The model language is intended as a guide for a human induced pluripotent stem cell repository. It is designed to incorporate the requirements of the CIRM MES regulations (California Code of Regulations, sections 100010 – 100110), California Health and Safety Code 24173, the recommendations of the CIRM Standards Working Group, and model language from CIRM grantees performing iPSC derivation. Actual language should be modified to be consistent with the study protocol.

The language below is intended for protocols where there will be a review of medical information and ongoing donor interaction (as defined by 45 CFR Part 46).

Creation and Distribution of Stem Cell Lines from Donor Skin Sample

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

- Cells from your donation will be transformed to make stem cell lines
- The stem cell lines will be widely distributed (perhaps indefinitely) and used 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 the your cells or the resulting stem cell lines include:
    - Identifying the cell's genetic code / sequence
    - Changing some of the genetic code / sequence within these cells
    - Using these cells to screen 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.
- Researchers must tell you 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 request that your cells be made anonymous by removing all links to your identify, but donated cells and resulting stem cell lines may continue to be distributed and used by researchers.

Derivation and Distribution of Stem Cell Lines Created from Donor Skin Biopsy [Identify Appropriate Biological Specimens]

You are being invited to participate in research conducted by [names and degrees of PI] at [identify institution]. Your skin cells, blood or hair [identify appropriate biological specimens] will be used to create stem cell lines. . The resulting stem cell lines may be widely distributed and used for research, training and the development of medical products.

Taking part in [institution] research is entirely voluntary. You should read the information below and ask about anything you do not understand. The [institution] must document, in writing, that you have agreed to participate.

1.0: What is the nature and purpose of a study?

Your skin cells, blood or hair [identify appropriate biological specimens] will be used in research designed to create induced pluripotent stem cells (iPSCs). iPSCs are made by exposing donated cells to factors (genes or chemicals) that modify the donated cells' behavior yielding resulting cells with pluripotent abilities (described in 2.0).

If iPSCs are created successfully from your donation, they will most likely be stored in a cell repository or "bank." Cell banks are important because they allow iPSCs to be shared with researchers and medical professionals at universities, hospitals, research institutes, and companies around the world. The goal of the study is create a collection of iPSCs to be distributed for future research.

2.0: Why is this study being done?

iPSCs cells are important because they have unique "pluripotent" abilities. Pluripotent cells have: (1) the ability to form any type of cell in the body, such as muscle cells, brain cells or heart cells, through a process called differentiation; and (2) the ability to regenerate or replicate, perhaps indefinitely.

Researchers hope to learn more about human diseases by creating a collection of iPSCs produced from biopsies of people (1) with a history of different diseases or (2) without a history of disease. The iPSC collection from this study will be available to researchers across the US and in other countries. Cells will be used for training and in future studies designed to understand the disease process and develop medical products to treat patients.

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

By participating you will be providing biological samples (skin, blood and hair) and authorizing the study to obtain information about your medical history. To obtain biological samples we will perform a skin punch biopsy, blood draw, and remove a couple of hairs from your head.

A Skin Punch Biopsy: The 4-mm (about the size of a lentil) skin punch biopsy will be carried out 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).

A Hair Sample: We are asking you to provide a couple of hairs from your head. Cells from all these tissues may be used to create iPSCs.

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 this questionnaire to last approximately [time frame] including the consenting process and medical history.

To obtain information about your medical history, a review of your medical records will be conducted. If applicable, this section should provide information about one-time or continued access to medical information by the PI/Bank or other personally identifiable information that will be accessed]

3.1: Consent for future contact:

In the future, we may want to contact you to obtain additional information regarding past or current health conditions. The information may be important for research, developing medical products or treating disease. If you consent for future contact, initial below:

- I consent to being re-contacted in the future to obtain additional information.

- I do not consent to being re-contacted in the future to obtain additional information.

If you consent to being re-contacted, you have the right to withdraw this consent at any time. See section 12.1 for instructions.

4.0: 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 5-15ml 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.

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

If iPSCs are created successfully, they may be stored in a cell repository or "library" and then distributed to researchers. It is possible the cells and 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 iPSCs 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 stored stem cells include, but are not limited to, the following:

- Identifying the cell's genetic code / sequence
- Changing some of the genetic code / sequence within these cells
- Using these cells to screen 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

Information from your medical history will be also available to researchers, but it will not identify you personally.

5.1: Consent for gamete research

iPSCs 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 iPSC with other gametes to achieve fertilization. However, your cells or gametes or iPSCs generated from your biopsy will never be used to attempt to create an entire person. If you consent to gamete research, initial below:

- I consent for use of my cells for gamete research.
- I do not consent for use of my cells for gamete research.

6.0: Can I place limits on the use of my cells?

You have the right to place additional restrictions on how your specimens are used. The research team may choose to only use cells from donors who agree to all future uses without restriction.

7.0: Are there any potential benefits if I participate?

This research is not designed to provide direct medical benefit to you. The iPSCs may be useful for developing drugs or medical products to treat diseases. You may benefit from the knowledge that your participation may further scientific research or the development of medical products. You may not place restrictions on who may be treated with your cells or resulting medical products.

In rare cases, it is possible that researchers using the cells created from your sample could identify new information about your individual health. These are called incidental findings. Should you approve, we may return incidental findings to you after consulting with the IRB and confirming the finding in an approved clinical laboratory. This type of result is very uncommon, and most participants will not have a result like this. If contacted, you will be given a choice to learn or not learn the information.

7.1: Consent to return incidental findings to you:

Researchers will only attempt to confirm incidental findings for individuals who have consented to be re-contacted. If you consent for future contact to learn about incidental findings, initial below:

- I consent to being re-contacted in the future should researchers identify incidental findings that have been confirmed in an approved clinical laboratory and approved by the IRB.

- I do not consent to being re-contacted in the future to return incidental findings.

If you consent to being re-contacted, you have the right to withdraw this consent at any time. See section 12.1 for instructions.

8.0: Will information about my participation and me be kept confidential?

Any information obtained in connection with this study that can identify you will remain confidential. It will be disclosed only with your permission or as required by law. Researchers receiving distributed iPSCs will not know your identity. The iPSCs generated from your donated sample will be coded and will not contain your name or contact information. Coding is an effective means of protecting you but does not guarantee your identify will not be revealed.

9.0: Will I incur any costs from participation?

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

10.0: 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 in participation.

If any medical products result from your participation, you will not be entitled to any of the profits associated with such products.

11.0: Can I stop participating in the study?

You have the right to withdraw from this research project. If you decide to withdraw after your sample has been used to generate iPSCs, then your materials will be made anonymous by removing the codes that provide the link between the cells and your identity.

We will retain the research materials (e.g. any remaining skin, blood or hair sample and any resulting iPSCs and associated medical information) and we will continue distribution. Since iPSCs 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 links between the cells and your identity.

12.0: What are my options for withdrawing?

At any time you may exercise your right to withdraw from this research project.

Prior to creating iPSCs:

Option 1: Withdraw use of donated blood, hair or skin

You may withdraw your consent for the use of donated blood, skin or hair until the process of creating iPSCs (section 1.0) has begun.

After creating iPSCs:

Option 2: Request that your cells be made anonymous by removing all links to your identify. By removing these codes, researchers will not be able to contact you for any reason.

Option 3: Withdraw consent for future contact 3.1

If you consented to consent to being re-contacted in the future to obtain additional health information in section 3.1, you may withdraw this consent.

Option 4: Withdraw consent to return incidental findings to you

If you consented to allowing researchers to return incidental findings to you in section 7.1, you may withdraw this consent. By withdrawing this consent, researchers will not attempt to convey incidental findings to you. Donated cells and resulting stem cell lines may continue to be distributed and used by researchers.

12.1: Contact information:

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 being 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 is provided in section 12.1 [contact information].