**Somatic (body) cells donated for creation of pluripotent stem cells:**

***California Department of Public Health (CDPH) Guidelines for Human Stem Cell*** *Research - revised December 5, 2011*

* These guidelines are proposed pursuant to Health and Safety Code §125118. They apply to all individuals and institutions performing human stem cell research in California by deriving or using covered stem cell lines, or cells from those covered stem cell lines.
* “Covered stem cell line” means a culture-derived, human pluripotent stem cell population **derived from an embryo or product of somatic cell nuclear transfer** (**SCNT)** that is capable of: (1) sustained propagation in culture; and (2) self-renewal to produce daughter cells with equivalent developmental potential[[1]](#footnote-1).

***For CIRM funded studies****, this* ***definition includes both embryonic and non-embryonic*** *[pluripotent]**human stem cell lines* ***regardless of the tissue of origin*** *(i.e. requirements will apply for collecting tissue to create iPS cells).* “Pluripotent” means capable of differentiation into mesoderm, ectoderm, and endoderm”.

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| ***California Department of Public Health (CDPH) Guidelines for Human Stem Cell*** *Research and* ***CIRM Guidelines for CIRM Funded Studies*** | **Institution/ Consent** |
| Derived cells or cell products may be **kept for many years**. |  |
| Whether the **identity(ies) of the donor(s) will be ascertainable** to those who work with the resulting cells or cell products. |  |
| **If the identity(ies) of the donor(s) are retained (even coded),** researchers must discuss **any plans for recontact** of donors of materials used to derive cell lines and obtain consent for recontact. This requirement includes both recontacting donors to provide information about research findings and to ask for additional health information. Recontact may only occur if the donor consents at the time of donation. |  |
| Researchers may **use cell lines for future studies**, some of which **may** **not be predictable** at this time. |  |
| Derived cells or cell products may be used in **research involving genetic manipulation**. |  |
| Derived cells or cell products may be **transplanted into humans or animals**. |  |
| Derived cells or cell products are **not intended to provide direct medical benefit to the donor**(s), except in the case of autologous donation. |  |
| The donation is being made **without restriction regarding who may be the recipient** of transplanted cells, except in the case of autologous donations. |  |
| That neither consenting nor refusing to donate materials for research will **affect the quality of any future care** provided to potential donors. |  |
| That the results of research may be patentable or have commercial potential, and that the **donor will not receive patent rights** and **will not receive financial or any other benefits** from future commercial development. |  |

**45 CFR 46.116** (Health and Human Services Protection of Human Research Subjects) – **pre-2018 (added 2018 requirements in dark red)**

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| **Required** elements of Consent: | **Institution/ Consent** |
| A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental |  |
| A description of any reasonably foreseeable risks or discomforts to the subject |  |
| A description of any benefits to the subject or to others which may reasonably be expected from the research |  |
| A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |  |
| A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained |  |
| For research involving more than minimal risk, an explanation as to whether any compensation or any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained; |  |
| An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject |  |
| A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. |  |
| 2018 regulations only: Either: A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility |  |
| 2018 regulations only OR: A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies |  |

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| **Additional** elements of Consent:  *(When appropriate, one or more of the following elements of information shall also be provided to each subject required)* | **Institution/ Consent** |
| A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable |  |
| Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent |  |
| Any additional costs to the subject that may result from participation in the research |  |
| The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; |  |
| A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject |  |
| The approximate number of subjects involved in the study. |  |
| [2018 requirement] A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. |  |
| [2018 requirement] A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. |  |
| [2018 requirement] For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). |  |

**Consenting Donors of Gametes or Embryos for Research:**

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| **UCI hSCRO Program** – Policy Number 2: Informed Consent Requirements for Gamete or Blastocyst Donors - III. **Consenting Donors of Gametes or Embryos for Research** | **Institution/ Consent** |
| The **gametes or early human embryos** will be **used to derive** human pluripotent **stem cells for research**. |  |
| The gametes or early human **embryos will not survive** in the stem cell derivation process. |  |
| **Donors will not receive any information about subsequent testing** on the gametes or embryos or the derived human pluripotent cells. |  |
| **Compensation to donors allowed only for permissible expenses**: travel, housing, childcare, medical care, health insurance and actual lost wages [or direct expenses incurred as a result of the procedure, as determined by an IRB for women who undergo hormonal induction to generate *oocytes* specifically for research purposes (such as for SCNT)] |  |
| *Blastocysts*: donors shall be informed that they **retain the right to withdraw consent until the blastocysts are actually used** in cell line derivation |  |

**Embryo donation Consent requirements:**

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| **Embryo donation Consent requirements per California Health and Safety Code**; Div. 106; Part 5.5 Use of Human Cells –Section 125315 - *Effective January 1, 2004* | **Institution/ Consent** |
| A **physician and surgeon or other health care provider delivering fertility treatment shall obtain written consent** from any individual who elects to donate embryos remaining after fertility treatments for research. For any individual considering donating the embryos for research, to obtain informed consent, the health care provider **shall convey all of the following** to the individual: |  |
| (1)  A statement that the early human embryos will be used to derive human pluripotent stem cells for research and that the cells may be used, at some future time, for human transplantation research. |  |
| (2)  A statement that all identifiers associated with the embryos will be removed prior to the derivation of human pluripotent stem cells. |  |
| (3)  A statement that donors will not receive any information about subsequent testing on the embryo or the derived human pluripotent cells. |  |
| (4)  A statement that derived cells or cell lines, with all identifiers removed, may be kept for many years. |  |
| (5)  Disclosure of the possibility that the donated material may have commercial potential, and a statement that the donor will not receive financial or any other benefits from any future commercial development. |  |
| (6)  A statement that the human pluripotent stem cell research is not intended to provide direct medical benefit to the donor. |  |
| (7)  A statement that early human embryos donated will not be transferred to a woman’s uterus, will not survive the human pluripotent stem cell derivation process, and will be handled respectfully, as is appropriate for all human tissue used in research. |  |

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| **Embryo donation - NIH policy** - <https://stemcells.nih.gov/policy/2009-guidelines.htm>  Requirement are applicable to research funded by NIH - During the consent process, the donor(s) were informed of the following: | **Institution/ Consent** |
| the **embryos would be used to derive hESCs** for research |  |
| what **would happen to the embryos** in the derivation of hESCs for research |  |
| that hESCs derived from the embryos might be **kept for many years** |  |
| the donation was made **without any restriction or direction** regarding the individual(s) who may receive medical benefit from the use of the hESCs, such as **who may be the recipients of cell transplants** |  |
| the research was **not intended to provide direct medical benefit to the donor** |  |
| the results of research using the hESCs may have **commercial potential**, and that the donor(s) would **not receive financial or any other benefits** from any such commercial development |  |
| **whether information that could identify the donor(s) would be available** to researchers |  |
| the **embryos would be used to derive hESCs** for research |  |

**Fetal Tissue Research Regulations:**

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| **Federal regulation 42 U.S. Code § 289g–1 - Research on transplantation of fetal tissue**   * the term “[human fetal tissue](https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=42-USC-1748999528-486974113&term_occur=8&term_src=title:42:chapter:6A:subchapter:III:part:H:section:289g%E2%80%931)” means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.   **California Code of Regulations**. Amend. 17 section 100085: **§ 100085. Use of Fetal Tissue** | **Institution/ Consent** |
| **The woman** who donates the fetal tissue must sign a statement declaringthat | |
| the donation is being made for research purposes, |  |
| the donation is made without any restriction regarding who may be the recipient(s) of materials derived from the tissue [the recipient of the transplantations] |  |
| the woman hasnot been informed of the identity of any such individuals |  |
| **The attending physician** must sign a statement that he or she | |
| has obtained the tissue in accordance with the donor’s signed statement. |  |
| *In the case of tissue obtained pursuant to an induced abortion,*  Obtained the woman’s consent for the abortion before requesting or obtaining consent for the tissue to be used for research; |  |
| *In the case of tissue obtained pursuant to an induced abortion,*  Did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and |  |
| *In the case of tissue obtained pursuant to an induced abortion*,  Performed the abortion in accordance with applicable law. |  |
| **The attending physician** must disclose to the donor | |
| any interest (including financial) that the attending physician has in the research to be conducted with the tissue. |  |
| any known medical risks to the donor or risks to her privacy that might be associated with the donation of the  tissue and that are in addition to risks of such type that are associated with the woman's medical care. |  |
| **The principal investigator of the research project** must sign a statement certifying that he or she: | |
| Is aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion or pursuant to a stillbirth; |  |
| Is aware that the tissue was donated for research purposes; |  |
| had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy; and |  |
| **i**s not the donor’s attending physician. |  |
| has provided such information to other individuals with responsibilities regarding the [research](https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=42-USC-350895717-1350744094&term_occur=587&term_src=title:42:chapter:6A:subchapter:III:part:H:section:289g%E2%80%931) [*i.e. PI has provided the information listed under point (1) above to their research team which are listed on the protocol that includes the use of this tissue*]. |  |
| will require, prior to obtaining the consent of an individual to be a [recipient](https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=42-USC-820081177-1439979518&term_occur=32&term_src=title:42:chapter:6A:subchapter:III:part:H:section:289g%E2%80%931) of a transplantation of the tissue, writtenacknowledgment of receipt of such information by such [recipient](https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=42-USC-820081177-1439979518&term_occur=33&term_src=title:42:chapter:6A:subchapter:III:part:H:section:289g%E2%80%931) [*will inform the recipient of the tissue about the information* *listed under point (1) above]* |  |

**Additional requirements applicable to human fetal tissue obtained from elective abortions NIH research\* submitted after 08/23/2019** per [NOT-OD-19-137](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-137.html)

\*Research involves the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures ***obtained from elective abortions*** and includes the following:

* human fetal primary or secondary cell cultures, whether derived by the investigator or obtained from a vendor.
* animal models incorporating HFT from elective abortions, including obtaining such models from a vendor.
* derivative products from elective abortion tissues or cells such as protein or nucleic acid extracts.
* any human extra-embryonic cells and tissue, such as umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi, if obtained from the process of elective abortion.

If the research includes ONLY the following materials – the following requirement do not apply:

* human fetal primary or secondary cell cultures, **if cells were not derived** from an elective abortion
* already-**established (**[**as of June 5, 2019**](https://www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html)**) human fetal cell lines** (e.g. induced pluripotent stem cell lines from human fetal tissue, immortalized cell lines, differentiated cell lines).
* derivative products from human fetal tissue or cells (e.g. DNA, RNA, protein) **if not** **derived** from elective abortion.
* human extra-embryonic cells and tissue, including, but not limited to, umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi **if not derived** from elective abortion.
* human **fetal cells present in maternal blood or other maternal sources**
* **embryonic stem cells or embryonic cell lines**.
* research on transplantation of HFT for therapeutic purposes.

Submission to NIH must include the following information:

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| **Justification for why the research goals cannot be accomplished using an alternative to HFT** |  |
| **Indicate the methods used (e.g. literature review, preliminary data) to determine that alternatives could not be used** |  |
| **Plans for the treatment of HFT and the disposal of HFT when research is complete** |  |
| **Results from a literature review used to provide justifications** |  |
| **Description of planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained.** |  |
| **Include a sample of the IRB approved consent form with the application or during the JIT process. HFT Sample IRB Consent Form.**   * Provide a blank sample of the IRB approved consent form with the application. * The PDF-formatted form must be a blank sample and named ‘HFTSampleIRBConsentForm.pdf’. * Applications proposing HFT research that do not include this assurance will be administratively withdrawn and not reviewed. |  |
| The informed consent for use of HFT from elective abortion requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, |  |
| [The consent for use of HFT from elective abortion] occurred after the informed consent for abortion, |  |
| [The consent for use of HFT from elective abortion] will not affect the method of abortion |  |
| no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT |  |
| [The consent for use of HFT from elective abortion] is signed by both the woman and the person who obtains the informed consent. |  |
| **HFT Compliance Assurance.**   * The applicant institution must provide a letter signed by the PD/PI assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration. * The PDF-formatted letter must be named ‘HFTComplianceAssurance.pdf’. * Applications proposing HFT research that do not include this assurance will be administratively withdrawn and not reviewed. |  |

1. SCNT involves transferring the nucleus of a somatic cell into an enucleated egg cell, essentially cloning the donor cell's DNA. iPS cells, on the other hand, are created by reprogramming adult somatic cells using specific genes or factors to achieve a pluripotent state ([reference](https://onlinelibrary.wiley.com/doi/abs/10.1002/bies.201100174))

   [↑](#footnote-ref-1)