**ISSCR SAMPLE RESEARCH CONSENT FORM**

Sperm Donation for Research

(Includes Sperm Donation Specifically for Research

and Sperm in Excess of Clinical Need)

**Project Title:**

**Principal Investigator:**

**Participating Institution(s):**

**PROJECT INFORMATION**

You are being asked to donate sperm 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. Specify whether the investigator plans to use donated cryopreserved sperm, fresh sperm, or both. If this is a gene editing project, explain why the sperm and/or the resulting embryos will be modified.]**

**If this is an embryonic stem cell research project: [Name of principal investigator]** wants to collect new human embryonic stem cells from embryos that have been created with your sperm **[as applicable: created through androgenesis]**. **[As applicable: “Androgenesis” is the process by which a sperm cell is stimulated to begin going through the very early stages of human development. Stem cells that arise from androgenesis would be genetically matched to the person who provided the sperm.]**

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.

**VOLUNTARY CHOICE**

Donating your sperm for this research project is completely voluntary. You have the right to agree or to refuse to provide your sperm 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 sperm 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 donate your sperm 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 sperm 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 donate your sperm for this project. This must be your own decision, not someone else’s.

**WHAT WILL HAPPEN TO MY SPERM?**

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

Researchers will only use your sperm 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 sperm. Researchers will discard any sperm that is not used for this research project.

**As applicable for the fertilization of eggs using donated sperm:** 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 the fertilization of eggs using donated sperm:** 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. Sperm donors 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 sperm. 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 androgenesis]**.

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 man’s donated sperm may be used in potentially controversial future research. Sperm donors may be uncomfortable with the creation of research embryos or gametes, especially when they would be genetically matched to them. If the sperm donor’s disease or other factors make this kind of future research a foreseeable possibility, it may be reasonable to inform him 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.”***]**

**HOW WILL MY SPERM BE COLLECTED?**

**[As applicable: In the routine practice of fertility clinics, you will be asked to return a sample of your ejaculate in a sterile container, which will be provided for you.]**

**[As applicable: With your approval, your frozen sperm will be transferred by (name of institution) to the research team.]**

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

There are no foreseeable physical risks for you in donating sperm for this research project. However, there are some psychological risks you need to consider. Some people who donate sperm for research might experience feelings of anxiety or regret, especially when considering the possibility that their sperm may result in the creation of embryos that will be destroyed during the research. Some may also feel vulnerable and anxious during the consent process.

**[As applicable: As a sperm donor for this project, you will be asked to undergo medical screen tests for these genetic diseases: \_\_\_\_\_\_\_ (specify). Although these screen tests carry no foreseeable physical risks, some sperm donors may feel anxious about their test results.]**

Due care will be taken to help minimize these psychological risks. **[Specify how this will be done.]**

Donating sperm 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 ARE THE POTENTIAL BENEFITS OF DONATING MY SPERM 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 sperm 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 DONATING MY SPERM FOR THIS PROJECT?**

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

In the case that your sperm is retrieved but you decide not to participate any longer in this research project, you may (1) have your sperm discarded according to the routine practice of **[name of institution]**, (2) donate your sperm to other individuals for fertility treatment, or (3) store your sperm for your own fertility treatment, if necessary. Please note that these alternatives are possible only if your sperm has not already been prepared by researchers to create embryos for this project. Also, using your sperm for your own or others’ fertility treatment may involve additional screening tests.

**WHAT IF I CHANGE MY MIND?**

You may withdraw your consent for whatever reason at any time before the sperm collection process. Also, you may withdraw your consent after your sperm has been collected, but before it is 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 sperm donors, 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 a sperm donor 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 a sperm donor.

**WILL I RECEIVE PAYMENT?**

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

**[As applicable: You will not be reimbursed for the cost of sperm storage for the time period before your sperm is donated for this research project.**

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

**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 sperm 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 a sperm donor, contact:

(Review Board Member)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(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.

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| --- | --- | --- |
| Researchers may wish to contact you in the future to request additional health information or samples. If you are willing to be re-contacted, please initial in the “yes” box. | **Yes** | **No** |

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date:**\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **Signature of Sperm Donor Printed Name**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date:**\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Person Obtaining Consent Printed Name**

Copy given to donor:\_\_\_\_\_Yes