St. Louis Cord Blood Bank SSM Health Cardinal Glennon Children's Hospital Saint Louis University Department of Pediatrics	**CONSENT FOR DONATION**
Cellular Therapy Laboratory & St. Louis Cord Blood Bank 3662 Park Avenue, St. Louis MO 63110, 314-268-2787	**CL.05A.04**

CONSENT FOR DONATION OF UMBILICAL CORD BLOOD

Participant_____

Delivering Hospital_____Delivering Physician/CNM_____

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 that is routinely discarded. However, cord blood contains a large number of hematopoietic stem cells (the same type of stem cells found in bone marrow) that can be used to treat a child or adult with certain life-threatening conditions (such as cancer or a serious blood disorder) who might benefit from a stem cell transplant (also known as a "bone marrow transplant"). Many years of research have shown that umbilical cord blood can often be as effective as other stem cell sources in providing potentially life-saving stem cell transplants, so in 2011 the Food and Drug Administration (FDA) formally approved the use of umbilical cord blood for the treatment of a number of such diseases.

The purpose of this program is to collect, store and provide human umbilical cord blood as an alternative source of stem cells. By signing this consent, you agree to donate your baby's cord blood to the Saint Louis Cord Blood Bank (SLCBB) for potential use as a source of stem cells for transplantation.

WHAT AM I BEING ASKED TO DO?

Your participation will involve voluntarily donating your baby's excess umbilical cord blood to the SLCBB. The blood will be collected by your obstetrician/midwife after your 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 you or your baby. There is no change in the actual delivery process. Your obstetrician/midwife can cancel the cord blood collection at any time if he/she thinks it may expose either you or your baby to any added health risk.

In addition, you give permission for a nurse from the SLCBB to review your and your baby's medical records to make sure that there is no risk of transmitting any disease to a stem cell transplant recipient. You will be required to answer a detailed questionnaire about your and your baby's medical history and exposures to infectious diseases. You also consent to possible follow-up telephone calls and/or mailings to clarify and/or verify health information. This contact may occur shortly after your baby's birth, and again possibly years later. However, under no circumstances will you or your child be approached for further donations of any kind.

You will also be asked to donate a sample of your blood (about four teaspoons). Your blood and your 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. Your baby's cord blood will also be tested for abnormal hemoglobin (the protein in the blood cells that carries oxygen), such as

sickle cell disease and thalassemia. Abnormal test results will be reported to your obstetrician/midwife or your child's pediatrician, and some tests must, by state law, be reported to the Department of Health of your state of residence. The SLCBB has an obligation to inform you of an abnormal test result that may affect your health or your baby's health, when appropriate, so that you may seek appropriate medical care if necessary. You should understand that testing related to donation could reveal new information that might not have otherwise been discovered and could potentially impact you or your baby's health care now or in the future.

If your baby's umbilical cord blood meets criteria for banking, it will be processed and frozen until needed by a patient for transplantation. Reference samples associated with the processed unit will also be stored at the SLCBB in case future testing is required to determine ongoing safety and effectiveness. After processing, the unit will be registered and accessible to programs where physicians anywhere in the world can match patients against a list of cord blood donors. The programs and organizations that may have access include, but are not limited to: the SLCBB, the National Marrow Donor Program's (NMDP) *Be The Match* 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, and accrediting organizations. 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 or provided to the hospital performing the transplant that could be used to identify you or your baby.

WHAT ELSE CAN HAPPEN TO THE CORD BLOOD THAT I DONATE?

Sometimes a unit may not meet <u>all</u> of the FDA's specific criteria for banking but may still be considered suitable for transplantation. Also, there may be times when a unit <u>does</u> meet the FDA's requirements for banking, but a potential recipient has a disease that is not included in the FDA's list of approved uses. While the use of cord blood in these situations would be considered "investigational", we could still provide the unit for transplantation if that use is specifically approved by the FDA and/or the local hospital's Institutional Review Board (the organization which is responsible for approving all research on human subjects).

In addition, a unit may not be suitable for transplantation—for instance, if the volume of the cord blood collected is too small or it has too few of the cells required for transplantation—but might still be usable for research into stem cell biology or other health-related research. In that case, we would require that the persons conducting the research have approval of their local Institutional Review Board to insure that the research is meeting federal guidelines regarding such research.

Finally, some units will not meet the requirements required for banking for transplantation or be needed for research, in which case they will be discarded.

You should understand that by donating your baby's umbilical cord blood to the SLCBB, you and your child will have no rights to the umbilical cord blood now or in the future. However, if in the future your child or other blood relative ever requires medical treatment for a serious life threatening disorder that includes treatment with stem cell transplantation, and if the cord blood was banked and is still available, the SLCBB may be able to provide it to them. However, you

should understand that the cord blood may have already been used for another person, used for research, or discarded.

You should understand that in the event your child becomes seriously ill or develops a genetic disorder, especially including an illness affecting the immune system or a blood related disease, we ask you to promptly notify the SLCBB as this could impact the patient receiving the product for transplantation.

HOW LONG WILL THE UNIT I DONATE BE STORED?

If the collection meets criteria for storage and potential patient use, the unit will remain stored as long as it might still be usable for transplantation (at least 15-20 years and perhaps longer). Further interaction between you and the SLCBB may be necessary as long as the unit remains stored in our bank in order to provide updated health information on your child and family that may influence whether the unit is appropriate for a potential recipient.

If the collection is not suitable for patient transplantation, your participation ends at the time of collection and completion of paperwork.

ARE THERE RISKS INVOLVED WITH DONATING?

In general, donation of cord blood is extremely safe. There is a remote risk of complications 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 your own blood, which usually is drawn from your arm, you may experience some local discomfort and possibly a bruise at the site of the needle stick.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to donate your child's cord blood for banking. Other alternatives to donating your baby's cord blood to the SLCBB include:

- storing your baby's cord blood for private use,
- donating for other research purposes, or
- discarding the cord blood.

If you wish to privately store your child's cord blood for potential family use, you must make arrangements with a private cord blood storage facility prior to your delivery. There is a charge for private storage services. The SLCBB does not offer private storage.

WILL MY AND MY CHILD'S HEALTH INFORMATION BE KEPT PRIVATE?

If your child's cord blood unit is suitable for storage, a confidential link will be maintained by the SLCBB so that we can update medical information that might affect a potential donor. However, these records will be kept in a locked file and under no circumstances will any information that might identify you or your child be released to any treating physician, recipient or recipient's family, nor will any identifying information be released to any researcher who receives a cord blood unit for research purposes. While there remains a theoretical risk of violation of privacy, this risk is extremely small.

In exceptional circumstances (such as natural disasters that threaten the cord blood units stored at the SLCBB) it may be necessary to transfer units to another cord blood bank for storage or distribution; in that case, they would be bound to maintain the same level of privacy as the SLCBB.

WHAT ARE THE COSTS AND PAYMENTS?

While neither you nor your baby will be paid for donating cord blood, there are also no costs to you associated with donating to the SLCBB. The SLCBB will pay for all costs associated with collecting, processing, and storing the unit for any future use.

Should your child or a close relative develop a medical condition for which the donated unit is appropriate and approved for release for treatment, you or your insurance company will be responsible only for the direct costs associated with that product.

WHAT HAPPENS IF I FEEL THAT I HAVE BEEN INJURED BY DONATION?

Many thousands of cord blood units have been collected over the last 2 decades and the risk of any complication is extremely low. If you should have any concerns regarding potential complications related to donating your child's cord blood, please contact the SLCBB as described below.

WHO CAN I CALL IF I HAVE QUESTIONS?

If you have any questions or concerns regarding donation of your child's cord blood, of if any problems arise, you may call the SLCBB at 314-268-2787 or 888-453-2673.

STATEMENT OF CONSENT

I give my informed and voluntary consent to donate my child's umbilical cord blood for public banking as described above. I will be given a copy of this document for my records.

_____ _____
Signature of baby's mother Date

_____
Print Mother's Name

_____ _____
Signature of Witness Date