Dental Pulp / STEM CELL BANKING REGISTRATION FORM

Client Information			
First Name:	Last Name:	Middle Initial:	
Home Address:		Apt/Unit #:	
City:	State:	Zip Code:	Country:
Phone:	Secondary Phone:		
Email Address:	Date of Birth:		
Emergency Contact Name:	Phone Number:	Relationship to Client:	

Healthcare Provider			
Medical Facility Name:	Healthcare Provider Name:		
Address:	Phone:		
City:	State:	Zip:	Country:

I, Client, understand that adipose tissue is for autologous use only: _____

Client Name (Please Print)

_____

Client Signature

_____

Date

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

Dental Pulp Banking Enrollment Agreement

This Enrollment Agreement (this "Agreement") sets forth the terms and conditions regarding the processing and storage of your dental pulp stem cells by Celebration Stem Cell Centre ("CSCC"). Dental Pulp will be collected by your physician using methods approved by CSCC's Medical Director.

I agree to pay CSCC the initial fee and the annual storage fees as more specifically described in the Dental Pulp Banking Enrollment Agreement attached hereto and by this reference made a part of this Agreement.

I understand that I may terminate this Agreement for any reason by providing CSCC a thirty (30) day notice in writing with a ("Termination Notice"). I agree to continue to pay the banking fees until the transfer of my dental pulp stem cells. Upon my termination of this Agreement, I understand that I have the right to have the dental pulp stem cells transferred to a facility of my choice within 120 days after CSCC's receipt of my Termination Notice. I understand that I am responsible for any expenses incurred by CSCC for transferring the dental pulp stem cells to another facility. I understand further that if I terminate this agreement after CSCC processes the dental pulp stem cells, I will not receive a refund of any fees paid to CSCC under this Agreement, but that I will have no further liability after the date this Agreement terminates for future processing and/or storage fees.

I understand that any unpaid fees after 30 days wills accrue interest on a daily basis rate of 18% per annum from the due date. I understand that if I fail to pay CSCC any fees within sixty (60) days of the payment due date, CSCC may immediately terminate this agreement. Upon termination of this agreement for non-payment, all ownership rights to the adipose tissue and/or stem cells shall be transferred to CSCC. Neither CSCC nor I will have any continuing obligations to the other after termination of this Agreement, except as specifically provided in this Agreement.

If the dental pulp stem cells are collected and delivered to CSCC, CSCC agrees to use the proper and customary care under standard processing and storage protocols.

I understand that CSCC shall not be held responsible for damage or loss of the dental pulp stem cells due to acts of terrorism, civil strife, war, national emergency or acts of God. CSCC will not be liable for anything beyond its direct control including but not limited to: loss by a courier, contamination, accidents in shipment, misuse, untimely use, incorrect preparation at other premises, or any other conditions that prevent CSCC from complying with its standard operating procedures and policies. CSCC shall not be liable for any incidental or consequential damages resulting from loss or damage of the dental pulp stem cells. In any event, I agree that CSCC's liability shall be limited solely to a refund of the fees paid for processing and storage of the dental pulp stem cells.

I have read this Enrollment Agreement and hereby enter into this contractual relationship for the processing and storage of my dental pulp stem cells with Celebration Stem Cell Centre. I have selected the desired payment plan and understand the option to prepay the annual storage fee as listed below on the "dental pulp Banking Enrollment Agreement". I have read and understood all of the terms in this Agreement, the consent documents listed on page one of this agreement and health history

questionnaire. I certify that all of the information I have provided to CSCC is true and correct to the best of my knowledge.

I understand that this Agreement and the legal relations between the parties shall be governed by, and construed and enforced in accordance with, the substantive laws of the State of Arizona, without regard to conflict of laws principles. Any action brought to enforce the terms of this agreement must be commenced and maintained in the appropriate state or federal court in Maricopa County, Arizona. This Agreement shall be binding upon, and inure to the benefit of, the parties and their heirs, fiduciaries, successors and assigns. If any provision of this Agreement, or the applicability in any provision to a specific situation, is held to be invalid or unenforceable, the provision shall be modified to the minimum extent necessary to make it or its application valid and enforceable, and the validity and enforceability of all other provisions of this Agreement and all other applications of such provisions will not be affected by any such invalidity or unenforceability.

_____

Print Client's Full Legal Name

_____

Signature of Client

_____

Date

Service Plan

Isolated and Cryopreserving Stem Cells
Stem Cells shall be isolated using a proprietary method that is currently considered to be "minimal manipulation". (1-4 teeth shipped together).
$650.00

****Collection kit ($250.00 non-refundable)**

Annual Storage Fee: $150.00 Per Year

Credit Card Authorization: I hereby authorize Celebration Stem Cell Centre to charge the following credit card account according to the plan(s) selected above. I understand that I am responsible for recurring charges and additional late fees if my credit card is cancelled or otherwise not available for payment.

□ **Visa** □ **Master Card** □ **American Express** □ **Discover**

_____ _____ _____

Card Number 3 Digit Code Expiration Date

_____

Authorized Signature Today's Date

_____

Name as it appears on the card

_____

_____

Billing Address

CELEBRATION STEM CELL CENTRE

DONOR INFORMATION AND HEALTH HISTORY QUESTIONNAIRE

NAME:	LAST 4 DIGITS OF SOCIAL SECURITY NUMBER:
ADDRESS: APT #:	CITY: STATE: ZIP CODE:
HOME PHONE: WORK PHONE:	EMAIL:
BIRTH DATE:	

PHYSICIAN NAME:	CLINIC NAME:
PHONE:	CLINIC ADDRESS: CITY: STATE: ZIP CODE:

RACE AND ETHNICITY INFORMATION

ETHNICITY: RESPONSE IS REQUIRED, PLEASE CIRCLE ONE. **HISPANIC OR LATINO** **NOT HISPANIC OR LATINO**

Race: Response is required. Of which group(s) are you 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	

Please read the following Health Questionnaire ***carefully***. You may contact Celebration Stem Cell Centre if you need help understanding any of the questions. Our toll-free number is 1-877-522-2355.

Completion of all the requested information on the health questionnaire is required before Adipose tissue/stem cell unit can be eligible for use. The questionnaire should be filled out privately by the patient only or in a private interview by an approved screener. Your answers to these questions are confidential. Please refer to Celebration Stem Cell Centre Notice of Privacy Practices included in this packet.

My signature below confirms that the information provided on this document is true and accurate to the best of my knowledge.

SIGNATURE: _____**DATE**:_____

Dental Pulp Stem Cell Informed Consent Form

TITLE: Collection, Processing, and Storage of Dental Pulp Stem Cells

PROTOCOL NO.: None

SPONSOR: Celebration Stem Cell Centre

SITES: 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

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

- Being in a 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
4. The possible risks to you
5. Other options you could choose instead of being in this study
6. How your 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 invites you to participate in a research study that has potential importance to you. The study will take place in several 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 treatment or procedure to you that are not currently known or are not foreseeable.

Although hundreds of dental pulp stem cell samples have been collected and stored, the process of banking Dental Pulp Stem Cells is not yet licensed by the US Food and Drug Administration (FDA) and is therefore considered experimental. This is a relatively new technology and it is currently being studied in numerous clinical trials to determine the safety and efficacy of using Dental Pulp Stem Cells for Regenerative Medicine Applications.

Purpose

The purpose of this document is to inform you about a program to collect human dental pulp stem cells and to request your participation in this study. If you decide to participate in this study you must provide us with your written, informed consent. It is important that you understand the meaning of each and every part of this document before deciding whether or not to sign it. If there is anything in this document that you do not understand, you should ask that the point be clarified. You have the right to change your mind about participating in the study, and you may revoke consent even after you have given it.

In the pulp chamber of teeth resides a unique population of stem cells referred to as Mesenchymal Stem Cells (MSCs). MSCs have the capability to differentiate (mature) into several types of mature cells including bone, muscle, nerve, fat and connective tissue. Based on the unique capabilities of these cells, they have the potential to be used in numerous Regenerative Medicine Applications. When a child's tooth becomes loose, or the removal of teeth for an Orthodontic procedure (the removal of wisdom teeth) tissue inside the tooth contains a population of stem cells that can be harvested and banked. Normally this "left-over" material is treated as medical waste and discarded. Celebration Stem Cell Centre is asking you to participate in this program where you will bank your child's dental pulp stem cells which will potentially be used to treat him/her in the future or be used for research purposes. Your decision to bank these cells is completely voluntary.

The collection of the dental pulp takes place after your child has a tooth removed. **The collection of the dental pulp will not place either your child at risk of injury. However, your child may feel some minor discomfort from the tooth removal**.

Your Dental Practitioner has your child's health as his/her primary concern and will not collect the dental pulp if he/she feels like it may interfere with either individuals' health or well-being. The tooth/teeth that are extracted will be sent to the Celebration Stem Cell Centre in Gilbert, Arizona where

it will be tested, processed and frozen. You will be asked a series of questions about your child's health history. 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 dental pulp. You and your child's identity and the answers to these questions will be kept confidential to the fullest extent allowed by law. While Celebration Stem Cell Centre has to maintain a link between your child's dental pulp and information identifying you, this will be protected by multiple levels of security.

PROCEDURES

If you agree to bank your child's dental pulp stem cells, you will be agreeing to the following:

1. Filling out a Questionnaire – with 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). The questionnaire will take about 30 minutes to complete. This questionnaire will be confidential. It is extremely important to be honest. If you do not wish to complete this questionnaire, you will not be permitted to bank your dental pulp stem cells.
2. The shipping of the extracted tooth/teeth – to Celebration Stem Cell Centre where it will be processed, tested and stored under cryogenic conditions.
3. Allowing the review of your medical charts – These records will be kept confidential.

Foreseeable Risks/Discomforts

Tooth/Teeth Extraction –in order to collect the dental pulp stem cells, the tooth/teeth need(s) to be extract by a dental professional. This is also the case for milk/baby teeth. Extraction once the tooth becomes loose is important because if you wait for the too to fall out, the blood supply to the dental pulp is lost and the tissue will die. There will be some discomfort associated with the tooth extraction, but typically this is diminished due to the use of a local anesthesia.

Compensation For Injury - Immediate necessary care would be available at the dental professional where you will be having the tooth extracted should you be injured from participating in this program. However, there is no provision for free medical care or for monetary compensation for such injury.

Alternative Procedures – you may elect not to allow collection and storage of your child's dental pulp stem cells. In that case, the tooth/teeth will be discarded as is normally done.

Cost/Reimbursement – You will not be paid for donation of dental pulp stem cells.

Source of Funding – Celebration Stem Cell Centre's public cord blood bank is funded by Celebration Stem Cell Centre's private bank and by the owners of Celebration Stem Cell Centre.

Costs of this Program – there are costs associated with participating in this program. Please refer to the enrollment documents for the costs of participating in this program

Confidentiality

Your participation in this study will be kept strictly confidential and the results will be only available to the Investigators carrying out this program and authorized representatives of regulatory activities. It is a 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 Celebration Stem Cell Centre to check the information collected for this program. 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 Celebration Stem Cell Centre policies, which are in compliance with HIPAA. Records that identify you, including your medical record number, 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)
- Celebration Directors and Lab team
- Regulatory officials

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

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 bank your dental pulp stem cells.

You have the right to review or copy your information.

You may withdraw or revoke your permission to release your or your baby's health information, but this permission will not stop automatically. To withdraw your permission to use and disclose your health information, you must send written notice to Celebration Stem Cell Centre. If you withdraw your permission, no new health information identifying you 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.

Questions About Research or Subject's Rights

At any time, you are permitted to and are encouraged to ask the dental professional 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.

Voluntary Participation

Your decision to participate is voluntary and you are free to withdraw from the program 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 Celebration Stem Cell Centre 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 your physician 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 program, you will continue to receive your usual medical care. If you withdraw from the study after your dental pulp stem cells that have been sent to Celebration Stem Cell Centre, 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 dental professional feels at any time that continued participation is not in your best interest, they may decide not to extract the tooth/teeth.

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 program. At the discretion of your doctor(s) and Celebration Stem Cell Centre you may be asked to sign a revised informed consent or consent addendum that provides this information.

You understand that you may ask questions at any time about this study. If you feel that you have experienced an adverse reaction to the tooth extraction procedures, you should call Celebration Stem Cell Centre at 480-722-9963.

Signatures

I have discussed the collection of my child's dental pulp stem cells 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 program is voluntary. 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 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/Parent or Guardian _____ (Print Name)

_____ _____ (Date)

(Signature)

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.

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

_____ _____

Printed Name of Person Conducting The informed Consent Discussion

Position

_____ _____

Signature of The Person Conducting The Informed Consent Discussion

Date