

## 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.

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### III. *POSSIBLE RISKS AND BENEFITS*

There are no physical risks to you or your 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.

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**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.