Amend 17 Cal. Code of Regs. section 100100 to read:

§ 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 tissue for derivation of new covered stem cell lines:

(1) CIRM-funds may not be used for research that violates the documented preferences of donors with regard to the use of donated materials. The SCRO committee or IRB must confirm that donors 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 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 will be ascertainable by those who work with the resulting cells or cell products. If the identity of the donor is to remain associated with the cells or cell products, then the investigator must inform the donor of any plan for recontact whether for the purpose of providing information about research findings to donors, or for the purpose of requesting additional health information. After donation, an investigator may recontact a donor only if the donor consents at the time of donation.

(C) Cell lines may be used in future studies which are not 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, except in the case of autologous donation.

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

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

(I) Although the results of research including donated materials may be patentable or have commercial value, the donor will have no legal or financial interest in any commercial development resulting from the research.

(2) A donor must be given the opportunity to impose restrictions on future uses of 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, 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) Any relationship between the attending physician and the research or researcher(s) must be disclosed to an 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 her right to determine the method of recontact. The donor must be informed that she has the option to initiate recontact. 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 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) 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 the donor or any other individual.

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

(v) Stem cell lines developed from 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 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 funded research involving the donation and destruction of human embryos for stem cell research, the informed consent process shall include a disclosure that embryos will be destroyed in the process of deriving embryonic stem cells.

(5) Research that uses human umbilical cord, cord blood or placenta, consent shall be obtained from the birth mother.

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

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Sections 24173, 125290.35, 125290.40, 125290.55 and 125315, Health and Safety Code.