

NEW ENGLAND CRYOGENIC CENTER RESEARCH CONSENT FORM

**Project Title: Somatic Cell Donation for Stem Cell Research:
Hospital and Dental Donation Plan**

Principal Investigator: _____, PhD

Participating Institution: _____ Cryogenic Center,

PROJECT INFORMATION

You are being asked to donate cord blood, umbilical cord, placental samples, follicular tissue, dental samples, or adipose (fat) tissue to create cell lines for human stem cell research project led by _____, PhD at _____ Center. These samples could be donated or sold to other institutions for further research not explained in this consent. If you agree to the donation and it is sold, your name and any identifiers will not be sent with the sample. You are being asked to participate in this project because samples you may donate could lead to potential treatments using stem cells. The purpose of this project is to collect adult stem cells that can be grown to create more stem cells.

Adult stem cells can be found in many organs and tissues within the human body. These stem cells have the potential to turn into many kinds of specialized human cells, such as liver cells, heart cells, pancreatic cells, or nerve cells. For this reason, adult stem cells can be used to study, and possibly one day help treat, diseases or injuries that have caused patients' specialized cells to die or become damaged – diseases and injuries such as Parkinson's disease, heart disease, diabetes, and spinal cord injury.

Cryogenic Center wants to collect cells from umbilical cords or new human adult stem cells from tissues that are normally discarded in medical or dental treatments. To do this, researchers will put the cells into specialized growth conditions in order to expand (grow) the numbers of cells into large quantities. If successful, this process, called cell culture expansion, can generate stem cells in very large numbers that contain stem cells which have the same DNA as the cell donors. In the future, this may be used to create a person's cells that could improve or cure a medical condition.

For reasons of safety, you should not donate if:

- You know, or think that you might be infected with hepatitis B or hepatitis C.
- You know, or think that you might be infected with HIV – the AIDS virus
- You have a sexual partner who is infected with hepatitis or HIV
- You are unwell at the moment

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- You are anemic or receiving treatment for anemia or iron deficiency
- You are, or may be, pregnant

VOLUNTARY CHOICE

Donating your cells for this research project is completely voluntary. You have the right to agree or to refuse to provide your tissue or cells for this project. The quality of your current or future medical care and your relationship with your doctor or the hospital or institution where the samples were obtained will NOT change in any way whether you agree or refuse to provide any cells for this research project.

WHAT IS THE PURPOSE OF THIS CONSENT FORM?

Study staff is authorized to give you information and to answer your questions about this research project. It is very important that you have a detailed conversation with this person so that you can make a careful, voluntary decision about whether or not you want to donate your cells for this research project.

Your signature on the last page of this consent form is meant to show that you have had this conversation and that you freely agree to donate your cells for this research project. This consent form must not replace actually having this conversation, so be certain you have this conversation and ask as many questions as needed for you to understand what you are agreeing to do.

Please take as much time as you need to ask questions and to talk about this project with your family or friends before you decide whether or not to sign this consent form. You may take this form home with you before you decide what to do. Do not sign this form if you feel pressured in any way by any person to donate your cells for this project. This must be your own decision, not someone else's.

WHAT WILL HAPPEN TO MY CELLS?

It is the intent of Dr. _____ and _____ Cryogenic Center that when the cells are sold, none of the cells you provide will be used in unethical or controversial research such as human cloning or be used in unlicensed or untested medical treatments. These stem cells are for research purposes only. Care will be taken when choosing the institutions that request them. However, once sold, this cannot be guaranteed. It can be guaranteed that your name and any direct identifiers will not be sent along with the cells derived from your tissue samples.

Researchers at _____ Cryogenic Center will only use your cells in relevant scientific experiments either under in vitro conditions (out of body) or using experimental animals. Once the stem cells are collected from the tissue of origin, any remaining tissue

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will be destroyed. These stem cells may also be stored at very low temperatures for future research purposes.

There is no guarantee that viable (able to be used) stem cells will be isolated from your cells. There is no guarantee that researchers will be able to get stem cells from any donated tissue. Researchers will routinely discard as medical waste cells or tissues they do not use for this research project.

WHAT WILL HAPPEN TO THE COLLECTED STEM CELLS?

It is likely that the retrieved stem cells, which would be genetically matched to you, will be stored for many years. Adult stem cells have the ability to self-renew (multiply) for extended periods of time, and they are likely to be used by researchers at other institutions and for many other research purposes.

One possible research use of these stored stem cells might involve changing some of their genes. Another possible research use might be to study some of the stem cells by placing them into laboratory animals. In addition, the stored stem cells might be used in the future for new research related to human stem cell transplantation. These are just three common examples of what might happen to the stored stem cells. But there are many other future possible research uses that are simply unknown at this time.

You will have no say as to which institutions or researchers may share the stem cells isolated from your tissue that were expanded in cell culture. Stem cell transplantation studies may be developed in the future; your stem cells may be used to develop such procedures. Any stem cells grown from your tissues will only be used for research.

Cryogenic Center will not provide your stem cells for clinical use. For example, none of your stem cells will ever be transplanted into any other person for treatment of any disease.

Future uses of stored stem cells must be approved by local ethical and scientific review committees to make sure that they are used in scientifically, ethically, and legally appropriate ways. Please contact the individuals listed on the last page of this form if you have any questions or concerns about the future possible uses of the stem cells collected through this research project.

HOW WILL MY CELLS BE COLLECTED?

Cord Blood: Following birth of the child and expulsion of the placenta (afterbirth) the placenta is elevated and a needle attached to a syringe is inserted into the umbilical vein. The cord blood is collected into the syringe by gravity. The cord blood is then inserted into a sterile collection bag, packaged into a transport box and sent by courier to the New England Cryogenic Center Laboratory.

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Placenta and Umbilical Cord: The placenta and attached umbilical cord are placed into a tissue bucket which is then sealed and sent by courier to the _____ Cryogenic Center Laboratory.

Teeth and Follicular Tissue: Follicular tissue is the sac that surrounds molars and can be easily isolated after wisdom teeth extraction. It is a rich source of stem cells. Following extraction of teeth and or removal of follicular tissue that only occurs during treatment under the care of a dentist, teeth or follicular tissue is placed into a vial containing sterile transport media and sent by courier to the New _____ Center Laboratory.

Adipose Tissue: Adipose or fat tissue can be readily obtained through liposuction, and is a very rich source of stem cells. Plastic surgeons may perform elective liposuction in a hospital or outpatient setting. The fatty tissue obtained from the liposuction procedure would normally be discarded. If donated for this study, the tissue would be placed into a sterile tube and sent by courier to the _____ Cryogenic Center Laboratory.

I am agreeing to donate: _____ **tissue.**

With your approval, your stored sample will be transferred by the site or institution where it was collected to the research team at _____ Cryogenic Center.

WHAT IF I CHANGE MY MIND?

You may withdraw your consent for whatever reason at any time before your cells are isolated for this project.

However, once the resulting stem cells have been isolated (separated out) following the tissue collection process, you will not be able to change your mind or request that any of the collected stem cells be removed from this research project. These cells will be identified only by a unique code number which can only be linked back to you by a key to unlock the code which is held in a locked file under the control of Dr. _____ or the study coordinator. This is to maintain your privacy and confidentiality.

If you decide to withdraw your consent after you have signed this form, please contact any of the individuals listed at the end of this document immediately.

WHAT ARE THE ALTERNATIVES TO DONATING MY CELLS FOR THIS PROJECT?

One of your alternatives is to refuse to participate at all in this research project.

In the case that your cells are collected but you decide not to participate any longer in this research project and your cells have not been isolated, you may (1) have your cells discarded according to the routine practice of the site or hospital where they were collected (2) donate your cells to another research project, or (3) if they are cells to be saved only for you, return your cells or tissue to storage.

WHAT ARE THE POTENTIAL BENEFITS OF DONATING MY CELLS FOR THIS PROJECT?

This research project is not intended to provide any direct medical benefit to you or anyone else. You would be donating your cells only for the advancement of this research project and stem cell research in general.

The stem cells that are collected from the resulting tissues may have significant commercial potential in the future. However, by signing this form you understand that there are no plans for you to receive any direct financial benefits from any future commercial development and scientific patents of discoveries made through the use of these stem cells.

WHAT ARE THE POTENTIAL RISKS OF DONATING MY CELLS FOR THIS PROJECT?

There are no foreseeable physical risks for you in donating cells for this research project. Any donated tissue would generally be discarded as medical waste.

Donating cells for this project involves some risk to your privacy. Efforts to protect you against this risk are discussed in the next section.

HOW WILL MY PRIVACY BE PROTECTED?

The records of your involvement with this research project will be kept confidential. **However, confidentiality cannot be absolutely assured.**

Identification codes will be used instead of donors' names, and all records will be kept in a private database or file that can only be accessed by Dr. . Under no circumstances will the donor's identity, medical information or any other information which could be used to identify the donor be seen by anyone except the principal investigator. This information is kept under strict security. Technical staff working with these cells will only have access to a unique identifier.

If your cells are used to create tissues such as bone, cartilage, muscle or nerve, then the resulting stem cells and any new tissues that they produce will be a complete genetic match to you. To protect your genetic privacy, only the identification code, not your

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name, will be provided to the researchers who may receive the stem cells from the resulting tissues and the researchers who may later work with the resulting stored stem cells. The results of any tests on the tissue/cells will also be confidentially handled through the use of identification codes instead of names.

Local and other regulatory agencies such as the US Food and Drug Administration (FDA), monitors, auditors, institutional review board (IRB), (which is a committee that has reviewed this research study to help ensure that your rights and welfare as a research participant are protected and that the research study is carried out in an ethical manner), and project sponsors and funding agencies may review the research project records to ensure that your rights as a cell/tissue donor were adequately protected. However, your identity will not be readily discoverable by these individuals. They can request to see your names if it is necessary, however.

Any report that the researchers publish will not include any information that will make it possible for readers to identify you as a cell/tissue donor.

WILL I RECEIVE PAYMENT?

You will not receive any cash or payment with goods or services for the cells/tissue you donate to this research project.

DISCLOSURE OF RESEARCHERS' POTENTIAL FINANCIAL INTERESTS

In addition to their scientific interests in this research project, the individuals conducting this stem cell study might profit financially from the research. There may be current or potential financial benefits to the Principal Investigator, the sponsor, the participating institution(s) and their staff, and other research institutions or researchers arising from discoveries made through this research project and the stem cells collected from the resulting tissues. If you have any questions or concerns about these matters, please contact the persons listed below. The principal investigator, study coordinator and technical staff have no ownership in [redacted] Cryogenic Center, and are solely employees or consultants to this company.

It is important that your treating physician inform you of any personal benefits he or she may gain by your agreement to donate your cells for this research project.

The person who has been authorized to provide you with information may also have a personal vested interest in this research project. You can ask this person to disclose his/her financial interests.

CONTACT INFORMATION

If you have any questions about this research project, contact:

Principal Investigator: _____, PhD at (_____)

Study Coordinator, _____ (_____)

Quality Manager, _____ (_____)

For those participating from Brockton Hospital:

If you have any questions about your rights as a research subject, or complaints regarding this research study, you should call _____, R.N., Chief Nursing Officer (main number, _____). Signature Healthcare Brockton Hospital Institutional Review Board is an independent committee established to help protect the rights of research subjects.

If you have any questions about your rights as a cell/tissue donor and research participant, you may also contact:

Liberty IRB at _____ or in writing at _____

SUMMARY

- 1. The cells or tissues that are being removed during your procedure would normally be thrown away. If you want to, you can donate them to a research project.**
- 2. There is no additional treatment or procedure, no pain or injury if you decide to donate your cells or tissues.**
- 3. You, your family, or your doctor or dentist will not be receiving any money or gift for your participation.**
- 4. Your name will be kept secret if you participate.**
- 5. You do not have to participate. You can say no, and there is no problem if you don't want to donate your discarded cells or tissue. No one will be angry if you do not donate your cells or tissue.**
- 6. IF YOU DO NOT WANT TO DONATE YOUR CELLS OR TISSUE, DO NOT SIGN THIS CONSENT. JUST GIVE IT BACK TO YOUR DOCTOR, DENTIST OR THE NURSE WHO GAVE IT TO YOU.**
- 7. If you want to donate your cells or tissue, go to the next section, Consent and Signature.**

CONSENT AND SIGNATURE

Please read the statements below, think about your choice, and sign if and when you are ready to agree, or take this form home and discuss it with anyone you wish to and then return it to us later if you wish to participate in this research:

The study staff has fully explained to me the nature and purpose of this research project in a way that I have understood.

I have been encouraged to be actively involved during the information interview and have been given responses to my questions and concerns in a satisfactory and respectful way.

I have been offered opportunities to consult with an independent person whom I trust, including a counselor or a physician, before making my decision and have been given adequate time to decide.

I hereby give my voluntary consent to donate my tissue or cells for the research project conducted by **Grace M. Centola, PhD** at **New England Cryogenic Center**. I have been told I will receive a signed and dated copy of this consent.

	Date: _____
Signature of Cell Donor	Printed Name
	Date: _____
Signature of Parent or Legal Guardian If Cell Donor is a Minor or Decisionally- Incapacitated	Printed Name
	Date: _____
Signature of Person Obtaining Consent	Printed Name

Signed and dated copy given to donor: _____ Yes

Copy given to parent or legal guardian (if applicable): _____ Yes