BC CHILDREN'S HOSPITAL BIOBANK

Title	Informed Consent
Policy number	POL 1
Effective Date	1 Dec 2014
Approved by	Suzanne Vercauteren

1.0 BACKGROUND

Under best practice guidelines such as the TCPS 2 and privacy legislation (FOIPPA), consent must be obtained for the collection, use and/or disclosure of personal information for research purposes. Consent for treatment and consent for information collection/use/ disclosure are separate activities although they may be combined within a common process. Risk statements must also clearly separate risk to the individual's person from risk to their privacy through the inappropriate or prejudicial use or disclosure of their information. Research participants must be clearly informed that their treatment is in no way impeded if they do not wish to consent to information collection/use/disclosure. Voluntary and informed consent from legally competent individuals or authorized third parties is a fundamental principle in research involving humans, and specifically for use of their personal data. Research participants can decline consent or withdraw from a study at any time.

2.0 PURPOSE

Informed and voluntary consent is a fundamental requirement for ethical research involving human subjects. The consent process requires sensitivity to the dignity, cultural notions and physical integrity of the individual participant in the BC Children's Hospital BioBank (BCCHB) program.

The consent process includes opportunities to inform participants about research by providing an appropriate level of information about study objectives and goals, possible risks, as well as information about the organization's data protection policy and controls. Consent reduces risk to the individual's privacy by having them actively opt in to research activities.

Consent is obtained in order to reduce risk to the organization due to misunderstandings on the part of research subjects.

3.0 SCOPE

The policy applies to all personal information collected, used and/or disclosed through the BCCCHB. Informed Consent may be declined or revoked or withdrawn for future contact at any time. Informed Consent may be presented to participants going for surgical or diagnostic procedures or at the time of autopsy.

4.0 REFERENCE TO OTHER SOPs OR POLICIES

BCCHB SOPs:
PRM 003-01 Obtaining Informed Consent
PRM 004-01 Revoked Consent and Withdrawal of Consent for Future Collections
PRM 005-01 Developing and Revising Consent Forms
RMD-006-01 Data Entry Procedures
TRN 001-01 Education and Training

BCCHB Policies:
POL 1 Informed Consent
POL 4 Privacy and Security
POL 7 Material and Information Handling
POL 5 Records and Documentation

This Policy is modified from the Canadian Tumour Repository Network (CTRNet) Informed Consent Policy (POL 001 v.2.0).

5.0 RESPONSIBILITY

This policy applies to BCCHB personnel involved in all aspects of the biobank program that are involved in conducting informed consent, management and daily operations of the biobank.

6.0 POLICY STATEMENTS

The following statements will guide the overall actions of the BCCHB regarding Informed Consent and are reiterated in **BCCHB SOP: PRM 003-01 Obtaining Informed Consent**

- The collection and use of human tissue for research should be undertaken with voluntary and informed consent of competent participants.
- Consent should also be obtained to collect or access personal and clinical information from medical records.
- Consent should be obtained voluntarily, without manipulation, influence or coercion. It must also be made clear that a participant can revoke consent at any time, and that a decision not to participate in the program will in no way compromise the standards of medical care the patient will receive.
- Consent should be obtained in writing.
- When seeking consent, information for participants, legally acceptable representatives, impartial witnesses or an intermediary should be presented in a clear form that can be easily understood.
- Lack of proficiency in the operating language should not disqualify participants. In this case, an intermediary competent in the language should translate the relevant information and the participant should acknowledge in his or her language an

understanding of the project, the extent of his or her participation, the risks involved and freely give consent.

- Participants should be aware of financial consideration. It should be made clear that they will not receive any compensation for their participation in the program.
- If any new tests, discoveries or products with potential commercial value result from research on their tissue, they will not share in financial benefits.
- Issues of privacy and confidentiality should be discussed with the participant. If relevant, the participant should be informed about identifying information attached to specific tissue and its potential traceability. How this could affect privacy should also be covered.
- Safeguards to protect the individual's privacy and confidentiality should be outlined.
- The written informed consent form and any other written information to be provided to the participants should have the written approval/favourable opinion of an appropriate REB. Any revisions to the informed consent form or the written information should receive the REB approval/favourable opinion in advance of use.

<u>Informed Consent</u>

- Explicit informed consent will be employed for the collection and use of tissue, blood and other biospecimens, and for the collection, use and disclosure of data.
- Consent will be given by the participant or, if under the legal age, the parent(s) or guardian(s) in writing.
- Consent may be obtained in a prospective or retrospective manner (see definitions). In both situations, the following standard operating procedures (SOP) will be followed:
    - **BCCHB SOP: PRM-001 on Participant Recruitment into BC Children's Hospital BioBank Program**
    - **BCCHB SOP: PRM 003-01 Obtaining Informed Consent**
- For the purpose of obtaining free and informed consent, the BCCHB shall provide potential donors with information about:

    - the purpose of the BCCHB ;
    - the amount of data to be collected;
    - the type of data to be collected;
    - the manner in which biospecimens will be taken;
    - the potential uses for the biospecimens and the data;
    - limits on use, disclosure and retention of biospecimens and data;
    - the safeguards to protect the individual's privacy and confidentiality;
    - the identifying information that will be attached to specific blood and tissue specimens and its potential traceability;
    - how the use of the biospecimens and data could affect privacy;
    - the patient's right of access to their own data, and
    - the process for complaint.

    - Individuals, who require translators to assist with interpretation, will be invited to participate and all procedures and criteria for interpretation are explicitly laid out in **BCCHB SOP: PRM 003-01 Obtaining Informed Consent.**

Assent

- For participants that are children, capable of understanding but are not legally competent to consent, they and their parent(s) or guardian(s) will be presented with an Assent Form (**BCCHB SOP: PRM 003-01 Obtaining Informed Consent).**
- When a child participant in the BCCHB reaches the age of 19 years, a reasonable attempt will be made to contact the participant and obtain their consent for continued participation in the BCCHB:
- The BCCHB will be queried monthly to find participants that have turned 19 years old.

Autopsy Consent

- Participants that are terminally ill or have been ordered to have a routine hospital autopsy are eligible for inclusion in the BCCHB program. All procedures for approaching patients, and their parent(s) and guardian(s) are detailed in **BCCHB SOP: PRM 003-01 Obtaining Informed Consent**

Verbal Consent

- Verbal consent may be collected in:
  - acute situations where it is not possible to approach a patient, parent(s) or guardian(s) for consent AND
  - the REB has approved acceptable scenarios for the collection of verbal consent
- After the participant has agreed to verbally consent to the BCCHB, the designate obtaining the verbal consent will fill out a 'BCCHB Witness of Verbal Consent' form.
- Verbal consent will always be followed up at a later date with a formal informed consent meeting.
- A copy of this document will be kept on file and the original will be sent to the collection laboratory with the accompanying laboratory requisition for biospecimens.

Waiver of Consent

- The BCCHB may apply to the REB for a waiver of consent. Following Article 5.5 of the TCPS2 it is noted:

"Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that:

a. identifiable information is essential to the research;
b. the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
c. the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
d. the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
e. it is impossible or impracticable to seek consent from individuals to whom the information relates; and
f. the researchers have obtained any other necessary permission for secondary use of information for research purposes.

If a researcher satisfies all the conditions in Article 5.5 (a) to (f), the REB may approve the research without requiring consent from the individuals to whom the information relates."

- The BCCHB may apply to the REB for a waiver of consent if a potential participant is deceased or no longer in long term follow-up at C&W.
- The BCCHB may apply to the REB for a waiver of consent in situations where BCCHB is asked to absorb an existing collection of biospecimens at any of the Children and Women's Health Centre sites.

Decline of consent

- A potential participant may decline or withdraw from research at any time without affecting their standard of medical care at BCCH.
- Procedures and practices for handling decline of consent is described in:
    - **BCCHB SOP: PRM 004-01 Revoked Consent, Withdrawal of Consent for Future Collections and Contact, Decline of Consent** for procedures related to documentation of a declined consent.

Consent Documentation

- Participants will be given a copy of the signed Informed Consent form and if applicable the Assent Form.
- In the case of BioBank Autopsy Consent, parent(s) or guardian(s) will be given a copy of the signed BioBank Autopsy Consent form
- A copy of the Informed Consent (or BioBank Autopsy Consent) signature page and if applicable the Assent form will be included in the participant's hospital chart.
- Original Informed or BioBank Autopsy Consent forms and if applicable the signed Assent Form will be retained for BCCHB records.
    - Security safeguards for paper and electronic data and documents is described in:
        - **BCCHB POL 4 Privacy and Security**
        - **BCCHB POL 7 Material and Information Handling**
        - **BCCHB POL 5 Records and Documentation**
        - **BCCHB SOP RMD-006 Data Entry Procedures**

Consent for historical collections

- The BCCHB may be asked to appropriate historical collections (collected prior to the establishment of the BCCHB). Consent for these collections may have been obtained for a single research project, for teaching, or for use as clinical assay controls. Alternatively, the consent may not meet the current standards for informed consent, or the parameters of consent may not have been adequately documented, or consent may not have been obtained. The BCCHB will describe a process on how these historical collections will be appropriated into the BCCHB (**see BCCHB POL 4 Privacy and Security**). The ultimate use of these collections will be guided by the REB.
- Any new research projects that involve access to such collection will be reviewed by an REB, as is the case for use of all biobank materials. The researchers seeking access to these tissues should be made aware, if historical collections are provided, about the potential deviations, if any (or lack of information), from the currently established Standard Operating Procedures (SOPs). This information will be disclosed to researchers if the conditions of accrual and storage are documented.

7.0 REFERENCES

1. British Columbia's Freedom of Information Protection Act
   http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/96165_00

2. Canadian Standards Association (CSA) Model Code for the Protection of Personal Information
   http://www.csagroup.org/ca/en/services/codes-and-standards

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

5. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8.
   http://www.ich.org/products/guidelines.html

6. 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

7. 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

8. 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.

9. Hoeyer K., Olofsson BO., Mjorndal T., Lynoe N. The ethics of research using biobanks: reason to question the importance attributed to informed consent. 2005; 165(1):97-100.

10. Canadian Tumour Repository Network (CTRNet) Policy POL 001 e2.0. Informed Consent

8.0 REVISION HISTORY

Title - Informed Consent				
Policy Code -Version No.	**Date Revised**	**Approved By**		**Summary of Revisions**
		Print Name	**Signature**	
POL 1-01				Original version