

BC Children's Hospital BioBank

Assent Form (Children age 14 -18 years)

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

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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 assent form is to help you decide if you want to participate in the BCCHB. Trained BCCHB staff will be happy to answer all your questions.

Your participation is voluntary

Your participation is entirely voluntary. Before deciding, it is important for you to understand what BioBanking involves. This assent form will tell you about the banking of samples, why biobanking is being done, and what will happen to these samples, in addition to the possible benefits, risks and discomforts to you.

If you decide to participate, you will be asked to sign this form. You are still free to withdraw at any time and without giving any reasons. If you do not wish to participate, you do not have to provide any reason for your decision not to participate nor will you lose the benefit of medical care to which you are entitled or are presently receiving. Please take time to read the following information carefully and to discuss it with your family, friends and doctor before making a decision.

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, urine, stools, fluid, and bone marrow from participants with their consent and assent. 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.

Who can donate to the BCCHB?

All children and young adults who are seeking medical care at BC Children's Hospital are eligible to contribute samples to the BCCHB.

How long will samples be collected and stored?

If you decide to donate samples to the BioBank and sign this assent 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 assent form those samples could also be banked.** You will NOT be asked to assent 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 as a clinical benefit to you.

Where does the BioBank store samples?

Samples are stored 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 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.

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 it is your wish to be informed about research findings that may be important to you, members of your health care team, the C&W Research Ethics Board and the BioBank will discuss whether these results are of benefit to you. The results have to be confirmed and must be of direct benefit to you, in which case the BioBank will be requested to re-identify you and you will be contacted by your physician. If necessary, a genetic counselor will be involved.

What are the benefits of donating to the BCCHB?

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 BCCHB BioBank take?

Aside from the time it takes you to read this assent form and ask questions regarding the banking of your samples, participation in this research will not require any time on your part. The total time involved including optional biospecimen collection should not be more than 45 minutes.

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 assent to participate?

Participation in the BCCHB is entirely voluntary. You may change your mind, withdraw your BioBank assent 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 has 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?

You will be informed by letter if the BioBank closes. All samples as well as paper and electronic documentation will 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

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

If you have any questions or would like to have more information about donating to the BioBank you can contact Dr Suzanne Vercauteren, 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 BCCHB?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in 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 assent form in no way limits your legal rights against the investigators, or anyone else involved in the BCCHB.



BC Children's Hospital BioBank

Assent to Participate

My signature on this assent form means:

- I have read and understood the participant information and assent form.
- I have had time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have understood the answers 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 participation in the BioBank is voluntary and that I am 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 receive.

Signature of Participant

Name of Participant (Please Print)

Date

I have asked the participant if they have any questions regarding the information in this assent form. The participant has understood the nature of my answers to any of their questions regarding the information contained in this assent form.

Signature of Designate Obtaining Consent

Name of Designate Obtaining Consent

Date

Language of Translation (if applicable)

Signature of Translator

Name of Participant (Please Print)

Date

Copy to: Participant
Clinic chart
BCCHB office