

CIRM hiPSC Initiative – Appendix A Model Consent Form

The model language is intended as a guide for a human pluripotent stem cell repository. It is designed to incorporate the requirements of the California Institute for Regenerative Medicine (CIRM) MES regulations (California Code of Regulations, sections 100010 – 100110), the recommendations of the CIRM Standards Working Group, and model language from CIRM grantees performing human induced pluripotent stem cell derivation. State and federal privacy laws must also be addressed to permit use and disclosure of individually identifiable health information. Actual language should be modified to be consistent with the research protocol.

Creation and Distribution of Stem Cell Lines from Donor [Identify Tissue Type] Sample

Highlights: Key point to consider before you consent to participate:

- Cells from your [tissue type] donation will be transformed to make stem cell lines.
- The stem cell lines will be deposited in a repository or cell-library. The California Institute for Regenerative Medicine will own the cell lines, and the library will distribute them widely (perhaps indefinitely) for research, training and the development of medical products.
- Research is not designed to provide direct medical benefit to you and will not be restricted to a specific disease or condition.
- Possible uses of your cells or the resulting stem cell lines include:
 - Testing the cells' DNA (this is referred to as a cell's genetic code or sequence) and making the information known to other researchers
 - Changing some of the genetic code / sequence within these cells
 - Using these cells to test or select drugs to treat disease
 - Transplanting cells or resulting products to humans or animals
 - Distributing cells widely (nationally and internationally) for research, training or commercial medical product development
 - Future research unforeseen at this time
- If any medical products result from your participation, you will not be entitled to any of the profits associated with such products.
- You must be told prior to your donation what medical or other information that might identify you or link you to the cells will be retained, and how they will maintain your confidentiality.
- You may limit your participation in the future by requesting: (1) that your [tissue type] donation be destroyed and/or (2) that the code linking you to the stem cell lines be removed. Previously created stem cell lines will continue to be used and distributed without any way of identifying them as yours.

Creation and Distribution of Stem Cell Lines from Donor Skin Sample [Identify Appropriate Biological Specimens]

[names and degrees of PI] at [identify sponsor] is in charge of this research. The research is designed to create stem cell lines from donated skin cells, blood or hair. The resulting stem cell lines will be widely distributed and used for additional scientific studies.

Creating and distributing cell lines from your donated sample is not intended to provide you with direct medical benefit. Donating to research is entirely voluntary. You should read the information below and ask about anything you do not understand. [Sponsor name] must document, in writing that you have agreed to participate.

1.0: What is the nature and purpose of the research?

Your [skin, blood or hair] will be collected and used to create induced pluripotent stem cells, also known as “iPS” cells. iPS cells are made by exposing donated cells to genes or chemicals that modify their behavior. The resulting cells have pluripotent characteristics (described in [2.0](#)).

If iPS cells are created successfully from your donation, they are likely to be stored in a cell repository or “library.” The goal of this project is to create a library containing iPS cells to be distributed for additional research. CIRM will own the iPS cell lines and the cell library will share them with researchers and medical professionals at universities, hospitals, research institutes, and companies around the world.

2.0: Why are iPS cells important for research?

iPS cells are important because they have unique “pluripotent” characteristics. Pluripotent cells can: (1) become all types of cell in the body, such as muscle cells, brain cells or heart cells, through a process called differentiation; and (2) regenerate or replicate, perhaps indefinitely.

Researchers hope to learn more about human diseases by creating a collection of iPS cells from donors (1) with a history of disease or (2) without a history of disease. The iPS cell library will be available to researchers in the United States and in other countries. Cells will be used for training and in future studies designed to understand the disease process and as tools to develop medical products.

3.0: What will happen if I participate in this project?

By participating you will be providing biological samples (skin, blood or hair) and authorizing us to obtain information about your medical history. To obtain biological samples we will perform a skin punch biopsy, blood draw, or remove a few hairs from your head. Cells from all these tissues may be used to create iPS cells.

A Skin Punch Biopsy: The 4-mm (about the size of a lentil) skin punch biopsy will be performed by someone trained in the procedure. The skin at the back of your arm (upper thigh, buttocks or behind the ear) will be cleaned with an alcohol swab. A few drops of anesthesia (e.g. 1% lidocaine with epinephrine) will be injected with a needle. The injection will cause a less than 1/5-inch wide bubble to form under the skin and

produce numbness at the injection site. A punch biopsy instrument will be used to remove a piece of skin. The skin defect will be closed with an adhesive skin closure strip and an antibiotic ointment covered Band-Aid.

A Blood Sample: Trained staff will use the standard hospital method to obtain a sample of 5ml – 15ml (approximately 1 - 3 teaspoons full) of blood.

A Hair Sample: We are asking you to provide a few hairs from your head.

Medical Information: To obtain information about your medical history, a questionnaire will be administered at the time of donation. The questionnaire will ask about your family's history with common types of disease. The medical history may be used to identify cells to study or to help explain research findings.

We expect that completing the medical history questionnaire will last approximately [time frame].

3.1: Opt out of future contact:

In the future, we may want to contact you to (1) obtain additional samples or updates on your health or (2) inform you about significant new findings that may impact you, or (3) to get your permission for research not covered in this consent form.

With this consent form, you are asked to agree to be re-contacted by the [identify sponsor] in the future. However, if you DO NOT agree to be re-contacted, please indicate your preference below:

- _____ Check and initial here if you DO NOT consent to being re-contacted in the future.

You have the right to take away consent for re-contact at any time.

4.0: How will the resulting stem cell lines be used?

If iPS cells are created successfully, they may be stored in a cell repository or “library” and then distributed to researchers. It is possible the cells and your associated medical information will be stored and distributed indefinitely.

Researchers may study the basic biology of stem cells, the biology of certain diseases and disorders, and study whether it is possible to transplant iPS cells or products of cells as a treatment for many diseases. If you are invited to participate because of a history of disease, studies may not be limited to your specific condition. Some common examples of what might happen to the stem cells include the following:

- Testing the cells' DNA (this is referred to as the cell's genetic code or sequence) and making the information known to other researchers
- Changing some of the genetic code or sequence within these cells
- Using cells to test or select drugs to treat disease

- Transplanting cells or resulting products to humans or animals
- Distributing cells widely (nationally and internationally) for research, training or commercial medical product development
- Future research and uses unforeseen at this time

Information about your medical history will be also available to researchers, but it will not identify you personally. Information related to your cells' genetic code or sequence may be shared with other researchers by depositing the information in a database. For example, a database called dbGaP is designed to help researchers study the connection between genetic code and observable traits such as the presence or absence of disease.

4.1: Opt out of gamete research:

iPS cells may be used to create human gametes (eggs or sperm). Human gametes may be used to study infertility, embryogenesis (very early human development) or early disease development. Such research may require combining gametes derived from iPS cells with other gametes to achieve fertilization. Your cells or gametes or iPS cells generated from your biopsy will never be used to attempt to create an entire person. However, if you DO NOT agree to gamete research, please indicate your preference below:

_____ Check and initial here if you DO NOT consent for use of your cells for gamete research.

5.0: Will my personal or health information be kept confidential?

Any information obtained in connection with this study that can identify you will be held confidentially by [identify sponsor]. Confidentiality will be maintained by removing your name, birth date and other personally identifying information, and replacing it with a code number. The code will be stored by [identify sponsor] Your identity will be disclosed only with your permission or as required by law.

Researchers receiving distributed iPS cells will only know the code number. Coding is an effective means of protecting you but does not guarantee your identity will not be revealed. If you have previously undergone genetic testing and your genetic code or sequence is known to others, there is a greater chance your identity could be revealed. Should your identity be revealed, Federal law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

6.0: What are the discomforts and risks?

Skin Biopsy:

- It is possible to have an allergic reaction to the anesthetic used to numb the skin.
- Light-headedness or a stinging sensation may also result from the anesthesia.

- Some people experience significant local irritation that may persist for several days, but requires no treatment and will resolve by itself.
- An occasional participant may have bleeding, bruising, or infection at the biopsy position or where blood is taken.
- If the skin around the biopsy becomes red or increasingly tender, you should call the study coordinator.

Blood Donation:

- Discomfort from a 5ml - 15ml blood sample is rare.
- Occasionally one or more of the following side effects may occur: pain, bruising, slight bleeding, light-headedness, fainting and (rarely) an infection.

Personal, Genetic & Medical Information:

There is some risk of a loss of confidentiality. Coding iPS cell lines does not guarantee your identity will not be revealed.

Community or Group Information:

Studying your cells may reveal information about people (1) with your disease, (2) with your geographic background or (3) in your ethnic group. Revealing this information may upset you or others in your group. Some people may use this information unfairly.

7.0: Are there any potential benefits if I participate?

This research is not designed to provide direct medical benefit to you. The iPS cells may be useful for developing drugs or medical products to treat diseases. The products may be patentable or have commercial value and you will not own or have a financial interest in them. You may benefit from the knowledge that your participation may further scientific research and help others in the future. You may not place restrictions on who may be treated with any resulting medical products.

8.0: Will I incur any costs from participation?

There will be not costs to you for participation in this study.

9.0: Will I receive any payment for participation?

You will not be paid for participation in this study. You are eligible for reimbursement for any direct expense incurred as a result of participation. If any medical products result from your participation, you will not be entitled to any payments.

10.0: Can I stop or limit my participation in the study?

There are three options for stopping or limiting the use of your samples or personal information in this study. At any time, you may:

- (1) Request your donated [skin, blood, and hair] samples be destroyed.**

If you request this option **prior** to the generation of iPS cells, your donated materials will be destroyed, all identifying codes and information will be removed and there will be no further contact by the research team.

If you request this option **after** the generation of iPS cells, your donated materials will be destroyed and the iPS cells will continue to be distributed. We will not destroy iPS cells once they are created. iPS cells that have been shared with other researcher will not be retrievable.

(2) Request that the code linking your donated [skin, blood, and hair] and derived iPS cells to you be removed.

If you request the code linking your [skin, blood, and hair] samples and resulting iPS cells to you be removed, the donated samples and iPS cells will continue to be used and distributed without any way of identifying them as yours. Since iPS cells made from your cells contain your genetic information, there is a very small risk that they could potentially be linked to you in the future even though we will have removed all direct identifiers linking the cells to your identity.

(3) Request both 1 & 2 above.

If you request both of the above after generation of iPS cells, your [skin, blood, and hair] sample will be destroyed and the code linking your [skin, blood, and hair] samples and resulting iPS cells to you be removed. The iPS cells will continue to be used and distributed without any way of identifying them as yours.

Describe process for withdrawing consent for re-contact

CALIFORNIA RESEARCH PARTICIPANT'S BILL OF RIGHTS

These rights are the rights of every person who is asked to be in a medical research study. As a research participant, I have the following rights:

1. I have the right to be told what the research is trying to find out.
2. I have the right to be told about all research procedures, drugs, and/or devices and whether any of these are different from what would be used in standard practice.
3. I have the right to be told about any risks, discomforts or side effects that might reasonably occur as a result of the research.
4. I have the right to be told about the benefits, if any, I can reasonably expect from participating.
5. I have the right to be told about other choices I have and how they may be better or worse than participating in the research. These choices may include other procedures, drugs or devices.
6. I have the right to be told what kind of treatment will be available if the research causes any complications.
7. I have the right to have a chance to ask any questions about the research or the procedure. I can ask these questions before the research begins or at any time during the research.
8. I have the right to refuse to be part of the research or to stop at any time. This decision will not affect my care or my relationship with my doctor or this institution in any other way.
9. I have the right to receive a copy of the signed and dated written consent form for the research.
10. I have the right to be free of any pressure as I decide whether I want to be in the research study.

If I have any questions or concerns I can ask the researcher or the research assistant. Contact information [contact information].