

1 **§ 100095. Additional Requirements for CIRM-Funded Research Involving Oocytes.**

2 When procurement of oocytes are required for derivation CIRM-funded research, the  
3 SCRO committee must confirm the following conditions have been met:

4 (a) The clinic performing oocyte retrieval is a member of the Society for Assisted  
5 Reproductive Technology.

6 ~~(b) For oocytes provided for reproductive uses, either for use by the donor or another~~  
7 ~~woman, the disposition of oocytes shall not knowingly compromise the optimal reproductive~~  
8 ~~success of the woman in infertility treatment.~~

9 ~~(1) Oocytes provided by a woman for her own reproductive uses may not be~~  
10 ~~donated to research unless (a) the woman has determined that she does not want or need~~  
11 ~~them for her own reproductive success, and (b) the donation of oocytes for research is~~  
12 ~~done without valuable consideration.~~

13 ~~(2) Oocytes provided by a donor for a recipient's reproductive use may not be~~  
14 ~~donated to research unless: (a) the donation is expressly permitted by the oocyte donor;~~  
15 ~~(b) the recipient has determined that she does not want or need them for her own~~  
16 ~~reproductive success; and (c) the donation of oocytes for research is done without~~  
17 ~~valuable consideration.~~

18 ~~(b) The procurement and disposition for research purposes of oocytes initially provided~~  
19 ~~for reproductive uses, either for use by the donor or another woman, shall not knowingly~~  
20 ~~compromise the optimal reproductive success of the woman in infertility treatment. Pursuant to~~  
21 ~~this requirement, the SCRO shall confirm the following:~~

22 **Option 1:**

1 (1) The infertility treatment protocol is established prior to requesting or obtaining  
2 consent for a donation for research purposes and that the prospect of donation for research does  
3 not alter the timing, method, or procedures selected for clinical care.

4 (2) The woman in infertility treatment makes the determination that she does not want or  
5 need the oocytes for her own reproductive success.

6 (3) The donation of oocytes for research is done without valuable consideration either  
7 directly or indirectly.

8 (4) If the procurement of oocytes involves a donor providing oocytes for another  
9 woman's reproductive use, then the donation to research must be expressly permitted by the  
10 original donor.

11 **Option 2:**

12 (1) The infertility treatment protocol is established prior to requesting or obtaining  
13 consent for a donation for research purposes and that the prospect of donation for research does  
14 not alter the timing, method, or procedures selected for clinical care.

15 (2) The woman in infertility treatment makes the determination that she does not want or  
16 need the oocytes for her own reproductive success.

17 (3) The donation of oocytes for research is done without valuable consideration either  
18 directly or indirectly.

19 (4) If the procurement of oocytes involves a donor providing oocytes for another  
20 woman's reproductive use, then the donation to research must be expressly permitted by the  
21 original donor.

1 (5) If the procurement of oocytes involves use of materials donated for reproductive use  
2 by another woman and with valuable consideration in excess of reimbursement for permissible  
3 expenses for the oocyte donor, then the oocytes may not be used for CIRM-funded research  
4 except when all the following apply:

5 (A) The oocytes fail to fertilize or otherwise are biologically unusable for  
6 reproductive purposes.

7 (B) The clinician determining that the oocytes are unusable for reproductive  
8 purposes does not know whether to donor has consented to donation to research at the time of  
9 making such a determination.

10 (C) The clinician has no conflict of interest.

11 **Option 3:**

12 (1) The infertility treatment protocol is established prior to requesting or obtaining  
13 consent for a donation for research purposes and that the prospect of donation for research does  
14 not alter the timing, method, or procedures selected for clinical care.

15 (2) The woman in infertility treatment makes the determination that she does not want or  
16 need the oocytes for her own reproductive success.

17 (3) The donation of oocytes for research is done without valuable consideration either  
18 directly or indirectly.

19 (4) If the procurement of oocytes involves a donor providing oocytes for another  
20 woman's reproductive use, then the donation to research must be expressly permitted by the  
21 original donor.

1 (5) If the procurement of oocytes involves use of materials donated for reproductive use  
2 by another woman and with valuable consideration in excess of reimbursement for permissible  
3 expenses for the oocyte donor, then oocytes may not be used for CIRM-funded research.

4 (c) The CIRM-funded institution shall develop procedures to ensure that an individual  
5 who donates oocytes for CIRM-funded research has access to medical care at no cost to the  
6 donor that is required as a direct and proximate result of that donation. If a donor is medically  
7 insured, the donor shall not be required to claim any treatment costs through her own insurance  
8 policy.

9 (d) The physician attending to any donor and the principal investigator shall not be the  
10 same person unless exceptional circumstances exist and an IRB has approved an exemption from  
11 this requirement.

12 (e) The physician performing oocyte retrieval shall not have a financial interest in the  
13 outcome of the research.

14 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),  
15 Health and Safety Code.

16 Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

1 Adopt 17 Cal. Code of Regs. section 100100 to read:

2 **§ 100100. Informed Consent Requirements.**

3 (a) All CIRM-funded human subjects research shall be performed in accordance with  
4 Title 45 Code of Federal Regulations, Part 46 (Protection of Human Subjects), revised June 23,  
5 2005, and California Health and Safety Code section 24173. In accordance with existing law,  
6 California Health and Safety Code section 24173 does not apply to a person who is conducting  
7 research as an investigator within an institution that holds an assurance with the United States  
8 Department of Health and Human Services pursuant to Title 45 Code of Federal Regulations Part  
9 46, revised June 23, 2005, and who obtains informed consent in the method and manner required  
10 by those regulations.

11 (b) In addition to the requirements of 17 California Code of Regulations Section 100080,  
12 the following provisions apply when CIRM funded research involves donation of gametes,  
13 embryos, somatic cells or human tissue or derivation of new covered stem cell lines which  
14 donation or derivation occurs after the effective date of this Chapter:

15 (1) CIRM-funds may not be used for research that violates the documented preferences  
16 of donors with regard to the use of their donated materials. The SCRO committee or IRB must  
17 confirm that donors of gametes, embryos, somatic cells or human tissue to be used to derive stem  
18 cell lines have given voluntary and informed consent in accordance with this section. To ensure  
19 donors are fully informed of the potential uses of donated materials, researchers shall disclose, in  
20 addition to the general requirements for obtaining informed consent identified in subdivision (a)  
21 of this regulation, all of the following, unless a specific item has been determined by the SCRO  
22 committee or IRB to be inapplicable:

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

2           (B) Whether the identity(ies) of the donor(s) will be ascertainable to those who  
3 work with the resulting cells or cell products. If the identity(ies) of the donor(s) are  
4 retained (even coded), CIRM-funded researchers must discuss any plans for recontact of  
5 donors of materials used to derive cell lines and obtain consent for recontact. This  
6 requirement includes both recontacting donors to provide information about research  
7 findings and to ask for additional health information. Recontact may only occur if the  
8 donor consents at the time of donation.

9           (C) Researchers may use cell lines for future studies, some of which may not be  
10 predictable at this time.

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

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

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

16           (G) The donation is being made without restriction regarding who may be the  
17 recipient of transplanted cells, except in the case of autologous donations.

18           (H) That neither consenting nor refusing to donate materials for research will  
19 affect the quality of any future care provided to potential donors.

20           (I) That the results of research may be patentable or have commercial potential,  
21 and that the donor will not receive patent rights and will not receive financial or any  
22 other benefits from future commercial development.

1           (2) Researchers shall offer donors an opportunity to document their preferences  
2 regarding future uses of their donated materials. Researchers may choose to use materials only  
3 from donors who agree to all future uses.

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

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

11           (B) The physician must disclose his or her relationship to the research or  
12 researcher(s) to the egg donor.

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

19           (D) The researcher shall ascertain that the donor has understood the essential  
20 aspects of the research, following a process approved by the designated IRB or SCRO  
21 committee. Understanding the essential aspects of the research includes understanding at  
22 least that:

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

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

4           (iii) The research will not benefit them or any other individuals directly at this  
5 time.

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

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

10          (vi) If stem cells are to be transplanted into patients, researchers might recontact  
11 the donor to get additional health information.

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

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

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

20          (6) For CIRM-funded research that uses the umbilical cord, cord blood or the placenta,  
21 consent shall be obtained from the birth mother.

1           (7) For CIRM-funded research involving the donation of somatic cells for SCNT,  
2 informed consent shall include a statement as to whether the donated cells may be available for  
3 autologous treatment in the future.  
4 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),  
5 Health and Safety Code.  
6 Reference: Sections 24173, 125290.35, 125290.40, 124290.55, 125315, Health and Safety Code.