

ESSCB MODEL RESEARCH INFORMED CONSENT FORM

Egg Donation for Human Embryonic Stem Cell Research
(Eggs Collected During the Course of Fertility Treatment
and in Excess of Clinical Need)

Project Title:

Principal Investigator:

Participating Institution(s):

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.

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Please be aware that this document does not address the risks of the fertility treatment that you will undergo or have undergone. It addresses only the risks associated with donating for research eggs in excess of those used for your fertility treatment. Please discuss these risks with your personal physician.

This form can be used to document your consent for research only if you will not be given extra hormones to increase the number of eggs available for research beyond what would normally be needed for fertility treatment.

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 donate any eggs you decide not to use in the course of your own or others' fertility treatment for the purposes of the research. **[Specify whether the eggs to be used are normal or failed-to-fertilize eggs.]**

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 donated eggs. 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.

Embryos can be created from eggs in a variety of ways, which will be explained further in the section "WHAT WILL HAPPEN TO THE EGGS?" Regardless of how the embryos are created, they 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

Donating eggs for this research project is completely voluntary. You have the right to agree or decline to donate eggs 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 donate eggs 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 by any person to donate eggs 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 donate eggs for this research project.

HOW WILL THE EGGS BE RETRIEVED?

This informed consent form and the related discussion concerns only your decision about donating excess eggs collected in the course of fertility treatments for this research project. There is a separate form regarding your consent to the proposed fertility treatment, including the retrieval of your eggs as part of that treatment. You should carefully discuss the nature of that treatment and the risks, benefits, and alternatives to that treatment with your fertility clinician.

By agreeing to participate in this research, you are not agreeing to any change in the nature and extent of the risks of the treatment by your fertility clinician. In particular, you are not consenting to any change in the type or dosage of hormonal stimulants used or the number of eggs retrieved in connection with your fertility treatment, in order to promote the purposes of this research project.

In order to donate eggs for stem cell research, you must 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.]**

WHAT ARE THE POTENTIAL RISKS OF PROVIDING EXCESS EGGS FOR THIS RESEARCH PROJECT?

Beyond those associated with medical screening, there are no additional physical risks posed to you by your donating some of your eggs to this stem cell research project.

However, there may be some psychological risks involved in providing eggs for this research project, possibly related to the medical screening 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 automatically provided or provided only upon request, and whether associated expenses will be covered.]**

WHAT ARE THE POTENTIAL BENEFITS OF PROVIDING EGGS 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 eggs donated 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 EGGS?

Researchers will use eggs to create embryos, from which they will attempt to remove stem cells. The embryos will be destroyed during the stem cell collection process.

None of the eggs you may donate for this research project will be used to produce a pregnancy, and no embryos created from eggs will be allowed to develop for more than a total of 14 days. If any of the resulting embryos are frozen, the time that they remain frozen is not counted as part of the 14 day limit.

Embryos can be created from eggs in a variety of ways. For this research project, an embryo will be created by **[select the applicable method from the following]:**

[As applicable: Union of Sperm and Egg] is the process by which the egg is fertilized using donated sperm in a test tube to create embryos for research, just as is typically done for *in vitro* fertilization.]

[As applicable: **Somatic Cell Nuclear Transfer** is the process by which the nucleus – the part of the cell that contains the genetic material – is removed from the unfertilized egg. Researchers then place the nucleus from non-reproductive cells (such as blood or liver cells) from another donor into the eggs. If successful, this technique will create embryos that contain stem cells which are genetically matched to the non-reproductive cell donor.]

[As applicable: **Parthenogenesis** is the process by which an unfertilized egg is stimulated to begin going through the very early stages of human development. Stem cells that arise from parthenogenesis would be genetically matched to you.]

[As applicable: **Androgenesis** is the process in which DNA in the nucleus of the egg is replaced by DNA from sperm. The egg is then stimulated for embryonic development, and stem cells derived from the process would match genetically to the sperm donor.]

If you object to [any of] the methods for creating embryos from the eggs you donate that are listed above, please specify these limits (if any) here. Please bear in mind that if you include restrictions, the researchers may decline to use your eggs for this research.

- I object to researchers using the eggs I donate to create embryos for scientific purposes using the following methods:
-
-

- I do not object to any of the methods described above.

(please initial here: _____)

Eggs, or the embryos created from eggs, 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 eggs, or that researchers will be able to get stem cells from any resulting embryos. Researchers will discard any unused eggs 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 after parthenogenesis).]

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 eggs 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 eggs might be used in the future in ways unknown to you, then you should not agree to donate eggs for this research study.

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

There are several alternatives to providing eggs for this research project, including declining to donate your eggs. The study staff is available to talk with you about possible alternatives to providing eggs for this research project.

If you provide consent to donate eggs for this research project, you may withdraw your consent for whatever reason at any time until the eggs have been used in the research, as long as the information linking your identity to the eggs has not been removed. The research process may be considered to be underway once an egg has been used to create an embryo or has 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 eggs have been retrieved 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, (3) donate them to other individuals for fertility treatment, if possible, or (4) use them for your own fertility treatment, if possible. **[As applicable: include any other disposition options available at the egg retrieval site.]** Please note that the retrieved eggs will not be suitable for reproductive use once they have been prepared for research.

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.

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

Medical costs associated with the donation of your eggs will be covered by **[insert details of medical coverage]**. If a physical injury results, now or in the future, from your participation, 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 number or the quality of the eggs you donate for this research project, or for the time, effort, and inconvenience associated with the egg harvesting process, as the harvesting occurred for purposes not associated with this research project.

[As applicable: Any reimbursements for expenditures you incurred to participate in the consent process will be decided by local and other relevant review committees.]

HOW WILL MY PRIVACY BE PROTECTED?

Protocols will be followed in order to protect your privacy. However, providing eggs for this project involves 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 eggs 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 egg donors can be identified)**].

[Specify all other ways that an egg 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 egg 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 an egg donor.

[As applicable: Insert information regarding any plans to recontact egg 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 eggs 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 or other 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 an egg donor, contact:

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

If you have any questions about the egg retrieval 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 donate eggs 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 eggs for the research project entitled [Project Title] conducted by [Principal Investigator] at [Participating Institution(s)].

Signature of Egg Donor _____ **Date:** _____ **Printed Name** _____

Signature of Person Obtaining Consent _____ **Date:** _____ **Printed Name** _____

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