needs and diagnosis (only tissue deemed surplus by the Pathologist or delegate is considered bankable).
- 7.2.2 It is recommended that the operating room staff notifies the pathologist or designate about the time of ischemia (when blood vessels were clamped).
- 7.2.3 Immediately after being notified by the operating room 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 laboratory (or designated biobank laboratory) in a manner optimal for preservation of cellular and molecular integrity.
- 7.2.4 Transport the tissue from the operating room to the pathology laboratory using a rapid specimen transport protocol. It is recommended that the tissue be transported on ice.
- 7.2.5 Prepare tissue collection kits in advance, if possible. Store kits as appropriate for contents (*CTRNet Policy 7 Material and Information Handling*).
- 7.2.6 No more than 30 minutes should elapse between the time of biopsy/resection and time of freezing of a given sample. Records must clearly document the actual time period.

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Processing/preservation of tissue samples can be found in *CTRNet SOPs: 08.03.002 (Tissue Harvesting), 08.03.003 (Snap Freezing of Tissue), 08.03.004 (Freezing of Tissue in OCT), and 08.03.005 (Preservation of Tissue: Paraffin Embedding).*

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

- 8.1 Declaration of Helsinki
<http://www.wma.net/en/30publications/10policies/b3/index.html>
- 8.2 Tri-Council Policy Statement 2; 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, December 2010.
<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>
- 8.3 Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics
<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420>
- 8.4 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/Search/search.asp?zoom_query=best+practices+for+repositories
- 8.5 US National Biospecimen Network Blueprint
<http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp>
- 8.6 International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8.
<http://www.ich.org/products/guidelines.html>
- 8.7 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>
- 8.8 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.

9.0 APPENDICES

- 9.1 Appendix A – Sample Form - Tissue Collection/Harvesting Worksheet

10.0 REVISION HISTORY

SOP Number	Date revised	Author	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.
8.3.001 e1.0	Oct. 2011	MMA	Added definitions Updated references Other minor revisions: wording and formatting
8.3.001 e1.0	Mar. 2012	SD	See comments above and also SOP 07.001
8.3.001 e1.0	June 2012	CMG	<ul style="list-style-type: none"> • Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates • Updated SOP references • Section 4.0: Added last sentence. • Title Change: Deleted "to Pathology"

SAMPLE FORM - TISSUE COLLECTION HARVESTING WORKSHEET

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 Laboratory	
Time Sample is Received by Pathology Laboratory	
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: Laboratory Technician/Technologist 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 (e.g. In RNAlater®) Yes No
Date: Storage Location: