



## Cord Blood Services

### Mother's Consent to Donate Cord Blood

**Background:** Umbilical cord blood, normally discarded after delivery, is rich in blood stem cells, the immature blood cells that produce new blood cells in the body, and can be used as a source of these cells in life-saving bone marrow transplantation in patients with leukemia, other blood malignancies, and a variety of other diseases. Since the required degree of matching is less for cord blood transplantation, ethnic minorities and patients with rare tissue types often can only find suitable matches by using cord blood. Over 20% of transplants done through the National Marrow Donor Program are cord blood transplants.

Your consent allows you to donate your baby's cord blood in a process that does not harm the baby. This is a product that would normally be discarded. You will have your blood drawn for infectious disease tests such as human immunodeficiency virus (HIV) and hepatitis. Cord blood units available and stored in public banks save thousands of patients' lives every year. If you participate in this program, your baby's cord blood will be collected, and, if it qualifies for storage, stored frozen at the Bloodworks Cord Blood Services. It may be included in the National Cord Blood Inventory (NCBI) and made available to patients in need of transplantation through the C.W. Bill Young Cell Transplantation Program and the "Be the Match" registry. The unit may be transferred and stored at another NCBI site. The National Marrow Donor Program (NMDP) operates the "Be the Match" registry and is one of the contractors to the U.S. Government for the C.W. Bill Young Cell Transplantation Program.

**Procedures:** You will answer a detailed questionnaire about your and your family's medical history. There are also questions about your current and past lifestyle, including sexual history and drug use questions that are similar to those asked of blood donors. Bloodworks will also review your and your baby's medical record related to the delivery. All of this information is confidential and is only used to determine if the cord blood is suitable for banking for future transplantation.

Umbilical cord blood will be collected after your baby is delivered and after the umbilical cord has been clamped and cut. The timing of the clamping of the cord is determined by your obstetrician/midwife according to his/her usual practice and is not affected by whether or not cord blood will be collected. Collecting cord blood should cause no risk to either you or your baby. The cord will be cleansed, a needle placed in the umbilical cord vein, and the cord blood drained into a collection bag. The collection bag is then sealed, labeled, and sent to the Bloodworks where tests are done to determine whether the cord is suitable for banking for future transplantation. If the cord blood has a high enough cell count and passes all biologic tests, the unit is processed along with the test samples. The cord blood and samples are then frozen and may be stored indefinitely. The units are stored at the Bloodworks in Seattle, WA. If your unit is stored but found not to qualify later, it will be removed from inventory and destroyed. If it is not suitable for banking, it may be discarded, used for quality control purposes, used to improve methods for processing cord blood, or used for other research. If your

baby's cord blood is used for research, it will not be labeled in any way that would allow researchers to identify you or your baby. Some examples of the research projects that cord blood units are sent for are expansion of the cord blood stem cells to assist transplant patients and expansion of cord blood stem cells into red cells or platelets. There is no cost to you for donating your cord blood and participating in this program.

**Testing:** A sample of your blood will be collected near the time of your baby's birth. If the cord blood unit qualifies for banking, your blood and your baby's cord blood will be tested for a variety of genetic conditions, such as unusual hemoglobins, and infectious agents, including HIV and hepatitis. Hemoglobin testing is automatically done on children born in the state. By signing this form, you authorize the state newborn screening program to release hemoglobin testing information to the bank in order to qualify the cord blood unit for banking. The knowledge that you or your baby has an infectious disease or genetic condition will allow you to seek treatment but may make it difficult for you to get health insurance. Your blood may also be tissue typed, and some of your blood and the cord blood may be stored for possible future testing. You may experience pain or bruising at the site of the blood draw.

**Other information:** There is no cost to you for participating in this public cord blood banking program. If we become aware of any results that are of importance to your or your baby's health or that affect your eligibility to donate, we will notify you. To better interpret and understand the results of such studies or tests, it may be necessary to contact you for follow-up testing. All donor records are strictly confidential. However, state law in the state where you live requires that the Bloodworks report to the local health department the names of all persons with confirmed positive tests for certain infectious agents such as HIV and hepatitis. Donor records may be reviewed by regulatory agencies such as the Food and Drug Administration (FDA), funding agencies such as the Health Resources and Services Administration, the National Marrow Donor Program and accrediting organizations. We will make every effort to protect your and your baby's confidentiality. When the cord blood is received at the Bloodworks, it will be issued an identifying number. This will be used for all cord blood samples during testing and processing. Donor records that link your name with your number will be kept in a locking file cabinet and stored on a computer in restricted areas of the Bloodworks.

When your baby's cord blood unit information is shared with potential transplant centers, no personally identifying information will be shared. That private information will be held securely by the blood center. There is a remote possibility that your privacy could be compromised but the Bloodworks Cord Blood Services keeps all linked donor information in secure and confidential storage so that only authorized individuals have access and no personal information is shared with research investigators. If there is a change in your baby's health, the Bloodworks Cord Blood Services would like to know about it as it may affect the suitability of the unit for transplantation. If your baby's cord blood unit is requested for transplant, we will try to contact you to ask about your child's health since the cord blood donation.

There are private ("family") cord blood banks which will bank your baby's cord blood for only the baby's or baby's family use. This service is available for a fee and must be pre-arranged if you wish to have it. Additionally, you may elect to donate your baby's cord blood specifically for research uses. You should speak with your healthcare provider or the hospital where you will be delivering if you wish to see if this option is available to you. Finally, you may elect to do nothing with your baby's cord blood in which case it will be discarded as medical waste.

With this donation of your cord blood, you are agreeing that your donated cord blood may be used for stem cell transplantation (also known as bone marrow transplant), for research and development, or in commercial products that may be used to help people with their medical problems. This donation will not result in any financial payment to you. Once your cord blood is donated you will not have a say in how it will be used for transplant, research or commercial purposes and it cannot be returned once it is used.

If you have questions you may call Cord Blood Program Donation Coordinators at (206) 689-6696 or 1-800-DONATE-1, ext. 6696.

**Mother's Statement:** The information I have provided regarding my medical history and HIV risk factors is accurate and true. I understand that by donating my baby's cord blood, my child and I will have no right to the cord blood now or in the future. However, if in the future my child or other blood relative requires treatment with stem cell transplantation, and the cord blood is still available, the Bloodworks may be able to provide it to them. I understand all of the donor information presented, all of my questions have been answered, I agree to donate, and I permit sharing with Bloodworks such healthcare information of myself and my infant as is necessary to facilitate donation.

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Mother's signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Mother's Printed Name

\_\_\_\_\_  
Mother's Date of Birth