CTRNet Policy Material Release			
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Approved By:	CTRNet Management Group (CMG)	08-Feb-2013
	Per: Brent Schacter	08-Feb-2013

1.0 INTRODUCTION

Advances in knowledge and discoveries coming from basic and translational research on tumour tissue has the potential to contribute to improved cancer care and new treatments. Collaboration between tumour biobanks and researchers, and ethical use of resource controlled by the biobank, require harmonization of rules and policies regarding issues such as tissue and data release.

One goal of the Canadian Tumour Repository Network (CTRNet) is to develop, assist and harmonize use of standardized mechanisms for release/use of tissues and products to research collaborators by member biobanks. Release mechanisms should be designed to promote the goals of the biobanks (advancing cancer research) as well as safeguarding the interests of the participants.

2.0 DEFINITIONS

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

3.0 PURPOSE

The Canadian Tumour Repository Network (CTRNet) is committed to promoting and educating biobanks as to their adherence to high ethical standards and practices in the release of human biological material (HBM) for research purposes. The purpose of this CTRNet policy is to outline general principles that can be used to ensure that access to and release of tissue samples is equitable, ethical, peer reviewed and efficient.

4.0 SCOPE

This policy applies to major ethical, legal and practical considerations that arise in the process of releasing tissue samples from the 'custodian' (tissue biobank) to the researchers requesting samples from the biobank.

5.0 RESPONSIBILITY

This policy applies to CTRNet member biobanks and to biobank personnel involved in all aspects of the tumour biobank program. In particular, it applies to those personnel involved in the process of handling requests and releasing tumour biobank material.

6.0 POLICIES

The use of HBM and accompanying data is critical for medical research. The public and participants should have confidence that biobanks and researchers will use and handle such material with sensitivity and responsibility. It is important to ensure that collections of HBM are used ethically and optimally to benefit health and knowledge. Clearly, the process should focus on timely and equitable access to HBM and associated data without excessive administrative burden. The following principles should guide the CTRNet biobanks in processing requests for tissue and releasing the resource it controls.

6.1 Researchers Access to HBM – General Considerations

6.1.1 Access should preferably be to derived tissue products (such as DNA, RNA or proteins), tissue sections and associated information rather than direct release of whole tissue in order to maximize the use of each samples; particularly if the biobank determines that the tissues requested are rare, available in limited number or that several competing requests have been received for the material in question. The decision to offer access to derived/processes tissues should be made in consultation with the researchers.

6.1.2 Personal and medical information relating to the participant and tissue sample should always be treated as confidential. Access should be to coded tissue samples and associated data.

6.1.3 Access should be granted only after review by an established scientific review process.

6.1.4 Access should only be approved if the proposed research is in accordance with the mission and goals of the biobank.

6.1.5 Access should only be approved with evidence of approval of the proposed research by an REB.

6.2 Request Review Process

6.2.1 The review process should be equitable, have minimal administrative burden and be designed to ensure rapid turnaround of requests.

6.2.2 The request process should be standardized through a common request form that is readily accessible to potential researchers and easy to use.

6.2.3 The review of researcher requests should be conducted by a Tissue Access Committee.

6.2.4 The Tissue Access Committee should include representation from the academic research community and may also include representatives from lay community, patient advocacy groups and government or industry members.

6.2.5 As part of the review process the Tissue Access Committee should evaluate if the research meets release criteria in order to maximize utilization of the resource.

6.2.6 Research evaluation/release criteria should include:

a) Scientific merit of the request

b) Experimental or study design is capable of answering the questions being proposed

c) Originality and innovative use of materials

d) Awareness of similar studies being done or published

e) Established methodology and ability to complete study within a defined time period

f) Adequate funding to complete study

g) Potential for research to be published, lead to patents or aid in discovery and development of new therapeutic agents and biomarkers (data to support regulatory submission).

6.3 Prioritization of Access to HBM in the Biobanks

6.3.1 Tumour tissue samples are scarce and valuable (especially small samples from certain rare cancers). Distribution, especially against competing demands for specimens, should be prioritized in a fair and equitable manner.

6.3.2 Prioritization of distribution should be conducted by the regional tumour biobank management. The following issues should be considered when prioritizing distribution:

a) Researchers affiliation to an institution connected to or supported by regional tumour biobank may be a priority.

b) Geographic location of requesting institution (regional biobanks may have the mandate to meet the needs of researchers from that region first).

c) Importance of the proposed study to address the mandate of the tumour biobank.

d) Researchers track record and former collaborations with the tumour biobank if relevant.

e) Utilization of the resource is maximized. Consider if the tissue needed for a study might be obtained from other sources (alternate sources such as prospective or retrospective collections, without associated or outcome data if adequate).

6.4 Contractual Agreement between the Tumour Biobank and Approved Researcher

6.4.1 Tumour biobanks are responsible for tissue and personal information in its custody, including information transferred to a third party for research purposes. The biobank should use contractual means to provide a comparable level of protection while the tissue and information is being used by the third party.

6.4.2 Custodians of the tissue samples should bear responsibility for keeping proper records of all uses that have been made of the materials, whether by themselves or others. If transfer of material occurs, appropriate material transfer procedures should be followed and documented.

6.4.3 Biobanks should ensure the use of a Material Transfer Agreement (MTA) to transfer tissue and information to any outside organization or individual. The use of a specific MTA for academic and commercial collaborators may be warranted.

6.4.4 The MTA should contain information/clauses about the following:

a) Clarification about custodianship of the samples

b) Tissue being supplied ‘as is’ with no representations or warranties unless otherwise specified by the MTA

c) Potential for tissue to have unknown characteristics or carry infectious agents

d) Restrictions on the use of the tissue if any

e) Privacy and Confidentiality principles that must be adhered to

f) Instructions about return, retention or disposal of unused tissue if applicable

g) Specific conditions for publication of research results if any

h) Specific conditions for sharing data if any

i) Specific conditions for managing intellectual property if any

j) Specific conditions about compensation for material transfer if relevant

k) List of samples (identification codes) released to researcher

l) Tissue cannot be provided by a third party without written consent and the development of a new MTA

7.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

7.1 Declaration of Helsinki.
http://www.wma.net/en/30publications/10policies/b3/index.html

7.2 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/.

7.3 Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series. http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420

7.4 Canadian Federal Personal Information Protection and Electronic Documents Act. http://laws-lois.justice.gc.ca/eng/acts/P-8.6/index.html

7.5 Hakimian, R and Korn, D. Ownership and Use of Tissue Specimens for Research. JAMA. 2004; 292(20):2500-2505.

7.6 UKCCSG Guide to Biological Studies Version 1.0, 2002

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

7.8 Teodorvic, I. et al. Human tissue research: EORTC recommendations on its practical consequences. Eur J Cancer 2003; 39:2256-2263.

7.9 See *ROP 4 on Governance* for further direction regarding request review process (section 3.2.3).

8.0 APPENDICES

None

9.0 REVISION HISTORY

Policy Number	Date Effective	Author	Summary of Revisions
POL 006.001	Feb 2006	JDSH	Original document
POL 6 e1.1	Apr 2009	P. Geary	Updated format. Revised numbering.
POL 6 e2.0	Feb 2013	CMC	• Reviewed and revised by CTRNet Management Committee • Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates