

SAINT LOUIS UNIVERSITY / SSM CARDINAL GLENNON CHILDREN'S MEDICAL CENTER
CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES
(INFORMED CONSENT)

St. Louis Cord Blood Banking Program

Participant _____	Institutional Review Board # <u>8390</u>
<u>Principal Investigator:</u> Dr. William S. Ferguson, MD Director, Division of Hematology/Oncology Department of Pediatrics SSM Cardinal Glennon Children's Medical Center/ Saint Louis University	<u>Co-Investigators:</u> William V. Miller, MD, Medical Director E. Swierkosz, PhD Associate Professor, Pediatrics Kristine Wassmer, RN, BSN, Research Nurse Virginia Stackle, RN, Research Nurse Jill Jackson, RN, BSN, Program Nurse Kathy Mueckl, RN, BSN, Clinical Coordinator Vicki Geiler, RN, Nurse Recruiter
<u>Participating Hospital:</u> SSM Cardinal Glennon Children's Medical Center, and _____	<u>Obstetrician/Midwife:</u> _____

1. I understand that the purpose of this program is to collect and store donated human umbilical cord blood. Cord blood contains sufficient hematopoietic stem cells (the same type of stem cells found in bone marrow) to be used for a stem cell transplant to treat a serious blood disorder or cancer in a child or an adult. This bank involves the collection and storage of umbilical cord blood as an alternative source of stem cells. During pregnancy, umbilical cord blood from the placenta provides nutrition and oxygen to the developing fetus. After the baby is delivered and the umbilical cord is clamped and cut, there is excess blood in the cord and placenta which is routinely discarded. By signing this consent, I agree to donate my baby's cord blood and be a participant in this program.

2. My participation will involve voluntarily donating my baby's excess umbilical cord blood to the St. Louis Cord Blood Bank (SLCBB). The blood will be collected by my obstetrician/midwife after my baby is delivered and separated from the placenta and cord. While waiting for delivery of the placenta, the cord will be cleansed and the umbilical cord vein will be accessed with a needle attached to a collection bag. The blood remaining in the placenta and cord will drain by gravity into the collection bag. As the blood is draining, the collection should cause no risk to me or my baby. There is no change in the actual delivery process. My obstetrician/midwife can cancel the cord blood collection at any time if he/she thinks it will expose either me or my baby to any added health risk.

I give permission for a nurse from the SLCBB to review my and my infant's medical chart. I will answer a detailed questionnaire about my and my baby's medical history and exposures to infectious diseases. I also consent to possible follow-up telephone calls and/or mailings to clarify and/or verify health information

I will also donate a sample of my blood (about four teaspoons). My blood and my baby's cord blood will be tested for infections, including HIV (the AIDS virus), syphilis, hepatitis, and other viruses. This testing is important to minimize the risk of transferring diseases with the cord blood if it is used to treat patients. Some tests may be investigational and not yet approved by the Food and Drug Administration (FDA). The data collected from performing these tests will be used to establish whether continued testing in the future is needed. My baby's cord blood will also be tested for abnormal hemoglobin, such as sickle cell disease and thalassemia. Abnormal test results will be reported to my obstetrician/midwife or my child's pediatrician, and some tests must, by state law, be reported to the Missouri or Illinois Department of Health. The SLCBB has an obligation to inform me of an abnormal test result that may affect my health or my

baby's health so that I may seek appropriate medical care if necessary. I understand that testing related to donation could reveal new information that might not have otherwise been discovered and could potentially impact my or my baby's health care now or in the future.

If my baby's umbilical cord blood meets criteria for banking, it will be registered in programs where physicians anywhere in the world can match patients against a list of cord blood donors. The programs include, but are not limited to: the SLCBB, the National Marrow Donor Program's (NMDP) Be The Match Registry, the Caitlin Raymond International Registry, the Health Resources and Services Administration (HRSA) funded National Cord Blood Inventory (NCBI), which is part of the C.W. Bill Young Cell Transplantation Program. These cord blood units may then be used in the treatment of a patient with a serious life-threatening disorder who may benefit from a stem cell transplant. There will be no information in the registry that could be used to identify me or my baby. If the unit does not meet criteria for banking, it may be used or sold for research, quality control, validation studies, or discarded. The most common reasons a unit is not eligible for being used in transplantation are because the amount of cord blood collected is too small and/or contains too few cells.

I understand that by donating my baby's umbilical cord blood to the SLCBB, my child and I will have no rights to the umbilical cord blood now or in the future. However, if in the future, my child or other blood relative ever requires medical treatment for a serious life threatening disorder and need treatment with stem cell transplantation, and the cord blood was banked and is still available, the SLCBB may be able to provide it to them. I understand the cord blood may have already been used for another person or used for research or discarded.

I understand that in the event my child becomes seriously ill or develops a genetic disorder, illness affecting the immune system or blood related disease, I will notify the SLCBB as this could impact the patient receiving the product for transplantation.

3. The program has been explained to me in detail in person, via written material or by telephone. I understand that there are no financial costs to me or my baby if I agree to participate in the study. There is a remote risk of serious outcome if there is an unexpected twin which is not yet delivered. The risk of this is extremely low, but it is the policy of this bank to only collect during single birth deliveries. In donating a sample of my blood, I may experience some local discomfort and possibly a bruise at the site of the needle stick.

4. I understand that the results of the research study may be published but that my name or identity will not be revealed and that my record will remain confidential. In order to maintain confidentiality, Dr. William Ferguson/colleagues will maintain all records in a locked file. The Saint Louis University Institutional Review Board, the National Marrow Donor Program, and the FDA or other regulatory bodies may review these records. Though every precaution is taken to protect confidentiality, there remains a theoretical risk of violation of privacy. Once the cord blood product has been frozen a confidential linkage between me, my infant and the cord blood will be maintained by the SLCBB in case of future concerns for either my child or the recipient of the cord blood. Therefore, a follow-up phone call may be necessary from Dr. William S. Ferguson/colleagues in the future to verify or update my/my child's health information. I understand that under no circumstances will my child/family be approached for further donations. There will be reference samples of blood stored at the SLCBB for possible future testing. In the event it becomes necessary to transfer responsibility of the inventory from the SLCBB, products and samples would be transferred to another bank. NCBI products would be transferred to another NCBI bank. All product information would accompany the unit and be subject to the strict confidentiality guidelines adhered to by the SLCBB.

5. I understand that I/my child will not receive any direct benefits from my participation in this project. Society may benefit from cord blood as a useful alternative source of hematopoietic stem cells for transplantation and research.

6. I understand that the alternatives to donating my baby's cord blood to the SLCBB include: storing my child's cord blood for private use, donating for other research purposes, or discarding the cord blood. If I wish to privately store my child's cord blood, I need to make arrangements with a private cord blood storage facility prior to my delivery. There is a charge for private storage services.

7. I understand that my participation is voluntary and that refusal to participate will involve no penalty to me or loss of any benefits to which I/my child am/are otherwise entitled. I understand that I may withdraw from the research study without penalty or prejudice.

8. Any questions that I have concerning my participation in the research study will be answered by Dr. William S. Ferguson/colleagues, who can be reached at (314) 268-2787 (daytime), (314)294-7068 (emergency).

9. If you believe that you are injured as a result of your participation in the research study, please contact the research study doctor and/or the Chairperson of the Institutional Review Board as stated in section 10. The University will provide medical treatment in the event that an injury results because of your participation in this research; however, the University reserves the right to make decisions concerning payment for medical treatment for injuries solely and directly relating to the research. A "research related-injury" means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research. You have not waived your legal rights by signing this form. If you have questions, please call the Saint Louis University General Counsel's office at 314-977-5767.

10. If I have any questions about my rights as a research subject or in the event I believe I have suffered an injury as a result of participation in the research project, I may contact the Chairperson of the Saint Louis University Institutional Review Board (314)977-7744, who will discuss my questions with me or will be able to refer me to the individual who will review the matter with me, identify other resources that may be available to me, and provide further information as to how to proceed.

11. I have read the above statement and have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator. I hereby give my informed consent to be a participant in this study.

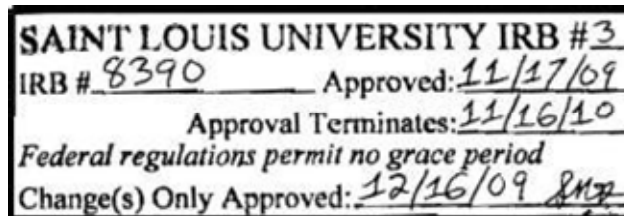
Date

Consent Signature of Mother

Print Name of Mother

Other Signature (witness)

This form is valid only if the IRB's current stamp of approval is shown below.



12. I certify that the program has been explained to the above individual(s) including the nature and purpose, the potential benefits and possible risks associated with participation in this research study, and have answered any questions that have been raised.

13. These elements of informed consent conform to the assurance given by Saint Louis University to the Department of Health and Human Services (DHHS) to protect the rights of human subjects.

14. A copy of this consent document has been provided to the subject/patient.

Date

Signature of Investigator

(The investigator signing here must be authorized in the protocol to obtain consent)