

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

2 When procurement of oocytes are required for CIRM-funded research, the SCRO
3 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) The procurement and disposition for research purposes of oocytes initially provided
7 for reproductive uses, either for use by the donor or another woman, shall not knowingly
8 compromise the optimal reproductive success of the woman in infertility treatment. Pursuant to
9 this requirement, the SCRO shall confirm the following:

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

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

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

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

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

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

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

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

11 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
12 Safety Code. Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.