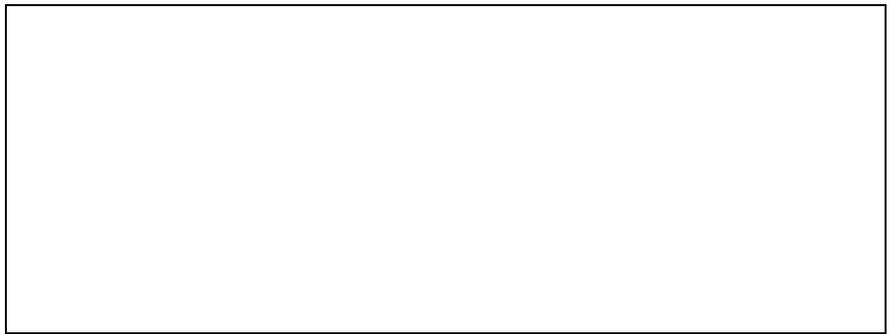




## **INFORMED CONSENT Umbilical Cord Blood for Testing, Storage and Transplantation Information**



**Introduction:** You are being asked to participate in Canadian Blood Services' Cord Blood Bank program. The Cord Blood Bank collects, tests, stores and distributes donated human umbilical cord blood.

The following information is provided to you to explain the purpose of the program, what you will be asked to do as a voluntary participant and the potential risks and benefits of your participation. Choosing not to participate in the program will not have any impact on you or your family's medical care. You are encouraged to ask questions before deciding to participate and at any time during your participation in the program.

**Description:** You are being asked to participate in the program because you have just delivered your baby and you gave permission to collect your baby's cord blood. With your consent, we will now test your baby's cord blood. If the results are acceptable for transplantation, your baby's cord blood will be frozen and placed into long-term storage for future use for any patient who requires a stem cell transplant. Your baby's cord blood unit will be included on the Canadian Blood Services OneMatch Stem Cell and Marrow Network for any patient who might need it for transplantation, in Canada or around the world.

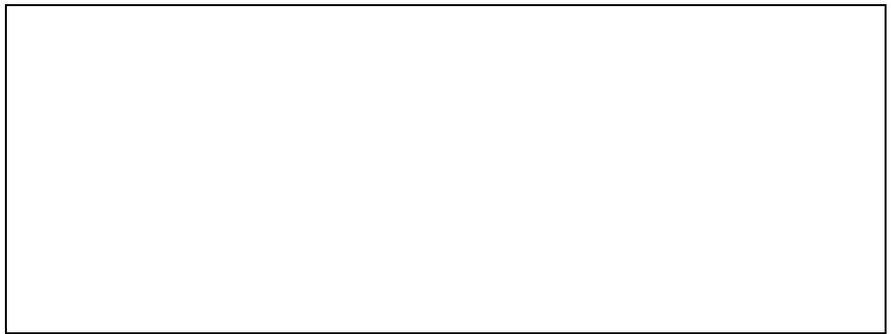
To allow the Cord Blood Bank to use your baby's collected cord blood unit in the transplantation program, you are asked to agree to the following:

1. The Cord Blood Bank will evaluate your baby's cord blood collection, as described below, and if all results are acceptable we will test, freeze and store your baby's cord blood so that it can be used for transplantation for any patient who may need it.
2. The Cord Blood Bank staff will review your current hospital medical record and your baby's current hospital medical record before or after discharge.
  - This helps us learn about possible complications of pregnancy and aspects of your baby's health that might affect the cord blood stem cells.
3. We will ask you questions about your pregnancy, medical and social history.
  - Answers to some questions help us determine which patients are most likely to benefit from the cord blood transplant because their ethnic background is similar to your own.
  - Some questions relate to familial or inherited conditions that might affect your baby's cord blood stem cells.
  - Some questions are asked routinely of all blood donors to help determine whether they may have come in contact with any transmissible infectious diseases that might be present in the blood. It is important to answer all questions truthfully. To make a false statement is a serious matter and could harm others.
  - You will be asked these questions confidentially in a private interview.

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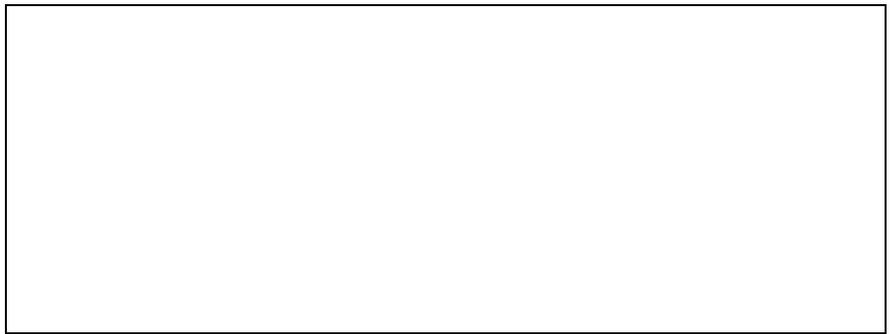


4. A blood test is required. Staff will draw six small tubes of blood (total of about 3 tbsp.) from you, unless you were given intravenous fluids during delivery, in which case, the blood samples may have been drawn at that time.
5. Your blood sample will be tested for certain transmissible diseases including, hepatitis, syphilis, human immunodeficiency virus ("HIV", the virus that causes acquired immune deficiency syndrome-AIDS), West Nile virus and other factors to make sure your donation is as safe as possible. Any positive test results for these diseases will be reported to you and your physicians per Canadian Blood Services' policy, and will also be reported to the appropriate public health authorities.
6. The Cord Blood Bank will also test your baby's cord blood and your blood sample for certain genetic markers, including tests for compatibility and to rule out inherited conditions.
  - The results of any tests that could indicate a significant health risk to you or your baby will be reported to your physician as per Canadian Blood Services' policy and he/she will discuss with you the meaning of these results. **If you would rather NOT be informed of such results, you will not be eligible to participate in the program.**
  - If such a disease that may have come from your baby's cord blood is ever identified in the patient after transplant, we will make every effort to inform you via your physician.
7. If your baby's cord blood is determined to be suitable for transplantation, the cord blood bank will keep samples of your baby's cord blood and of your blood for future testing for infectious diseases and genetic disorders that could be transmitted to a patient who receives a transplant of the cord blood unit.
  - Future testing means that newer tests for the infectious disease markers have become available or other infectious or genetic disorders are identified that require testing.
  - If your baby's cord blood is selected for a transplant, additional tests may be done by the transplant physicians.
8. If your baby's cord blood is suitable for transplant, the Cord Blood Bank staff will attempt to contact you by mail after your baby's birth inquiring as to your health and your baby's health. This is to ensure no problems exist that might affect the suitability to use your baby's cord blood for transplant.
9. If your baby's cord blood is suitable for transplant, it may be stored indefinitely by the Cord Blood Bank, but we reserve the right to discard the cord blood for any reason at any time.
10. If your baby's cord blood is found to be unsuitable for storage and if you have consented to donating your baby's cord blood to biomedical research, Canadian Blood Services may distribute your baby's cord blood for biomedical research. If it is unsuitable for storage and you have not consented for biomedical research, your baby's cord blood and your blood samples will be discarded, unless they are used for quality assurance purposes.

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## **INFORMED CONSENT Umbilical Cord Blood for Testing, Storage and Transplantation Information**



11. If you have consented to donating your baby's cord blood to biomedical research, the components of your baby's cord blood (manufacturing by-products) that are discarded during the preparation of cord blood for storage may be distributed for biomedical research. If you have not given consent for biomedical research your baby's cord blood manufacturing by-products will be discarded, unless they are used for quality assurance purposes.
12. It is very important that you contact the Cord Blood Bank if problems regarding your health or your baby's health arise that may also affect the cord blood, such as leukemia or other disorders. It may be necessary for the Cord Blood Bank to contact your physician to request supporting documents related to this information.
- Contact the Cord Blood Bank at 1 888 2 DONATE (1-888-236-6283).

**Costs and Reimbursements:** There will be no cost to you to participate in the program. There will be no reimbursements to you for any aspect of your cord blood donation. In the event that research with your baby's cord blood leads to material that is patentable or has commercial value, you will not own or have any financial interest in them.

**Potential Risks and Discomforts:** The Cord Blood Bank does not interfere with the natural process of delivery of your baby. There are no significant risks related to participating in the Cord Blood Bank as blood stem cells are collected from the umbilical cord/placenta after the delivery of your baby. If blood samples are drawn from you for infectious disease testing, the amount of blood drawn from you is small (about three tablespoons) and will not affect your health. There is a small risk of slight pain and bruising at the site where the blood is taken, lightheadedness, possible fainting and, rarely, infection.

Some of the questions we will ask you are of a personal nature and will be asked in a private area.

**Potential Benefits:** Though neither you nor your baby will directly benefit from the donation, it may provide a patient with a life-threatening disease with a chance for a healthy life. If you consented to the use of your baby's cord blood for biomedical research, you may also benefit from the knowledge that your participation will further research and help others in the future.

**Withdrawing from the National Public Cord Blood Bank:** Your participation in the Cord Blood Bank is voluntary and may be withdrawn at any time by calling 1 888 2 DONATE (1-888-236-6283). Your baby's cord blood unit will be discarded if it has not already been used for transplantation, quality assurance, or for biomedical research purposes. A "Withdrawal of Consent to Participate in the Canadian Blood Services Cord Blood Bank" form will be provided to you for completion and return.

The personal information that has been collected up to the date of your withdrawal will remain in the Cord Blood Bank, but no further information about you or your baby will be collected, used or disclosed. We may use your personal information to contact you for safety reasons, if necessary. Please know that choosing to not participate will not have any impact on you or your family's medical care in any way.

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**INFORMED CONSENT  
Umbilical Cord Blood for Testing,  
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Information**

**About this Consent:** By signing this form, you freely and voluntarily consent to participate in the program described above. You are giving consent based on the verbal and written information provided to you with the understanding that you are medically and physically qualified to participate. You will receive a copy of this signed consent form for your records.

**CONSENT**

I have read and understood the information provided on cord blood donation and have had the opportunity to ask questions which have been answered satisfactorily. I will answer all medical, travel and social history questions truthfully. I have read and understood the Privacy Notice for the Canadian Blood Services' Cord Blood Bank and consent to the collection, use and disclosure of my personal information and my baby's personal information, including my medical record and other personal health information for the purposes outlined therein. I understand I may withdraw my consent.

I voluntarily agree to participate and to donate my baby's cord blood to the Cord Blood Bank and to be included in the OneMatch Stem Cell and Marrow Network for transplantation to any patient who might need it. I also consent for a blood sample to be taken from me, if required.

\_\_\_\_\_  
(Mother's printed name) (Mother's signature) (Date form signed)

\_\_\_\_\_  
(CBB Staff member/Midwife printed name) (CBB Staff member/Midwife signature) (Date form signed)

**For CBB User Only:**

**Change of Information:**     Name     Postal Code     Phone Number

Verification of information discrepancy from maternal hospital unique ID label to documented information by mother:

CBU Unique ID Number