CTRNet Standard Operating Procedure Completion of an MTA (Material Transfer Agreement)			
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Approved By:	CTRNet Management Group (CMG)	01-June-2012
	Per: Brent Schacter	28-June-2012

1.0 PURPOSE

During the operation of a tumour biobank human biological material (HBM) 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 biobank, an agreement is signed to outline the terms of the transfer, which include details regarding maintaining donor privacy, intellectual property rights (if relevant), terms for data sharing and other similar ethical and legal requirements. The purpose of this document is to outline procedures that should be followed when completing an MTA.

2.0 SCOPE

This Standard Operating Procedure (SOP) covers the procedures for completing an MTA once the transfer of the sample has been approved by a Research Ethics Board (REB) and the body that adjudicates specimen release. 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

Note: When adopting this SOP for local use please reference CTRNet.

3.1 *CTRNet Policy: POL 5 Records and Documentation*
3.2 *CTRNet Policy: POL 6 Material Release*
3.3 *CTRNet Policy: POL 4 Privacy and Security*
3.4 *CTRNet Policy: POL 2 Ethics*
3.5 *CTRNet Standard Operating Procedure: SOP 09.004 Material Request and Release*

4.0 ROLES AND RESPONSIBILITIES

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

Tumour Biobank Personnel	**Responsibility/Role**
Tumour Biobank Manager/Director	Determine that the Tissue Access Committe has approved the study. Determine that REB approval has been obtained for Material Release. -Complete MTA -Document Completion of MTA

Pathology Coordinator and/or Manager of Finance and Operations	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

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

7.0 PROCEDURES

Samples are received following an informed consent process. Tumour biobanks essentially have "custodianship" of the samples. Release of the sample to a third party requires that we ensure 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 biobanks to accommodate diversity in the practice of when the MTA is completed (before or after REB approval).

7.1 Completion of the MTA

7.1.1 Once an application for tissue has been received and approval for the release of samples has been given, an MTA should be drafted between the researcher and / or their host institution receiving the samples and the biobank that is releasing them. An REB approval should be on file indicating that the researcher has obtained appropriate REB approval before the material is released.

7.1.2 The researcher and the appropriate representative from the Tumour Biobank must sign the MTA. In some situations, institutional signatures from the Office of Research Services (or equivalent institutional office) may be required.

7.1.3 The MTA might contain the following elements. It should be adapted to fit the laboratory's practice:

a. Clarification about custodianship of the samples.
b. Outline of the research objectives.
c. Tissue being supplied 'as is' with no representations or warranties unless otherwise specified by the MTA.
d. Potential for tissue to have unknown characteristics or carry infectious agents.
e. Restrictions on the use of the tissue/clinical data if any.

f. Privacy and Confidentiality principles that must be adhered to.
g. Instructions about return, retention or disposal of unused tissue if applicable.
h. Specific conditions for publication of research results if any.
i. Specific conditions for sharing data if any.
j. Specific conditions for managing intellectual property if any.
k. Specific conditions about compensation for material transfer if relevant.
l. 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).
m. Specify if annotating data is being included.

7.1.4 Do not supply tissue to a third party without the approval of the recipient and/or biobank's REB (or equivalent) and the signing of an MTA.

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

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

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

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 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/Search/search.asp?zoom_query=best+practices+for+repositories

8.4 US National Biospecimen Network Blueprint
http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp

8.5 International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8.
http://www.ich.org/products/guidelines.html

8.6 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/dhp-mps/compli-conform/clini-pract-prat/reg/1024-eng.php

9.0 APPENDICES

None

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
9.1.002 e1.0	June 2012	CMG	• Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates • Updated SOP references • Section 4: Added “and/or Mgr Finance & Operations” to table. • Section 7.1.1 and 7.1.2 revised • Changed section 7.1.3 to say that the MTA might contain the following elements instead of saying the MTA should contain the following elements.