Celebration STEM CELL CENTRE

CSCC ID # Sticker

MATERNAL DEMOGRAPHIC FORM

☐ Public Donation ☐ Private Banking

BABY'S MOTHER'S INFORMATION			
Last Name:		Maiden Name (if applicable):	
First Name:	Middle Name:	Mother's Date of Birth:	
Mailing Address:		Apt/Unit #:	
City:	State:	Zip Code:	Country:
Cell Phone:	Secondary Phone:	Last 4 Digits of Social Security #:	
Email Address:			
Baby's Due Date:	Baby's Name: (if already known)		
Total # of pregnancies:	# of living children:	# of Children Expecting:	

BABY'S FATHER'S INFORMATION			
Last Name:	First Name:	Middle Name:	
Mailing Address (if different than baby's mother's address):		Apt/Unit #:	
City:	State:	Zip Code:	Country:
Cell Phone:	Secondary Phone:	Date of Birth:	
E-mail Address:			

DELIVERING HOSPITAL			
Hospital Name:			
Hospital Address:		Phone:	
City:	State:	Zip:	Country:

OBSTETRICIAN / MIDWIFE INFORMATION			
Physician/Certified Nurse Midwife Name:			
Practice Name:		Phone:	
Address:			
City:	State:	Zip:	Country:

PEDIATRICIAN INFORMATION			
Pediatrician's Name:			
Practice Name:		Phone:	
Address:			
City:	State:	Zip:	Country:

IRB APPROVED
AS MODIFIED
Feb 22, 2019

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

Subj. Initials_____

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

Celebration STEM CELL CENTRE

CSCC ID # Sticker

BABY'S RACE AND ETHNICITY INFORMATION

Since certain HLA types may be more common in each ethic group, the information below will help in selecting a cord blood unit for transplant.

BABY'S ETHNICITY:

RESPONSE IS REQUIRED, PLEASE CHECK ONE: ❒ **HISPANIC OR LATINO** ❒ **NOT HISPANIC OR LATINO**

BABY'S RACE:

Of which group(s) is your baby a member? (Select all that apply.)

American Indian or Alaska Native
- ❒ Alaska Native or Aleut (ALANAM)
- ❒ North American Indian (AMIND)
- ❒ American Indian South or Central American (AMIND)
- ❒ Caribbean Indian (AMIND)

Black or African American
- ❒ African (AFB)
- ❒ African American (AAFA)
- ❒ Black Caribbean (CARB)
- ❒ Black South or Central American (SCAMB)

Asian
- ❒ Chinese (NCHI)
- ❒ Filipino (Philipino) (FILI)
- ❒ Japanese (JAPI)
- ❒ Korean (KORI)
- ❒ South Asian (SCSEAI)
- ❒ Vietnamese (SCSEAI)
- ❒ Other Southeast Asian (SCSEAI)

Native Hawaiian or Other Pacific Islander
- ❒ Guamanian (OPI)
- ❒ Hawaiian (HAWI)
- ❒ Samoan (OPI)
- ❒ Other Pacific Islander (OPI)

White
- ❒ Eastern European (CAU) □ Northern European (CAU)
- ❒ Mediterranean (CAU) □ Western European (CAU)
- ❒ Middle Eastern (MENAFC) □ White Caribbean (CAU)
- ❒ North Coast of Africa (MENAFC) □ White South or Central American (CAU)
- ❒ North American (CAU) □ Other White (CAU)

SIGNATURE

I have received information from the cord blood bank necessary to complete the following forms:

- Maternal Demographic Information
- Maternal Risk Questionnaire
- Family Medical History Questionnaire

I have completed these forms to the best of my knowledge. I understand that only authorized staff from the cord blood bank will have access to my personal information.

Forms completed by:

_____ Today's Date:_____

Signature

Thank you for donating your baby's cord blood. The blood in the umbilical cord and placenta is unique because it contains a large number of blood-forming cells. Seriously ill patients, whose bodies cannot make healthy cells of their own, can be helped by a donation of healthy cord blood cells from a matched unit. Cord blood donations give more patients hope of finding a match.

In the event that an illness affecting the immune system or a blood related disease should develop in your baby, or if you learn of a reason which would exclude you from donating or feel that it should not be transfused to a patient, please call Celebration Stem Cell Centre: (480) 722-9963 or toll-free at 1-877-522-2355.

Celebration STEM CELL CENTRE

MATERNAL RISK AND FAMILY MEDICAL HISTORY QUESTIONNAIRE

CSCC ID# Label

MATERNAL RISK QUESTIONNAIRE

Please ***read carefully*** and answer the following questions "YES" or "NO".

1.	Have you ever donated or attempted to donate cord blood using your current or a different name to this cord blood bank?	❒ Yes	❒No
2.	Have you, for any reason, been deferred or refused as a blood or cord blood donor, or been told not to donate blood or cord blood? ***If yes***, why?_____	❒ Yes	❒No
3.	Are you know taking or have you ever taken any of the following medications? (check all that apply):		
	a. Insulin from cows (bovine or beef insulin)?.....	❒ Yes	❒No
	b. Growth hormone from human pituitary glands ever?.....	❒ Yes	❒No
	c. Rabies vaccination in the past year?.....	❒ Yes	❒No
	d. Hepatitis B Immune Globulin?.....	❒ Yes	❒No
	e. Unlicensed Vaccine?.....	❒ Yes	❒No
4.	Are you currently taking an antibiotic?	❒ Yes	❒No
5.	Are you currently taking any other medication for an infection?	❒ Yes	❒No
6	**In the past 8 weeks,** have you had any vaccinations or other shots? ..... ***If yes***, please describe: _____	❒ Yes	❒No
7.	**In the past 12 weeks**, have you had contact with someone who had a smallpox vaccine?..... (Examples of contact include physical intimacy, touching the vaccination site, touching the bandages or covering of the vaccination site, or handling bedding or clothing that had been in contact with an unbandaged vaccination site.)	❒ Yes	❒No
8.	**In the past 4 months,** have you experienced **two (2)** or more of the following: a fever (>100.5°F or 38.06°C), headache, muscle weakness, skin rash on trunk of the body, or swollen lymph glands? ..... **If yes,** which symptoms and when? Please specify: _____	❒ Yes	❒No
9.	Have you ever had any type of cancer, including leukemia?..... ***If yes,*** please describe:_____	❒ Yes	❒No
10.	**In the past 5 years**, have you had a bleeding problem, such as hemophilia or other clotting factor deficiencies, and received human-derived clotting factor concentrates?	❒ Yes	❒No
11.	**In the past 12 months,** have you been told by a healthcare professional that you have West Nile Virus infection or received any positive test for West Nile Virus?	❒ Yes	❒No
12.	Have you ever had a diagnosis of clinical, symptomatic viral hepatitis after age 11?	❒ Yes	❒No
13.	Have you ever had a parasitic blood disease (for example, Leishmaniasis, Babesiosis, Chagas disease)or any positive tests for Chagas or T. cruzi, including screening tests?	❒ Yes	❒No
14.	Have you ever been diagnosed with Creutzfeldt-Jakob Disease (CJD), variant CJD, dementia, any degenerative or demyelinating disease of the central nervous system, or other neurological disease?	❒ Yes	❒No
15.	Have any of your blood relatives ever been diagnosed with Creutzfeldt-Jakob Disease (CJD), or have you been told that your family has an increased risk for CJD?	❒ Yes	❒No
16.	Have you received a dura mater (brain covering) graft?	❒ Yes	❒No
17.	Have you ever had a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from an animal?	❒ Yes	❒No

Celebration STEM CELL CENTRE

MATERNAL RISK AND FAMILY MEDICAL HISTORY QUESTIONNAIRE

CSCC ID# Label

18.	Have you ever lived with or had sexual contact with anyone who had a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from an animal?	❒ Yes	❒No
	In the past 3 years:		
	19. Have you had malaria?	❒ Yes	❒No
	20. Have you been outside the United States or Canada?	❒ Yes	❒No
	If yes, please list ***where***, ***when***, and for ***how long***:_____		
	_____		
21.	**In the 12 months prior to the collection of the cord blood unit**, have you had a blood transfusion?	❒ Yes	❒No
	In the past 12 months:		
	22. Have you had a transplant or tissue graft from someone else such as organ, bone marrow, stem cell, cornea, bone, skin, or other tissue?	❒ Yes	❒No
	23. Have you had a tattoo or ear, skin, or body piercing?	❒ Yes	❒No
	If yes, answer question 22. **If no**, skip to question 23.		
	24. Were shared or non-sterile inks, needles, instruments, or procedures used for the tattoo or piercing?	❒ Yes	❒No
	25. Have you had an accidental needle stick, or have you come into contact with someone else's blood through an open wound (for example, a cut or sore), non-intact skin, or mucous membrane (for example, into your eye, mouth, etc.)?	❒ Yes	❒No
	26. Have you had or been treated for a sexually transmitted disease, including syphilis?	❒ Yes	❒No
	27. Have you given money or drugs to anyone to engage in sex with you?	❒ Yes	❒No
	28. Have you engaged in sex with anyone who had taken money or drugs for sex in the **past 5 years**?	❒ Yes	❒No
	29. Have you had sexual contact or lived with a person who has active or chronic viral Hepatitis B or Hepatitis C?	❒ Yes	❒No
	30. Have you had sex, even once, with anyone who has used a needle to take drugs, steroids, or anything else <u>not</u> prescribed by a doctor in the **past 5 years**?	❒ Yes	❒No
	31. Have you had sex with a male who has had sex with another male, even once, in the **past 5 years**?	❒ Yes	❒No
	32. Have you had sex, even once, with anyone who has taken human-derived clotting factors for a bleeding problem in the **past 5 years**?	❒ Yes	❒No
	33. Have you had sex, even once, with anyone who has HIV/AIDS or had a positive test for the AIDS virus?	❒ Yes	❒No
	34. Have you been in juvenile detention, lockup, jail or prison for more than **<u>72 continuous hours</u>**?	❒ Yes	❒No
	In the past 5 years:		
	35. Have you engaged in sex in exchange for money or drugs?	❒ Yes	❒No
	36. Have you used a needle, even once, to take drugs, steroids or anything else <u>not</u> prescribed for you by a doctor?	❒ Yes	❒No
37.	Do you have AIDS or have you ever tested positive for HIV (including screening tests)?	❒ Yes	❒No

Celebration Stem Cell Centre
3495 S. Mercy Rd.
Gilbert, AZ 85297

Celebration Stem Cell Centre

MATERNAL RISK AND FAMILY MEDICAL HISTORY QUESTIONNAIRE

CSCC ID# Label

38.	**Do you have any of the following:**		
	38a. Unexplained night sweats?	❒ Yes	❒No
	38b. Unexplained blue or purple spots on or under the skin or mucous membrane?	❒ Yes	❒No
	38c. Unexplained weight loss?	❒ Yes	❒No
	38d. Unexplained persistent diarrhea?	❒ Yes	❒No
	38e. Unexplained cough or shortness of breath?	❒ Yes	❒No
	38f. Unexplained temperature higher than 100.5°F (38.06°C) for more than 10 days?	❒ Yes	❒No
	38g. Unexplained persistent white spots or sores in the mouth?	❒ Yes	❒No
	38h. Multiple lumps in your neck, armpits, or groin lasting longer than one month?	❒ Yes	❒No
	38i. Any infections during your pregnancy?	❒ Yes	❒No
39.	Have you ever tested positive for HTLV (including screening tests) or had unexplained paraparesis (partial paralysis affecting the lower limbs)? HTLV refers to Human T-cell Lymphotrophic Virus.	❒ Yes	❒No
40.	If a person has the AIDS virus, do you understand that the person **can give it to someone else** even though they may feel well and have a negative AIDS test?	❒ Yes	❒No

For Questions 41 through 50 please refer to the charts below for a list of countries involved:

Albania	France	Netherlands (Holland)	Switzerland	Yugoslavia (Federal Republic of)
Austria	Germany	Norway	United Kingdom (UK)	Kosovo
Belgium	Greece	Poland	England	Montenegro
Bosnia-Herzegovina	Hungary	Portugal	Northern Ireleand	Serbia
Bulgaria	Ireland (Republic of)	Romania	Scotland, Wales	
Croatia	Italy	Slovak Republic	The Isle of Man	
Czech Republic	Liechtenstein	Slovenia	The Channel Islands	
Denmark	Luxembourg	Spain	Gibralter	
Finland	Macedonia	Sweden	The Falkland Islands	

41. **Since 1980, have you ever lived in or traveled to Europe?** ***(refer to chart above).*** **If yes,** answer questions **42** through **45**. **If no**, skip question **48**	❒Yes	❒No
42. **From 1980 through 1996,** did you spend time that adds up to 3 months or more in the United Kingdom (refer to chart above)?	❒Yes	❒No
43. **Since 1980,** have you received a transfusion of blood or blood components while in the UK or France?	❒Yes	❒No
44. **Since 1980,** have you spent time that **adds up to 5 years or more** in Europe (refer to chart above), including time spent in UK between 1980 and 1996?	❒Yes	❒No
45. **From 1980 through 1996,** were you a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military or civilian military employee? **If yes**, answer **46**and **47**. **If no,** skip to question **48**	❒Yes	❒No
46. **From 1980 through 1990,** did you spend **a total of 6 months or more** associated with a military base in any of the following countries: UK, Belgium, Netherlands or Germany?	❒Yes	❒No
47. **From 1980 through 1996,** did you spend a **total of 6 months or more** associated with a military base in any of the following countries: Spain, Portugal, Turkey, Italy or Greece?	❒Yes	❒No

Reference Guide for Questions 46 – 48: African Countries

Benin	Central African Republic	Congo	Gabon	Niger	Senegal	Zambia
Cameroon	Chad	Equatorial Guinea	Kenya	Nigeria	Togo	

48. **Since 1977,** were you born in, have you lived in, or have you traveled to any African country listed above?	❒Yes	❒No

If yes, answer question 49. ***If no***, skip to question **50.**		
49. While in one of the African countries listed above, did you receive a blood transfusion or any other medical treatment with a product made from blood?	❒Yes	❒No
50. Have you had sexual contact with anyone who was born in or lived in any African country listed above **since 1977**?	❒Yes	❒No

FAMILY MEDICAL HISTORY QUESTIONNAIRE

1.	Were you and/or the baby's father adopted at early childhood?	❒Yes	❒No
	1a. ***If yes,*** is a family medical history available for you and/or the baby's father?	❒Yes	❒No
2.	Are you and the baby's father related, except by marriage? (e.g. first cousins)	❒Yes	❒No
3.	Did this pregnancy either use a donor egg or donor sperm?	❒Yes	❒No
	3a. ***If yes***, is a family medical history questionnaire available for the egg or sperm donor? (please attach copy)	❒Yes	❒No
4.	Have you ever had an abnormal result from a prenatal test (e.g. amniocentesis, blood test, ultrasound)?	❒Yes	❒No
	If yes, answer the following questions. ***If no***, skip to questions **5.**		
	4a. Which test was abnormal?_____		
	4b. What was the abnormal test result?_____		
	4c. Was a diagnosis made?	❒Yes	❒No
	If yes, specify diagnosis:_____		
5.	Have you had any children who died within the first 10 years of life?	❒Yes	❒No
	5a. ***If yes,*** what was the cause?_____		
6.	Have you ever had a stillborn child?	❒Yes	❒No
	6a. ***If yes,*** what was the cause?_____		

For the remainder of the questionnaire, describe the relationship between the baby and the immediate family member with the disease. Please refer to the following codes:

Family Relationship Codes: **BM** Baby's Mother **BF** Baby's Father **BGP** Baby's Grandparent **BS** Baby's sibling **BMS** Baby's Mother's Sibling* **BFS** Baby's Father's Sibling *

*(Parent's sibling (BMS and BFS) refer to the baby's aunts and uncles by blood, and does not include aunts and uncles who are in-laws of the parents).

7.	**Cancer or Leukemia?**	❒Yes	❒No			
	If yes, please specify all that apply in **7A-7J**. ***If no***, skip to question **8.**	**BM**	**BF**	**BS**		
	7a. Brain or other nervous system cancer	❒	❒	❒	**IMMEDIATE FAMILY ONLY**	
	7b. Bone or joint cancer	❒	❒	❒		
	7c. Kidney (including renal pelvic) cancer	❒	❒	❒		
	7d. Thyroid Cancer	❒	❒	❒		
	7e. Hodgkin's Lymphoma	❒	❒	❒		
	7f. Non-Hodgkin's Lymphoma	❒	❒	❒		
	7g. Acute or chronic myelogenous/myeloid leukemia	❒	❒	❒		
	7h. Acute or chronic lymphocytic/lymphoblastic leukemia	❒	❒	❒		
	7i. Skin Cancer	❒	❒	❒		

	7j. Other cancer/leukemia..... Specify Type:_____ Specify Type:_____	❒	❒	❒				
Answer Questions **8-12** for any Blood Disorders or Diseases. ***If yes,*** please specify as applicable.								
8.	**Red Blood Cell Disease?** ❒Yes ❒No							
	If yes, please specify that all apply in **8a-8d.** If no, skip to question **9.**	**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**	
	8a.. Diamond-Blackfan Syndrome.....	❒	❒	❒	❒	❒	❒	
	8b. Elliptocytosis.....	❒	❒	❒	❒	❒	❒	
	8c. Spherocytosis.....	❒	❒	❒	❒	❒	❒	
	8d. G6PD or other red cell enzyme deficiency.....	❒	❒	❒	❒	❒	❒	
9.	**White Blood Cell Disease?** ❒Yes ❒No							
	If yes, please specify all that apply in **9a-9d.** ***If no,*** skip to question **10.**	**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**	
	9a. Chronic Granulomatous Disease.....	❒	❒	❒	❒	❒	❒	
	9b. Kostmann Syndrome.....	❒	❒	❒	❒	❒	❒	
	9c. Schwachman-Diamond Syndrome.....	❒	❒	❒	❒	❒	❒	
	9d. Leukocyte Adhesion Deficiency (LAD).....	❒	❒	❒	❒	❒	❒	
10.	**Immune Deficiencies?** ❒Yes ❒No							
	If yes, please specify all that apply in **10a-10h.** If no, skip to question **11.**	**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**	
	10a. ADA or PNP Deficiency.....	❒	❒	❒	❒	❒	❒	
	10b. Combined Immunodeficiency Syndrome (CID), Common Variable Immunodeficiency Disease (CVID).....	❒	❒	❒	❒	❒	❒	
	10c. DiGeorge Syndrome.....	❒	❒	❒	❒	❒	❒	
	10d. Hereditary Hemophagocytic Lymphohistiocytosis (HLH) including FEL.....	❒	❒	❒	❒	❒	❒	
	10e. Hypoglobulinemia.....	❒	❒	❒	❒	❒	❒	
	10f. Nezeloff Syndrome.....	❒	❒	❒	❒	❒	❒	
	10g. Severe Combined Immunodeficiency.....	❒	❒	❒	❒	❒	❒	
	10h. Wiskott-Aldrich Syndrome.....	❒	❒	❒	❒	❒	❒	
11.	**Platelet Disease?** ❒Yes ❒No							
	If yes, please specify all that apply in **11a-11g.** ***If no***, skip to question **12.**	**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**	
	11a. Amegakaryocytic Thrombocytopenia.....	❒	❒	❒	❒	❒	❒	
	11b. Glanzmann Thrombasthenia.....	❒	❒	❒	❒	❒	❒	
	11c. Hereditary Thrombocytopenia.....	❒	❒	❒	❒	❒	❒	
	11d. Platelet Storage Pool Disease.....	❒	❒	❒	❒	❒	❒	
	11e. Thrombocytopenia with absent radii (TAR).....	❒	❒	❒	❒	❒	❒	
	11f. Ataxia-Telangiectasia.....	❒	❒	❒	❒	❒	❒	

	11g. Fanconi Anemia.....			❒	❒	❒	❒	❒	❒
12.	**Other blood disease or disorder?** Specify type:_____	❒Yes	❒No	❒	❒	❒	❒	❒	❒
Hemoglobin Problems				**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**
13.	Sickle cell disease, such as sickle-cell anemia or sickle thalassemia? Specify disease:_____	❒Yes	❒No	❒	❒	❒	❒	❒	❒
14.	Thalassemia, such as alpha thalassemia or beta-thalassemia?	❒Yes	❒No	❒	❒	❒	❒	❒	❒
15.	**Metabolic/Storage Disease?**	❒Yes	❒No						
	If yes, please specify all that apply in **15a-15q**. If no, skip to question **16.**			**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**
	15a. Hurler Syndrome (MPS I).....			❒	❒	❒	❒	❒	❒
	15b. Hurler-Scheie Syndrome (MPS I H-S).....			❒	❒	❒	❒	❒	❒
	15c. Hunter Syndrome (MPS II).....			❒	❒	❒	❒	❒	❒
	15d. Sanfilippo Syndrome (MPS III).....			❒	❒	❒	❒	❒	❒
	15e. Morquio Syndrome (MPS IV).....			❒	❒	❒	❒	❒	❒
	15f. Maroteaux-Lamy Syndrome (MPS VI).....			❒	❒	❒	❒	❒	❒
	15g. Sly Syndrome (MPS VII).....			❒	❒	❒	❒	❒	❒
	15h. I-cell disease.....			❒	❒	❒	❒	❒	❒
	15i. Globoid Leukodystrophy (Krabbe Disease).....			❒	❒	❒	❒	❒	❒
	15j. Metachromatic Leukodystrophy (MLD).....			❒	❒	❒	❒	❒	❒
	15k. Adrenoleukodystrophy (ALD).....			❒	❒	❒	❒	❒	❒
	15l. Sandhoff Disease.....			❒	❒	❒	❒	❒	❒
	15m. Tay-Sachs Disease.....			❒	❒	❒	❒	❒	❒
	15n. Gaucher Disease.....			❒	❒	❒	❒	❒	❒
	15o. Niemann Pick-Disease.....			❒	❒	❒	❒	❒	❒
	15p. Porphyria.....			❒	❒	❒	❒	❒	❒
	15q. Other or unknown metabolic/storage disease..... Specify type:_____			❒	❒	❒	❒	❒	❒
Acquired Immune System Disorders				**BM**	**BF**	**BS**	**IMMEDIATE FAMILY ONLY**		
16.	**HIV/AIDS?**	❒Yes	❒No	❒	❒	❒			
17.	**Severe autoimmune disorder?**	❒Yes	❒No	❒	❒	❒			
	If yes, please specify all that apply in questions **17a-17d.** ***If no***, skip to question **18.**			**BM**	**BF**	**BS**			
	17a. Crohn's Disease or Ulcerative Colitis.....			❒					
	17b. Lupus.....			❒					
	17c. Multiple Sclerosis (MS).....			❒					
	17d. Rheumatoid Arthritis.....			❒					

18.	Any other or unknown immune system disorders? Specify Disorder:_____	❒Yes	❒No	❒	❒	❒			
Answer Questions 19-25				**BM**	**BF**	**BS**	**BGP**	**BMS**	**BFS**
19.	Required chronic blood transfusions?	❒Yes	❒No	❒	❒	❒	❒	❒	❒
20.	Have you been told you or your family member(s) have hemolytic anemia?	❒Yes	❒No	❒	❒	❒	❒	❒	❒
21.	Had spleen removed to treat a blood disorder?	❒Yes	❒No	❒	❒	❒	❒	❒	❒
22.	Had gallbladder removed before age of 30?	❒Yes	❒No	❒	❒	❒	❒	❒	❒
23.	Had Creutzfeldt-Jakob Disease (CJD)?	❒Yes	❒No	❒	❒	❒	❒	❒	❒
24.	Other serious or life-threatening diseases affecting the family?..... ***If yes,*** list affected family member(s) and type of disease. Specify Type:_____ Specify Type:_____ Specify Type:_____	❒Yes	❒No	 ❒ ❒ ❒	 ❒ ❒ ❒	 ❒ ❒ ❒	 ❒ ❒ ❒	 ❒ ❒ ❒	 ❒ ❒ ❒
25.	In answering these questions, have you answered for both your family and the baby's father's family?	❒Yes	❒No						

Addendum A: Zika Virus			
1.	Have you had a medical diagnosis of ZIKV infection **at any point** during your pregnancy?	❒Yes	❒No
2.	Have you resided in, or traveled to, an area with active ZIKV transmission* **at any point** during your pregnancy?	❒Yes	❒No
3.	Have you had sex during your pregnancy with a male who is known to have: a. A medical diagnosis of ZIKV within the six months prior to the contact b. Resided in, or traveled to, an area with active ZIKV transmission* within the six months prior to that contact i. Country(ies) traveled to:_____ ii. Date(s) of travel:_____	❒Yes	❒No
Addendum B: Mycobacterium Tuberculosis			
1.	Have you ever had a positive test for tuberculosis (TB) infection (including a positive skin test, blood test, or sputum test)?	❒Yes	❒No
2.	Have you ever had a medical diagnosis of TB disease or infection?	❒Yes	❒No
3.	Have you ever had a diagnosis of latent TB infection (LTBI)?	❒Yes	❒No
4.	Were you born in an area of the world where TB is common (e.g., Latin American countries, the Caribbean, Africa, Asia, Eastern Europe, Russia)?	❒Yes	❒No
5.	Have you ever lived in an area of the world where TB is common (e.g., Latin American countries, the Caribbean, Africa, Asia, Eastern Europe, Russia)?	❒Yes	❒No

6.	Have you ever traveled to an area of the world where TB is common (e.g., Latin American countries, the Caribbean, Africa, Asia, Eastern Europe, Russia)?	❒Yes	❒No
7.	Have you ever lived in a jail, prison, or correctional facility?	❒Yes	❒No
8.	Have you ever worked in a jail, prison, or correctional facility?	❒Yes	❒No
9.	Have you ever lived in a long-term care facility, or homeless shelter?	❒Yes	❒No
10.	Have you ever worked in a long-term care facility, or homeless shelter?	❒Yes	❒No
11.	Have you ever lived with (resided in the same dwelling) another person who has TB?	❒Yes	❒No
12.	Have you ever been a close contact of another person with TB?	❒Yes	❒No
13.	Do you have a medical condition that can impair your immune function (e.g., diabetes, chronic kidney disease/end stage renal disease with or without dialysis)?	❒Yes	❒No
14.	Are you taking medications that can impair your immune function?	❒Yes	❒No
	Addendum C: Sepsis		
1.	Do you currently have a medical diagnosis of sepsis or suspicion of sepsis?	❒Yes	❒No

Consenter Review (if applicable):

Reviewed by: _____ **Date** _____

TO BE COMPLETED BY CELEBRATION STEM CELL CENTRE:

I have reviewed the above responses and have determined all requirements met and responses are acceptable: ❒Yes ❒No

If NO, specify reason: _____

Reviewed by: _____ **Date** _____

Ineligible Donor Statement:
Based on information noted above, this donor is determined to be ineligible to donate her cord blood product.

Medical Director, Celebration Stem Cell Centre: _____ **Date** _____

CSCC ID # Label

CELEBRATION STEM CELL CENTRE
HIV TEST INFORMED CONSENT

HUMAN IMMUNODEFICIENCY VIRUS AND TRANSMISSION:

Human Immunodeficiency Virus (HIV) is a virus which can be transmitted from individuals through body fluids, primarily blood and semen. The spread is not through air or food or by casual social contact. It is passed on when the blood or body fluids of an infected person mix with your own. Being infected with HIV through sexual contact mainly happens by having contact with semen of a person who has HIV. Women, as well as men, can infect their sexual partners with the virus. The HIV virus has also been found in vaginal secretions, tears, and saliva, but there is no proof that HIV can spread by contact with saliva. Intravenous drug users and persons receiving blood transfusions can be exposed to the virus through infected blood or body products. A baby may become infected during pregnancy, delivery, or when breast feeding if its mother has the disease. A person may carry the virus for months before testing positive and may carry the virus for months or years before any symptoms appear. A person with HIV can still spread the disease even though he or she may appear healthy.

When HIV enters the blood stream it invades and destroys cells in the body's infection and cancer fighting system and reduces the body's ability to fight infections. The HIV virus attacks the immune system, so that infections which one wouldn't normally get (opportunistic infections) start developing, and then the infected person has Acquired Immunodeficiency Syndrome (AIDS). The HIV virus is not what kills a person with AIDS; it is the opportunistic infections which cause death.

BEHAVIORS THAT INCREASE YOUR RISK OF BEING EXPOSED TO HIV:

Recent blood, plasma, or blood product transfusion, intravenous drug use, especially with sharing of needles or syringes, or having sexual contact with someone who: (a) has tested positive for HIV infection, (b) is at risk of infection through his or her own sexual practices, (c) uses IV drugs, or had a recent blood transfusion, (d) uses illicit intravenous drugs, (e) received blood transfusions, plasma, or clotting factor before 1985, (f) within the last twelve months, has more than one sexual partner, especially partners who could be at risk of HIV infection, or (g) is a man who has had sexual relations with another man.

THE HIV TEST AND VOLUNTARY TESTING

The HIV tests are blood tests for the presence of the HIV virus and antibodies to the HIV virus. A positive test result means that you have been exposed to the virus, and either have made antibodies or are infected. It may not mean that you have AIDS now or that you will become sick with AIDS in the future. A negative test means that you are probably not infected with the virus. It takes about 12 days to detect the virus from time of infection to time of detection. Please note, if you do not wish to have your blood tested for HIV, you will not be eligible to donate your baby's cord blood.

CONSENT

Taking the HIV test is voluntary, and results are confidential by law. Results can only be given to people you allow, and a release form must be signed prior to releasing this information. The law requires Celebration Stem Cell Centre to report any positive HIV test result to the Arizona Department of Health or state equivalent if not in Arizona.

I have read the above information and have had my questions about the test answered. I agree to take the HIV test. I allow the test results to be made available to Celebration Stem Cell Centre and to private physician(s):

Dr._____. Physician's Name

_____ _____ Mother Sign Here

Signature of Expectant Mother **Date**

_____ Mother Print Here

Print Name (Expectant Mother)

Person Authorized Pursuant to Law to Consent to Health Care for the Expectant Mother
(if Expectant Mother is a minor or unable to sign)

_____ _____

Signature Date

_____ _____

Print Name Relationship to Expectant Mother

Celebration Stem Cell Centre, LLC
3495 S. Mercy Rd.
Gilbert, Arizona 85297

Celebration Stem Cell Centre

Collection, Processing, Storage and Distribution of Human Umbilical Cord Tissue and Placenta for Medical Research

I. INVITATION AND PURPOSE

You are invited to donate your baby's placenta and/or cord tissue for medical research. You are being invited because you have already agreed to donate your baby's cord blood to Celebration Stem Cell Centre (hereafter CSCC) for patients in need of a transplant. The use of Mesenchymal stem cells found in umbilical cord tissue and use of the placental matrix is a recent advancement in medical research. Mesenchymal stem cells have the capability to become nerve, muscle, cartilage and bone cells. The umbilical cord contains three blood vessels which are surrounded by Wharton's jelly, a gelatin-like substance that contains mesenchymal stem cells. These cells are currently being used to treat sports injuries and diabetic ulcerations of the skin. Recently, these cells have been used to treat serious conditions such as Multiple Sclerosis and Parkinson's disease. The use of placental matrix has also showed positive results in regenerative medicine. Your baby's cord tissue and placenta are normally discarded as medical waste after your baby is delivered.

CSCC gives investigators cord tissue and placental tissue to use in medical research. Although the exact studies for which tissue units may be used is not known at this time, the following are types of uses in which the tissue may be utilized:

- To examine the safety and efficacy of unrelated cord tissue stem cell transplants.
- To evaluate different methods of processing the tissue to produce optimal numbers of stem cells available for stem cell transplants.
- To study other factors that contribute to transplant recipient success (such as growth factors and anti-inflammatory mediators)
- To examine whether the way the cord tissue and placenta is collected, processed, and stored has any effects on survival and complications in transplant recipients.

In addition, researchers may conduct research studies with cord and placental tissue that have had all identifiers removed. In these studies, there will be no way for the tissue to be linked to you or your baby. CSCC may allow researchers to use the anonymous cord and placental tissue for many other kinds of studies. These studies are not limited to the types of studies listed above, or related to transplantation in general. CSCC may charge a fee for service basis for development of diagnostic tests or other products or other research.

II. PROCEDURES

If you agree to donate your baby's cord or placental tissue for medical research, nothing additional is required from you. Your baby's cord or placental tissue may also be frozen and stored indefinitely for possible use in future research studies. Cells from the cord tissue may be grown in the lab so there are more of them that can be used in research studies. DNA, the genetic portion of the cells, may be used in some of the studies.

III. POSSIBLE RISKS AND BENEFITS

There are no physical risks to your or baby by donating the cord or placental tissue to be used in medical research.

There is a small risk that an unauthorized person could find out which cord or placental tissue is your baby's. CSCC has procedures in place to keep your data private. No identifiable information about you will be given to the researchers, nor will it be published or presented at scientific meetings.

You or your baby will not be helped by donating your baby's tissue for medical research. However, this research may help future patients who need a transplant or other medical treatment.

IV. CONFIDENTIALITY

CSCC will not intentionally tell anyone that you donated your baby's cord or placental tissue for medical research. CSCC will make sure no one outside CSCC will know which tissue is yours. Your name or your baby's name or other identifying information will not appear on the umbilical cord or placental tissue unit or on any study records maintained outside of CSCC. Authorized staff from CSCC will have access to your and your baby's personal information. CSCC will not disclose your or your baby's participation by any means of communication to any person or organization, except by your written request or permission, or unless required by federal, state, or local laws, or regulatory agencies. You will not know who receives the umbilical cord tissue stem cells and the recipient of the umbilical cord or placental tissue will not be given the identity of you or your baby.

V. REIMBURSEMENT AND COSTS

You will not be paid for donating your baby's cord or placental tissue for medical research. It will not cost you anything to donate your baby's cord or placental tissue for medical research.

VI. VOLUNTARY PARTICIPATION IN AND WITHDRAWAL

It is up to you if you want to donate your baby's cord or placental tissue for medical research.

If you decide to donate your baby's cord or placental tissue for medical research you may change your mind at any time in the future. If you decide you don't want your baby's cord or placental tissue used for medical research, your baby's cord or placental tissue will be destroyed. This will not affect your relationship with CSCC. Contact CSCC at (480) 722-9963 if you'd like to withdraw.

VII. ALTERNATIVE TO PARTICIPATION

You may choose not to donate your baby's cord or placental tissue for medical research. If you choose not to you can also choose to store the cord tissue privately at your own expense (placental tissue will not be stored) or have the cord tissue destroyed.

VIII. QUESTIONS OR CONCERNS

If you have questions, about donating your baby's cord tissue for medical research contact Lorri Lawson at (480) 722-9963.

You will be given a copy of this consent form for your records.

IX. SUBJECT'S STATEMENT OF CONSENT

I have read this consent form and I have been given the opportunity to ask questions. I voluntarily agree to donate my baby's cord or placental tissue for medical research studies as defined in this consent form.

_____ _____

Subject Signature *Date*

_____

Print Name of Subject

Person Authorized Pursuant to Law to Consent to Health Care for the Expectant Mother (if Expectant Mother is a minor):

_____ _____

Print Name of Authorized Person *Signature of Authorized Person*

_____ _____

Date *Relationship to Expectant Mother*

Based on the information that has been provided to me, I elect the following for my Cord Tissue and Placenta (please select one):

□ I elect to have my Cord Tissue and Placenta processed and cryopreserved at Celebration Stem Cell Centre

□ I elect to have my Cord Tissue and Placenta donated to Celebration Stem Cell Centre for medical research.

Use of an Interpreter: Complete if the subject is not fluent in English and an interpreter was used to obtain consent.

Print name of interpreter: _____ Date: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the subject in _____ (state language) by an individual proficient in English and _____ (state language). See the attached short form addendum for documentation.