CTRNet Standard Operating Procedure Completing a Material Transfer Agreement			
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Subject:	Completing a Material Transfer Agreement	Category	Materials Request and Release

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REVISION HISTORY

SOP Number	Date Issued	Summary of Revisions

1.0 PURPOSE

During the operation of a tumour bank human biological material and clinical information may be transferred to researchers at academic or commercial research institutions. The purpose of the Material Transfer Agreement (MTA) is to ensure that before the tissue or data is shared with approved parties outside the repository, an agreement is signed to maintain donor privacy, intellectual property rights (if relevant), terms for data sharing and other similar ethical and legal requirements. The purpose of this SOP is to outline procedures that should be followed when completing an MTA.

2.0 SCOPE

The SOP covers the procedures for completing an MTA once the transfer of the sample has been approved by an Research Ethics Board. Depending on the individual or organization the material is being transferred to, specific MTAs may be used.

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

1. CTRNet Policy: POL 005.001 Records and Documentation
2. CTRNet Policy: POL 006.001 Material Request and Release Policy
3. CTRNet Policy: POL 004.001 Privacy and Security
4. CTRNet Policy: POL 002.001 Ethics
5. CTRNet SOP: 9.1.004 Material Request and Release

4.0 ROLES AND RESPONSIBILITY

The SOP applies to all qualified tumor bank personnel that are responsible for completing MTAs before releasing samples from the tumour bank. This may include the following personnel:

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Tumour Bank Manager/Director	-Determine that REB approval has been obtained for Material Release. -Complete MTA -Document Completion of MTA	
Pathology Coordinator	Complete MTA -Document Completion of MTA	

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)**
Inventory Database	
REB approval for reference	
Appropriate MTA	

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.

Sample: A single unit containing material derived from one specimen.

Specimen: A specific tissue, blood sample etc. taken from a single donor at a specific time.

Tumor Bank or Repository: Regional, provincial or local repositories that coordinates the collection, processing, storage and distribution of tumour tissue and associated annotated data; normally derived from consented participants for the purpose of medical research. The term ‘bank’ and ‘repository’ is used interchangeably.

7.0 PROCEDURES

Samples are received by the informed consent process. Tumour banks essentially have "custodianship" of the samples. Release of the sample to a third party requires insurance that ethical, legal and privacy issues of the donor will be upheld. Proper completion of a contractual agreement (the MTA) is an important step in the material release process. The sequence of the steps outlined below may vary slightly at member banks to accommodate diversity in the practice of when the MTA is filled out (before or after REB approval).

7.1 Completion of the MTA

1. Once an application for tissue has been received initiate that the researcher fills out a:
    - Sample Request Application Form
    - Material Transfer Agreement Form

2. After review to make sure that the request meets distribution criteria, submit the application to the REB.

3. Upon approval of release by the REB, make sure that the MTA is signed by the researcher and the appropriate representative from the Tumour Bank.

4. The MTA should ideally contain the following elements:

    - Clarification about custodianship of the samples
    - Outline of the research project
    - Tissue being supplied 'as is' with no representations or warranties unless otherwise specified by the MTA
    - Potential for tissue to have unknown characteristics or carry infectious agents
    - Restrictions on the use of the tissue/clinical data if any
    - Privacy and Confidentiality principles that must be adhered to
    - Instructions about return, retention or disposal of unused tissue 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 be appended to the form before sample release)
    - Specify if annotating data is being included

5. Do not supply tissue to a third party without the approval of the REB and the signing of a MTA.

6. Release of tissue to academic or commercial researchers may warrant the use of tailored or specific MTAs.

7. The signed MTAs are valuable documents for tracking material utilization. MTAs should be documented and signed copies filed.

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

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. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8. http://www.ich.org http://www.ich.org/UrlGrpServer.jser?@_ID=276&@_TEMPLATE=254
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials. Division 5. Canada Gazette Part II, Vol. 135, No. 13, June 7, 2001 Section C.05.010 Sponsor Obligations http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/food_drug_reg_amend_1024_gcp_tc_e.html
4. 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
5. 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
6. US National Biospecimen Network Blueprint http://www.ndoc.org/about_ndc/reports/NBN_comment.asp

