Réseau de recherche sur le cancer du FRSQ

Réseau de recherche sur le cancer

Material Request and Release

Policy Number:	POL 06	Category:	Policy
Supercedes:		Effective Date	
Subject:	Material Request and Release		

BRIEF INTRODUCTION TO POLICY

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 treatment. Collaboration between tumour repositories and researchers and ethical use of resource controlled by the repository require harmonization of rules and policies regarding issues such as tissue and data release.

A goal of the Réseau de la recherche sur le cancer du FRSQ (RRCancer) is to standardize mechanisms for release/use of tissues and products to research collaborators. Release mechanisms should be designed to promote the goals of the repository (advancing cancer research) as well as safeguarding the interests of the participants.

1.0 PURPOSE

The RRCancer is committed to high ethical standards and practices in the release of HBMs for research purposes. The purpose of this RRCancer 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.

2.0 SCOPE

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

3.0 RESPONSIBILITY

This policy applies to RRCancer member repositories and to repository personnel involved in all aspects of the tissue repository program. In particular, it applies to

those personnel involved in the process of handling requests and releasing tumour bank material.

4.0 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 regulated by 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: 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 agrees 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 responsible 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.

Translational Research: Integrated clinical-laboratory investigations designed to improve the prevention, diagnosis and/or treatment of cancer. Involves both clinical and laboratory investigations, or laboratory investigations on clinical material.

Tissue Release Review Committee (TRRC): A working committee that reviews and decides access to the tumour repository samples.

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

5.0 POLICIES

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

5.1 Researchers Access to HBMs – General Considerations

- 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.

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

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

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

- Creating a framework for sharing and comparing research results would add value to the tissues within the repository. Researchers granted access to samples within the repository should be required or encouraged to make research generated information available to the RRCancer database and these results linked back to the original sample.

5.2 Request Review Process

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

- The request process should be standardized through a common request form that is readily accessible to potential researchers.

- The review of researcher requests should be conducted by a Tissue Release Review Committee (TRRC).

- The TRRC should include representation from the academic research community, lay community or patient advocacy groups and possibly government or industry.

- As part of the review process the TRRC should evaluate if the research meets release criteria in order to maximize utilization of the resource.

- Research evaluation/release criteria should include:
    - Scientific merit of the request
    - Experimental or study design is capable of answering the questions being proposed
    - Originality and innovative use of materials
    - Awareness of similar studies being done or published
    - Established methodology and ability to complete study within a defined time period
    - Adequate funding to complete study
    - Potential for research to be published, lead to patents or aid in discovery and development of a new therapeutic agent (data to support regulatory submission).

5.3 Prioritization of Access to HBMs in the Repositories.

- 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.

- Prioritization of distribution should be conducted by the regional tumour repository management. The following issues should be considered when prioritizing distribution:
    - Researchers affiliation to an institution connected to or supported by regional tumour repository
    - Geographic location of requesting institution (regional banks may have the mandate to meet the needs of researchers from that region first)

- Importance of the proposed study to address the mandate of the tumour repository.
- Researchers track record and former collaborations with the tumour repository if relevant
- The requesting researchers willingness to deposit research data with RRCancer
- 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).

5.4 Contractual Agreement between the Tumour Repository and Approved Researcher.

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

- 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.

- Repositories 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.

- The MTA should contain information/clauses about the following:
  - Clarification about custodianship of the samples
  - 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 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

- List of samples (identification codes) released to researcher
- That tissue cannot be provided to a third party without the written consent of TCBD and the signing of a new MTA.

6.0 POLICY HISTORY

SOP Number	Date Issued	Summary of Revisions
POL 06.001	04.11.2005	Original
POL 06.002		Brief description of revision. Sections of SOP affected.

7.0 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. 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
3. Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series. http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf
4. Hakimian, R and Korn, D. Ownership and Use of Tissue Specimens for Research. JAMA. 2004; 292(20):2500-2505.
5. Canadian Federal Personal Information Protection and Electronic Documents Act. http://laws.justice.gc.ca/en/p-8.6/93196.html
6. UKCCSG Guide to Biological Studies Version 1.0, 2002 http://www.ukccsg.org/hp/biological_studies/webguideBs.html
7. US National Biospecimen Network Blueprint http://www.ndoc.org/about_ndc/reports/NBN_comment.asp
8. Teodorvic, I. et al. Human tissue research: EORTC recommendations on its practical consequences. Eur J Cancer 2003; 39:2256-2263.