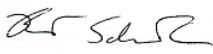


CTRNet Standard Operating Procedure Tissue Harvesting			
SOP Number:	08.03.002	Version:	e2.0
Supersedes:	8.3.002 e1.0	Category:	Material Handling and Documentation – Solid Tissue
Approved By:	CTRNet Management Group (CMG)	01-June-2012	
	Per: Brent Schacter 	26-June-2012	

1.0 PURPOSE

Tissue samples are collected from patients that have been through the informed consent process and agreed to participate in the tumour biobank program. Tumour tissues are obtained by personnel qualified by training to do so and are collected for the tumour biobank only if present in excess to that required for pathological assessment and diagnosis. The purpose of this document is to outline standardized procedures for CTRNet biobanks to follow during tumour tissue harvesting.

2.0 SCOPE

This standard operating procedure (SOP) describes how tissues should be harvested. 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 08.03.001 Tissue Collection and Transportation

3.6 CTRNet Standard Operating Procedure: SOP 08.01.002 Biohazardous Material Waste Management

4.0 ROLES AND RESPONSIBILITIES

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

Tumour Biobank Personnel	Responsibility/Role
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

5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed here 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, ink and pens	
Clean forceps	
Cold saline for rinsing tissue if needed	
Clean scalpels for trimming tissue	
Tissue collection kits (containing collection media if relevant)	
Cryovials for storage of frozen tissue	
Dry shipper for transportation of Liquid nitrogen	
Needle/sharps disposal unit	
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 #
Needle/sharps disposal unit	
Optimal Cutting Temperature Compound (OCT)	

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 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 Harvesting

7.1.1 Treat all tissue as potentially infectious.

7.1.2 The pathologist performs processing unless the responsibility is delegated by the pathologist to the pathology assistant or designated tumour biobank technician/technologist.

- 7.1.3 Ensure that the resected tissue never desiccates or is contaminated by surrounding tissue or other samples. If appropriate, change scalpel blades between dissecting tumour tissue and surrounding uninvolved tissue.
- 7.1.4 Based on consultation with the pathologist, mark the margins with ink.
- 7.1.5 Slice the tissue with a clean scalpel. Always use a clean scalpel between tissue samples or between normal and tumour tissue.
- 7.1.6 Select tumour tissue for banking without compromising the tissue for pathological examination.
- 7.1.7 Attempt to preserve and store normal (matching) adjacent tissue as well.
- 7.1.8 If possible, allow for the banking of multiple samples from one specimen. The tissue may be banked as:
 - a. Samples snap frozen in liquid nitrogen suitable for extraction of DNA, RNA and protein.
 - b. Tissue samples processed directly for the extraction of DNA, RNA and protein.
 - c. Sample frozen in optimal cutting temperature (OCT) compound is suitable for producing frozen tissue sections.
 - d. Samples fixed in formalin and paraffin embedded for paraffin sections.
- 7.1.9 For the snap frozen tissue samples, attempt to have as many cryovials as possible.
- 7.1.10 Based on the tissue harvested, label the necessary cryovials, RNA or DNA tubes, cassettes for OCT or tubes for formalin processing.
- 7.1.11 Use cryovials suitable for submersion in liquid nitrogen.
- 7.1.12 It is recommended to have no less than 250 mg of tissue per vial.
- 7.1.13 For a small tumour attempt to harvest samples that are 2-3 mm³ (depending on tumour size and availability).
- 7.1.14 If there is abundant tumour, attempt to harvest about 3-4 mm³ or more (depending on size and availability).
- 7.1.15 Depending on the method of processing/storage, transfer the tissue to the appropriate receptacle for the processing step.
- 7.1.16 Timing is critical. Ideally, no more than 30 minutes must elapse between the time of biopsy/resection and time of freezing of a given sample. Records must clearly document actual time period (in hours or minutes).

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 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>
- 8.7 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.
- 8.8 Guideline – Fresh Tissue Working Group of BIG and NCI breast cancer Cooperative Groups

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
08.3.002 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

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: