BC CHILDREN'S HOSPITAL BIOBANK

Title	Material and Information Handling
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Approved by	Suzanne Vercauteren

1.0 BACKGROUND

Translational research using advances in molecular biology, biospecimens and annotated data, is pursued to aid in the elucidation of the disease process and discovery of new diagnostic and treatment modalities. A collection of stored and well-annotated biospecimens and derivatives is a valuable resource, important to the research process. The quality of the biospecimens and the extent of the accompanying data is a determinant of value.

2.0 PURPOSE

The BC Children's Hospital BioBank (BCCHB) aims to adhere to high ethical standards and practices in the collection and storage of biospecimens and accompanying information for research purposes. The purpose of this BCCHB policy is to outline general principles that can be used to ensure that biospecimens and data are handled and stored in a manner sensitive to the rights of the participant, responsible to the safety of BioBank personnel and protective of the quality and integrity of the collection.

3.0 SCOPE

This policy applies to the operational and practical considerations that arise in the process of collecting, storing and maintaining biospecimens and annotated data. The policy is intended to ensure that the goals of the BioBank network are met and that the quality and value of the collection is maintained.

4.0 REFERENCE TO OTHER SOPs OR POLICIES

BCCHB SOPs:

- FMO 003 Maintenance of Biospecimen Storage Facility and Equipment
- MHD 002 Inventory Verification
- MHD 006 Blood Collection
- MHD 007 Blood Processing and Storage

- MHD 011 Tissue Collection and Transportation
- MHD 012 Tissue Harvesting
- MHD 013 Snap Freezing of Tissue
- MHD 022 Biospecimen Retrieval
- MTR 001 Biospecimen Shipping and Transportation
- MTR 003 Material Request and Release
- PRM 003 Obtaining Informed Consent
- SFT 001 Handling Hazardous Chemical Waste
- SFT 002 Handling Biohazardous Substances
- TRN 001 Education and Training
- RMD 001 Information Access Control
- RMD 007 Request and Creation of User Accounts

BCCHB Policies:

- POL 1 Informed Consent
- POL 3 Education and Training
- POL 4 Privacy and Security
- POL 5 Records and Documentation

This Policy is modified from the Canadian Tumour Repository Network (BCCHB) Material and Information Handling (POL 007 v.2.0).

5.0 RESPONSIBILITY

This policy applies to BCCHB personnel involved in all aspects of the BioBank program. In particular, it applies to those personnel involved in processing, storing and handling biospecimens, derivative products and/or accompanying data.

6.0 POLICY STATEMENTS

The use of biospecimens 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, responsibility and concern for maintaining the value of the collection. The following principles will guide the BCCHB in collecting, processing and storing biospecimens and information in its custody.

6.1 Material handling – General Considerations

BCCHB aims to provide users of the BioBank standardized, high quality biospecimens that are readily accessible for their research needs. The following considerations guide the actions of the BCCHB:

a) To meet the needs of the users, the biospecimens will be collected, processed and stored in a manner that optimally maintains the quality of the biospecimens and the molecular integrity of the DNA, RNA, and proteins in the biospecimens.

b) All steps will be performed by staff that are suitably qualified or have adequate training to perform the tasks required by their position **(see BCCHB POL: POL 3 Education and Training)**.

c) Established standard operating procedures (SOPs) will be in place for all procedures involved in collection, processing, storing and retrieving biospecimens and annotated information including BCCHB SOPs:

- FMO 003 Maintenance of Biospecimen Storage Facility and Equipment
- MHD 006 Blood Collection
- MHD 007 Blood Processing and Storage
- MHD 011 Tissue Collection and Transportation
- MHD 012 Tissue Harvesting
- MHD 013 Snap Freezing of Tissue
- MHD 022 Biospecimen Retrieval
- MTR 001 Biospecimen Shipping and Transportation
- MTR 003 Material Request and Release
- PRM 003 Obtaining Informed Consent
- SFT 001 Handling Hazardous Chemical Waste
- SFT 002 Handling Biohazardous Substances
- TRN 001 Education and Training

d) Laboratory equipment and infrastructure will be appropriate to ensure proper collection, storage, processing, quality control and distribution (**see BCCHB SOP: FMO 003 Maintenance of Biospecimen Storage Facility and Equipment**).

e) Computer/Informatics infrastructure will be appropriate to enable the BCCHB to collect, store and share de-identified data in an efficient and secure method (**see BCCHB POL 5 Records and Documentation**).

f) Quality Assurance (QA) procedures such as routine audits and quality control analysis will be performed to ensure that integrity and quality of the collection is maintained (**see BCCHB SOP: MHD 002 Inventory Verification**).

g) The BCCHB will certify with the Biobank Resource Centre Biobank Certification Program (www.biobanking.org).

6.1.1 Biospecimen Collection

a) Biospecimens should be obtained only after all patient diagnostic needs have been met and will be accompanied by documented, informed consent or a waiver of consent from the relevant Research Ethics Board (REB) (**see BCCHB Policy: POL 1 Informed Consent).**

b) Where possible, biospecimens should be collected from a wide range of patients (with matched normal biospecimens whenever possible). If possible, biospecimens should be collected in sufficient quantity and diversity to be of value in a variety of study designs.

c) Broader molecular profiles can be obtained from biospecimens that have been collected using rigorous and standardized procedures. Collection procedures should be geared to allow use of the biospecimens in genomic and proteomic research.

6.1.2 Biospecimen Processing

a) To ensure suitability for genomic and proteomic research, the processing of biospecimens (including tissues, blood, fluids, etc.) should be done in a manner to protect biospecimen quality and the integrity of molecular products (**see BCCHB SOPs: MHD 012 Tissue Harvesting; MHD 013 Snap Freezing of Tissue; MHD Blood Processing and Storage**)

b) To ensure suitability for genomic and proteomic research the time elapsed between blood collection, surgical or autopsy resection of a lesion and freezing ideally should be rapid to ensure preservation. Adequate documentation should capture the timeframe for quality assurance purposes (**see BCCHB SOPs: MHD 011 Tissue Collection and**

Transportation; MHD 006 Blood Collection; MHD 012 Tissue Harvesting; MHD 013 Snap Freezing of Tissue; MHD Blood Processing and Storage).

c) Biospecimens should be handled as being potentially biohazardous and laboratory staff should take appropriate precautions when handling tissue or fluids such as whole blood and blood products (**See BCCHB SOP: SFT 001 Handling Hazardous Chemical Waste; SFT 002 Handling Biohazardous Substances; TRN 001-01 Education and Training; BCCHB Policy: POL 3 Education and Training**).

d) Desiccation and degradation of specimens should be avoided. The method of transport of the biospecimen from the operating room, autopsy, in patient clinic area or any other area to the processing laboratory area should be documented.

e) All precautions to avoid cross-contamination of specimens during processing, product isolation or aliquoting should be employed. This should include using fresh containers, pipette tips and blades between specimens and between different areas of the same specimen (e.g. between malignant and associated uninvolved tissue).

f) Snap freezing or freezing in a cryoprotectant should be done by suitable means (**see BCCHB SOP: MHD 013 Snap Freezing of Tissue**).

g) Biospecimens in the collection are useless if incorrectly identified. All specimens should be accurately labelled.

6.1.3 Biospecimen Storage and Retrieval

The storage method of biospecimens, or derived products affects the suitability of the specimen for use in specific genomic or proteomic studies.

a) Storage procedures should be geared to protecting the integrity of the collection and should allow for efficient and accurate retrieval of biospecimens.

b) Biospecimens should be stored in a manner optimal for their intended category and use. This should be documented.

c) Frozen biospecimens should be stored in screw-capped, plastic containers or cryovials that can be sealed. Vials should permit appropriate labelling, prevention of contamination or specimen desiccation and should withstand freezing in liquid nitrogen (**see BCCHB SOP: MHD 013 Snap Freezing of Tissue**).

d) If mechanical or liquid nitrogen systems are used for storage of frozen biospecimens, adequate back-up capacity should be in place to ensure that operating temperatures are maintained at all times. Events such as equipment failure or power-outage emergency should be planned for and processes should be in place to deal with possible emergencies (**see BCCHB SOP: FMO 003 Maintenance of Biospecimen Storage Facility and Equipment**). The BCCHB is currently working on an Emergency Preparedness Plan for the BioBank.

e) For mechanical freezers, manual defrost feature is optimal as freeze-thaw cycles of automatic units can degrade biospecimens.

f) Ideally, alarm systems should be used to monitor temperatures in the storage freezers and procedures should be in place to permit corrective action before the temperatures falls out of

range (**see BCCHB SOP: FMO 003 Maintenance of Biospecimen Storage Facility and Equipment**).

g) Proper procedures will be followed for biospecimen retrieval to ensure that proper conditions are maintained to protect the biospecimen, and that documentation is completed to record any change in inventory (**see BCCHB SOP: MHD 022 Biospecimen Retrieval**).

h) Shipping and transportation procedures will be established to ensure that containers, labels, conditions and methods are optimal for biospecimen protection (**see BCCHB SOP: MTR 001 Biospecimen Shipping and Transportation**).

i) Tracking and auditing of biospecimens is critical. A high quality inventory will be employed so that every sample can be tracked and audited. This will be a main feature of the BCCHB Database. All records pertaining to biospecimen retrieval, use, or removal should be maintained to facilitate tracking. All paper records related to each case will be linked to the case via the BCCHB Biospecimen Code to allow for continuity.

6.2 Informatics – Collection and Handling

6.2.1 Access to personal information will be based on defined roles and responsibilities of individuals in the BCCHB. Access to this personal information and user account creations are detailed in **BCCHB SOPs: RMD 001 Information Access Control; RMD 007 Request and Creation of User Accounts.**

6.2.2 Annotation data (e.g. person, lifestyle, diagnosis, laboratory, clinical and research generated) should be accurate, quality-controlled and standardized as far as possible.

6.2.3 Data collected will contain common data elements from the following categories including:

a) Personal
b) Longitudinal clinical and diagnostic information
c) Treatment and outcome information
d) Biospecimen information
e) Lifestyle and family history

6.2.4 Computerized inventory and bioinformatics systems used to handle and store annotated data will:

a) Be responsive to the needs of the BioBank and ultimately, the de-identified information will be suitable for users outside the BCCHB
b) Be available for a long period of time
c) Use standardized terms to categorize specimens and enter data
d) Use an automated data extract system or permit multiple checks of data entry to ensure accuracy
e) Have the ability to feed back or link standard research results and genomic and proteomic results into the system
f) Be searchable by BCCHB personnel
g) Provide security and access control to ensure privacy rights are protected
h) Have an inventory management system
i) Support integration and expansion if needed
j) Have maintenance features and back-up capabilities
k) Track biospecimens and de-identified data that have been released to users

See BCCHB Policy 5: Records and Documentation; BCCHB Policies: RMD 001 Information Access Control; RMD 005 Data Entry Procedures; RMD 007 Request and Creation of Accounts and CFRI Policies: 167 Network Acceptable Use; 168 Network Security; 169 Systems Security; 172 Account and Password; 173 Electronic Data Storage; 177 Personal Device; 179 Loss, Damage, Theft and Disposal of Electronic Data; 200 Performing and Retaining Data Backups.

6.3 Safety Considerations

All personnel in contact with biospecimens or involved in the operations of the BioBank should be trained in safety procedures to minimize injuries to them and protect the material and information held in the BioBank. Safety procedures should be:

a) Given to staff before they begin their work
b) Updated as needed
c) Led by knowledgeable trainers
d) Appropriate for the background of each employee and to the risks to which each employee is exposed
e) Documented and tracked by the BCCHB Administrative Manager

See BCCHB SOP: SFT 002 Handling Biohazardous Substances; TRN 001-01 Education and Training Safety training

6.3.1 Relevant personnel should handle all biospecimens as being biohazardous.

6.3.2 The use of liquid nitrogen and dry ice poses specific safety hazards. Appropriate gloves, a face shield and a protective garment should always be used when handling these materials. When dry ice is used, controls to ensure sufficient air and oxygen levels should be ensured.

6.3.3 Precautions should be taken to minimize risks to injury and damage from biological, chemical, physical, electrical hazards and fire.

6.3.4 Written guidelines should be developed to ensure safety precautions based on national, regional and local regulations. The BCCHB recognizes that the C&W Department of Pathology has many in-house guidelines on biohazards, appropriate handling and disposal.

6.3.5 Personnel coming in contact with patients and patient information should be trained in maintaining safe and healthy practices.

6.3.6 Overall BioBank security should be implemented by limiting access of unauthorized personnel to the workplace.

6.3.6.1 Visitors to the BCCHB will be logged and escorted and will not be in an area where personal information is visible.

6.3.6.2 The BCCHB will work with Facilities Management to ensure that all work and storage spaces are secured and accessible by pertinent personnel.

7.0 REFERENCES

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   http://www.mrc.ac.uk/news-events/publications/human-tissue-and-biological-samples-for-use-in-research/

4. UKCCSG Guide to Biological Studies Version 1.0, 2002

5. US National Biospecimen Network Blueprint
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   http://www.isber.org

7. Qualman, S.J. et al. Establishing a tumour bank: banking, informatics and ethics. Br. J. Cancer (2004). 90-1115-1119.

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

9. Canadian Tumour Repository Network (BCCHB) Policy POL 007 e2.0. Material and Information Handling

8.0 REVISION HISTORY

BCCHB Policy – Material and Information Handling				
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		Print Name	**Signature**	
POL 7				Original version