

CONSENT FORM TEMPLATE

Derivation and Distribution of Induced Pluripotent Stem (iPS) Cell Lines Created from Donor Specimens

INTRODUCTION

We invite you to take part in a research study at [*name of research institution*].

Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at [*institution*] or with family, friends, or your personal physician or other health professional.

If you are signing this consent form as the parent or guardian of a minor who will participate, “you” in this consent form refers to your child. When your child turns 18 years old, she or he will be able to make decisions regarding ongoing participation in this research for herself or himself.

WHY IS THIS STUDY BEING DONE?

[Instructions to investigators: If there is a preliminary plan to use samples now for a specific project, state the purpose of that project first, in addition to the following generic language.]

The purpose of this research is to create, use, and share induced pluripotent stem cells, also known as “iPS” cells.

WHAT ARE iPS CELLS?

“Pluripotent” stem cells are cells that can be converted into many different kinds of cell types, such as muscle, nerve, and liver cells. They can be kept alive and stored indefinitely in the laboratory and in stem cell banks. There are different kinds of pluripotent stem cells. Induced pluripotent stem cells (iPS cells) can be derived from many different kinds of donated samples, such as skin, blood, or hair. This is different from embryonic stem cells, which can only be derived from embryos. This study involves the creation and use of iPS cells that are derived from donated samples.

We can learn a lot by studying iPS cells that are made from samples collected from people with different conditions, and people without these conditions. iPS cells are used for research on various medical conditions and potential treatments for those conditions. They are also used to develop better techniques for making iPS cells and to train researchers in how to make them.

In the future, iPS cells may be used in other ways. For example, research may include:

- Looking at the DNA sequence/genetic code in your cells
- Altering some of the DNA within these cells
- Testing in animals to model diseases and treatments
- Developing and testing new drugs and treatments
- Techniques and uses that we cannot predict at this time

Your iPSC cells may be used in research on possible treatments for various diseases and conditions. This may include transplanting cells or tissues made from iPSC cells directly into another patient to treat a disease (known as “regenerative medicine”). At this time, there are no plans to use your iPSC cells in this way, but it may be done in the future.

Society and medical research benefit from sharing cells and information among many researchers and institutions. The iPSC cells and medical information from participants in this study will be made available to researchers at universities, private companies, and other institutions in the United States and internationally. We may share your cells with our own research collaborators. We will set up a repository of the iPSC cells, also known as a “stem cell bank,” so that other researchers and companies can apply to use the banked iPSC cells in their own research. The stem cell bank will only release cells to researchers and others under certain conditions. *[Investigator instructions: Specify the terms of release established by the repositories.]*

[If applicable:] Information about your DNA will be put into a database called “dbGaP,” along with information from the other research participants. This information will be available to other researchers who have received approval from an NIH Data Access Committee.

WHAT DOES MY PARTICIPATION IN THIS STUDY INVOLVE?

This study involves obtaining a sample from you, as well as collecting information on your medical history from you and your medical records. The samples will be used to create iPSC cells.

HOW WILL I GIVE SAMPLES FOR STEM CELLS?

[Instructions to investigators: Check those that are appropriate from the list below, and instruct the participant to initial next to the box(es) checked to indicate their acknowledgement.] With this consent form, you are asked to provide blood, skin biopsies, or hair samples as indicated in the checked boxes below. Please initial on the line to indicate that you agree to the procedure.

- _____ **Skin Biopsy:** A small area of skin will be washed with iodine and alcohol. We will inject a local anesthetic to numb the area. Then we will remove a 1/4-inch piece of skin with a biopsy tool. After the biopsy, the site will be covered by a dressing. You will receive instructions on how to care for area.
- _____ **Blood Donation:** Blood will be drawn through a needle in your arm. We will draw no more than ___ teaspoons (or ___ cups) of blood at one time *[note: protocols vary with regard to volume; confirm amount with protocol]*.
- _____ **Hair Sample:** We will remove a few hairs from your head at the root by pulling sharply.

[Will vary by institution/study] If you are having a biopsy or other surgery, we will ask for your permission to use a part of the blood or tissue samples being removed to create iPSC cells for research. We will only use this blood or tissue for research if it is not needed for your care or treatment.

COLLECTION OF MEDICAL INFORMATION

We will interview you about your medical history. We will review your medical records. We will ask about your family's racial and ethnic background and where they came from. We will provide limited medical information about you, such as your sex, age at the time of sample donation, and diagnosis to the cell bank and to other researchers along with iPSC cells and samples.

HOW MANY VISITS ARE REQUIRED?

Obtaining these samples usually requires one outpatient visit. We will obtain the samples during a visit scheduled for another reason whenever possible.

WILL I BE RE-CONTACTED BY THE RESEARCHERS?

We may want to contact you in the future.

- We may contact you to obtain additional samples or to request updates on your health. If we ask, keep in mind you are under no obligation to donate additional samples or provide additional information.
- At the present time, research on your iPSC cells is not likely to provide any information on your personal health. In rare cases, it may be possible that researchers could identify new information that they believe is urgently related to your health. In this very unlikely event, we may contact you to give you a choice about whether or not to learn the information.
- We may contact you if we discover that the iPSC cells made from your sample could be useful for research that is not covered by this consent form, and that we want to get your permission to do. This might include research on sperm and egg cells, reproduction, and infertility. It might include some research using new techniques or for new purposes that we simply cannot predict at this time.
- We may send periodic notifications about the types of research being done with your samples, and about the scientific and medical progress that has been made.
- Please remember to update [*insert institution name*] or the research team with your contact information if it changes. Otherwise, they may not be able to find you.
- [*Instructions to investigator: Describe plans for handling re-contact requests from secondary researchers. For example:*] If a researcher at another institution who has received your samples or medical information wishes to contact you, they will notify us so that we can let you know about their request.

Remember that you can re-contact the research team at any time, now or in the future, and ask any questions you have.

With this consent form, you are asked to agree to be re-contacted by the researchers in the future for a variety of reasons. However, if you do not wish to be re-contacted, please indicate your preference below:

_____ Check and initial here if you **DO NOT** agree to be re-contacted in the future by the research team for any reason.

ARE THERE LIMITS ON HOW MY CELLS WILL BE USED?

All research on your cells must comply with all applicable laws and policies. The iPSC cells generated from your tissue samples will never be used to clone (known as “reproductive cloning”) or to otherwise create an entire human being. Research with human iPSC cells may involve transplanting or testing them with animals, within the limits imposed by laws and regulations.

The stem cell bank that we will be creating with iPSC cells from this study is not the same as storing umbilical cord blood or other stem cell storage services. You will not be able to retrieve your donated samples or iPSC cells from the researchers for personal use.

CAN I PLACE OTHER LIMITS ON THE USE OF MY CELLS?

By agreeing to be in this study, you agree to the terms and limitations described in this consent form. We are not able to honor personal restrictions. For example, you may not place restrictions on who may or may not be treated with your cells or resulting medical products. You also may not place limits on the types of diseases that may be studied with your cells. If you have questions about these terms, please feel free to ask us.

WHAT ARE THE RISKS OF THE STUDY?

- **Skin Biopsy:** There is usually not much pain at the biopsy site. Bleeding and infection are rare. Biopsy wounds usually heal with a very small, nearly unnoticeable scar, but there may be a raised scar or visible lump. We will take the biopsy from a place on your body that is not easily seen.
- **Blood Donation:** You may have some discomfort and bruising at the site of needle entry. There is a very small risk of fainting. Infection in the area of the needle insertion is rare.
- **Emotional Risks of Research on Your Sample:** Emotional and psychological risks are also possible with the donation of samples for iPSC cells. We may publish results of this research study in the medical literature. When we publish results, we do not use names or personally-identifiable information. However, it is possible that you or family members could be recognized because of the rarity of your disease or based on your DNA sequence. It would be very difficult to identify any individual based on such published data, but it is a potential risk. Risk arises if your genetic information could be misused. For example, if research results suggested a serious problem with your health, it could be used to make it harder for you to get or keep a job or insurance.

Although there is a small risk that your personal information will be released inadvertently, there are laws in place that make it illegal for an employer or health insurance company to discriminate against an individual based on their genetic information.

- **Group Risks:** Information on your ethnic and geographic background will be included with other medical information about you in the database as part of the stem cell bank. Research on the samples you provide may lead to results which are upsetting to you and others in your group, which you may disagree with, or which could be stigmatizing for your community.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Your name, birth date, and other personally-identifying information will be removed from your data and samples. They will be linked to your sample only by code number. The code key for the samples will be stored in password-protected database under control of the [*institution*] investigators. Medical information, samples, and iPSC cells that are shared with others will be coded and will not include identifying information (name, address, telephone number, or personal identification number). Only the original investigators will be able to trace your samples and information to you.

Information collected in this study may be reviewed by authorized individuals from the Food and Drug Administration (FDA), the National Institutes of Health (NIH), or other agencies for the purpose of making sure that proper systems, procedures, and regulations are being followed.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Participation in this study will not benefit you or your family directly.

It will take a long time for research to progress and to yield safe, effective treatments based on iPSC cells obtained in this study. Your participation will help medical research better understand various diseases and develop better treatments, which may help you or others in the future.

WHAT ARE MY OTHER OPTIONS?

Taking part in research is entirely voluntary. You do not have to participate in this study if you do not want to do so. Your decision about whether or not to participate will in no way affect your present or future medical care at [*related hospital/clinical center, as applicable*], your participation in other research studies at the [*institution*], or your relationship with the research team.

WHAT IF I CHANGE MY MIND?

If you join the study but change your mind later and wish to withdraw, please let us know. We are able to honor such requests as follows:

- You may withdraw your consent to be contacted by us about this study in the future.
- You may withdraw your consent for the use of all of your original donated blood, skin, or hair until these samples are used to create iPSC cells.
- Once the iPSC cells have been created, you may request that any original materials that are leftover and not being used in a research project can be destroyed.
- We can remove the codes from your cells and information so that they cannot be linked back to you in any way. We can ask that other researchers and institutions that we know have received your cells and information remove the codes as well. We will continue to distribute and use your samples and limited medical information, but there will no longer be any way to identify them as yours.

We will NOT be able to destroy iPSC cells once they are created. iPSC cells that have been shared with other researchers will not be retrievable.

WILL I RECEIVE PAYMENT FOR BEING IN THIS STUDY?

[Instructions to investigators: Indicate whether or not participants will be paid for their participation in this study. For example: “You will not be paid for taking part in this study.”]

Your samples will be used for research, and they may also be used to make commercial products and treatments, meaning that they can be bought and sold in order to treat other people. The research done with your samples may help to develop new products in the future. You will not receive any financial compensation, should this occur.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Building, Room, Telephone. You may also call the [INSTITUTION] Patient Representative at xxx-xxx-xxxx. Please keep a copy of this document in case you want to read it again.

SIGNATURES *[per institutional format]*