



BC CHILDREN'S HOSPITAL BIOBANK

Title	Privacy and Security
Policy number	POL 4
Effective Date	1 Dec 2014
Approved by	Suzanne Vercauteren

1.0 BACKGROUND

The value of the human biospecimens for research purposes is greatly enhanced by the accompanying personal or clinical data related to the individual donating the biospecimen. Personnel should treat any information about the individual, however derived, as confidential. Rules protecting the privacy of personal information collected for research purposes are outlined in national research ethics guidelines. Privacy is also protected by several Canadian statutes; for the purpose of this project, Freedom of Information and Protection of Privacy Act (FOIPPA) is the most applicable regulation and has been referenced at length. Local policies and guidelines are also referenced.

To comply with the guidelines on privacy and confidentiality, participants should be informed about how information about them will be used. BC Children's Hospital BioBank (BCCHB) will have each participant's explicit consent to obtain, store and use information about them. Participants should also be aware of the safeguards that are in place to protect their confidentiality.

2.0 PURPOSE

The BCCHB is committed to compliance with national and provincial guidelines and laws safeguarding the privacy and confidentiality of participants that have provided personal and clinical data and biospecimens to the BCCHB. The purpose of this BCCHB policy is to outline general principles to ensure that the privacy of the patient is safeguarded.

3.0 SCOPE

This policy applies to privacy and confidentiality considerations that arise in the conduct of biobanking and research. The issues concern storage, transmission, retention and sharing of participant information in a manner compliant with legislative and ethical requirements.

4.0 REFERENCE TO OTHER SOPs OR POLICIES

BCCHB SOP:

PRM 003-01 Obtaining Informed Consent
PRM 007 Notification of Significant and Relevant Findings
RMD 002 Database Backup Systems
RMD 004 Document Maintenance
SOP: TRN 001-01 Education and Training

BCCHB Policies:

POL 1 Informed Consent
POL 2 Ethics
POL 5 Records and Documentation
POL 7 Material and Information Handling

PHSA Policies:

IA_020 Privacy and Confidentiality
IA_100 Managing Privacy Breaches
RM-110 Release of Patient or Client Personal Information and Personal Effects to Police and Other Agencies

This Policy is modified from the Canadian Tumour Repository Network (CTRNet) Privacy and Security Policy (POL 004 v.2.0).

5.0 RESPONSIBILITY

The obligations in this policy apply to all BCCHB staff relating to personal information and other confidential information in any format including paper, electronic, film, and verbal discourse.

6.0 POLICY STATEMENTS

The use of biospecimens and accompanying data is critical for medical research. The public, participants and their families should have confidence that the BCCHB and associated researchers will use and handle these materials with confidentiality. It is important to ensure that sensitive information is used ethically and optimally for the research to benefit health and knowledge. Safeguarding the privacy of the participants should be of primary importance.

Personal Information will be collected, used, disclosed, retained and destroyed in accordance with the Freedom of Information and Protection of Privacy Act (FOIPPA) and other relevant legislation. The following set of policies or principles will guide the BCCHB in collecting, maintaining and managing the confidential information it controls:

Accountability for Personal Information

- The BCCHB is a program within the Children and Women's Hospital Health Centre which is authorized through section 77(a) Part 2 of FOIPPA. The President of Children and Women's Health Centre and the Director of the BCCHB are accountable for compliance with the applicable legislation and regulations.
- The Director of the BCCHB is accountable for the policies and practices of the BCCHB.

- The BCCHB Biobank Oversight Committee (BOC) and C&W REB support the Director of the BCCHB, in fulfilling this responsibility by serving as the ethical stewards of the data and biospecimens held in the custody of the BCCHB.
- As the custodian of personal information, the BCCHB, will use contractual means, such as a Material Transfer Agreement (MTA), to ensure a comparable level of protection for transferring personal information to a third party or protecting the information while it is being used by the third party.
- Personnel involved in handling personal information will be asked to sign:
 - PHSA Confidentiality and Disclosure Acknowledgment
 - BCCHB Confidentiality and Disclosure Agreement
- All responsible staff must complete on-line PHSA Privacy and Ethics tutorials.
- All responsible staff must also be familiar with the following local policies:
 - **Privacy and Confidentiality Policy; IA_020**
 - **Managing Privacy Breaches; IA_100**

Identifying Purposes for the Collection of Personal Information

- Personal and linked medical information relating to the participants and biospecimens will always be treated as confidential.
- Personal information which the BCCHB has collected from research subjects/participants and other entities are to be used solely for the purpose of research. The participant will be made aware of the type of personal and medical information that will be used by researchers.
- Use of the BCCHB data for purposes other than those listed here is considered a breach of policy and is subject to consequences up to and including removal of privileges and dismissal (**see 5.6 Privacy Breaches below**).

Consent for the Collection, Use and Disclosure of Personal Information

- Consent is required for the collection of personal information and the subsequent use and disclosure of this information. The BCCHB will seek consent for the use or disclosure of the information in and around the time of biospecimen collection. (**BCCHB SOP: PRM 033-01 Obtaining Informed Consent**).
- For participants that are children (age 7-14 years), capable of understanding but not legally competent to consent, they and their parent(s) or guardian(s) will be presented with an Assent Form.
- 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.
- In keeping with the concept of 'informed consent', the BCCHB will make an effort to ensure that the participants are advised of the overall purposes for which their information will be used. Participants should be confident that biobanks will follow the guidance of a Research Ethics Board (REB) for reviewing and approving access to their material.
- Information will not be used for purposes that have not been specifically identified in the consent process without seeking the guidance of the REB.

Limiting Collection

- The BCCHB biobank will not collect personal information indiscriminately. Both the amount and the type of information will be limited to that which is necessary for the purposes identified by the biobank in the consent process.

- The requirement that personal information be collected fairly and lawfully means that the BCCHB will not mislead or deceive individuals about the purpose for which the information is being collected, or obtain consent to collect the information through deception.
- When collecting personal information indirectly from another source, an information sharing agreement will be put in place.

Limiting Use, Disclosure, and Retention of Personal Information

Personal information will not be used or disclosed for purposes other than those for which it was collected.

USE

- Within the BCCHB, access will not be based on position within the organization but rather on the duties that the position fulfills. Where individuals require access privileges outside of a defined profile, those privileges will be assigned to the individual user on an as-needed basis.
- Researchers will not be given access to personal information. All information released to researchers will be de-identified and a code held in the custody of the BCCHB.
- The BCCHB will control the release of information to researchers by evaluating each request for scientific merit and compliance with approved ethical standards.
 - Researchers using the BCCHB can only use biospecimens or disclose information in accordance with the terms and conditions outlined in a Material Transfer Agreement (MTA).
- Data use restrictions pertaining to the database will be reinforced by the information technology architecture of the BCCHB information system.

Disclosure

- No personal information will be disclosed for research purposes.
 - In the event that personal information needs to be disclosed to a researcher, the disclosure of personal information for research purposes must be done in accordance with section S.35 of FOIPPA, after approval from the applicable REB.
- Original records and documents must not be released or removed from the site except in the case of a subpoena or in specific circumstances, where the original record personal information is required for the continuity of care.
- Disclosure of personal information will be consistent with the originally defined purpose unless required by legislation, subpoena, warrant, or court order, or in an emergency where the life, health or security of an individual is threatened. Disclosure for research purposes must meet the requirements of S.35 of FOIPPA.
 - Disclosure of personal information for police and other agencies will follow the PHSA Policy entitled “**Release of Patient or Client Personal Information and Personal Effects to Police and Other Agencies; RM-110**”
- The BCCHB will ensure that there is no risk of residual disclosure. If required, BCCHB staff will work with researchers to develop strategies for preparing data sets so that they have no foreseeable potential risk of residual disclosure, and still meet the analysis requirements for the approved protocol.

Notification and Disclosure of Significant and Relevant Findings

- If valuable medical information becomes available from research using BCCHB biospecimens and data, the decision to contact the patients or their families to offer benefits of that research will be guided by the REB and best clinical practice and guidelines set out in the TCPS II.
- Researchers will not be given personal information with regard to the participant; the BCCHB will work with the REB, primary physicians and medical experts to determine the best course of action.
- Notification and disclosure of findings will be carried out in accordance with **BCCHB SOP: PRM 007 Notification of Significant and Relevant Findings**.

Retention

- Original, signed paper consent, assent and questionnaire forms will be stored in a secure and confidential manner for an indefinite period (**BCCHB SOP: RMD 004 Document Maintenance**).
- Biospecimens will be retained for an indefinite period. They will be stored with a code and will not include any personal information.
- The BCCHB will retain all electronic records indefinitely in a secure database. Backup mechanisms including frequency is outlined in **BCCHB SOPs: RMD 002 Database Backup Systems; RMD 004 Document Maintenance**.

Transfer of Custodianship

1. Transfer of 'Historical Collections' to the BCCHB

There are several collections of biospecimens and data at the BC Children and Women's Health Centre – these have been collected prior to the existence of the BCCHB. Two likely categories include:

- 1) Known collections: collections for which (a) current custodian(s) may want to donate the biospecimen and related data to the BCCHB
- 2) Crypto-historical collections: collections for which no owner or custodian exists and the premise under which the collection was acquired is unknown

In both categories, these collections may be derived from single research projects, formal biobank collections, pathology collections or clinical research projects. (see **BCCHB POL 1 Informed Consent; POL 2 Ethics**).

1. Closure or transfer of BCCHB custodianship

The BCCHB is the custodian of biospecimens and data held in the biobank. As such, provisions for unforeseen circumstances related to the closure of the BCCHB (e.g. loss of funding or infrastructure) to ensure privacy of personal information and use of information, consistent with the original condition for collection, use and disclosure are necessary.

The BCCHB will work with relevant parties to develop a plan and policy on transfer of custodianship for the biospecimens and data collected into it. As such, the policy and documentation will address:

- Who will the biospecimens and data be transferred to?
- Who will guide the transfer of biospecimens and data (e.g. REB, PHSA, UBC)?
- What provisions must be in place to transfer biospecimens and data?
- What conditions must be met or set in place for transfer of biospecimens and data?
- What level of information (personal, de-identified, anonymized) data can be transferred?
- When is it appropriate to destroy biospecimens and data instead of transfer?
- What would an agreement to transfer custodianship require of the new custodian?
- What are the necessary conditions of use, disclosure and ethical approval process?

Privacy Breaches

Personal information, which may or may not be sensitive, within its possession (custody) and control or under the custody of the BCCHB to which its employees have access to, BCCHB has an ethical obligation to prevent the loss, theft, intentional or inadvertent unauthorized collection, use, disclosure, storage or disposal of personal information when contrary to FOIPPA. Further:

- The BCCHB staff (which may be hired through PHSA or University of British Columbia- UBC) will complete the online PHSA Privacy and Ethics tutorial.
- The BCCHB will follow the PHSA policy **Managing Privacy Breaches; IA_100** and accompanying documentation for the purpose of containment, reporting, investigation, compliance, and disciplinary action around privacy breaches.

Accuracy of Personal Information

To minimize the possibility that inappropriate or insufficient information may be used to make decisions or conclusions about the research undertaken, personal information and data should be accurate, complete and up-to-date.

The BCCHB will make every reasonable effort to ensure that the personal information they collect is accurate and complete.

Ensuring Safeguards for Personal Information and Biospecimens

The security safeguards should protect biospecimens and personal information against loss or theft as well as unauthorized access, disclosure, copying, use or modification. BCCHB will protect personal information and biospecimens regardless of the format in which it is stored.

Methods of ensuring safeguards of personal information and biospecimens include the following methods:

- Security evaluations are necessary to assess security risk so that risk mitigation can be applied. The BCCHB will undertake internal consultative and constructive reviews as well as external reviews, when deemed necessary.
- Access to the BCCHB information and systems will be controlled on the basis of business and security requirements. User registration and de-registration procedures for granting access will be applied. User privileges will be controlled on a need-to-know basis and reviewed at regular intervals for unauthorized or changed privileges.

- Managing the confidentiality of, and all activity performed, on a user account is the responsibility of the individual user. Users must ensure that unattended equipment has appropriate protection.
- Information systems are monitored to support operation, maintenance, auditing, security and investigative activities.
- All personal information concerning participants and employees is confidential and is only to be used by individuals who require access to it in order to fulfill the functions of their role. Users who are authorized to obtain data must ensure that it is protected to the extent required by legislation or policy after it is collected.
- Personal information stored on paper will be locked in a filing cabinet in a locked room with defined access according to role.
- Biospecimens will be secured behind a locked room with card swipe access. Access to these facilities will be defined by role.
- System users will receive adequate training so that they have a clear understanding of their role and responsibility as it relates to security.
- Security guidelines, standards, or procedures that refine the provisions of this policy for specific activities under their purview, in conformance with this policy and other applicable policies and laws will be established.
- Failure to comply with the security standards and requirements stated in policies will result in disciplinary action up to and including loss of privileges or termination.

Emergency Preparedness

Emergencies can cover a wide range of natural and man-made disasters, all of which may have varying effects on the biobank facility and on the ability of a biobank to carry out its essential functions. The type and duration of disasters may depend on the geographic location at which the biobank is located. For the Vancouver and lower-mainland area and concern of the BCCHB, most commonly described potential natural disasters include - but are not limited to earthquake, fire and flood.

It is important that BCCHB takes these steps to protect the precious biospecimens within the biobank but also mitigate any risk to personal information stored electronically and in other forms (e.g. paper, CD, DVD etc.). As such the BCCHB will work with facility management, data coordinators, managers, and all biobank staff and PHSA related resources and regulations to develop a written disaster recovery/incident response plan for responding to a wide variety of emergency situations and this plan will:

- be tested periodically (i.e. at least annually) to ensure that all personnel are trained and that the plan meets the anticipated needs.
- be distributed to all appropriate staff
- be reviewed and revised as necessary

Openness about Personal Information Policies and Practices

BCCHB will be open about its policies and practices with respect to management of personal information. The BCCHB will make readily available to individuals specific information about its policies and practices relating to the management of personal information. This information is available on request in hard copy which can be obtained by contacting the BCCHB or viewing the BCCHB web site. This website will be added to this document when it has been launched. This website will include:

- Contact information of the BCCHB Director and Administrative Manager to request copies of BCCHB policies.
- The name, title, and business address of the person(s) at UBC and PHSA accountable for responding to:
 - Queries relating to the published policies and practices,
 - Requests for access to personal information,
- Statements of data use, job descriptions and organizational structure etc of the BCCHB in publicly available information;
- Information on any regular disclosures provided to other organizations.

Individual Access to Own Personal Information

Personal information includes data that has been collected as part of the clinical care of the participant (including lifestyle and clinical data) but does not include data created by research.

- All requests for access to records containing personal information shall be made in writing and addressed to the attention of the BCCHB Administrative Manager. A preliminary review of the request will be conducted prior to forwarding the request to the BCCHB Director and REB.
- When an individual requests access to their own personal information, they will be required to verify that they are the person to whom the information relates or the legal representative of that individual.
- Upon receipt of written verified request, a research participant shall be informed of the existence and disclosure of his or her personal information in the custody and control of the BCCHB and shall be informed of the types or research studies to which his or her information has been released. (This will not include the names of the researchers). He or she shall be given access to this information with limited exception. This will include all personal information and clinical data that has been collected, but will not include any data created by research (such as genetic information).
- All requests for access will be responded to as promptly as possible, and within 30 days, at no cost to the individual requesting their personal information.

Requesting Correction to Personal Information

The BCCHB has a duty to ensure that the personal information it controls is accurate and complete.

- All requests for correction of records shall be made in writing and addressed to the BCCHB Administrative Manager.
- Where an individual successfully demonstrates the inaccuracy or incompleteness of personal information concerning the individual, the information will be amended within a maximum of 120 days by correcting or adding information as required.
- A record will be kept of all research studies to which the individual's information has been provided enabling subsequent notification of a correction or annotation to a record. Where appropriate, the BCCHB will promptly transmit the amended information

to the research studies to which the BCCHB has previously provided the information in question. Where the information was collected from another source such as a hospital, the BCCHB will notify the source.

- Where a challenge is not resolved to the satisfaction of the individual, the substance of the unresolved dispute will be recorded by the Director of the BCCHB. Where appropriate, the existence of the unresolved dispute will be promptly transmitted by the BCCHB to the research studies to which BCCHB has previously provided the information in question.

Complaints

An individual can challenge the BCCHB compliance with legislation and the principles of privacy protection to the BCCHB Director, who is accountable for the BCCHB compliance. Individuals also have the right to make a complaint to the UBC and/or Children and Women's Health Centre of BC (C&W) or the PHSA Information and Access & Privacy Office and ultimately to the BC Privacy Commissioner.

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. 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>
4. 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/>
5. Canadian Standards Association (CSA) Model Code for the Protection of Personal Information.
<http://www.csagroup.org/ca/en/services/codes-and-standards>
6. Canadian Federal Personal Information Protection and Electronic Documents Act
<http://laws-lois.justice.gc.ca/eng/acts/P-8.6/index.html>
7. British Columbia's Freedom of Information Protection of Privacy Act
http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/96165_00
8. International Society for Biological and Environmental repositories (ISBER) Best Practices 2012. 2012 Best Practices for Repositories Collection, Storage, Retrieval, and Distribution of Biological Materials for Research.

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9. Office of Biorepositories and Biospecimen Research National Cancer Institute (NCI) National Institutes of Health. U.S. Department of Health and Human Services 2011. NCI Best Practices for Biospecimen Resources.
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10. American Society of Clinical Oncology Policy Statement Update: Genetic Testing for Cancer Susceptibility. 2003. J. Clin. Oncol. 21(12):2397-2406.
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13. Presidential Commission for the Study of Bioethical Issues. 2013. Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts.
http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf
14. Release of Patient or Client Personal Information and Personal Effects to Police and Other Agencies Reference Number: RM_110; January 24, 2012.
15. 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
16. Canadian Tumour Repository Network (CTRNet) Policy POL 004 e2.0. Privacy and Security.
17. PHSA Policy Privacy and Confidentiality Policy; IA_020
18. PHSA Policy Managing Privacy Breaches; IA_100
19. PHSA Policy Release of Patient or Client Personal Information and Personal Effects to Police and Other Agencies; RM-110

8.0 REVISION HISTORY

BCCHB Policy : Privacy and Security				
Policy Code -Version No.	Date Revised	Approved By		Summary of Revisions
		Print Name	Signature	
POL 4				Original version

