VITALANT PUBLIC CORD BLOOD DONATION PROGRAM
INFORMED CONSENT FOR DONATION OF CORD BLOOD AND RELATED TISSUES
FOR USE IN CLINICAL TRANSPLANTATION OR RESEARCH

NOTE: Please read this form carefully before you decide to donate. You are being asked to donate your baby's cord blood to be part of a public registry to be used to find blood stem cells that are matched for a specific patient's need. This consent form is designed to help you make an informed decision. The process will be explained to you. Participation is voluntary and refusal to participate will not negatively impact the physical well-being of you, your pregnancy, or your baby in any way. Your decision not to participate will not change your future relationship with any healthcare provider. There will be no penalty or loss of benefits to you. You may withdraw your consent at any time until the cord has been assigned to a patient or used in research. Please ask any questions you may have, such as any words or information that you do not clearly understand. If you have any questions or concerns, please use the contact information below.

I. PURPOSE AND BACKGROUND

Publically-banked cord blood saves thousands of lives every year. The placenta along with the umbilical cord and cord blood are usually discarded after delivery, but are rich in young stem cells that can produce many types of blood cells and can be used to treat patients with a variety of blood or other types of cancers and other diseases. Since cord blood cells often do not require the same degree of matching required for adult stem cells, they may be the best or only option for patients with certain ethnic (especially mixed ethnic) backgrounds. Recently, some studies have suggested that cord blood may also be a source of stem cells for tissue repair and regeneration.

II. PROCEDURE: WHAT YOUR DECISION TO DONATE MEANS

Your consent cannot directly harm the baby since collection occurs after the cord is cut. If you choose to participate, you will have your blood drawn for infectious disease tests such as human immunodeficiency virus (HIV) and hepatitis (see below). Your baby's cord blood and possibly, the cord tissue and placenta (collectively, "cord blood unit"), will be collected. If any portions qualify for storage, they will be frozen and stored at the Vitalant Cord Blood Bank ("Cord Blood Bank"). Units may be stored for up to 15 years and perhaps longer. Your baby's cord blood unit will not be reserved for your private use. It may be listed with the National Marrow Donor Program's "Be the Match" registry ("Registry") or other national or international public registries for transplantation, or used for approved research. If your baby's cord blood is not used for transplantation or research, it will be properly discarded or utilized for laboratory quality testing activities.

Health History. You will be asked personal questions related to your medical history, genetic history, sexual and social history, as well as health history information about the biological father and his family. The medical, genetic, sexual and social history questions that are asked are of a sensitive nature. Answering the questions may cause you to feel uncomfortable. If you consent to donate, it is important that you are willing to answer these questions truthfully. You are free to refuse to answer any question; however, incomplete answers will make you ineligible for donation. Even after you have successfully donated, if there is a change in your baby's health, the Cord Blood Bank would like to know about it as it may affect the suitability of the unit for transplantation.

Testing. A sample of your blood will be collected near the birth of your baby. You may experience pain or bruising at the site where blood is drawn. If the cord blood unit qualifies for banking, your blood and your baby's cord blood will be tested for blood type (ABO/Rh) and tissue type (HLA – Human Leukocyte Antigens), a variety of genetic conditions (e.g., unusual hemoglobins), and certain infectious diseases, including HIV, hepatitis, and cytomegalovirus. Small samples of your blood and your baby's cord blood may be frozen and stored for possible future testing, such as additional infectious or genetic disease testing or other types of testing that help determine if the cord blood unit is suitable for patient use.

III. CONFIDENTIALITY AND ALLOWABLE USES AND DISCLOSURES OF SENSITIVE INFORMATION

Every effort will be made to protect your and your baby's confidentiality. Only authorized staff members at the Cord Blood Bank have access to your or your baby's identifiable confidential information and records. Once a cord blood unit is received at the Cord Blood Bank, it will be issued a unique identifying number which will be used to identify all products and test results instead of using your name or your baby's name.

Information entered into the Registry. De-identified information about the cord blood unit and some information you provide will be entered into the Registry and made available to the treating physician of the potential recipient of your baby's cord blood. Your name, your baby's name, and other identifying information will not appear on the cord blood unit or on any transplantation, quality control, or research records maintained outside the Cord Blood Bank. Vitalant will not disclose your or your baby's participation to any person or organization, except by your written request or permission, or unless required by federal, state or local laws or regulations. The identity of the recipient of your cord blood unit will not be shared with you, nor will the recipient be given your information.

Notification of Test Results. By signing this form, you authorize the state newborn screening program (See Testing, above) to release their testing information to the Cord Blood Bank to help qualify the cord blood unit for storage. Following receipt of test results, the Cord Blood Bank may contact you directly as required by law, regarding any unexpected test results or to ask follow-up questions about certain risks or the general health of your child. State law requires that abnormal test results for some diseases or genetic conditions be sent to your state's Department of Health. The knowledge that you or your baby has an infectious disease or genetic condition will allow you to seek treatment but may affect your ability to get health insurance.

Record Review. In addition to individuals authorized by the Cord Blood Bank and as required by law, the Food and Drug Administration (FDA), US Department of Health and Human Services, the National Institutes of Health (NIH), the National Marrow Donor Program (NMDP), and the Health Resources and Services Administration (HRSA) may access your and your baby's confidential information during inspections and/or audits. In agreeing to donate, you consent to such inspections and to the copying of excerpts from these records for purposes of inspection or audit, as required by law.

IV. WHAT TO KNOW IF YOUR CORD BLOOD IS USED FOR APPROVED RESEARCH

On occasion, cord blood units may be used for non-clinical research purposes. Your agreement to participate will not involve any cost, additional procedures or time beyond the normal delivery process. The stem cells in your baby's umbilical cord can help researchers better understand how these cells work and how they may be used to treat diseases or medical conditions. You will not receive financial or other benefits from this research. Research may lead to a better understanding of disease as well as factors that affect transplant outcome, tissue matching, processing techniques, and storage. Some of the research may include forms of genetic testing. Without your specific additional consent, we will not allow research involving whole genome sequencing, which examines the entire length of a person's genetic code.. It is extremely unlikely that results could be used to identify you or result in discrimination by insurers or employers. Once released for research to blood centers, universities, government agencies, and drug or health companies from the US and around the world, the sample or unit may be stored indefinitely and may ultimately be used for commercial purposes.

Confidentiality in Research. Donor confidentiality is maintained for research samples and units, and researchers will not be given any information that would allow them to identify you. You will not usually be informed of the purpose or details of specific studies, to which you may or may not have chosen to otherwise consent, or their results. We may contact you to see if you want to participate in other research, ask for more samples, or gather more health information. If you are interested in participating in additional research, you will be given specific study details and a separate informed consent.

V. POSSIBLE RISKS AND BENEFITS TO DONATION

- The doctors and nurses have been instructed to never collect the cord blood if the process of collection would expose either you or your baby to any added health risk.
- Your doctor can cancel the cord blood collection at any time if he/she thinks it might harm you or your baby.
- The blood sample taken from your arm prior to your delivery may cause pain, bruising, infection or fainting like any routine blood sample drawn at your doctor's office.
- There is no direct benefit to you or your baby if you donate cord blood, cord tissue, and/or placenta, except the knowledge that you may be helping a patient by providing a life-saving gift or helping lead to a better understanding of health and disease and possible new kinds of treatments in the future.
- You will be informed of abnormal infectious disease test results or other routine blood donor screening test results that are likely to impact your health.
- It is possible that certain medical conditions, which were not apparent at the birth of your baby, may become known to the cord blood bank staff after testing of the cord blood. You and/or your physician may be notified of some abnormal test results. This may cause you to address health concerns that may or may not result in future consequences. In addition, if required by federal, state or local law, some abnormal results will be reported directly to your state health department.
- Cord Blood Bank personnel may contact you approximately 1 to 6 months after the birth of the baby to ask about any changes in your baby's health which may affect the suitability of the cord blood for transplantation.

VI. ALTERNATIVE TO PARTICIPATION

If you choose not to donate, your baby's cord blood unit will likely be discarded as medical waste.

VII. REIMBURSEMENT AND COSTS

The Cord Blood Bank will provide all materials necessary for the cord blood collection. You will not be charged for any expenses resulting from the collection of the cord blood or testing, nor will your insurance be billed. You will not receive any payment for your participation, whether the cord blood is used for transplantation or research.

VIII. QUESTIONS OR CONCERNS

Your consent to donate your baby's cord blood is your choice. If you choose not to consent, neither your care nor your baby's care will be negatively affected. If you wish to withdraw your consent or you believe that changes in your baby's health may affect the suitability of your baby's cord blood for transplantation or research, please contact us at 1-866-SAVCORD (1-866-728-2673) or (www.givecord.org).

IX. STATEMENT OF CONSENT

YOUR SIGNATURE BELOW INDICATES THAT YOU HAVE BEEN PROVIDED INFORMATION, HAVE READ AND UNDERSTAND THIS CONSENT FORM, HAVE BEEN GIVEN THE OPPORTUNITY TO ASK QUESTIONS, AND THAT YOU AGREE TO DONATE YOUR BABY'S CORD BLOOD AND, IF POSSIBLE, THE CORD TISSUE AND PLACENTA.

_____	_____
***SIGNATURE** of the Mother on behalf of her baby as Donor*	***DATE** of the Mother on behalf of her baby as Donor*
_____	_____
Name of Mother (PRINT)	***Name of Person Obtaining Consent (PRINT)***

If an interpreter was used to complete this consent: **Language requested:** _____

_____	_____
Signature and Date of Interpreter	***Name of Interpreter (PRINT)***