Title	Completing a Material Transfer Agreement
SOP Code	SOP125_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 procedures for completing a Material Transfer Agreement (MTA) for transferring a biospecimen from the biorepository to a researcher.

2.0 SCOPE

Depending on the individual or organization the material is being transferred to, specific MTAs may be used. The sequence of the steps outlined below may vary slightly to accommodate diversity in the practice of when the MTA is completed.

3.0 RESPONSIBILITIES

This SOP applies to all qualified biorepository personnel responsible for completing MTAs, before releasing samples from the biorepository.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Completion of the MTA

5.1.1 Once an application for biospecimen has been received, contact the researcher to complete a Sample Request Application Form, and an MTA.

5.1.2 The appointed Biorepository Review Committee must review the application, prior to submission to the REB/IEC.

5.1.3 Upon approval of release by the Research Ethics Board (REB)/Institutional Ethics Committee (IEC), ensure that the MTA is signed by the researcher, and the appropriate representative from the biorepository.

5.1.4 The MTA should ideally contain the following elements:
Clarification about custodianship of the samples
Outline of the research project
Biospecimen being supplied 'as is' with no representations or warranties, unless otherwise specified by the MTA
Potential for biospecimen to have unknown characteristics or carry infectious agents
Restrictions on the use of the biospecimen/clinical data if any
Privacy and Confidentiality principles that must be adhered to
Instructions about return, retention or disposal of unused biospecimen if applicable
Specific conditions for publication of research results if any
Specific conditions for sharing data if any
Specific conditions for managing intellectual property if any
Specific conditions about compensation for material transfer if relevant
If possible, a list of samples (identification codes) to be released to researcher (if the list is not finalized at the time of signing of the MTA, a complete list should beappended to the form before sample release)
Specify if annotating data is being included

5.1.5 Do not supply biospecimen to a third party without the approval of the REB/IEC and the signing of a MTA.

5.1.6 Release of biospecimen to academic or commercial researchers may warrant the use of tailored or specific MTAs.

5.1.7 The signed MTAs are valuable documents for tracking material utilization. Ensure that MTAs are documented and signed copies filed.

5.1.8 Retain signed copies of MTAs securely for audit purposes or to handle complaints.

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
SOP125_01	01-Aug-2012	Original version
SOP125_02	04-Jan-2016	5.1.3: REB and IET defined. Updated references. Removed OTRN logo.