

**CELEBRATION STEM CELL CENTRE
PRIVATE CORD BLOOD BANKING INFORMED CONSENT**

1. PURPOSE

I understand the service to be provided by Celebration Stem Cell Centre ("CSCC") is to process and store my child's umbilical cord blood after collection by my obstetrician/midwife or a trained collection specialist as more specifically provided in my Enrollment Agreement with CSCC. Cord blood contains sufficient hematopoietic stem cells (the same type of cells found in bone marrow) that may be used for a stem cell transplant to treat some blood disorders or cancer in a child or an adult. CSCC's service involves the processing and storage of umbilical cord blood as an intended alternative source of stem cells. During pregnancy, umbilical cord blood from the placenta provides nutrition and oxygen to the developing fetus. After the baby is delivered and the umbilical cord is clamped and cut, there is excess blood in the cord and placenta which is routinely discarded. By signing this consent, I agree to the processing and storage of my baby's cord blood by CSCC.

2. YOUR INVOLVEMENT

I understand that my participation in the processing and storage of my baby's excess umbilical cord blood, and my request for CSCC to perform those services is voluntary. The cord blood will be collected by my obstetrician/midwife and separated from the placenta and cord after my baby is delivered. While waiting for the delivery of the placenta, the cord will be cleansed and the umbilical cord vein will be accessed with a needle to a collection bag. The blood remaining in the placenta and cord will drain by gravity into the collection bag. As the blood is draining, the collection should cause no risk to me or my baby. There is no change in the actual delivery process. My obstetrician/midwife can cancel the cord blood collection at any time if he/she thinks it will expose either me or my baby to any added health risk.

I give permission for a CSCC staff member or approved hospital staff member to review my and my infant's medical records. I will answer a detailed questionnaire about my and my baby's medical history, the biologic family's medical and genetic history and exposures to infectious diseases to the best of my knowledge. I also consent to possible follow-up telephone calls and/or mailings from CSCC to clarify and/or verify health information.

I will also donate a sample of my blood (about four teaspoons). My 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 later used to treat my child or other blood relative. Some tests may be investigational and not yet approved by the Food and Drug Administration (FDA). The data collected from performing these tests will be used to establish whether continued testing in the future is needed. My baby's cord blood will also be tested for abnormal hemoglobin, such as sickle cell disease and thalassemia. I consent to CSCC reporting abnormal test results to my obstetrician/midwife or my child's pediatrician. I understand that some test results must, under state law, be reported by CSCC to the Arizona Department of Health. CSCC has an obligation to inform me of an abnormal test result that may affect my health or my baby's health so that I may seek appropriate medical care if necessary. I understand that testing could reveal new information that might not have otherwise been discovered and could potentially impact my or my baby's health care now or in the future. The cord blood unit will be tested for cell viability, total number of cells, stem cell concentration levels, blood type and the presence of bacteria and fungi. A cord blood unit may not be eligible for use in transplantation if the amount of cord blood collected is too small and/or contains too few cells. If the cord blood unit does not meet size or volume criteria for banking, CSCC will contact me as early as possible and provide me with the option to continue with the processing and storage of the stem cells or to terminate the Enrollment Agreement and make the cord blood unit available for research or validation purposes. If I choose, I may also direct CSCC to dispose of the cord blood product and not use it for research. I understand that cord blood must be processed within 48 hours of collection. CSCC will attempt to contact me within 72 hours to provide me with the option to proceed or terminate the services if CSCC believes that the cord blood does not meet the banking criteria, but CSCC does not guarantee that it will receive my instructions in time to process the cord blood. In that event, CSCC may use the cord blood unit for research or validation purposes.

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

3. POSSIBLE RISKS AND BENEFITS

The cord blood is collected after delivery of your baby either while the placenta is still in your body or after it has been delivered. The doctors and nurses have been instructed to never collect the cord blood if the process of collection would expose either you or your baby to any added health risk. There is no change in the actual delivery process. Furthermore, your doctor/midwife can cancel the cord blood collection at any time if he/she thinks it might pose a potential harm to you or your baby.

Blood (about 20 mLs) will be taken from your arm for infectious disease marker tests. This may cause pain, bruising, infection or fainting. The cord blood bank staff may review the hospital medical charts of you and your baby. They will look for prenatal test results including HIV (the virus that causes AIDS), syphilis, and hepatitis tests and other medical information that may be important for determining future use of your baby's cord blood unit.

It is possible that certain medical conditions, which were not apparent at the birth of your baby, may become known to the cord blood bank staff after testing of the cord blood. If they learn about these conditions in the future, they may contact you or your primary

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physician who may then inform you of the test results. If the infectious disease testing performed on your blood shows that you may have HIV (the virus that causes AIDS) or hepatitis, you will be informed by your physician or the cord blood bank personnel of these test results. This may cause you to have to deal with health concerns that may or may not happen in the future. In addition, if required by federal, state or local law, some positive results will be reported directly to your state health department. The medical, genetic, sexual and social history questions that are asked are of a sensitive nature. Answering the questions may cause you to feel uncomfortable.

4. CONFIDENTIALITY

The records maintained at CSCC are kept private and confidential. The security of your and your baby's identifying information at CSCC is verified during periodic inspections. Authorized staff from CSCC will have access to your and/or your baby's personal information. Additionally, authorized CSCC staff, the American Association of Blood Banks (AABB) and the FDA will have access to you and/or your baby's medical charts (i.e., the medical charts maintained on you and your baby as a donor) for inspections or audits. By signing this consent form, you consent to such inspections and to the copying of excerpts from your and your baby's donor medical charts, if required to meet regulatory requirements. CSCC will not disclose any information about you or your baby 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, or except as disclosed in this consent form.

5. OWNERSHIP, TRANSFER AND DISPOSITION

I understand that I hold all ownership rights to the cord blood unit on behalf of my child, as provided in the Enrollment Agreement. If I no longer wish my baby's cord blood unit to be stored, I must provide in writing to CSCC a written request to discontinue service and terminate the Enrollment Agreement. If I terminate the Enrollment Agreement, I have the right to (a) have the cord blood unit transferred to a facility of my choice within 120 days, (b) require that CSCC discard the cord blood unit, or (c) transfer all ownership rights to CSCC. I understand that I am responsible for any expenses for transferring the cord blood unit to another facility, and I will not receive any fee refund if I terminate the Enrollment Agreement after the cord blood unit is processed, as more specifically described in the Enrollment Agreement. Unless I specify otherwise in writing, CSCC will make my baby's cord blood unit available for research or validation purposes upon termination of the Enrollment Agreement. If I request my baby's cord blood unit to be discarded, CSCC will discard the cord blood unit according to approved CSCC standard operating procedures and any applicable laws or regulations.

6. ASSOCIATED COSTS

The initial fee for CSCC's services is \$1,975.00. This fee includes the cord blood collection kit, all transportation and courier fees, cord blood processing, testing, cryopreservation and first year storage. An additional storage fee of \$125.00 will be charged annually, beginning one year after the date of initial cryopreservation and subsequent years until the Enrollment Agreement is terminated as more specifically described in the Celebration Stem Cell Centre Enrollment Agreement and Private Banking Enrollment Form. Additional fees will apply if banking for multiple births. I agree to pay CSCC all fees as described in the Private Banking Enrollment Form and I understand that CSCC may terminate its services if I fail to make any payment within 60 days after a payment due date.

7. QUESTIONS OR CONCERNS

If you have any questions or concerns about your relationship with CSCC you may contact CSCC's Laboratory Director or Medical Director at 1-877-522-2355.

8. STATEMENT OF CONSENT

YOUR SIGNATURE BELOW INDICATES THAT YOU HAVE READ THIS CONSENT FORM, YOU HAVE BEEN PROVIDED INFORMATION CONCERNING THE RISKS, BENEFITS, AND ALTERNATIVES TO CORD BLOOD DONATION AND YOU HAVE BEEN GIVEN THE OPPORTUNITY TO ASK QUESTIONS AND YOUR QUESTIONS HAVE BEEN ANSWERED SATISFACTORILY. YOU AGREE TO THE TERMS AND CONDITIONS OF THE SERVICE.

Signature of the Mother on behalf of her baby as Donor

Date



Print Name of Mother

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

Signature

Date

Print Name

Relationship to Expectant Mother

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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: _____

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 addendum for documentation.

Certification of Physician/Hospital/Birthing Center Staff

I hereby certify that the nature and purpose, the potential benefits, and possible risks associated with the collection, processing, storage and use of cord blood banking have been explained to the above individual and that any questions about this information have been answered.

Counseling Healthcare Professional

Date

