BC CHILDREN'S HOSPITAL BIOBANK

Title	Material Access and Release
Policy number	POL 6
Effective Date	1 Dec 2014
Approved by	Suzanne Vercauteren

1.0 BACKGROUND

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

One goal of the BC Children's Hospital BioBank (BCCHB) program is to develop, assist and harmonize standardized mechanisms for release/use of biospecimens and products to research scientists. Release mechanisms should be designed to promote the goals of the biobanks as well as safeguarding the interests of the participants.

2.0 PURPOSE

The purpose of this BCCHB policy is to outline general principles that will be used to ensure that access to and release of biospecimens is equitable, ethical, peer reviewed and efficient.

3.0 SCOPE

This policy applies to major ethical, legal and practical considerations that arise in the process of releasing biospecimens from the BCCHB to the researchers requesting samples from the biobank.

4.0 REFERENCE TO OTHER SOPs OR POLICIES

PHSA Policy: IA_020 Privacy and Confidentiality

BCCHB SOPs:
PRM 003 Obtaining Informed Consent
PRM 007 Notification of Significant and Relevant Findings
TRN 001 Education and Training
MTR 003 Material Request and Release

BCCHB Policies:
BCCHB Policy: POL 1 Informed Consent
BCCHB Policy: POL 4 Privacy and Security
BCCHB Policy: POL 5 Records and Documentation

This Policy is modified from the Canadian Tumour Repository Network (CTRNet) Material Access and Release Policy (POL 006 v.2.0).

5.0 RESPONSIBILITY

This policy applies to BCCHB staff involved in all aspects of the biobank program that are involved in conducting informed consent, management and daily operations of the biobank. In particular, it applies to those staff members involved in the process of handling requests and releasing biobank material.

6.0 POLICY STATEMENTS

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

6.1 Researchers Access to Biospecimens

- Access should preferably be to biospecimen products (such as plasma, serum, buffy coat, DNA, RNA or proteins), biospecimen sections and associated information rather than direct release of whole biospecimens in order to maximize the use of each biospecimen; particularly if the biobank determines that the biospecimens requested are rare, available in limited number or that several competing requests have been received for the material in question.
- Personal information relating to the participant and biospecimen will always be treated as confidential. All biospecimens and data will be coded prior to release.
- Researchers and/groups must have an approved, valid REB approval prior to accessing biospecimens and data.
- Research evaluation/release criteria include:
    - Research that fits with the goals of the BCCHB
    - Scientific merit of the request including:
        - 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 or lead to patents or novel discoveries

        - Where small pilot studies have been undertaken, communication around initial results
    - That request does not exhaust the supply of the BCCHB, or if it does exhaust the supply of a specific specimen, there is documented agreement that the research project was worthy of such a specimen.
    - The quantity of the materials requested will be evaluated to fit with the BCCHB supply and reflect appropriate quantities needed for proposed research methods
- Researchers will be made aware of applicable user fees prior to release of materials
    - User fees will be communicated in a timely and clear fashion
    - User fees will be developed in a transparent and consistent manner (e.g. Biobank Resource Centre (BRC) Biospecimen User fee Calculator www.biobanking.com)
- Biospecimens and associated de-identified data will be released with a BCCHB 'Release Code'. This will be tracked and managed by the BCCHB Database and associated with the BCCHB Participant and Biospecimen Codes.
- Release of biospecimens and data will be accompanied by a:
    - Material Transfer Agreement (MTA)
    - Summary information regarding the materials released:
        - Biospecimen type
        - Biospecimen tissue site
        - Quantity
        - 'Release Code' tracking numbers
    - Invoice for all applicable costs (user fees, shipping fees, etc.)

6.2 Request and Review Process

- The request process to access biospecimens and data is described in **BCCHB SOP MTR 003 Material Request and Release** and outlined in Appendix 1.
- The request and review processes are equitable, have minimal administrative burden and are designed to ensure rapid turnaround of requests all-the-while ensuring appropriate review of requested materials.
- The request and review processes will be transparent and well communicated.
- The request process will be standardized through the **BCCHB Material and Data Access Application Form** that is readily accessible to potential researchers.
- The review process will include an efficient, complete and multi-level review process and is further defined in **BCCHB SOP MTR 003 Material Request and Release**:
    - Review by the BCCHB Administrative Manager for completeness and accuracy
    - Review by the BCCHB Chair of the BCCHB Biospecimen Access Committee (BAC) for operational feasibility and scientific validity
    - Review by the Scientific Access Subcommittee (SAS) for assessing the scientific merit of research applications
    - A final decision is made by the BCCHB Director and the Chair of the BAC and is based on the number of specimens available and subsequently the number of specimens which may be released.

6.3 Prioritization of Access to Biospecimens

- Biospecimens are scarce and valuable (especially small samples in the pediatric setting or biospecimens from certain rare disease). Distribution, especially against competing demands for biospecimens, should be prioritized in a fair and equitable manner.
- The following issues should be considered when prioritizing distribution:
    - Researchers' affiliation to the BCCHB, UBC or PHSA may be a priority.
    - Geographic location of requesting institution (i.e. mandate to meet the needs of researchers from UBC related research projects first).
    - Importance of the proposed study to address the mandate of pediatric and maternal health.
    - Researchers track record and former collaborations with the BCCHB if relevant.
    - Utilization of the resource is maximized. Consideration will be given to other collections/resources that the request can be sourced from (alternate sources such as prospective or retrospective collections, without associated or outcome data if adequate).

6.4 Contractual Agreement between the BCCHB and an Approved Researcher

- The BCCHB is responsible for biospecimens and personal information in its custody, including information (de-identified) 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.
- The BCCHB is the custodian of the biospecimens and thus bears the 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 will be followed and documented. These are described in detail in **BCCHB SOP MTR 003-01 Material Request and Release.**
- The BCCHB will use a BCCHB Material Transfer Agreement (MTA) to transfer biospecimens and information to any outside organization or individual. These are described in detail in **BCCHB SOP MTR 003-01 Material Request and Release**
    - BCCHB Internal Institutional Material Transfer Agreement – for all material requests that are requested from, and released to PIs, research groups or projects within the University of British Columbia (UBC), Children's Hospital, Women's Hospital and all others associated with the Oak Street Campus of the Hospital
    - BCCHB External Institutional Material Transfer Agreement – for all material requests that are outside the above mentioned groups
- Both MTAs contain information/clauses about the following:
    - Clarification about custodianship of the samples
    - 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 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
    - Specific conditions for managing intellectual property

- Specific conditions about compensation for material transfer
- List of samples (identification codes) released to researcher
- Biospecimen cannot be provided by a third party without written consent and the development of a new MTA

6.5 Release of Biospecimens and Data

- The BCCHB is responsible for the release of biospecimens and de-identified data to researchers. The BCCHB will utilize a checklist similar to below upon release of materials:

  - ✓ Biospecimens and associated data will be release with a 'Release Code' (**see BCCHB SOP MTR 003 Material Request and Release**)
  - ✓ A signed MTA will be in place and transferred
  - ✓ Material and Data Release Form with required biospecimen data
  - ✓ Associated data will be de-identified and in an agreed upon format (paper or electronic document, etc.)
  - ✓ Invoice to researcher for associated costs (user fees, shipping fees)
  - ✓ Packaging and shipping will be compliant with local guidelines and regulations

7.0 REFERENCES

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

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/

3. Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series. http://www.mrc.ac.uk/news-events/publications/human-tissue-and-biological-samples-for-use-in-research

4. Canadian Federal Personal Information Protection and Electronic Documents Act. http://laws-lois.justice.gc.ca/eng/acts/p-8.6/

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

6. UKCCSG Guide to Biological Studies Version 1.0, 2002

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

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

9. Canadian Tumour Repository Network (CTRNet) Policy POL 006 e2.0. Material Release

8.0 REVISION HISTORY

BCCHB Policy – Material Access and Release				
Policy Code -Version No.	**Date Revised**	**Approved By**		**Summary of Revisions**
		Print Name	**Signature**	
POL 6				Original version

9.0 APPENDICES

Appendix 1. BCCHB Biospecimen Access and Release Flow Diagram