



## **BC Children's Hospital BioBank Information and Consent Form**

### **COLLECTION AND BANKING OF MATERNAL SERUM, BLOOD SPECIMENS, CORD BLOOD, PLACENTA AND CLINICAL DATA**

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#### **Introduction**

Doctors and Scientists at BC Women's Hospital and BC Children'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 women and sometimes their families to create a bank (or library) of samples for use in research to better understand the causes of diseases of women and families, with the ultimate goal of improving treatment and preventing diseases. Please note that this consent form relates to you and your unborn child together, once your child is born you may be invited to sign an additional BioBank consent form on their behalf.

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 everyone donating samples to the BioBank 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 use of your samples for research projects. If there are current research projects that require samples from mothers and/or babies, a summary of these studies is included at the end of this consent form. Your sample may be used for some or all of these projects, and may also be stored for use in future research which as of now, is 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 Women'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 blood 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, hospital number, and any pregnancy-related information. 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. 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.

### **What type of samples am I being asked to donate?**

The BioBank would like to invite you to donate **your blood, the blood from your baby's umbilical cord at delivery and your placenta.**

There may be blood left over from pre-natal screening procedures or routine blood tests you may have completed or will be completing in the future. You will also have the option of giving an extra tube (about 5-10 milliliters, or 1-2 teaspoons) of blood to the BioBank at the time of a medical blood collection or of giving this tube of blood at a time when you are not actually having a clinical blood draw. This will be entirely optional.

You may have considered donating the blood from your baby's umbilical cord (cord blood) to the Canadian Blood Services (CBS) for clinical purposes. As you will recall, CBS will test your cord blood after the delivery of your child. If you have agreed to donate your cord blood to CBS and your sample meets CBS's clinical standards, your cord blood will be used by CBS. If it does not meet CBS's clinical standards, then you will have the opportunity to donate the cord blood to research instead. If you have agreed on this consent form to donate your cord blood to the BioBank then the BioBank will arrange for the collection of the unused cord blood sample.

The BioBank is also interested in collecting your placenta after your baby is born. Placentas are usually thrown away unless it needs to be examined for clinical purposes, you are participating in any other research studies, or have arranged for your placenta to be kept for personal reasons. If you agree the BioBank would like to collect your placenta for research purposes.

**Who can donate to the BioBank?**

All women who are seeking medical care at 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 that are collected throughout your pregnancy, along with you and your baby's clinical data, could be stored in the BioBank. You will NOT be asked to consent again. Some (or a portion) of your samples may be used for current studies, if suitable. Other samples will be stored in the BioBank until a time when they are requested for research. This could be a long period of time.

**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 BC Children's Hospital 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. 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, hospital number, and pregnancy-related information 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 a small chance that some genetic information could result in discrimination by employers or insurance providers toward you or your biological (blood) relatives. The chance that research data would be released to these outside parties is estimated to be small as the results of this research will not be added to your medical records.

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 other women and to understand pregnancy better. 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. Should you choose to participate this, 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 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. 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](mailto: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.

## BC Children's Hospital BioBank Information and 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 from you with these samples as outlined on page 2 of this consent form.

Yes	No	N/A	
			Left over blood
			Collection of additional blood when you are undergoing a clinical blood draw
			Collection of an additional blood draw when you are NOT undergoing a clinical blood draw
			Blood from the umbilical cord (cord blood) after you baby's delivery. <u>(see page 2 of consent form in regard to BioBank and CBS)</u>
			Placenta after your baby's delivery
			Other:

With your permission, the BioBank would like to collect your baby's hospital number and information from the first month of life (i.e.: newborn screening results, Apgar scores, birth weight, and the presence of any health conditions that are diagnosed in the newborn period.)

### 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 <b>email address</b> , please do so here:		



## BC Children's Hospital BioBank Information and Consent Form

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 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.
- I authorize access to my samples and associated information as described in this consent form.
- I understand that "my samples" includes samples as a result of a pregnancy and therefore could include traces of samples from my unborn child(ren).
- I understand that I am not waiving any of my 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.
- I will receive a signed copy of this consent form for my own records.

I consent to participate in the BioBank.

\_\_\_\_\_  
Participant'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 participant was seen in)*

This patient has declined to contribute left over or fresh blood to BioBank at this time.

- 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