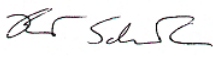


CTRNet Standard Operating Procedure Material Request and Release			
SOP Number:	09.004	Version:	e2.0
Supersedes:	9.1.004 e1.1	Category:	Material Request and Release
Approved By:	CTRNet Management Group (CMG)	01-June-2012	
	Per: Brent Schacter 	28-June-2012	

## 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 biobank (advancing cancer research) as well as safeguarding the interests of the participants.

## 2.0 SCOPE

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

## 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 6 Material Release
- 3.2 CTRNet Policy: POL 5 Records Documentation
- 3.3 CTRNet Policy: POL 2 Ethics
- 3.4 CTRNet Policy: POL 4 Privacy and Security

## 4.0 ROLES AND RESPONSIBILITIES

This SOP applies to biobanks and to biobank personnel involved in all aspects of the tissue biobank program. In particular, it applies to those personnel involved in the process of handling requests and releasing tumor biobank material.

Tumour Biobank Personnel	Responsibility/Role
Tumour Biobank Director or designate	Signing the MTA
Tumour Biobank Research Ethics Board REB	Reviewing and approving request
Tumour Access Committee	Reviewing and approving request
Tumour Biobank 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*	
MTA*	

\* See the Biobank Resource Centre (BRC) in the reference section for examples of forms.

## 6.0 DEFINITIONS

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

## 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

- a. Ideally, make access policies and standard Material Request Form available online.
- b. For an overview of the material request and release process, see the Canadian Biobank Resource Centre (see section 8.10).

#### 7.1.1 Material Request Form

Use the Material Request Form to obtain the following information from the requesting researcher:

- a. Applicant's name and contact information.
- b. Title and description of research project (including objectives and hypothesis).
- c. Duration and proposed start date.
- d. Methodology of research project.
- e. Funding source.
- f. Types and quantity of samples required.
- g. Ethics review and approval for research project.
- h. 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

Biobanks should consider the following points in considering applications for sample and data release;

- a. Access should be granted only after review by a documented review process, scaled as appropriate to the nature of the request:
- b. Applications for biobank access should be evaluated by an Access Committee (for small- and moderate-sized biobanks this may comprise a defined role for a single individual such as the biobank's Leader/Director/PI).
- c. Evaluation should be made on aspects such as the basis of the researchers' qualifications, scientific merit, feasibility including statistical justification, and evidence of adequate funding.
- d. Review of applications should be documented, such as through the use of a standardized reviewer form.
- e. The biobank should provide feedback on rejected applications if requested by the researcher-applicant.
- f. Reviews should be completed in a timely manner.

The biobank should require, at a minimum, that the researcher provide the following documentation prior to release of any biospecimens or data:

- a. Proof of approval for their project by their governing REB.

The biobank should establish a contractual agreement with the researcher prior to release of any biospecimens or data:

- a. Material transfer procedures should be followed and documented by way of an MTA that the biobank will retain securely and indefinitely.
- b. The MTA may contain information/clauses about the following:
  - Clarification about custodianship of the samples.
  - Privacy and Confidentiality principles that must be adhered to.
  - Statement that the recipient agrees to absolve the biobank for liability from any claims, costs, damages or expenses resulting from usage of the biospecimens provided.
  - Restrictions on the use of the tissue, if any.
  - Statement on the biohazardous nature of human biospecimens.
  - Instructions about return, retention or disposal of unused tissue if applicable.
  - Specific conditions for publication of research results, if any (e.g., that the biobank should be acknowledged appropriately in all resulting publications, and that copies of the publications should be returned to the biobank).
  - Specific conditions for sharing data, if any.
  - Specific conditions for managing intellectual property, if any.
  - Specific conditions about compensation for material transfer if relevant.
  - That tissue cannot be provided to a third party without the written consent of the biobank (that would require a new, revised MTA).

## 7.2 Turnaround Times for Handling Requests

CTRNet and its partners recognize that reviews of requests should be conducted in a timely manner.

7.2.1 The access committee should meet at regularly scheduled intervals or establish contact by email, to review requests.

7.2.2 Interval frequency should be determined on the basis of volume of requests.

7.2.3 Turnaround times for reviewing requests ideally should be 30 days or less from date of receipt of the request when possible.

7.2.4 Access committee review outcomes should be communicated to the researcher within 3 working days of the access committee decision when possible.

## 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 US National Biospecimen Network Blueprint  
<http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp>
- 8.5 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>
- 8.6 Hakimian, R and Korn, D. Ownership and Use of Tissue Specimens for Research. JAMA. 2004; 292(20):2500-2505.
- 8.7 Canadian Federal Personal Information Protection and Electronic Documents Act.  
<http://laws-lois.justice.gc.ca/eng/acts/P-8.6/index.html>
- 8.8 UKCCSG Guide to Biological Studies Version 1.0, 2002  
[http://www.ukccsg.org/hp/biological\\_studies/webguideBs.html](http://www.ukccsg.org/hp/biological_studies/webguideBs.html)
- 8.9 Teodorvic, I. et al. Human tissue research: EORTC recommendations on its practical consequences. Eur J Cancer 2003; 39:2256-2263.
- 8.10 Canadian Biobank Resource Centre. <http://obertools.pathology.ubc.ca/brc/>

## 9.0 APPENDICES

None

## 10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
SR 001.001	2005	JdSH	1 <sup>st</sup> Release.
9.1.004 e1.0	2008	JdSh	Revised to make minor formatting changes and reviewed to reflect current practice at the member banks
9.1.004 e1.1	June 2012	CMG	<ul style="list-style-type: none"> <li>• Grammatical and formatting throughout</li> <li>• Definitions removed</li> <li>• Revision History moved to bottom</li> <li>• Reference links updates</li> <li>• Updated SOP references</li> <li>• Section 2.0: Deleted “CTRNet is committed...” paragraph.</li> <li>• Section 7.1: Revised.</li> <li>• Section 7.2 – Deleted.</li> <li>• TRCC replaced with “access committee” throughout.</li> <li>• Section 7.1.3: This section was copied from the ROP Access and Release, and then minor revisions were made.</li> <li>• Added the Biobank Resource Centre as a reference for examples of forms as point 8.10</li> </ul>