Umbilical Cord Blood Informed Consent Form

TITLE:	Collection, Processing, Storage and Distribution of Human Umbilical Cord Blood for Transplantation
PROTOCOL NO.:	WIRB® Protocol #20131552
SPONSOR:	Celebration Stem Cell Centre
INVESTIGATOR:	Michael Graham, MD 3495 S. Mercy Road Gilbert, Arizona 85297 Unites States
SITE(S):	Celebration Stem Cell Centre 3495 S. Mercy Road Gilbert, Arizona 85297 United States
STUDY-RELATED PHONE NUMBER(S):	Celebration Stem Cell Centre 480-722-9963
SUB-INVESTIGATOR(S):	None

THIS CONSENT FORM CONTAINS IMPORTANT INFORMATION TO HELP YOU DECIDE WHETHER TO PARTICIPATE IN A RESEARCH STUDY

- Being in a research study is voluntary – your choice
- If you join this study, you can still stop at any time
- No one can promise that a study will help you
- Do not join this study unless all of your questions are answered

After reading and discussing the information in this consent form you should know:

1. Why this research study is being performed
2. What will happen during the study
3. Any possible benefits to you or your baby
4. The possible risks to you or your baby
5. Other options you could choose instead of being in this study
6. How your baby's personal health information will be treated during the study and after the study is over

7. Whether being in this study could involve any cost to you
8. What to do if you have problems or questions about this study

****PLEASE READ THIS CONSENT FORM CAREFULLY****

Background

Celebration Stem Cell Centre (further known as CSCC) invites you to participate in a research study that involves the donation of your baby's cord blood so that patients who need a stem-cell transplant can potentially benefit. The study will take place in numerous centers throughout the United States and will involve tens-of-thousands of subjects. This study involves research, which means that there may be risks or consequences of the procedures to you or your baby that are not currently known or are not foreseeable.

Cord blood is approved only for use in "hematopoietic stem cell transplantation" procedures, which are done in patients with disorders affecting the hematopoietic (blood forming) system. Cord blood contains blood-forming stem cells that can be used in the treatment of patients with blood cancers such as leukemias and lymphomas, as well as certain disorders of the blood and immune systems, such as sickle cell disease and Wiskott-Aldrich syndrome. Cord blood can be used for transplantation in people who need regeneration, that is, 'regrowth,' of these blood-forming cells. Transplanted stem cells from cord blood can help regrow healthy blood cells after the chemotherapy.

Not every cord blood unit will meet requirements for public banking, and may be used for research which is why this is considered a study. Stem cells collected from the umbilical cord blood of healthy babies can be tested, preserved in a stem cell bank (like CSCC), and given to a patient who matches them when needed. By collecting a large number of umbilical cord blood samples at many centers we hope to be able to "match" all patients who need a cord blood transplant regardless of their genetic background.

Purpose

You are being asked to participate in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. This research study is about the collection of human umbilical cord blood, which is normally thrown out at the time of birth, for possible transplantation into other individuals with life-threatening disorders. The stem cells in the cord blood can be used to treat some blood disorders such as leukemia and other otherwise incurable diseases.

If you agree to participate in this study you must provide us with your written, informed consent. By signing you confirm that you understand what is involved in the study and agree to be a part of the study. It is important that you understand the meaning of each part of this document before deciding if you wish to join in the study. If there is anything in this document that you do not understand, you should ask questions until you are comfortable that you do understand. You have the right to change your mind and can decide not to participate at any time even after you have agreed to join the study.

After a baby is born, the cord is normally clamped and then cut. The cord and any blood that is left in the cord (called umbilical cord blood) is typically thrown away as medical waste. However, the umbilical

cord blood that is usually thrown away contains cells (called stem cells) that can be used to treat certain forms of blood disorders like leukemia.

CSCC is asking you to participate in this study where you will donate your baby's cord blood, which could potentially be used to treat other individuals. Your donation of your baby's cord blood is completely voluntary and at no cost to you. Your baby's cord blood may become part of the national cord blood bank inventory and would be available to patients around the country and around the world. If the amount of blood is not enough or there are not enough cells to help these patients, the cells could be discarded or used for research purposes. Umbilical cord blood units are made available for research studies intended to improve patient outcomes. Some examples of this research might be looking at better ways to safely freeze and store cord blood or to look at other potential uses for cord blood. If the cord blood is used for research, any personal information will be removed.

The collection of the cord blood takes place after your new baby is born and after the umbilical cord has been clamped and cut in the usual fashion. The collection of the cord blood takes place from the part of the cord that is still connected to the placenta, not to your new baby. The cord blood will be collected while the Doctor is waiting to deliver the placenta, which is usually about 15 minutes after the baby is delivered. Your obstetrician has your health and the health of your newborn baby as their primary concern and will not collect the cord blood if they feel like it may interfere with either you or your baby's health. **The collection of the cord blood will not place either you or your baby at risk of injury**.

The cord blood that is collected will be sent to CSCC in Gilbert, Arizona where it will be tested, processed and frozen. As with the donation of blood for transfusion, it is important that infections are not transmitted with the blood. When blood is donated to a blood bank, volunteer donors are asked to fill out a confidential questionnaire about their risks for some infections (AIDS/HIV, Hepatitis, Malaria, etc.). You will be asked similar questions. In addition you will be asked some questions about your family history to check for the possibility of an inherited disease that could be transmitted with the cord blood. You will not be held responsible for any diseases given to the patient who receives the donated cord blood. Both your identity and that of your new baby will be kept confidential to the fullest extent allowed by law. While CSCC has to maintain a link between your cord blood and information identifying you and your baby indefinitely, this will be protected by multiple levels of security and will not be given out in the event that the umbilical cord blood is requested for transplant. Some positive test results are required by law to be reported to the Arizona Department of Health Services (ADHS). If you or your baby test positive for these diseases, we will notify the state as well as your doctor so that they can discuss any treatment that might be needed for you or your baby.

PROCEDURES

If you agree to donate your baby's cord blood, you will be agreeing to the following:

1. Fill out a Questionnaire – The questionnaire has questions similar to those asked of all blood donors, along with questions about your baby's family history (both on your and the biological father's sides). Some of the questions may be sensitive. Your answers to this questionnaire will be kept confidential. It is extremely important to be honest since some problems that you might be at risk for could be given to a patient who receives the cord blood stem cells. If you do not wish to complete this questionnaire, you will not be permitted to donate your baby's cord blood to this study.
2. Have your blood drawn– Blood is drawn from you for testing within 7 days of giving birth. Approximately 20 mLs will be taken from a vein by needle-stick and will be placed into multiple blood tubes. The blood sample may be collected along with the routine blood tests performed upon admission to the obstetric unit.
3. The collection of your new baby's umbilical cord blood after the cord has been clamped and cut.
4. The testing of both your blood and your baby's cord blood for certain infections: Infections would be a risk to a transplant patient, and these infections may or may not be a risk to you or your baby. The infectious diseases that are screened for (by law) on all blood donors (AIDS/HIV, Hepatitis B and C, Human T-cell lymphotropic viruses, West Nile Virus, Chagas' disease, and Syphilis). Should any of these test results be positive, CSCC will notify your Doctor in writing and he/she will contact you, as positive results may have implications for your or your baby's health. State law requires that the results of positive tests for HIV, Hepatitis B and C, and Syphilis be reported to the local health agency. Many women have these tests performed during their prenatal checkups. However, for this study they must be performed within 7 days before delivery or within 48 hours after birth.
5. The transport of your baby's cord blood to CSCC: A courier will pick up the cord blood from your delivery hospital and transport it to CSCC.
6. Allow the review of your and your baby's hospital charts – CSCC and/or hospital consenters will review your and your baby's hospital records, including the delivery record to check for complications of the delivery and the pediatrician's examination of your baby for signs of inherited disease.
7. Allow the release of the newborn screening test results from Arizona Department of Health Services (ADHS) – The Office of Newborn Screening in the Arizona Department of Health Services performs screens for 28 rare and serious disorders, as is required by law. This early test tells your physician if more specialized testing is required. The screening test cannot diagnose a particular disorder, rather the results demonstrate if your child has a greater risk of developing this disorder. The newborn screening tests for the following: Endocrine Disorders, Hemoglobinopathies, Enzyme Deficiencies, Amino Acid Disorders, Fatty Acid Oxidation Disorders, Organic Acid Disorder and Cystic Fibrosis. Greater risk of acquiring these disorders can disqualify you from donating your cord blood to CSCC's cord blood donation program. Therefore, we need your consent to acquire these results from ADHS to ensure that your child's cord blood is eligible for the CSCC donation program. The data collected from the Office of Newborn Screening from the Arizona Department of Health Services will be maintained under HIPAA requirements and will be accessible to Dr. Graham and other trained CSCC staff, and

potentially a Transplant physician, if your child's cord blood unit is a genetic match to a recipient.

8. Return an enclosed postcard or responding to a phone request for health updates on your baby 6 months to several years after delivery by Celebration Stem Cell Centre – this information is important to know before we transplant the cord blood into another patient.
9. If you baby's donated cord blood does not meet the requirements for transplantation, it will either be discarded or used for medical research to improve the science of cord blood stem cell transplantation. We will not tell you the specific use of your donated cord blood because in many cases we are not allowed to do so.
10. We will not use the cord blood for medical research if you note below on this form that you **do not** wish to have the cord blood used in medical research.

Once donated, the cord blood will become property of CSCC and could be released to treat a patient with a life-threatening disease. If the very rare occasion arises that your child or a first degree relative develops a disease for which a stem cell transplant might be needed, we encourage you to contact CSCC. In that case, we will determine whether the cord blood unit is still in the bank. If so, it would be made available to your child or relative if your doctors feel it would be appropriate. We cannot promise that the cord blood will still be available as it may have been used by a patient who needed it.

After your baby's cord blood has been collected, it is possible that it could be used for research being conducted at CSCC, as we are continually studying ways to improve cord blood processing, storage, and transplantation. Additionally, a small percentage of the cord blood units that we collect will have abnormal test results which would make them unacceptable for use in the bank. In that case, the stem cells may also be used for research. You may opt out of allowing your baby's discarded cord blood to be used for any research by checking the box beneath your signature later in this document.

Foreseeable Risks/Discomforts/Benefits

You will be made aware of any new or significant findings that may affect your decision to remain in this study.

Venipuncture – all possible efforts will be made to collect the blood samples needed from you for testing at the same time blood is being drawn for routine tests ordered by your obstetrician. When a needle is placed into your arm for a blood draw, it may hurt for a short period of time. A small amount of bleeding and bruising may occur under the skin where the needle was placed. There is also a small risk of a blood clot forming in the punctured vein (<1 in 100). There is a very small risk of infection or blood loss.

Complications of Cord Blood Collection – there is no risk to you or your baby by the collection of cord blood after the birth of your baby.

Possible Benefits – There are no direct benefits to you or your new baby for participating in this study. Your participation may help patients in the future by providing cord blood stem cells that may be useful for treating certain life-threatening illnesses. In the unlikely event that your baby or a first degree relative requires a stem cell transplant, it is possible that the cells may still be available to you or your family.

Compensation For Injury - Immediate necessary care would be available at the hospital where you will be delivering the baby should you be injured from participating in this study. However, there is no provision for free medical care or for monetary compensation for such injury.

Alternative Procedures – This is not a treatment research study and you may elect not to allow the collection and storage of your baby's umbilical cord blood. In that case, the blood will be discarded with the cord and placenta as is normally done. If you choose to give your baby's cord blood to a public bank, you give up the right to store it privately. Alternatively, you may arrange to have the cord blood collected for the CSCC private bank and stored for use by your child or your other children at your own expense. The funds collected by the CSCC private bank are used to fund the public bank.

Cost/Reimbursement – You will not be paid for donating the cord blood.

Source of Funding – CSCC's public cord blood bank is funded by CSCC's private bank and by the owners of CSCC.

Costs of this Study – the donation of cord blood to CSCC's public cord blood bank is at **no cost to you** for the collection, testing and storage.

Confidentiality

Your and your baby's participation in this study will be kept strictly confidential and the results will be available only to the Investigators carrying out research, Western Institutional Review Board (WIRB) and authorized representatives of regulatory activities. It is a study requirement that your involvement in this study be noted in your medical records. Direct access to your records will be required by authorized representatives of CSCC to obtain the information required for this study. Your medical records may also be reviewed and copies made by members of the Western Institutional Review Board (WIRB). By signing this consent form, you authorize access to this confidential information. When results of this or associated studies are reported in medical meetings or medical journals, the identity of all participants is withheld. Confidentiality of your medical records is maintained according to CSCC policies, which are in compliance with HIPAA (Health Information Portability and Accountability Act). Records that identify you and your baby, including your medical record numbers, records about phone calls made as part of this study and the consent form signed by you, may be looked at by the following people:

- Federal agencies that oversee human subject research, including the United States Food and Drug Administration (FDA)
- CSCC Directors and Lab team
- Western Institutional Review Board (WIRB)
- Regulatory agency officials

Your information will be disclosed to conduct the study and to ensure that it is done correctly.

The confidentiality of your medical records will be maintained to the extent permitted by applicable laws. If results of any study are published, your and your baby's identities will remain confidential.

This permission will not expire. If you decide not to give permission to use and give out your or your baby's health information, you will not be able to donate your baby's cord blood.

You have the right to review or copy the information for you and your baby that is kept at CSCC.

You may withdraw or revoke your permission to release your or your baby's health information. To withdraw your permission to use and disclose your health information, you must send written notice to CSCC. If you withdraw your permission, no new health information identifying you or your baby will be gathered after that date. Information that has already been gathered may still be used and given to others.

There is a risk that your information will be given to others without your permission. However, CSCC maintains the confidentiality of your medical records is in compliance with HIPAA.

Questions About Research or Subject's Rights

At any time you are permitted and are encouraged to ask the Doctor any questions about this study and have those questions answered to your satisfaction. If you have any questions concerning your participation in this study, or if you have questions, concerns or complaints about the study please contact Celebration Stem Cell Centre at 480-722-9963.

If you have any questions about your rights as a subject, or if you have questions, concerns or complaints about this study you should contact:

Western Institutional Review Board
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Voluntary Participation

Your decision to participate is voluntary and you are free to withdraw from the study at any time without penalty or loss of future participation or benefits to which you are otherwise entitled. Your participation in this study may also be discontinued without your consent by CSCC or regulatory agencies at any time if it is believed to be in your best interest, if you do not follow the study instructions, or for other administrative reasons.

You will need to notify CSCC if you decide to withdraw so that your part in the study may be stopped in an orderly manner. Refusal to participate will involve no penalty. If you do not take part in or withdraw from the study, you will continue to receive your usual medical care. If you withdraw from the study after your baby's cord blood and/or your maternal samples have been donated to CSCC, those specimens will be discarded immediately.

You are encouraged to ask questions at any time if any part of this study is unclear to you. You have the right to have your questions answered. If your physicians feel at any time that continued participation is not in your best interest, they may decide not to collect the cord blood.

You understand that you will be kept informed in a timely manner of any information that may relate to your willingness to continue participation in the study. At the discretion of your doctor(s) and CSCC, you may be asked to sign a revised informed consent or consent addendum that provides this information.

There can be no guarantee or assurance of success of the results of the services for the donation and storage of cord blood.

You understand that you may ask questions at any time about this study. If you feel that you or your baby have experienced an adverse event from the cord blood collection and storage procedures, you should call Celebration Stem Cell Centre at 480-722-9963.

Signatures

I have discussed the collection of my baby's cord blood and my blood, and I have read the above consent or it was read to me. I have been told about the possible risks and benefits of my participation. I know that being in this study is voluntary. If I choose to be in this study, I know I can stop participating in this study and I will still get the usual medical care. I will get a copy of this consent form.

(Initial all the previous pages of the consent form)

All of my questions have been answered to my satisfaction. I authorize the use and disclosure of my and my baby's protected health information to the parties listed in the authorization section of this consent for the purposes described above. I voluntarily consent to participate in this study.

Subject_____
(Print Name)

_____ _____
(Signature) (Date)

By signing this form, I have not waived any of the legal rights which I otherwise have as a participant in a research study. I understand that I will receive a signed copy of this consent form for my records.

☐ **If my cord blood volume is too small to be banked, please discard rather than use for medical research (checking this box will make this special request).**

----------Use this witness section only if applicable----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the study must be present for the consent and sign the following statement: **I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the study.**

_____ _____
(Signature of Impartial Witness) (Date)

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of the study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in the study?
4. What are the possible risks of participating in the study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in the study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

_____ _____
Printed Name of Person Conducting The Informed Consent Discussion — Position

_____ _____
Signature of Person Conducting The Informed Consent Discussion — Date

CONSENT FOR THE COLLECTION AND STORAGE OF UMBILICAL CORD BLOOD FOR TRANSPLANTATION
RELEASE OF NEWBORN SCREENING INFORMATION

I give permission to the Arizona Department of Health Services Office of Newborn Screening to release the results of blood tests for hemoglobinopathies performed on my baby to Celebration Stem Cell Centre, Gilbert, Arizona.

Subject Name: _____
(Print Name)

_____ _____
(Signature) (Date)

Collection Facility: _____

Mother's full name:_____

Mother's date of birth:_____

Baby's name:_____

Baby's date of birth:_____ (To be completed by CSCC)

This page will be sent directly to the State Laboratory for their records