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GESCR Consent Guidance

Consent Form Requirements for iPSC Derivation

The IRB requires that researchers use the Biomedical and Cancer consent template [1] for derivation protocols involving human subjects. In addition, GESCR asks that the following language be incorporated into the following sections of the template consent form:

Why is this study being done?

The purpose of this study is to learn more about [disease]. A new technique has been discovered which enables [state tissue type, i.e. skin cells and/or other types of tissue] to be changed to any cell type of the body, including [type of cell you plan to create]. This technique has been referred to as ?induced pluripotent stem cells? (iPS cells) or ?pluripotent stem cells?. Pluripotent stem cells are capable of developing into any tissue type and may be able to survive indefinitely. This research will focus on the study of [tissue type, such as heart cells] from the [tissue/cell type, such as skin cells] of [state population, such as ?people with?.., relatives of people with??. Or healthy volunteers unrelated to someone with???.]. It is also possible that your cells could be used to study other diseases.

What will happen to the tissue and cells that I donate?

There are several possible research uses for tissues and cells donated for pluripotent stem cell research. This research holds special importance in studying [state disease] and in the development of treatments for human diseases in general. The tissue and cells may be used by researchers at UCSF and may also be shared with researchers at other research institutions. Only [name of PI] and his/her study staff will know your identity. Potential uses include:

1. Injecting or transplanting the stem cells into animals for research purposes only
2. Testing for genetic and DNA composition. Genes may be analyzed and/or manipulated to study normal function or development.
3. Other, currently unknown uses. Science is always evolving and it is therefore difficult to determine exactly how these cells will be used in the future. UCSF will not permit your cells (including DNA or genes) to be used for reproductive research or ?cloning?. It is possible that your cells could be used to create a tissue-specific stem cell line which could be transplanted into another human for the purpose of treating people with [disease] or other disorders.
4. The derived stem cells, which include your DNA, could be patented for scientific or medical uses. You will not receive patent rights. You will not have control over the product sales and uses (except as stated in this consent).
5. In most instances your tissue or cells will be stored indefinitely in [PI?s name] laboratory located at [location].

Are there any other financial considerations?

Yes. If any new products, tests, discoveries or patents that result from this research have potential commercial value, you will not share in any financial benefits.

What Type of Consent is Required From the Original Tissue Donors?

It is important that a consent form signed by the original tissue donors explicitly say that stem cells created from their donated tissues may be distributed to other researchers and that these researchers may patent discoveries using their materials. A researcher distributing these tissues/cells to other researchers should be able to provide confirmation of consent.

The GESCR Committee and the IRB provide a Biomedical and Cancer consent template [2] to be used to create all consent forms involving human subjects.

For further information about tissue donor consent: Obtaining Consent for Future Research with Induced Pluripotent Cells: Opportunities and Challenges. [3]

Can Donors of Embryos, Oocytes or Sperm Be Recontacted?

Reasons for recontacting donors may include to obtain additional information from them, to provide them with information, to discuss commercialization or for other purposes.

Donors may be recontacted if, in the donation consent form, they have agreed to be recontacted. If researchers expect they may want to recontact donors, the initial consent form should describe the circumstances and purposes of recontact. Allowing recontact can be optional; there could be separate lines for subjects to initial to indicate whether they decline or consent to possible recontact. It may be desirable to allow donors to specify whether or not they are willing to be contacted for specific purposes or in specific manners.

If researchers want to recontact donors, but the consent form is silent about whether recontact is permissible, the researchers must seek IRB and GESCR approval before trying to make contact. The researchers, IRB and GESCR must weigh the intrusion on the donors? privacy against whatever personal or scientific benefit would come from the contact.

If the donation consent form states the researchers will not or may not recontact the donors, or if the consent form states all links between the donor?s identity and the donated material will be destroyed, or if the purpose or nature of the recontact exceeds what was agreed to in the consent form, no recontact can be attempted.

Exceptions to the above guidelines might occur in extraordinary circumstances where failure to recontact would lead to great clinical benefit or prevent great clinical harm to the donors. However, such exceptions would be extremely rare. Stringent IRB and GESCR review and approval would be required before recontact would be permitted in these circumstances. Even if the re-contact seemed ethically justified, it might be prohibited by privacy laws.

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Links
[1] http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/biomedical-cancer-consent.doc
[2] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/biomedical-cancer-consent.doc
[3] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2652391/?tool=pubmed