**ISSCR SAMPLE RESEARCH CONSENT FORM**

Somatic Cell Donation for Induced Pluripotent Stem Cell Research

**Project Title:**

**Principal Investigator:**

**Participating Institution(s):**

**PROJECT INFORMATION**

You are being asked to donate \_\_\_\_\_ **(insert type)** cells to create stem cells for a human stem cell research project led by **[name of principal investigator]** at **[name(s) of institution(s)]**. You are being invited to participate in this project because \_\_\_\_\_\_\_\_\_\_ **(identify participants’ medical condition).** The purpose of this project is to create stem cells that have \_\_\_\_\_\_\_\_\_\_\_\_\_ **(identify characteristic).**

Powerful stem cells can be created (or “induced”) by changing normal cells from your body, such as skin cells, into pluripotent cells in a laboratory. “Pluripotent” means that the cells can turn into any kind of cells such as brain, heart, or kidney cells. For this reason, induced pluripotent 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 create induced pluripotent stem cells using your donated cells. **[Insert additional information about this specific project using very simple language.]**

**VOLUNTARY CHOICE**

Donating your \_\_\_\_\_ cells for this research project is completely voluntary. You have the right to agree or to refuse to provide your cells 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 cells for this research project.

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

**[Name of person obtaining consent]** will give you information and 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 cells 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 ­­­cells 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 cells for this project. This must be your own decision, not someone else’s.

**HOW WILL MY \_\_\_\_CELLS BE COLLECTED?**

**[As applicable: You will be asked to provide a \_\_\_\_\_ sample.]**

**[As applicable: With your approval, your stored \_\_\_\_\_ sample will be transferred by [name of institution] to the research team.]**

**WHAT WILL HAPPEN TO MY \_\_\_\_\_\_\_CELLS?**

Your \_\_\_\_\_cells will be changed into induced pluripotent stem cells (iPS cells). These iPS cells can grow and divide outside of the body for many years, forming what is called a “stem cell line.” The stem cell line may be used in future studies by other researchers at [name of institution] or other institutions outside of [name of institution].

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

There is no guarantee that stem cells will be created from your \_\_\_\_\_ cells. Researchers will discard any \_\_\_\_\_ cells they do not use for this research project.

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

It is likely that the stem cells, which would be genetically matched to you, will be stored for many years. 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.

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

**[As applicable: Genetic testing could show unexpected information to researchers that may be important for your health. There (is/is not) a plan in place to share this found information 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. 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.*

*Example: “Research on the stem cells created from your donated cells may reveal information that could be important to your health. If you wish to be contacted in the future about any such information, please check yes at the end of this form. If you answered “yes” to this question, (name of institution) will, to the extent possible, pass to you any information that it is given from other researchers or other institutions regarding health information revealed through research on the stem cells.”***]**

You will not be able to say which institutions or researchers can share the stem cells that were created using your cells. 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 autologous transplantation].**

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 a donor’s cells may be used in potentially controversial future research. Donors may be uncomfortable with the creation of research embryos or gametes, especially when they would be genetically matched to them. If the donor’s disease or other factors make this kind of future research a foreseeable possibility, it may be reasonable to inform donors 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 would 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 ARE THE ALTERNATIVES TO DONATING MY \_\_\_\_\_ CELLS FOR THIS PROJECT?**

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

In the case that your cells are retrieved but you decide not to participate any longer in this research project, you may (1) have your cells thrown away by **[name of institution]**, (2) donate your cells to other research projects, or (3) **[as applicable: return your \_\_\_\_\_ sample to storage]**.

**WHAT ARE THE POTENTIAL BENEFITS OF DONATING MY \_\_\_\_\_ CELLS FOR THIS PROJECT?**

This research project is not designed to give any direct medical benefits to you or anyone else. You would be donating your cells solely help this research project and stem cell research in general.

**[As applicable: The stem cells created from your cells may have commercial value 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 patents of discoveries made through the use of these stem cells.]**

**WHAT ARE THE POTENTIAL RISKS OF DONATING MY \_\_\_\_\_ CELLS FOR THIS PROJECT?**

[**As applicable: specify any physical risks associated with the sample collection process.]**

Some people who donate cells for stem cell research might experience feelings of anxiety or regret. Some may also feel vulnerable and anxious during the consent process.

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

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

Donating cells for this project involves some risk to your privacy. Efforts to protect you against this risk are discussed in the next section.

**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 the researchers who create the stem cell line and the researchers who may later work with the resulting stored stem cells. 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 cell donors, and under what circumstances these donors 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 cell donor were adequately protected. However, your identity will not be easily 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 cell donor.

**WHAT IF I CHANGE MY MIND?**

You may withdraw your consent for whatever reason at any time before your cells are used to create a stem cell line for this project.

However, once the stem cells have been created, you will not be able to change your mind or request that any of the 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.

**WILL I RECEIVE PAYMENT?**

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

**[As applicable: You will not be reimbursed for the cost of your \_\_\_\_\_ sample storage for the time period before your cells are 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 stem cell 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 and the stem cell line created from your cells. **[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.

If you are a \_\_\_\_\_\_ **(specify medical condition)** patient, it is important that your treating physician inform you of any personal benefits he or she may gain by your agreement to donate cells 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 private 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 \_\_\_\_\_ cell 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.

|  |  |  |
| --- | --- | --- |
| 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 \_\_\_\_\_ 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 Parent or Legal Guardian Printed Name**

**If Cell Donor is a Minor or Decisionally-**

**Incapacitated**

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

**Signature of Person Obtaining Consent Printed Name**

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

Copy given to parent or legal guardian (if applicable):\_\_\_\_\_\_ Yes