

Title	Material Request and Release from Biorepositories
SOP Code	SOP124_02
Effective Date	04-Jan-2016

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the processes of handling material requests from researchers, and completing appropriate contractual agreements between biorepository and researchers.

2.0 SCOPE

This SOP applies to ethical, legal, and practical considerations that arise in the process of releasing tissue samples from the 'custodian' (biorepository) to the researchers requesting samples from the bank. These procedures ensure that access to, and release of tissue specimens; is equitable, ethical, and efficient.

3.0 RESPONSIBILITIES

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Material Request and Release Process Overview

5.1.1 Make access policies and standard Material Request Form available.

5.2 Material Request Form

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

- Applicant's 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

5.3 Fee Schedule

5.3.1 Set fees for the different materials and services provided.

5.4 Material Request from Researchers

5.4.1 The biorepository receives a completed Material Request Form from the requesting researcher.

5.4.2 Upon receipt of the request, arrange for a review by the appointed Biorepository Review Committee.

5.4.3 If the request is ultimately declined, accepted provisionally, or modifications to the application are required by the Biorepository Review Committee, the biorepository will communicate the outcome of the review to the requesting researcher.

5.4.4 Upon request approval, the biorepository will inform the researcher and initiate completion of the Material Transfer Agreement (MTA), if sent outside of the institution.

5.4.5 Document and file the signed agreement .

5.4.6 Upon receiving the signed MTA, release samples and information directly to the laboratory where the research will be conducted.

5.5 Turnaround Times for Handling Requests

5.5.1 The Biorepository Review Committee /Tissue Review Committee should meet at regularly scheduled intervals or establish contact by email, to review requests in a timely manner.

5.5.2 Determine interval frequency, based on volume of requests.

5.5.3 Turnaround times for reviewing requests should be 10 days or less for rush cases and up to 15 days for non-rush cases from date of receipt of the request, when possible.

5.5.4 Biorepository Review Committee review outcomes should be communicated to the researcher within 3 working days of the decision, when possible.

6.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

2011 NCI Best Practices for Specimen Resources. Office of Biorepositories and Biospecimen Research, National Cancer Institute, Bethesda, MD.
<http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf>

ISBER Best Practices for repositories: Collection, storage, retrieval and distribution of biological materials for research, 3rd Edition, 2012<http://www.isber.org>

CTRNET Standard Operating Procedures, Canadian Tissue Repository Network

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP124_01	01-Aug-2012	Original version
SOP124_02	04-Jan-2016	5.5.3: Revised turnaround times. Updated references. Removed OTRN logo.