§ 100080. Acceptable Research Materials.

All covered stem cell lines used in CIRM-funded research must be "acceptably derived." (a) To be "acceptably derived," the stem cell line must ~~have been~~ meet one of the following three criteria:

(1) The stem cell line is recognized by an authorized authority. To be recognized by an authorized authority the stem cell line must:

(A) Be~~en~~ approved by the National Institutes of Health; or

(B) Be~~en~~ deposited in the United Kingdom Stem Cell Bank; or

(C) Be~~en~~ derived by, or approved for use by, a licensee of the United Kingdom Human Fertilization and Embryology Authority; or

(D) Be~~en~~ derived in accordance with the Canadian Institutes of Health Research Guidelines for Human Pluripotent Stem Cell Research under an application approved by the National Stem Cell Oversight Committee; or

(E) Be~~en~~ derived in accordance with the Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells; or

(F) Be~~en~~ derived in accordance with California Code of Regulations, title 17, section 100090.

(2) The stem cell line is derived from human gametes, embryos, somatic cells, or tissue under the following conditions:

(A) Donors of human gametes, embryos, somatic cells or ~~human~~ tissue gave voluntary and informed consent; and

(B) Donors of human gametes, embryos, somatic cells or ~~human~~ tissue did not receive valuable consideration. This provision does not prohibit reimbursement for permissible expenses as defined in California Code of Regulations, title 17, section 100020, subdivision (h), as determined by an IRB; and

~~(3) A person may not knowingly, for valuable consideration, purchase or sell gametes, embryos, somatic cells, or human tissue for research purposes pursuant to this chapter. This provision does not prohibit reimbursement for permissible expenditures as approved by a SCRO committee or IRB, or permissible expenses as determined by an IRB. "Permissible expenditures" means necessary and reasonable costs directly incurred as a result of persons, not including human subjects or donors, providing~~

(C) Donation of human gametes, embryos, somatic cells or ~~human tissue for research purposes. Permissible expenditures may include but are not limited to costs associated with processing, quality control, storage, or transportation of materials.~~

~~(4) Donation of gametes, embryos, somatic cells or human~~ tissue was overseen by an IRB (or, in the case of foreign sources, an IRB-equivalent); and

(D) Individuals who consented to donate stored human gametes, embryos, somatic cells or ~~human~~ tissue were not reimbursed for the cost of storage prior to donation.

(3) The stem cell line is derived from non-identifiable human somatic cells under the following conditions:

(A) The derivation did not result from the transfer of a somatic cell nucleus into a human oocyte (SCNT) or the creation or use of a human embryo; and

(B) The somatic cells have no associated codes or links maintained by anyone that would identify to the investigator(s) the donor of the specimens, or, if such codes or links exist, that the identity of the donor is not readily ascertainable because, for example:

(i) the key to decipher the code or link is destroyed before the research begins;

(ii) an agreement prohibits release of the key to the investigators under any circumstances;

(iii) IRB-approved written policies and operating procedures for a repository or data management center prohibit releasing the key under any circumstances; or

(iv) the release of the key to the investigators is forbidden by law.

(b) In addition to the requirements of subdivision (a) of this chapter, the following requirements apply to the derivation and use of all covered stem cell lines.

(1) Any covered stem cell line derived from any intact human embryo, any product of SCNT, parthenogenesis or androgenesis after 12 days in culture may not be used unless prior approval is obtained from the Independent Citizens Oversight Committee, constituted under Health & Safety Code, section 125290.15. Use of any covered stem cell line derived from any intact human embryo, any product of SCNT, parthenogenesis or androgenesis after 14 days or after the appearance of the primitive streak is prohibited. The 12-14 day limit does not include any time during which the cells have been frozen.

(2) Any payments for the purchase of covered stem cell lines, somatic cells, or human tissue to persons other than the original donors shall be limited to those costs identified in Health & Safety Code, section 125290.35, subdivision (b)(5). Any payment for gametes and embryos, to persons other than the original donors, shall be limited to necessary and reasonable costs directly incurred as a result of providing materials for

research, which include but are not limited to expenditures associated with processing, quality control, storage, or transportation.

§ 100090. Additional Requirements for CIRM-Funded Derivation.

~~(a) Where CIRM funds are to be used to derive new human stem cell lines, in addition to the requirements of Code of California Regulations, title 17, section 100080, subdivision (e), the SCRO committee must confirm that donors of gametes, embryos, somatic cells or human tissue have given voluntary and informed consent in accordance with Code of California Regulations, title 17, section 100100.~~
(a) Where CIRM funds are to be used for research intended to derive a covered stem cell line from human gametes, embryos, somatic cells or tissue, the SCRO committee must determine the requirements of Code of California Regulations, title 17, section 100080, subdivision (a)(2), have been met. For CIRM-funded derivation occurring after November 22, 2006, the SCRO committee must also confirm that donors provided voluntary and informed consent in accordance with Code of California Regulations, title 17, section 100100, subdivision (b).

(b) California Code of Regulations title 17, section 100090(a), does not apply to CIRM funded research intended to derive a covered stem cell line from somatic cells when the SCRO committee has determined the requirements of California Code of Regulations title 17, section
100080, subdivisions (a)(3)(A) and (a)(3)(B), have been met.

(c) The modification of an acceptably derived stem cell line shall not be considered a CIRM-funded derivation.

§ 100100. Informed Consent Requirements.

(a) All CIRM-funded human subjects research shall be performed in accordance with Title 45 Code of Federal Regulations, Part 46 (Protection of Human Subjects), revised June 23, 2005, and California Health and Safety Code section 24173. In accordance with existing law, California Health and Safety Code section 24173 does not apply to a person who is conducting research as an investigator within an institution that holds an assurance with the United States Department of Health and Human Services pursuant to Title 45 Code of Federal Regulations Part 46, revised June 23, 2005, and who obtains informed consent in the method and manner required by those regulations.

(b) In addition to the requirements of Code of California Regulations, title 17, section 100080, subdivision (a)(2), the following provisions apply when CIRM funded research involves donation of human gametes, embryos, somatic cells or ~~human~~ tissue for derivation of new covered stem cell lines ~~which donation or derivation occurs after the effective date of this Chapter:~~

(1) CIRM-funds may not be used for research that violates the documented preferences of donors with regard to the use of ~~their~~ donated materials. The SCRO committee or IRB must confirm that donors ~~of gametes, embryos, somatic cells or~~

~~human tissue to be used to derive stem cell lines~~ have given voluntary and informed consent in accordance with this section. To ensure that donors are fully informed of the potential uses of donated materials~~, researchers shall disclose,~~ in addition to the general requirements for obtaining informed consent identified in subdivision (a) of this regulation, researchers shall disclose all of the following, unless a specific item has been determined by the SCRO committee or IRB to be inapplicable:

(A) Derived cells or cell products may be kept for many years.

(B) Whether or not the identity(ies) of the donor~~(s)~~ will be ascertainable ~~to~~ by those who work with the resulting cells or cell products. If the identity~~(ies)~~ of the donor~~(s) are retained (even coded),~~ is to remain associated with the cells or cell products, then the ~~CIRM-funded researchers~~ investigator must ~~discuss~~ inform the donor of any plan~~s~~ for recontact whether for the purpose of providing ~~of donors of materials used to derive cells lines and obtain consent for recontact. This requirement includes both recontacting donors to provide~~ information about research findings to donors, or for the purpose of requesting ~~and to ask for~~ additional health information. After donation, an investigator may recontact a donor only if ~~Recontact may only occur if~~ the donor consents at the time of donation.

(C) ~~Researchers may use cell~~ Cell lines may be used in ~~for~~ future studies~~, some of~~ which ~~may~~ are not ~~be predictable at this time~~ now foreseeable.

(D) Derived cells or cell products may be used in research involving genetic manipulation.

(E) Derived cells or cell products may be transplanted into humans or animals.

(F) Derived cells or cell products are not intended to provide direct medical benefit to the donor~~(s)~~, except in the case of autologous donation.

(G) The donation is being made without restriction on the ~~regarding who may be the~~ recipient of transplanted cells, except in the case where donation is intended for ~~of~~ autologous ~~donations~~ transplantation.

(H) ~~That n~~Neither consent~~ing~~ nor refusal~~ing~~ to donate materials for research will affect the quality of any ~~future~~ care provided to a potential donor~~s~~.

(I) ~~That~~ Although the results of research including donated materials may be patentable or have commercial ~~potential,~~ value, ~~and that~~ the donor will ~~not receive patent rights and will not receive financial or any other benefits from future~~ have no legal or financial interest in any commercial development~~.~~ resulting from the research.

(2) ~~Researchers shall offer donors an~~ A donor must be given the opportunity to ~~document their preferences regarding~~ impose restrictions on future uses of ~~their~~

donated materials. Researchers may choose to use materials only from donors who agree to all future uses~~.~~ without restriction.

(3) For CIRM-funded research involving the donation of oocytes, ~~the~~ an IRB finding that potential risks of donation are reasonable even if there is no anticipated benefit to the donor shall be documented and made available to the donor, SCRO and the CIRM. In addition, the following requirements apply:

(A) The description of foreseeable risk required in subdivision (a) of this regulation shall include but not be limited to information regarding the risks of ovarian hyperstimulation syndrome, bleeding, infection, anesthesia and pregnancy.

(B) ~~The physician must disclose his or her~~ Any relationship between the attending physician and ~~to~~ the research or researcher(s) must be disclosed to an ~~to the~~ egg donor.

(C) Prospective donors shall be informed of their option to deliberate before deciding whether or not to give consent. If a deliberation period is chosen, the donor shall be informed of ~~their~~ her right to determine the method of recontact. The donor must be informed that ~~they have~~ she has the option to initiate recontact. ~~The investigators~~ Investigators shall not initiate recontact unless the donor has consented, and this consent is documented in the research record.

(D) The researcher shall ascertain that the donor ~~has understood~~ understands the essential aspects of the research involving donated materials, following a process approved by the designated IRB or SCRO committee. Understanding the essential aspects of the research includes understanding at least that:

(i) ~~Their eggs~~ Eggs will not be used for reproductive purposes.

(ii) There are medical risks in oocyte donation, including the risks of ovarian hyperstimulation syndrome, bleeding, infection, anesthesia, and pregnancy.

(iii) The research is not intended to directly benefit ~~them~~ the donor or any other individual.~~s directly at this time.~~

(iv) Whether stem cell lines will be derived from ~~their~~ her oocytes through fertilization, SCNT, parthenogenesis, or some other method.

(v) Stem cell lines developed from ~~their~~ her oocytes will be grown in the lab and shared with other researchers for studies in the future.

(vi) If stem cells derived from her donation are to be transplanted into patients, researchers might recontact the donor to get additional health information.

(vii) Donors receive no payment beyond reimbursement for permissible expenses.

(viii) Stem cell lines derived as a result of ~~their~~ her oocyte donation may be patented or commercialized, but donors will not share in patent rights or in any revenue or profit from the patents.

(4) For ~~CIRM-~~funded research involving the donation and destruction of human embryos for stem cell research, the informed consent process shall include a ~~statement~~ disclosure that embryos will be destroyed in the process of deriving embryonic stem cells.

(5) ~~For CIRM-funded research~~ Research that uses ~~the~~ human umbilical cord, cord blood or ~~the~~ placenta, consent shall be obtained from the birth mother.

(6) For ~~CIRM-funded~~ research involving the donation of somatic cells for SCNT, the informed consent process shall include ~~a statement~~ disclosure as to whether the donated cells may be available for autologous treatment in the future.