BC Children’s Hospital BioBank
Information and Consent Form

COLLECTION AND BANKING OF BIOLOGICAL SPECIMENS AND CLINICAL DATA FROM PERSONS SEEKING MEDICAL CARE AT BC CHILDREN’S HOSPITAL

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Toll Free Number (BC only): 1-888-300-3088

If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When we say “you” or “your” in this consent form, we mean you and/or your child; “we” means the doctors and other staff.

Introduction

Doctors and Scientists at BC Children’s Hospital and BC Women’s Hospital have created the BC Children’s Hospital BioBank (hereafter called the BioBank). The BioBank would like to collect samples and clinical data from children and sometimes their families to create a bank (or library) of samples for use in research to better understand the causes of diseases of children and families, with the ultimate goal of improving treatment and preventing diseases.

The BioBank is governed by the ethical standards overseen by the University of British Columbia (UBC) / Children’s and Women’s Health Centre of BC (C&W) Research Ethics Board (REB) as well as the governing bodies of the BioBank. These groups ensure that all children donating samples to the BCCHB are protected as research participants by the applicable standards that govern the operation of biobanks.

This consent form is to help you decide if you want to participate in the BioBank. Trained BioBank staff will be happy to answer all your questions. It is important that you understand that if you sign this consent form, you are consenting to the banking of your samples for future research projects, which as of now, are undefined.

What is BioBanking?

BioBanking is the collection, storage, and use of human body samples and personal health information for research. The BioBank at BC Children’s Hospital is an important resource for research locally, across Canada, and around the world.

What does the BioBank do?

The BioBank collects samples such as tissue, blood, DNA, urine, stools, fluid, and bone marrow from participants with their consent. The samples are processed and stored in a special way to preserve them. The BioBank also collects information about the participants such as date of birth, diagnosis, date of diagnosis and treatment. This information or data are stored in a secure database on the hospital server. Scientists can apply to the BioBank to ask for certain types of samples and data to use for their research. If the BioBank and the Research Ethics Board thinks that the research is worthwhile and safe, samples will be given to the scientist. It is possible that scientists from other cities, provinces or countries apply for BioBank samples. These scientists also need ethical approval for their studies, before samples can be released to them.

Will donating to the BioBank be kept confidential?

If you chose to participate in the BioBank your confidentiality will be respected. You will be assigned a unique BioBank code. This number will NOT include any personal information that could identify you. This number will be used when samples are given to researchers so that your identity will be kept confidential. Information that contains your identity will remain in the BioBank database, which resides behind the hospital firewall and can only be accessed by BioBank staff. These staff members must have a hospital ID as well as an ID which is specific to the Biobank database. Your records in the BioBank database that match your name to the unique BioBank code will not be shown to anyone outside of the BioBank unless required by law or in the situation where research discovers something that may be important to you medically (this circumstance is described in more detail on page 3 of this consent form). However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of Health Canada and the UBC Research Ethics Boards for the purpose of monitoring the research.

Who can donate to the BioBank?

All children and families who are seeking medical care at BC Children's Hospital or BC Women's Hospital are eligible to contribute samples to the BioBank.

How long will the BioBank collect and store samples?

If you decide to donate samples to the BioBank and sign this consent form, samples will be collected for the duration of the time you receive medical attention at BCCH. **This means that if a sample is collected at your next visit or any future visit and you have signed this consent form those samples could also be banked.** You will NOT be asked to consent again. Samples will be stored in the BioBank until a time when they are requested for research. This could be a long period of time and therefore the BioBank will do their best to re-contact you when you reach the age of majority to ensure that you are still OK with your samples being stored in the BioBank. If the BioBank cannot re-contact you then your samples and clinical data will be de-identified. A trusted third party will be given the responsibility to hold a link that could allow your samples and data to be re-identified if necessary for clinical reasons. This would only happen with the approval of the research ethics board and would only be done if this is of clinical benefit to you.

Where does the BioBank process and store samples?

Samples are processed in the Biobank processing laboratory which is located in the Children's and Women's Laboratory and BC Children's and BC Women's Hospital. Samples are stored long term in a secure area in an access limited facility in the Child and Family Research Institute. Only BioBank staff will have access to this facility.

If I chose to participate, what are the potential consequences associated with donating to the BioBank?

The amount of sample taken from you has been carefully considered and it is unlikely that there will be any harm to you. For blood collections that are not done at the same time as blood testing for medical care, there is a risk of infection, bleeding, or bruising.

Because certain demographics, specifically your date of birth, diagnosis and sex are being collected, there is a risk of your identity being revealed but all efforts will be made to minimize this. In addition, if your sample is used for genetic research there is a very small risk that information gained from genetic research could eventually be linked to you and possibly other members of your biological family.

There is also a small possibility that results of research may show something that could be of importance to your health either now or in the future. If this occurs your health care team, the C&W Research Ethics Board and the BioBank will discuss whether these results are of benefit to you. If the findings are confirmed and are of direct benefit to you then someone from your health care team will discuss them with you, a genetic counselor may also be involved.

What are the benefits of donating to the BioBank?

You will probably not directly benefit from donating samples to the BioBank from a medical point of view. We hope that any information learned from the research conducted can be used in the future to benefit other children. Research carried out on your samples may help to develop new treatments for children with a variety of diseases. There is a small possibility that the results of the research may show something that could be of importance to you as discussed above.

How much of my time will donating to the BioBank take?

Aside from the time it takes you to read this consent form and ask questions regarding the banking of your samples, participation in this research will not require any time on your part, unless you have agreed to have an additional blood draw, buccal swab, urine/feces collection, or swab. Should you choose to participate in all of these, the time involved should not exceed 45 minutes.

We may ask for your feedback and input as to how to improve the BioBank in the future, but participation in these discussions will be entirely voluntary.

What if I choose not to donate?

If you do not wish to donate to the BioBank you will continue to receive the accepted standard of care. Your doctor will do the usual studies and tests that you would normally get. There is no difference in treatment between those who wish to donate and those who do not wish to donate.

What happens if I decide to withdraw my consent to participate?

Participation in the BCCHB is entirely voluntary. You may change your mind, withdraw your BioBank consent at any time and request that the samples that have been collected be destroyed or request that no future samples be collected. However, the BioBank will not be able to retrieve samples or medical information that have already been released for research purposes. In order to withdraw from the BioBank you can inform your doctor or you may call the office of the BioBank Administration, directly at 604 875-2000, extension 6423. Upon notice of withdrawal, a form will be completed by a BioBank staff member.

What happens to my samples if the BioBank has to close?

The governors of the BioBank and the REB will determine what happens to the samples should the BioBank have to close. You will be informed by a letter which will outline the closure plan. If you do not agree to the closure plan you will have the opportunity to request that your samples and electronic documentation be destroyed.

What will donating to the BioBank cost me?

You will not incur any expenses as a result of donating samples to the Biobank. You will not be paid for donating samples for research purposes. You will not financially benefit from discoveries or commercial products developed from samples you have donated. The BioBank will provide samples to researchers at a low cost; NO profit will be made by the BioBank

Privacy policy of the BioBank

The BioBank acts according to the Personal Health Information Act of British Columbia as well as the "Freedom of Information and Protection of Privacy Act of British Columbia." These acts protect your privacy and give you the right to access your information. You will also have the right to correct any errors in this information if necessary. Further details about these acts are available upon request.

Who do I contact if I have questions about donating to the Biobank?

If you have any questions or would like to have more information about donating to the BioBank you can contact the BioBank Director and Principal Investigator at 604-875-2939, or the BioBank Administration at (604) 875-2000 extension 6423.

Who do I contact if I have questions or concerns about my rights in relation to donating to the Biobank?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in the BioBank, contact the Research Participant Complaint Line of the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

Signing this consent form in no way limits your legal rights against the investigators, or anyone else involved in the BioBank. If you are interested in participating in the BioBank, please go to the next page for a description of the types of sample that the BioBank is interested in collecting.

What does participating in the BioBank actually involve?

Thank you for considering participating in the BioBank. At the end of this list of sample descriptions you will find some check boxes so that you can select which samples you agree to having collected from you and stored in the BioBank.

Tissue

At the time of surgery, your surgeon will remove whatever tissue is required for the benefit of your health as she or he will have already discussed with you. Some of this tissue will be used for diagnostic purposes and some will be stored by the Department of Pathology and Laboratory Medicine for future follow up care and further diagnosis. The remainder is usually discarded. The BioBank would like to collect this remaining material and store it in a systematic way so that it can be selected for specific research purposes. In some situations it may be safe for you to agree to an extra piece of tissue to be removed for the BioBank at the time of your surgery, but you will be informed of this prior to the surgery and this will require your consent on your consent for surgery form.

Bone Marrow

You may need to have your bone marrow checked for your diagnosis and/or treatment. If you agree to participate in the BioBank we request that a doctor take an extra amount of your bone marrow (about 2-5 milliliters, or ½ - 1 teaspoon). This will only occur if you are having a bone marrow procedure for medical reasons.

Blood

You may be asked to give an extra blood sample to the BioBank at the time of a medical blood collection. There is a possibility that you may be asked to give a sample of blood at a time when you are not actually having a medical blood draw. The amount of blood that we collect will be carefully calculated according to recommended guidelines for the size of your child. This will not exceed 5ml in children under the age of 3 years old and will not exceed 10ml in children under the age of 10 years and will not exceed 20ml in children under the age of 18 years, however these volumes will be reduced if your child has had a number of blood draws in the past month. You may also donate any blood that is left over from prior clinical procedures to the BioBank.

Cerebral Spinal Fluid (CSF), Leukopheresis products and other body fluids

If, after routine medical procedures, there is any CSF, leukopheresis products or other body fluids left-over, we ask your permission to store these left-over samples in the BioBank.

Genetic material from Cytogenetic and/or Molecular Genetic testing

If genetics tests are being carried out for your diagnosis, we ask your permission to store any left-over genetic material such as DNA after these tests have been completed. This material is usually discarded and would be very valuable for research purposes. It should be noted that DNA can be extracted from many of the biological samples listed. Please consider this when choosing which samples you agree to donate to the BioBank.

Stem cells

If you are donating peripheral blood stem cells or bone marrow harvested stem cells for a stem cell transplant (either for yourself or for a family member) and the transplant does not take place as planned, or there are cells left-over after treatment, and your doctor has determined they are no longer needed for treatment they will be discarded or you can arrange to have them transferred to a private facility of your choice or you have the option to store them in the BioBank for research. In the event that an abundant stem cell collection occurs and there are more cells than are medically required as per your doctor and apheresis director, some may be given to the BioBank provided you have agreed.

Buccal (inside of your cheek) cells or saliva

A buccal smear is obtained form the painless brushing of the inside of the cheeks to collect cells from the lining of the mouth that are normally shed and grow again. If you have mouth sores you can agree to do a mouth rinse and we will collect the discarded rinse in a container. In some situations we may ask for saliva instead of a buccal smear and this is simply collected as a result of “spitting” into a tube.

Excretory products

Urine or feces specimens may be collected for the BioBank**.** These samples may be requested at the time of medical collections but there is the possibility of additional collection of these sample types, purely for the BioBank. Parents of infants or children using diapers may be asked for the used diapers, in order to obtain these samples.

Old samples

If you had a previous procedure at BC Children’s Hospital or BC Women’s Hospital there may be old (archived) samples related to that time that are still stored in the Department of Pathology and Laboratory Medicine. Sometimes these are no longer required for medical purposes; we ask your permission to donate some of these old (archived) specimens to the BioBank if enough of this specimen is secured for potential future diagnostic purposes.

Other samples

It is possible that you may be asked about other samples that are not covered by this list. If this is the case, the sample type and collection procedure will be clearly outlined to you and recorded on this consent form.

Before signing this consent form, please fill out the check boxes below so that the BioBank staff understands the samples you are willing to donate for research purposes. Please understand that it is assumed that medical information will be collected with these samples as outlined on page 2 of this consent form.

I am willing to donate any of the samples described above ☐ Initial here

OR

I am willing to donate only the samples specified in the table on the following page

☐ Initial here

Yes	No	N/A		
			Tissue	
			Bone Marrow	
			Left-over Blood	
			Collection of extra blood at the time of a blood draw	
			Collection of an additional blood draw when you are not undergoing a medical blood draw	
			Left-over CSF	
			Left-over Leukopheresis Products	
			Left-over genetic material from molecular and/or cytogenetic tests	
			Left-over Stem Cells	
			Buccal Swabs	
			Saliva	
			Urine	
			Stool	
			Use of samples previously collected and no longer necessary for medical purposes	
			Other (including "other" body fluids)	If applicable please state sample type:

Additional Contact

In addition to the above information, we would like your permission to be able to contact you in the future about other research which may be unrelated to the scope of research carried out by the BioBank. We may also like to re-contact you for administrative purposes for example to inform you of changes in the structure of the BioBank. Please indicate in the box below if you are willing to be contacted in the future. You may also be interested in providing the BioBank with your email address so that we can send you periodic updates about the BCCHB including newsletters. Trained BioBank staff will be the only people who will have access to your personal or contact information and thus it would be their responsibility to contact you. We will not share your information with anyone else.

Yes	No	
		I am willing to be contacted in the future regarding other research
		I am willing to be contacted in the future for administrative purposes
		I would like to receive periodic updates and/or newsletters from the BioBank

If you are willing to provide your **email address**, please do so here:

My signature on this consent form means:

- I have read and understood the participant information and consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential to the extent possible and that the results will only be used for scientific objectives.
- I understand that my/my child's participation in the BioBank is voluntary and that I am/ my child is completely free to refuse to participate or to withdraw from the BioBank at any time without changing in any way the quality of care that I/my child receive(s).
- I authorize access to my/my child's samples and associated information as described in this consent form.
- I understand that I am not waiving any of my/my child's legal rights as a result of signing this consent form. I understand that it is very unlikely that the BioBank will provide any direct benefits to me/my child.
- I will receive a signed copy of this consent form for my own records.

The parent(s)/guardian(s)/substitute decision-maker (legally authorized representative) and the investigator are satisfied that the information contained in this consent form was explained to the child/participant to the extent that he/she is able to understand it, that all questions have been answered, and that the child/participant assents to participating in the research.

I consent to my/my child ________________________________participation in the BioBank.
Insert child's name

____ ________________________________
Participant or's Parent /Substitute Decision-Maker's Signature Printed name

____
Date

____ ___________________________
Signature of Person Obtaining Consent Printed name

____
Date

____ ___________________________
Signature of Translator (if applicable) Printed name

____________________ ____________________________
Date Language of Translation

Copy to: Participant
Clinic chart
BCCHB office

BC Children's Hospital BioBank
Decline to Consent Form

I have explained the BC Children's Hospital BioBank (BCCHB) initiative to a patient on

___________________in the Department of ___________________________________
(Insert date) *(Insert department that the patient was seen in)*

This patient has declined to participate in the BioBank.

☐ a) This patient would like to have their identifiers stored in the BioBank database as they do not wish to be re-contacted in the future about the BioBank

Identifiers that will be stored are:

Patient name	
Date of Birth	
PHN or MRN	

☐ b) This patient does not want to have their identifiers removed from the BioBank database, they understand that this may mean that they are re-contacted in the future about the BioBank

This form is proof to the patient that the BioBank acknowledges their decline. The form will be filed for statistical purposes and personal identifiers will only be included if the patient has agreed to keep their identifiers in the BioBank database (see (a) above).

Name of BCCHB staff or designate *(Please Print)*	Signature of BCCHB staff or designate	Date

Copy to: Participant
BCCHB office