CTRNet Standard Operating Procedure Material Request and Release			
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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
SR 001.001	2005	JdSH	1st Release.
9.1.004 e1.0	2008	JdSh	Revised to make minor formatting changes and reviewed to reflect current practice at the member banks

1.0 PURPOSE

A goal of the Canadian Tumour Repository Network (CTRNet) is to standardize mechanisms for release/use of tissues and products to research collaborators. Release mechanisms should be designed to promote the goals of the repository (advancing cancer research) as well as safeguarding the interests of the participants.

CTRNet is committed to high ethical standards and practices in the release of Human Biological Materials (HBMs) for research purposes. The purpose of this CTRNet Standard Operating Procedure (SOP) is to outline procedures that can be used to ensure that access to, and release of tissue samples; is equitable, ethical, and efficient.

2.0 SCOPE

The SOP applies to ethical, legal and practical considerations that arise in the process of releasing tissue samples from the 'custodian' (tissue bank) to the researchers requesting samples from the bank. The SOP covers the processes of handling material requests from researchers and completing appropriate contractual agreements between repository and researchers.

3.0 REFERENCE TO OTHER SOPS/POLICIES

1. CTRNet Policy: POL 006.001 Material Request and Release Policy
2. CTRNet Policy: POL 005.001 Records and Documentation
3. CTRNet Policy: POL 002.001 Ethics
4. CTRNet Policy: POL 004.001 Privacy and Security

4.0 ROLES AND RESPONSIBILITY

This SOP applies to CTRNet member repositories and to repository personnel involved in all aspects of the tissue repository program. In particular, it applies to those personnel involved in the process of handling requests and releasing tumor bank material.

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Tissue Bank Director	Signing the MTA	
Tissue Bank REB/TTRC	Reviewing request	
Tissue Bank Coordinator	Reviewing request, coordinating sample release	

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)**
Material Request Form	
Material Transfer Agreement	

6.0 DEFINITIONS

Custodianship: Responsibility for safe keeping of tissue samples and associated data and control of their use and eventual disposal in accordance with the terms of the consent given by the participant and as regulated by the Research Ethics Board. Custodianship implies some rights to decide how the samples are used and by whom, and also responsibility for safeguarding the interests of donors.
Human Biological Material (HBM): 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.

Material Transfer Agreement (MTA): A Material Transfer Agreement is a document, which defines terms and conditions attached to the transfer of human biological material

from one organization to another. In this case it is from the tumour repository to the researcher requesting and receiving HBMs.

Participant: An individual (patient or healthy volunteer, if applicable) who participates in the Tumour Repository Program. The terms patient, participant, subject and potential donor may be used interchangeably.

Research Ethics Board (REB): An independent body (a review board or a committee, institutional, regional, national or supranational) constituted of medical and scientific professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in research and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the research project, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the research program participants.

Researcher: A scientist or clinician from an academic institution or commercial enterprise such as a biotechnology or pharmaceutical company who is involved in a laboratory and/or clinical research project, and is interested in obtaining material from the tumour repository for research purposes. The term 'user' may be used interchangeably.

Translational Research: Integrated clinical-laboratory investigations designed to improve the prevention, diagnosis and/or treatment of cancer. Involves both clinical and laboratory investigations, or laboratory investigations on clinical material.

Tissue Release Review Committee (TRRC) or equivalent: A working committee that reviews and decides access to tumour repository samples.

7.0 PROCEDURES

A consistent standard of scientific and ethical review for tissue requests will ensure that all requests meet consistent ethical standards and a high level of scientific merit. The procedure is also geared to ensure efficient handling of requests and adequate completion of contractual agreements.

7.1 Material Request and Release Process Overview

1. Make access policies and standard Material Request Form available online.
2. For an overview of the material request and release process, see Attachment 1.

7.1.1 Material Request Form

1. Make standard Material Request Form available online.
2. Use the Material Request Form to obtain the following information from the requesting researcher:

- Applicants name and contact information
- Title and description of research project (including objectives and hypothesis)
- Duration and proposed start date
- Methodology of research project
- Funding source
- Types and quantity of samples required
- Ethics review and approval for research project
- Curriculum Vitae of the applicant

7.1.2 Fee schedule

For the applicable fee schedule, consult the CTRNet pricing guides.

7.1.3 Material Request from Researchers

1. CTRNet receives a materials request as completed online from requesting researcher.
2. Determination is made on the routing of the request to a regional bank based on the province of origin and size of the request.
   a. The regional tumour bank for the province of origin has first right of refusal.
   b. If the regional bank for the province of origin can satisfy the request as determined by inventory in the CTRNet catalogue, then the request will be forwarded to that bank only.
   c. If the regional bank for the province of origin cannot satisfy the entire request, the request will also be sent to other CTRNet members in rotation.
   d. The decision to fulfill a request lies solely with the regional tumour bank. Should a bank decline to participate, the request will be sent to other CTRNet members in rotation along with the reason for decline of all previous members.
3. Upon receipt of the request arrange for a review by the REB/TRRC.
4. If the request is ultimately declined, accepted provisionally or modifications to the application are required by the TRRC, CTRNet will communicate the outcome of the review to the requesting researcher.
5. Upon request approval, CTRNet will inform the researcher and initiate completion of the Material Transfer Agreement specific for academic researchers.
6. The signed agreement is documented and filed.
7. Upon receiving the signed MTA release samples and information directly to the laboratory where the research will be conducted using the procedure outlined for shipping samples (SOP #: 9.1.001)
8. CTRNet will mediate any appeal or complaint (or modification of application) between the regional repository and the requesting researcher.

7.2 Material Transfer Agreements (MTA)

An MTA, defining the terms of agreement between the requesting researcher and the repository will be signed before material or associated information is transferred.

1. Read Section 5.4 CTRNet Policy: POL 006.001 Material Request and Release Policy. The standard MTA should contain the elements outlined in Section 5.4.
2. Use the appropriate CTRNet MTA to facilitate and document material transfer to an approved researcher.
3. Signed MTAs are valuable documents for tracking HBM utilization. The local repository and CTRNet should retain signed MTAs in a secure location to perform audits or to handle complaints.

7.3 Turnaround times for handling requests

CTRNet recognizes that reviews of requests should be conducted in a timely manner.

1. The TRRC should meet at regularly scheduled intervals or establish contact by email, to review requests.
2. Interval frequency should be determined on the basis of volume of requests.
3. Turnaround times for reviewing requests should be 30 days or less from date of receipt of the request when possible.
4. TRRC review outcomes should be communicated to the researcher within 3 working days of the TRRC decision when possible.

8.0 APPLICABLE REFERENCES, REGULATONS 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.
4. http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf
5. Hakimian, R and Korn, D. Ownership and Use of Tissue Specimens for Research. JAMA. 2004; 292(20):2500-2505.
6. Canadian Federal Personal Information Protection and Electronic Documents Act. http://laws.justice.gc.ca/en/p-8.6/93196.html
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. UKCCSG Guide to Biological Studies Version 1.0, 2002
http://www.ukccsg.org/hp/biological_studies/webguideBs.html

9. US National Biospecimen Network Blueprint
http://www.ndoc.org/about_ndc/reports/NBN_comment.asp

10. Teodorvic, I. et al. Human tissue research: EORTC recommendations on its practical consequences. Eur J Cancer 2003; 39:2256-2263.

