

ESSCB MODEL RESEARCH INFORMED CONSENT FORM

Egg Donation for Human Embryonic Stem Cell Research
(Eggs Provided Directly and Solely for Stem Cell Research)

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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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 the retrieval of your eggs and the donation¹ of those eggs for the purpose of the research.

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 eggs provided. Stem cells will then 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 produce 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 eggs for this research project is completely voluntary. You have the right to agree or decline to provide 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 provide 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

¹ This form uses the terms "provider" and "providing" interchangeably with the terms "donor" and "donating."

whether to sign it. You should not sign this form if you feel pressured in any way by any person to provide 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 provide eggs for this research project.

HOW WILL THE EGGS BE RETRIEVED?

If you decide to provide eggs for this research project, several steps and procedures are involved. You will meet with **[specify with whom the donor will meet, i.e., fertility physicians, nurses, or other trained and knowledgeable clinicians if this is a different individual that the person presenting information and answering questions]** to discuss in detail the medical procedures involved in egg retrieval, as well as the risks associated with and hormonal stimulation and egg retrieval.

Screening and Medical Tests

In order to provide eggs 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.]**

You will also undergo additional medical and screening procedures to ensure that you are suitable to provide eggs, which may include hormonal tests, gynecological exams and vaginal ultrasounds. **[Specify in detail which screening tools will be used, including sonograms or blood tests, as well as the risks and side-effects associated with those tests.]**

You should disclose whether or how many times you have previously undergone hormonal stimulation for your own personal reproductive purposes or for purposes of donating your oocytes, as expert guidelines have suggested that donors limit their total number of cycles of hormonal stimulation; some experts have suggested a maximum of six cycles within a donor's lifetime.

Egg Retrieval

After your medical and screening tests, you will be given a medication that will temporarily interrupt the normal functioning of your ovaries. You will then be given fertility medication to stimulate your ovaries to produce several mature eggs in one cycle. The type and dosage of fertility medications that will be used is similar to those used for *in vitro* fertilization treatment.

To administer the medications, you will be asked to give yourself hormonal injections daily for up to three weeks. If you are unable or unwilling to do so, you may have another person do it for

you. During this time, your response to the medication will be monitored closely with blood tests, and ultrasounds will be used to view your ovaries. **[Insert number of office visits required for monitoring.]**

When your ovaries are ready, the mature eggs will be retrieved during a minor surgical procedure **[called *transvaginal ovarian aspiration*]**. Doctors will retrieve the eggs by inserting a needle into your vagina and one or both of your ovaries, and suction will be used to remove the mature eggs. The procedure will take about thirty minutes, and anesthesia and/or sedation will be used to make you comfortable. After the procedure, you will be allowed to go home after an appropriate number of hours to ensure your stability and recovery.

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

The procedures used to stimulate ovaries and retrieve eggs have been used in the context of *in vitro* fertilization for decades and generally are considered safe. However, there are several risks associated with hormonal stimulation and egg retrieval. **[As applicable, if this person is different from the person presenting information and answering questions:** A fertility physician, nurse, or other trained and knowledgeable clinician who is not a member of the research team will discuss these risks with you in more detail.]

Physical Risks

[Name of medications], used to stimulate your ovaries, can cause a variety of relatively minor side effects, including bleeding, discomfort, mood swings, cramping, and **[insert any additional symptoms]**. You may also develop soreness, redness or mild bruising around the injection site, or an allergic reaction to **[name of medications]**, although this is very rare.

One of the most common risks of **[hormonal stimulation/name of medication]** is ovarian hyper-stimulation syndrome (OHSS), which can cause swelling of the ovaries, abdominal pain, and nausea. In extremely rare cases, OHSS can be a serious medical condition that, if left untreated, may lead to blood clots, kidney failure, infertility, symptoms requiring ovary removal, and death. These risks can be reduced if doctors use low doses of hormonal stimulation drugs and if your response to these drugs is monitored closely by health professionals. These safety measures will be followed for your care: **[specify safety precautions]**.

Hormonal stimulation may also pose long-term health risks, some of which are not fully known at this time. A definitive link between fertility medications and cancer has not been established. The evidence to date does not support a causal relationship between fertility drugs and ovarian or breast cancer. There is limited evidence of a correlation between the use of fertility medication and a very slight increased risk of uterine cancer. Ongoing research is necessary to clarify the question of whether or not fertility drugs increase the risk of certain cancers.

Based on the available evidence, hormonal stimulation and increased ovarian production of eggs should not impact your future fertility. Further research on this issue is necessary, however.

The egg retrieval procedure carries some risk that the needle used to retrieve the mature eggs from your ovaries might accidentally puncture one of your organs or blood vessels, which may cause internal bleeding. Although it is extremely rare, serious damage to an organ or severe internal bleeding may require you to undergo abdominal surgery to correct it. There is a slight risk of infection from the procedure, and an antibiotic will be administered to try to prevent this from occurring.

There is also a risk of complications from anesthesia used during the retrieval procedure. **[Specify type of anesthesia used and all possible side effects and complications.]**

After the procedure, you may experience moderate discomfort or pain, and you may be instructed to restrict your physical activities accordingly.

You should discuss any concerns you may have about the physical risks of providing eggs for this research project with a physician or other knowledgeable healthcare provider. Counseling services will be made available to you to help address any concerns you may have as you decide whether or not to donate your eggs for this research project. **[Specify whether counseling services will be automatically provided or provided only upon request, and whether associated expenses will be covered.]**

Fertility drugs temporarily will increase your fertility and your chances of becoming pregnant if you engage in sexual intercourse. For this reason, it is recommended that you abstain from sexual intercourse for two weeks prior to the egg retrieval and for two weeks following the retrieval if you wish to avoid pregnancy.

Psychological Risks

There also may be psychological risks involved in providing eggs for this project, possibly related to the screening process, the egg retrieval procedure, 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. The process of egg donation is also time-consuming and may be stressful, or you may experience anxiety related to the medical or other procedures involved with the donation process.

You may experience psychological effects from hormonal stimulation such as mood swings. You may feel depressed or unusually irritable. Such symptoms are similar to those associated with premenstrual syndrome (PMS). Less common psychological side effects can include bipolar episodes (manic depression).

It may not be possible to determine how or whether you will experience psychological risks, but care will be taken to help minimize them. If you experience any emotional effects that cause you concern, please contact the persons listed at the end of this form.

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 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 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 provide 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 provide 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 provide 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 for 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, as there is no 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 have your eggs collected. 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 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.

Any financial implications of deciding to terminate participation in this research project after egg retrieval 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 eggs 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?

[As applicable, but MUST insert if any reimbursements are provided: Compensation is provided solely to reimburse you for your out-of-pocket expenses, and the time, effort, and inconvenience associated with the donation process. You will not receive any cash or payment with goods or services for the number or the quality of the eggs you provide for this research project.]

[As applicable: You will be reimbursed for out-of-pocket expenses, such as travel, medical care, child care, or similar expenses incurred as a result of your participation.]

[As applicable: You will receive \$_____ in recognition of the time, effort, and inconvenience associated with the donation process. This amount has been 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 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 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 providers can be identified).**]

[Specify all other ways that an egg provider'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 provider.

[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 provide 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 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 provider, 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 provide 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 provide eggs for the research project entitled [**Project Title**] conducted by [**Principal Investigator**] at [**Participating Institution(s)**].

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

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

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