



**BC WOMEN'S
HOSPITAL+
HEALTH CENTRE**



An agency of the Provincial Health Services Authority

BC CHILDREN'S HOSPITAL BIOBANK

Title	Education and Training
Policy number	POL 3
Effective Date	1 Dec 2014
Approved by	Suzanne Vercauteren

1.0 BACKGROUND

Adequate knowledge of the BC Children's Hospital BioBank (BCCHB) processes, related regulations and guidelines are essential to safeguarding the interests of the participant, achieving program goals, maintaining program compliance, sustaining data and biospecimen integrity and overall quality assurance at the BCCHB. BCCHB personnel must understand the responsibilities of the BCCHB as the "custodian" of biospecimens and associated data for research purposes and be appropriately qualified by education, training and experience to perform his or her task in an efficient, professional and ethical manner.

2.0 PURPOSE

The BCCHB is committed to high ethical standards and practices in the collection, processing and storage of biospecimens and associated data for research purposes. The purpose of this BCCHB policy is to outline general principles that can be used in most situations to ensure that personnel working at the BCCHB are adequately educated and trained to perform their tasks.

3.0 SCOPE

This policy describes recommendations for areas and material that will be the focus of any educational or training process to ensure that ethical and operational standards are maintained at the BCCHB.

4.0 REFERENCE TO OTHER SOPs OR POLICIES

BCCHB SOP: TRN 001-01 Education and Training
BCCHB SOP: ADM 003 Administration of Standard Operating Procedures
BCCHB SOP: ADM 004 Job descriptions, Roles and Responsibilities
BCCHB Policy: POL 4 Privacy and Security
BCCHB Policy: POL 1 Informed Consent

This Policy is modified from the Canadian Tumour Repository Network (CTRNet) Education and Training Policy (POL 003 v.2.0).

5.0 RESPONSIBILITY

This policy applies to all personnel involved in all aspects of the BCCHB. The BCCHB Director is ultimately responsible for the BCCHB personnel training, as well as ensuring that he/she has adequately trained personnel to carry out the processes of the BCCHB. The BCCHB personnel have a professional responsibility to obtain and maintain the knowledge and skill sets necessary to perform their relevant duties.

6.0 POLICY STATEMENT

Learning is a dynamic process. All BCCHB personnel will be qualified by education, training and experience to assume their responsibility for the proper conduct of the program.

- It is imperative that all those involved in the BCCHB program have the necessary skills, knowledge and a clear understanding of the processes and policies that define the running of a compliant, efficient and successful program.
- It is important that the personnel have a clear understanding of their role within the BCCHB organization and have access to the appropriate level of information to support their decisions and actions.
- Training will be provided for personnel who are new and have not previously received such training and for experienced personnel who need to keep current with new developments, new methods, updated equipment or software and evolving regulatory requirements.
- Training will be designed to meet the needs of the personnel working at the collection, storage and central sites if applicable. The scope, detail and content of the training will reflect the particular responsibilities of each site or individual.
- Training will be designed to include general issues such as:
 1. The ethical and privacy issues associated with the use of biospecimens in research
 2. General research, regulatory and ethical training issues pertinent to pediatric and maternal health research as well as in the context of biobanking
 3. Regulatory requirements that must be complied with
 4. Best practices for record keeping and reporting
 5. Security regarding issues of privacy and confidentiality
 6. Material Handling (biospecimen and information processing and storage)
 7. Biospecimen and Information release (material release)
- Training should be designed to include institutional and regional specific issues including:
 1. Facility security and procedures
 2. Occupational and Environmental health and safety

3. Technical procedures and processes relevant to operations at the site (e.g. deriving biospecimen products such as DNA, RNA, protein and tissue microarrays, etc.)
 4. Maintaining records, updating inventories and databases
- A detailed list of specific training topics for each of the above categories and subcategories is outlined in **BCCHB SOP: TRN 001-01 Education and Training**
 - BCCHB will implement procedures by which they can assess and evaluate whether or not personnel has achieved the learning outcomes of the training component.
 - Tools used for training such as sets of policies or standard operating procedures (SOPs) will be updated in a timely manner so as to accurately reflect current practice.
 - Personnel will be encouraged to keep current in their area of expertise. This could include attending relevant seminars, conferences, continuing education courses and keeping professional certification current as necessary.
 - Training logs will be used to document and track personnel training. Relevant certificates related to training will be attached and stored with the training logs.

7.0 REFERENCES

1. Declaration of Helsinki.
<http://www.wma.net/en/30publications/10policies/b3/index.html>
2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8.
<http://www.ich.org/products/guidelines.html>
3. 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, December 2010.
<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>
4. USA Food and Drug Administration FDA Code of Federal Regulations, Title 21, Part 50: Protection of Human Subjects.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm>
5. Office for Protection from Research Risks, US Department of Health and Human Services, Tips on Informed Consent.
<http://www.hhs.gov/ohrp/policy/ictips.html>
6. 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/>

8.0 REVISION HISTORY

BCCHB Policy : Education and Training				
Policy Code -Version No.	Date Revised	Approved By		Summary of Revisions
		Print Name	Signature	
POL 3-01				Original version