

CTRNet Standard Operating Procedure Tissue Harvesting			
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Subject:	Tissue Harvesting	Category	Material Handling and Documentation

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REVISION HISTORY

SOP Number	Date Issued	Summary of Revisions
LP 002.001	2005	CTRNet Generic SOP for Collection and Processing of Tumour Tissue
8.3.002	2008	Revised to cover tissue harvesting only

1.0 PURPOSE

Tissue samples are collected from patients that have been through the informed consent process and agreed to participate in the tumour repository program. Tumour tissues are obtained by personnel qualified by training to do so and are collected for the tumour bank 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 repositories to follow during tumour tissue harvesting.

2.0 SCOPE

The 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 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 SOP: 8.3.001 Tissue Collection and Transportation
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 harvesting tissue from the consented participant.

Tumour Bank Personnel	Responsibility/Role	Site Specific Personnel and Contact Information
Pathologist	Diagnosis of Tissue Malignancy, grossing of tissue and resection of excess tumour tissue for the bank	
Pathology Assistant	Assists with resection, harvesting and transportation of tissue and performs tasks delegated by the pathologist. May communicate with Lab technician.	
Lab Technician	Transportation of tumour tissue, harvesting processing and storage	

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, 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 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 #
Needle/sharps disposal unit	

6.0 DEFINITIONS

Cryopreservation: A process for storing biological material at very low temperatures for lengthy periods of time.

Matching adjacent tissue: Tissue collected during surgery that is next to the diseased tissue, but appears normal by inspection conducted by qualified personnel.

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.

1. Treat all tissue as potentially infectious.
2. Processing is performed by the pathologist unless the responsibility is delegated by the pathologist to the pathology assistant or designated tumour repository technician.
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.
4. Based on consultation with the pathologist, mark the margins with ink.
5. Slice the tissue with a clean scalpel. Always use clean scalpel between tissue samples or between normal and tumour tissue.
6. Select tumour tissue for banking without compromising the tissue for pathological examination
7. Attempt to preserve and store normal (matching) adjacent tissue as well.

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 OCT suitable for producing frozen tissue sections.
 - d. Samples fixed in formalin and paraffin embedded for paraffin sections.
9. For the snap frozen tissue samples, attempt to have as many cryovials as possible.
10. Based on the tissue harvested, label the necessary cryovials, RNA or DNA tubes, cassettes for OCT or tubes for formalin processing.
11. Use cryovials suitable for submersion in liquid nitrogen.
12. It is recommended to have no less than 250 mg of tissue per vial.
13. For a small tumour attempt to harvest samples that are 2-3 mm³ (depending on tumour size and availability).
14. If there is abundant tumour, attempt to harvest about 3-4 mm³ or more (depending on size and availability)
15. Depending on the method of processing/storage, transfer the tissue to the appropriate receptacle for the processing step.
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. If, due to practical considerations, the elapsed time is greater, records must clearly document what the actual time period is (in hours).

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
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
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. Guideline – Fresh Tissue Working Group of BIG and NCI breast cancer Cooperative Groups http://ctep.cancer.gov/forms/guidelines_fresh_tissue.pdf

Appendix A. Worksheets

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 id 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: