

ESSCB MODEL RESEARCH INFORMED CONSENT FORM
Somatic Cell Donation for Human Embryonic Stem Cell Research

<p>Project Title:</p> <p>Principal Investigator:</p> <p>Participating Institution(s):</p>
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Note: This form is intended as a model only and not as a comprehensive legal document. Legal counsel should be consulted to ensure compliance with applicable federal and state law and regulation, including, without limitation, relevant laws on human subjects research, privacy, genetic testing, and tissue banking.

Note: This form is intended only to address the collection of somatic cells for the purpose of human embryonic stem cell research, rather than for the purpose of creating induced pluripotent stem cells (iPS cells).

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PROJECT INFORMATION

[Name of principal investigator] is conducting a human embryonic stem cell research project at **[name(s) of institution(s)]**. **[He/she]** is asking whether you would consent to providing **[type of cells]** for the purpose of the research about **[identify medical condition being investigated]**.

Embryonic stem cells can be found in human embryos around the fifth day of development. These stem cells have the unique ability to turn into any of the many kinds of specialized human cell, such as liver, heart, pancreatic, or nerve cells that make up the human body. For this reason, embryonic stem cells can be used to study, and possibly one day help treat a range of diseases and injuries such as Parkinson's disease, heart disease, diabetes, and spinal cord injury.

In order to collect new human embryonic stem cells for this research project, embryos will be created with the **[insert type of somatic cells]** provided. Stem cells then will be collected from the embryos and will be used to create a stem cell line. The embryos will be destroyed when the stem cells are collected.

To do this, researchers will put the nucleus – the part of the cell with the genetic material – of **[insert type of somatic cell]** into an unfertilized egg that has had its nucleus removed. If successful, this process would create embryos that are genetically matched to the donor of the **[insert type of somatic cell]**. Stem cells from these embryos would also match the donor. This process is called **Somatic Cell Nuclear Transfer**.

Embryos will not be used to create a pregnancy, and will not be allowed to develop beyond 14 days.

[Insert additional information about this project using very simple language.]

INFORMED CHOICE

Providing cells for this research project is completely voluntary. You have the right to agree or decline to provide your **[insert type of somatic cells]** for this project. The quality of your current or future medical care will NOT change in any way as a result of your decision, no matter what you decide to do.

[Name of person presenting information and answering questions, who should have no vested interest in the research protocol, whenever possible], 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 decision about whether or not you want to provide cells for the project. This discussion is meant to provide an opportunity for you to think about your decision in consultation with a knowledgeable person.

The informed consent document you are holding in your hand is meant to serve only as a guide for a discussion between you and **[name of person presenting information and answering questions]**. This consent form must not replace actually having a conversation with **[him/her]**.

Please take as much time as you need to ask questions and to talk about this project with **[name of person presenting information and answering questions]** and with people close to you and/or your personal physician. You may take this form home with you before you decide whether to sign it. You should not sign this form if you feel pressured in any way to provide cells for this project. This must be your own decision, not someone else's.

Your signature on the last page of this consent form is meant to show that you have had a conversation with **[name of person presenting information and answering questions]**, reviewed this informed consent form, and that you freely agree to provide your **[insert type of somatic cells]** for this research project.

HOW WILL MY [insert type of somatic cells] BE COLLECTED?

In order to provide **[insert type of somatic cells]** for stem cell research, you must first undergo medical testing to screen for genetic conditions and infectious diseases. The term "genetic" is used to describe characteristics that are passed on in families from parents to offspring through their genes. For these tests, your blood will be drawn and screened for specific conditions. **[Specify here or in a separate form which tests will be conducted and whether the participant will have access to these test results.]**

[Insert in simple language a description of the techniques that will be used to harvest the somatic cell(s).]

[As applicable: With your approval, your stored **(insert type of somatic cells)** sample will be transferred by **(name of institution)** to the research team.]

WHAT ARE THE POTENTIAL RISKS OF DONATING MY [insert type of somatic cells] FOR THIS RESEARCH PROJECT?

[As applicable: Beyond those associated with medical screening, there are no foreseeable physical risks for you in donating **(insert type of somatic cells)** for this research project **OR insert description of foreseeable physical risks of the donation process.]**

However, there are some psychological risks involved in providing cells for this project, possibly related to the screening process or your decision to participate. For example, a screening test could uncover a medical or genetic condition that you are currently unaware of, which may have an unexpected or undesired emotional impact. If you experience any emotional effects that cause you concern, please contact the persons listed below.

It may not be possible to determine how or whether you will experience psychological risks, but care will be taken to help minimize them. Counseling services will be made available to you to help address any concerns you may have as you decide whether or not to participate in this research project. **[Specify whether counseling services will be automatic or provided upon request, and whether associated expenses will be covered.]**

WHAT ARE THE POTENTIAL BENEFITS OF PROVIDING CELLS FOR THIS PROJECT?

This research project is not intended to provide any direct medical benefit to you or anyone else; however, this research may potentially benefit patients in the future. The cells provided to this project might advance the important research goals discussed above, as well as stem cell research in general. **[Insert details about potential general benefits and research goals of this project.]**

WHAT WILL HAPPEN TO THE [insert type of somatic cells]?

Researchers will only use your **[insert type of somatic cells]** to create embryos from which they will attempt to get stem cells before the 14 day limit. The resulting embryos will be destroyed during the stem cell collection process.

None of the **[insert type of somatic cells]** you donate will be used to produce a pregnancy. And none of the resulting embryos will be allowed to develop for more than a total of 14 days after they have been created using nuclear transfer. If any of the resulting embryos are frozen, then the time that they remain frozen is not counted as part of the 14 day limit.

Embryos created from donated cells may be stored in a tissue bank or other licensed storage facility until they are transferred to researchers.

There is no guarantee that embryos will be created successfully from your cells, or that researchers will be able to get stem cells from any resulting embryos. Researchers will discard any unused cells or embryos according to routine lab practices.

WHAT WILL HAPPEN TO THE COLLECTED STEM CELLS?

The stem cells that are collected for this research study will be used to **[provide details about the purpose of the research study, including, but not limited to, the type of disease or condition being studied the procedures involved in the research, and the potential of any possible discoveries].**

After the stem cells are used for this research project, it is possible that the retrieved stem cells will be stored for many years in a cell bank. Cell banks are useful because they allow the sharing of stem cells and other biologic materials with researchers at other universities, hospitals, research institutes, and companies around the world. You should

also be aware that embryonic stem cells have the ability to renew indefinitely, and it is very likely that these cells will be stored for many years. Thus, researchers across the US and in other countries may utilize the collected stem cells and their associated materials in future research in ways not described here. Future uses of the stem cells will be explained further in the following section of the form titled “FUTURE RESEARCH USE(S) OF THE STORED STEM CELLS.”

FUTURE RESEARCH USE(S) OF STORED STEM CELLS

[As applicable: The stem cells collected in this research project may be stored and used in the future by researchers at other institutions and for other research purposes that are not described here. You will not be able to control which institutions or researchers may use the stored stem cells. There are many possible research uses (**insert examples of future uses**), some of which may reveal genetic information. Future uses of stored stem cells must be approved by local ethical and scientific review committees to ensure that they are used in scientifically, ethically, and legally appropriate ways.]

[As applicable: If stem cell transplantation studies or treatments are developed in the future, you will have no say as to who may be a transplant recipient of the stem cells (**as applicable:** except in the case of autologous transplantation).]

If there are specific research uses of the stem cells that you find objectionable, you should discuss those objections with **[name of person providing information to you and answering your questions]**. **[He/she]** may be able to provide you with assurances that such research will not be conducted on stem cells derived from your cells in this research study. It is important to understand that any restrictions may be limited to the initial use of your cells, since no one can guarantee that future researchers will adhere to these restrictions. Please express any concerns you have about the possible future uses of the stem cells collected through this research project now, and in the future you may contact the individuals listed at the end of this form if you have any questions or concerns.

If you are not comfortable with the idea that stem cells derived from the cells might be used in the future in ways unknown to you, then you should not agree to donate cells for this research study.

WHAT ARE THE ALTERNATIVES TO PROVIDING CELLS FOR THIS PROJECT, AND WHAT IF I CHANGE MY MIND?

One alternative to providing cells for this research is to decline to participate at all in this research project.

If you provide consent to donate cells for this research project, you may withdraw your consent for whatever reason at any time until the cells have been used in the research, as long as the information linking your identity to the cells has not been removed. The research process may be considered to be underway once the cells have been used to create an embryo or have been otherwise prepared for research. If you decide to

withdraw your consent prior to that time, please contact any of the individuals listed at the end of this document immediately.

In the event that you decide not to participate in this research project after your cells have been donated but before they are used in the research, you may: (1) have them discarded according to the routine practice of **[name of institution]** and applicable law, (2) donate them to another research project, [or (3) **as applicable**: return your **(insert type of somatic cell)** sample to storage]. **[As applicable: include any other disposition options available at the cell donation site.]**

You will not be able to request that the collected stem cells be removed from this research project or otherwise recalled once the stem cells have been derived from the embryos.

Any financial implications of deciding to terminate participation in this research project after cell extraction but prior to usage will be explained further in the section of the form titled “WILL I RECEIVE PAYMENT?”

WHAT WILL HAPPEN IF I DEVELOP A RESEARCH-RELATED INJURY?

Medical costs associated with the collection and donation of your cells will be covered by **[insert details of medical coverage]**. If a physical injury results, now or in the future, from the donation process, we will **[arrange for health care by an independent provider/reimburse for health care expenses]** to treat those injuries. You will not be responsible for these costs. Whether the injury is caused by the research project will be determined by **[insert details about the responsible party/process in place to make this determination]**. If you have any questions or concerns or would like more information, please contact the persons listed at the end of this document.

WILL I RECEIVE PAYMENT?

You will not receive any cash or payment with goods or services for the **[insert type of somatic cell]** you donate to this research project.

HOW WILL MY PRIVACY BE PROTECTED?

Protocols will be followed in order to protect your privacy. However, providing cells for this project may involve some risk that private information may be discoverable.

The results of your genetic and medical screening tests will be handled confidentially in compliance with state and federal law [as well as any additional institutional policies]. **[Specify how the confidentiality of screening tests will be ensured.]**

Any stem cell lines derived from the cells will carry some of your DNA, which could potentially be matched to you. **[As applicable: Genetic information may be revealed about the collected stem cells as a part of this research project (Insert details about any**

genetic information that might be revealed as a result of the research project).] [As applicable: The following efforts will be made to protect your identity so it is not discoverable to the researchers who collect these stem cells and the researchers who may later work with the resulting stored stem cells: **(Specify how identifying information will be protected, including the use of identification codes, and under what circumstances cell donors can be identified)**].

[Specify all other ways that a cell donor's identity will be protected and whether and how the identification codes or other forms of de-identification will be used.]

[As applicable: Some stem cell researchers working with genetic diseases may want to see genetic information about the somatic cell donors, including, for example, any family history of genetic disease and/or the results of your genetic screening tests. If this information is shared with researchers, your identity will be protected. **(Insert information about how the identifying information will be protected.)** Do you agree to allow these researchers to see this coded information? _____ Yes _____ No]

[As applicable: Regulatory agencies and project sponsors may have access to your information, as required by law.]

Any report that the researchers may publish will not include any information that will make it possible for readers to identify you as a **[insert type of somatic cell]** donor.

[As applicable: Insert information regarding any plans to recontact cell provider regarding genetic or other information about health risks, as well as benefits and risks associated with recontact.]

DISCLOSURE OF RESEARCHERS' POTENTIAL FINANCIAL AND OTHER INTERESTS IN THE RESEARCH

The stem cells that are collected from the resulting embryos may have significant commercial potential in the future. However, by signing this form you acknowledge that you will NOT benefit financially from any future commercial development or scientific patents of discoveries made through the use of these stem cells.

The individuals and institutions conducting this stem cell study might profit from the commercial potential of this research project. There may be current or potential financial benefits to the Principal Investigator, **[insert name]**, the participating institution(s), **[insert name(s)]**, and other research institutions or researchers arising from discoveries made through this research. In addition, these individuals and institutions may have current or future non-financial benefits, such as academic publication or fulfillment of tenure requirements. Local and other relevant review committees have reviewed potential conflicts of interest and determined that the following should be disclosed:

[Specify any financial (and non-financial) interests the researchers or the institution(s) may have in the research.]

[Name of person presenting information and answering questions] may also have a personal vested interest in this research project. **[Disclose here any potential financial (and non-financial) interests this person may have in this research protocol.]**

[As applicable: Your personal treating physician (for fertility treatments or other conditions) who has referred you to or is otherwise involved in this research project may also benefit from your agreement to donate cells for this research project.] **[Disclose here any potential financial (and non-financial) interests the treating physician may have in this research protocol.]**

If you have any questions or concerns or would like more information about these matters, please contact the persons listed below.

CONTACT INFORMATION

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

(Principal Investigator) _____ (phone) _____
[List any toll-free or reverse-charge line.]

(Research Administrator) _____ (phone) _____
[List any toll-free or reverse-charge line.]

If you have any questions about your rights as a cell donor, contact:

(Review Board Member) _____ (phone) _____
[List any toll-free or reverse-charge line.]

If you have any questions about the cell donation process, contact:

(Physician) _____ (phone) _____
[List any toll-free or reverse-charge line.]

This study is being conducted by: **[Insert Institutional name and contact information]**

CONSENT AND SIGNATURE

Please read the statements below, think about your choice, and sign if and when you are ready. You may also take this form home and discuss it with anyone you wish and then return it to us later if you decide to provide cells for this research project:

[Name of person presenting the information and answering questions] has fully explained to me the nature and purpose of this research project in a way that I have understood.

[He/she] has encouraged me to be actively involved during the information interview and has responded to all of my questions and concerns in a satisfactory and respectful way.

[He/she] has offered me opportunities to consult with an independent person whom I trust, including a counselor or a physician, prior to my making my decision and has given me adequate time to decide.

I hereby give my voluntary consent to donate cells for the research project entitled [Project Title] conducted by [Principal Investigator] at [Participating Institution(s)].

_____ Date: _____
Signature of Cell Donor Printed Name

_____ Date: _____
Signature of Person Obtaining Consent Printed Name

Copy given to cell donor: _____ Yes (_____ Initial)