BC CHILDREN'S HOSPITAL BIOBANK

Title	Ethics
Policy number	POL 2
Effective Date	1 Dec 2014
Approved by	Suzanne Vercauteren

1.0 BACKGROUND

Biospecimens have been the basis of pathological inquiry for a very long time. However, with the advancement of molecular biology and genetic insights, scientists have greatly increased their use and demand for properly prepared and clinically annotated biospecimens that yield valuable insights into the mechanisms and pathways of human disease.

Research on human biospecimens has not been always formally regulated or extensively harmonized by governing agencies. Existing guidelines for the protection of human subjects in clinical research continue to provide oversight for the use of biospecimens in basic and translational research in general.

Biobanking of pediatric biospecimens and data for research purposes brings its own ethical dilemmas. Current ethical concerns in pediatric biobanking include consent of children participants and their parents; re-contacting children at age of consent; use of personal information by researchers and breach of security safeguards to name a few. Existing guidelines and best practices have been applied to dealing with issues related to collection, study, storage, transfer and disposal of biospecimens and associated patient/participant (pediatric and adult) data.

As biospecimens are becoming a valuable and irreplaceable resource and society's interest in the advancement of medical knowledge is increasing, this policy is intended to foster a consistent and coherent ethical framework that should govern biospecimen use in the BC Children's Hospital BioBank (BCCHB).

2.0 PURPOSE

The BC Children's Hospital BioBank (BCCHB) is committed to high ethical standards and practices in the collection and storage of biospecimens for research purposes. The purpose of this BCCHB policy is to outline general principles that can be used to ensure that the interests of participants are safeguarded.

3.0 SCOPE

This policy applies to major ethical considerations that arise in the conduct of biobanking and/or research. The issues concern custodianship, risk, confidentiality, consent and quality of research.

4.0 REFERENCE TO OTHER SOPs OR POLICIES

PHSA Policy: IA_020 Privacy and Confidentiality

BCCHB SOPs:
PRM 003-01 Obtaining Informed Consent
PRM 007 Notification of Significant and Relevant Findings
TRN 001-01 Education and Training
MTR-001-01 Sample Shipping and Transportation
MTR-002-01 Completion of an MTA
MTR 003-01 Material Request and Release
RMD 006-01 De-identification of Data

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

This Policy is modified from the Canadian Tumour Repository Network (CTRNet) Ethics Policy (POL 002 v.2.0).

5.0 RESPONSIBILITY

This policy applies to BCCHB staff involved in all aspects of the biobank program.

6.0 POLICY STATEMENT

The use of biospecimens and accompanying data is critical for medical research. The public and program participants should have confidence that the BCCHB and researchers will use and handle such material according to recognized ethical standards. It is important to ensure that collections of biospecimens are used ethically and optimally for research to benefit knowledge of pediatric and maternal health and disease. The clinical care of participants should always take precedence over the interests of research, science and society.

The following principles should guide the BCCHB in collecting, maintaining and managing the resources it controls:

6.1 Ethics Review

The following principles should guide the BCCHB personnel in the process of obtaining consent:

- To ensure that the interests of the participant are safeguarded, processes such as informed consent, collection and storage of biospecimens and clinical data will be reviewed and approved by the University of British Columbia / Children's and Women's Health Centre of British Columbia Research Ethics Board (UBC C&W REB).
- The standard of "minimal risk" should be considered in the review process. The physical risks in donating biospecimens as well as the risk that information from research on the biospecimen and annotated data could harm the privacy and confidentiality of the participant should be considered and communicated to the participant as part of the Informed Consent process **(BCCHB SOP: PRM 003-01 Obtaining Informed Consent).**
- Collection of biospecimen and annotation data will be conducted under REB approved collection protocols.
    - In some circumstances the REB may provide a "waiver of consent" on behalf of the participants. (**BCCHB SOP: PRM 003-01 Obtaining Informed Consent).**
- Researchers that request access to biospecimens and de-identified data from the BCCHB will seek independent REB approval for each study. Requests for biospecimens and de-identified data will be reviewed the BCCHB Biospecimen Advisory Committee (BAC) Chair and Scientific Advisory Subcommittee. (SAS) (**BCCHB SOP: MTR 003-01 Material Request and Release**).

6.2 Confidentiality

Personal and medical information and research results relating to the participant and biospecimen will always be treated as confidential. The participants and legal guardians will be made aware of the type of personal and medical information that will be collected by the BCCHB and what safeguards will be in place to protect their confidentiality and anonymity. The BCCHB will only release de-identified specimens and de-identified data to researchers **(BCCHB Policy: Pol 4 Privacy and Security; BCCHB SOP: RMD 006-01 De-identification of Data).**

6.3 Economic Factors

Financial compensation may provide motivation for participants to participate in the BCCHB but this could compromise the quality and safety of the collection. Participants and their families will not be offered or receive any financial compensation for their participation in the BCCHB. Biospecimens and annotated clinical data collected from participants will be treated as donations.

The collection of human biospecimens and annotated data should not give rise to financial gain of the BCCHB. The BCCHB will not sell (for a profit) biospecimens that they have collected. A reasonable user fee charged to researchers to recover costs of obtaining, managing, processing and handling, maintaining and storing the BCCHB collection is however acceptable. The BCCHB will consult the Biobank Resource Centre (BRC) 'Biospecimen User Fee Calculator' online at www.biobanking.org in deriving user fees.

6.4 Custodianship of biospecimen data

The BCCHB, acting as custodian, bears responsibility for the biospecimens and data in its collection and as such, will safeguard the interests of the participants (**BCCHB POL 4: Privacy and Security**).

BCCHB bears responsibility for keeping proper records of all uses that have been made of biospecimens and data. If transfer of material occurs, appropriate material transfer procedures will be followed and documented (**BCCHB SOPs: MTR-001-01 Biospecimen Shipping and Transportation; MTR-002-01 Completion of an MTA; MTR 003-01 Material Request and Release**).

Any donation of 'Historical Collections' to the BCCHB will be reviewed by the BCCHB Executive Committee for evaluation from an operational standpoint as well as the BAC from a scientific standpoint. The BCCHB will seek guidance and approval of the REB with respect to incorporating such collections including clinical data into the BCCHB (**see BCCHB POL 1 Informed Consent; POL 4 Privacy and Security**).

6.5 Commercialization and Intellectual Property Issues

The development of new drug therapies and diagnostics to a point where they can be made available to universally benefit society is dependent on commercial involvement. Access by the commercial sector to biospecimens within the BCCHB should be facilitated if consistent with the goals of the BCCHB. However, no single commercial enterprise will be given exclusive rights of access to the collection. Patients will be informed in the consent process that biospecimens or their clinical data may be used by academic researchers as well as researchers in the commercial sector and that they will not be entitled to a share of the profits that may ensue from research. Disclosure that there is the possibility or intent to commercialize research might help alleviate ethical concerns that participants are not aware of intended uses of their biospecimen.

Intellectual property (IP) rights arising from research using biospecimens may be sold or licensed in the same way as other IP rights. Before allowing access to biospecimens by either academic or commercial sector researchers, the BCCHB will make clear (by contractual agreement) its policies on ownership of IP in the form of a Material Transfer Agreement (**BCCHB SOP: MTR 003-01 Material Request and Release**).

6.6 Genetic Testing

The ability to study the genetic makeup of biospecimens stored in the biobanks has raised concerns over identification risk of participants potentially resulting in discrimination or stigmatization of individuals. Genetic testing of pediatric biospecimens heightens these risks as the decision of children to participate in biobanks is made by their parents or legal guardians. Privacy of research results should never be breeched, as the consequences for the participant are likely to be social, economic and psychological. Privacy and security of information is covered in **BCCHB Policy: POL 4 Privacy and Security.**

Much genetic information derived from research is of unknown or uncertain predictive value. Should researchers find genetic information that may be significant or relative to a patient/participant's future health concern, the BCCHB has a mechanism in place to have such results evaluated, addressed and communicated. Results will not be disclosed to the

patient or added to medical records unless approved by the REB. This is described in detail in **BCCHB SOP: PRM 007 Notification of Significant and Relevant Findings**.

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/cfcfr/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. Meslin, E. and Quaid, K. Ethical issues in the collection, storage, and research use of human biological materials. J Lab Clin Med. 2004;144:229-34

7. 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. National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol I: Report and recommendations of the National Bioethics Advisory Commission. August 1999.
   https://repository.library.georgetown.edu/bitstream/handle/10822/559356/nbac_biological1.pdf?sequence=1

9. The Best Practices for Health Research Involving Children and Adolescents (BPHR)
   http://www.genomicsandpolicy.org/en.

10. Privacy in Canadian Paediatric Biobanks: A Changing Landscape. A Report Delivered to the Office of the Privacy Commissioner of Canada.
    http://www.priv.gc.ca/resource/cp/2010-2011/p_201011_07_e.asp

11. Canadian Tumour Repository Network (CTRNet) Policy POL 002 e2.0. Ethics

8.0 REVISION HISTORY

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		Print Name	**Signature**	
POL2-01	September 01, 2013			Original version