ISSCR SAMPLE RESEARCH CONSENT FORM

Egg Procurement for Research

(Eggs Provided Directly and Solely for Research)

**Project Title:**

**Principal Investigator:**

**Participating Institution(s):**

**PROJECT INFORMATION**

You are being asked to provide eggs for a research project led by **[name of principal investigator]** at **[name(s) of institution(s)]**.

**[Insert additional information about this project using very simple language. If this is a gene editing project, explain why the eggs and/or the resulting embryos will be modified.]**

**If this is an embryonic stem cell research project:** Embryonic stem cells come from embryos during their fifth day of development. These stem cells have the ability to turn into any kind of human cell, such as liver cells, heart cells, or nerve cells. For this reason, embryonic stem cells can be used to study, and maybe one day help treat, diseases or injuries that have caused patients’ cells to die or become damaged.

**(Name of principal investigator)** wants to collect new human embryonic stem cells from embryos that have been created by **[as applicable: nuclear transfer; parthenogenesis; fertilization with donated sperm.]**

**[As applicable: “Nuclear transfer” is the process by which researchers place donated adult body cells into unfertilized eggs that have had their DNA removed. If successful, this technique can create embryos that contain stem cells which are genetically matched to the body cell donors.]**

**[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 the person who provided the unfertilized egg.]**

**VOLUNTARY CHOICE**

Providing your eggs for this research project is completely voluntary. You have the right to agree or to refuse to provide your eggs for this project. The quality of your current or future medical care and your relationship with **[name(s) of institution(s)]** will NOT change in any way whether you agree or refuse to provide any eggs for this research project.

**WHAT IS THE PURPOSE OF THIS CONSENT FORM?**

**[Name of person obtaining consent]** 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 provide your eggs 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 provide your eggs for this research project. This consent form must not replace actually having this conversation, so be certain you have this conversation.

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 provide your eggs for this project. This must be your own decision, not someone else’s.

**WHAT WILL HAPPEN TO MY EGGS?**

None of the eggs you provide for this research project will be used to produce a baby or a pregnancy.

Researchers will use your eggs to create embryos for their stated research purpose. The resulting embryos will be destroyed during this research project.

There is no guarantee that embryos will be successfully created using your eggs. Researchers will discard any eggs that are not used for this research project.

**As applicable for fertilized eggs:** It is likely that researchers will perform Whole Genome Sequencing (WGS) on the resulting embryos or their cells. WGS looks for random changes (mutations) in the DNA of the cells. Because the created embryos will be partially genetically matched to you, this may reveal genetic information about you and your family. Efforts will be made to protect your privacy, which will be explained in the Privacy section of this form.

**As applicable for fertilized eggs:** Genetic testing may show unexpected information to researchers that may be important for your health. There (is/is not) a plan in place to share these results with you.

**[*Point to consider. The return of health-related incidental findings -*** *Researchers and institutions may decide to have a plan in place regarding the return of incidental findings. This plan should include what kinds of conditions will be reported and how the results will be validated in a clinical laboratory. Egg providers should be made aware of this policy during the consent process, including what kinds of conditions may be found and whether they can opt out of receiving such information.*

**If this is a stem cell research project:**

**WHAT WILL HAPPEN TO THE COLLECTED STEM CELLS?**

**[As applicable: The created stem cell line will be stored in (name of biorepository). This is a place where cells are stored for future research. (Specify who will have access to the stem cells in the future.)]**

It is likely that the collected stem cells will be stored for many years. Embryonic stem cells have the ability to grow and make limitless copies of themselves, 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. Other researchers might use these stem cells to create small organ models called organoids. Another possible research use might be to study the stem cells by putting them into laboratory animals. These are just 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 not be able to say which institutions or researchers can share the stem cells made from embryos that were created using your eggs. If stem cell transplantations are developed in the future, you will not be able to say who should get the transplants **[as applicable: except in the case of transplantation back to yourself after parthenogenesis]**.

Future uses of stored stem cells must be approved by 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.

**[*Point to consider. Future research involving the creation of gametes and/or embryos -*** *Researchers should assess the likelihood that cells derived from the woman’s fertilized eggs may be used in potentially controversial future research. Egg providers may be uncomfortable with the creation of research embryos or gametes, especially when they would be genetically matched to them. If the egg provider’s disease or other factors make this kind of future research a foreseeable possibility, it may be reasonable to inform her and/or provide an opt-out.*

*Example: “Some stem cell researchers studying early human development or reproduction may want to use stem cells to create gametes (sperm and egg cells) or embryos. These gametes and embryos may be genetically connected to you. None of the embryos or gametes created from your cells will be used to produce a baby or pregnancy.”***]**

**WHAT IS THE EGG RETRIEVAL PROCEDURE?**

If you decide to provide your eggs for this research project, you will have to undergo several steps.

First you will meet with fertility physicians and nurses to discuss in detail the medical procedures involved in egg retrieval. These individuals are qualified to discuss with you in much more detail the procedures and the risks of hormonal stimulation and egg retrieval. You will be asked to sign another consent form for these medical procedures specifically.

It is important to emphasize that the consent form you now hold in your hands is not a substitute for these medical consent forms. **[As applicable: The person authorized to give you information about this research project is not authorized to lead you through an informative conversation about hormonal stimulation and egg retrieval.]**

You will undergo medical testing to screen you for genetic and infectious diseases. **[Specify which tests will be conducted and whether the volunteer will have access to these test results.]**

After your medical tests, you will have to give yourself hormonal injections daily for up to three weeks in order to stimulate your ovaries to produce mature eggs. If you are unwilling to give yourself these shots, you may have another person do this for you.

When your ovaries are ready, doctors will retrieve your eggs by inserting a needle through your vagina and into one or both of your ovaries. Anesthesia and/or sedatives will be used during this process, which will take about thirty minutes.

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

There are several risks associated with hormonal stimulation and egg retrieval. **[As applicable: A fertility physician who is not a member of the research team will discuss these risks with you in far more detail.]**

Hormonal stimulation poses a possible risk of severe ovarian hyperstimulation syndrome. This is a serious medical condition that, if left untreated, may lead to kidney failure, infertility, and in extremely rare cases, death. These risks can be greatly reduced if doctors use low doses of hormonal stimulation drugs and if your response to these drugs is monitored daily by health professionals. **[As applicable: Therefore, these safety measures will be followed for your care.]**

Other possible risks include bleeding, discomfort, infection, cramping, mood swings, unintended pregnancy, and complications associated with anesthesia.

Hormonal stimulation may also pose some unknown long-term health risks. At this time, scientists do not know for certain what kinds of long-term negative effects, if any, these drugs may have on your fertility or your risk for developing cancer. You should discuss any concerns you may have about these uncertainties with a physician.

The egg retrieval procedure carries some risk that the needle used to retrieve your eggs from your ovaries might accidentally puncture one of your organs or blood vessels.

There are some psychological risks involved in providing your eggs for this project.

Some women who provide eggs for research might experience feelings of anxiety or regret, especially when considering the possibility that their eggs may result in the creation of embryos that will be destroyed during this research. Some may also feel vulnerable and anxious during the consent process.

All egg providers will be asked to undergo medical screening tests for genetic and infectious diseases. While these medical tests involve minimal physical risk, such as from a blood draw, some women may feel anxious about their test results

Due care will be taken to help minimize these psychological risks. **[Specify how this will be done, e.g. whether counseling services will be provided upon request.]**

Providing eggs for this project involves some risk to your privacy. Efforts to protect you against this risk are discussed in the section entitled HOW WILL MY PRIVACY BE PROTECTED?

**WHAT WILL HAPPEN IF I GET A RESEARCH RELATED INJURY?**

We are obligated to inform you about **[name of institution(s)’]** policy in the event that injury occurs resulting from your participation. **[Insert description of the institution’s policy addressing provision of healthcare and/or compensation related to injury resulting from participation.]**

**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. You would be providing your eggs solely for the advancement of this research project and scientific research in general.

**[As applicable: The stem cells that are collected from the resulting embryos 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 ALTERNATIVES TO PROVIDING MY EGGS FOR THIS PROJECT?**

One of your alternatives is to refuse to participate at all in this research project. You may decide to do nothing, or you may decide to undergo hormonal induction specifically to donate your eggs for fertility treatment or another research project. The study staff would be happy to talk with you about other possible alternatives outside of this research project.

In the case that your eggs are retrieved but you decide not to participate any longer in this research project, you may (1) have them discarded according to the routine practice of **[name of institution]**, (2) donate your eggs to another research project, (3) donate your eggs to other individuals for fertility treatment, or (4) use them for your own fertility treatment, if necessary. Please note that your retrieved eggs will no longer be suitable for reproductive use once they are transferred to Dr. **(principal investigator)**’s laboratory and prepared for research. Also, if you decide to use your eggs for your own or others’ fertility treatment, you may have to undergo additional screening tests.

**WHAT IF I CHANGE MY MIND?**

You may withdraw your consent for whatever reason at any time before or during the egg retrieval process. Also, you may withdraw your consent after your eggs have been collected, but before they are used in research.

**For stem cell research projects:** Once the resulting embryos are destroyed in the stem cell 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.

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.

**HOW WILL MY PRIVACY BE PROTECTED?**

Although complete privacy protection is difficult to guarantee absolutely, records of your involvement with this research project will be kept confidential. Whenever possible, the results from this study will be published in scientific journals and presented at scientific conferences. However, you will not be identified personally in any way in any publication or presentation.

To protect your genetic privacy, only your identification code, not your name, will be available to researchers. Identification codes will be kept in a private database that can only be accessed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (person). The results of your medical screen tests will also be confidentially handled through the use of identification codes instead of names. **[Specify how this information will be protected and whether the identification code will be linked to the egg providers, and under what circumstances these providers will be identified.]**

**[As applicable: specify any protections your country provides against genetic discrimination. Example for US researchers: The Genetic Information Nondiscrimination Act (GINA) forbids employers and health insurance companies from discriminating against people based on their genes. Add any institutionally-approved statements about genetic discrimination policies here.]**

Local and other regulatory agencies, and project sponsors and funding agencies may review the research project records to ensure that your rights as an egg provider were adequately protected. However, your identity will not be readily discoverable to these individuals.

Although complete privacy protection is difficult to guarantee absolutely, any report that the researchers publish will not include any information that will identify you as an egg provider.

**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 provide for this research project.

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

**[As applicable: You will receive a compensation amount of $\_\_\_\_\_\_ in recognition of your time, effort, and inconvenience. This amount has been decided by local and other relevant review committees based on local community standards for paying other healthy research volunteers for their time, effort, and inconvenience.]**

**DISCLOSURE OF RESEARCHERS’ POTENTIAL FINANCIAL INTERESTS**

In addition to their scientific interests in this research project, the individuals conducting this study might profit financially from the research. There may be current or potential financial benefits to the Principal Investigator, **[name]**, the participating institution(s), **[names]**, and other research institutions or researchersarising from discoveries made through this research project. **[Disclose using plain language the researchers’ and the institution(s)’ financial interests in the research.]** If you have any questions or concerns about these matters, please contact the persons listed below.

**[As applicable: If you are undergoing fertility treatment, it is important that your physician inform you of any personal benefits he or she may gain by your agreement to provide eggs for this research project. (Disclose here any potential personal benefits the treating physician may receive through this research protocol.)]**

The person who has been authorized to provide you with information may also have a personal vested interest in this research project. **[Disclose here any potential personal benefits this person may have in this research protocol.]**

**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.]**

**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:

**[Name of person obtaining consent]** 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 up to \_\_\_\_\_\_\_\_\_\_ (insert number) 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 provider:\_\_\_\_\_Yes