

1 Amend 17 Cal. Code of Regs. section 100090 to read:

2 **§ 100090. Special Considerations for CIRM-Funded Procurement, Derivation and**
3 **Transplantation.**

4 (a) Where CIRM funds are to be used for research intended to derive a covered stem cell
5 line, the SCRO committee must determine or the designated institutional official must certify the
6 applicable requirements of Code of California Regulations, title 17, section 100080, subdivision
7 (a)(2) or (a)(3), have been met, subject to the following:

8 (1) For embryos created before November 22, 2006, consent exclusively from oocyte
9 donors is sufficient provided the sperm donor cannot be identified and the donation was made in
10 accordance with the legal requirements in force at the place and time of donation.

11 (2) For gametes or embryos, procured from human subjects, after November 22, 2006,
12 the SCRO committee must confirm that donors provided voluntary and informed consent in
13 accordance with Code of California Regulations, title 17, section 100100, subdivision (b).

14 (3) For research involving the use of embryos originally created using in vitro
15 fertilization for reproductive purposes, the physician performing oocyte retrieval or attending
16 physician responsible for infertility treatment may not be the CIRM-funded Principal
17 Investigator (as defined in title 17, California Code of Regulations, section 100500) unless the
18 SCRO committee has approved an exemption from this requirement.

19 (4) For human somatic cells, procured from human subjects after November 22, 2006,
20 and the CIRM-funded research is designed to develop cells for transplantation into a live born
21 human, the SCRO committee must confirm that donors provided voluntary and informed consent
22 including the requirements of Code of California Regulations, title 17, section 100100,

1 subdivision (b)(1)(E).

2 (b) CIRM funds may not be used to provide valuable consideration to donors of gametes,
3 embryos, somatic cells or tissue. This provision does not prohibit reimbursement for permissible
4 expenses as defined in California Code of Regulations, title 17, section 100020, subdivision (h).

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

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