

1 Amend 17 Cal. Code of Regs. section 100080 to read:

2 **§ 100080. Acceptable Research Materials.**

3 All covered stem cell lines used in CIRM-funded research must be “acceptably derived.”

4 (a) To be “acceptably derived,” the covered stem cell line must meet one of the
5 following three criteria:

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

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

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

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

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

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

17 (F) Be derived under license of the Australian National Health and Medical
18 Research Council; or

19 (G) Be derived in accordance with California Code of Regulations, title 17,
20 section 100090.

21 (2) The covered stem cell line is derived under the following conditions:

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

24 (B) Donors of human gametes or embryos did not receive valuable consideration.
25 For embryos originally created using in vitro fertilization for reproductive purposes and
26 are no longer needed for this purpose, “valuable consideration” does not include
27 payments to original gamete donors in excess of “permissible expenses.” Original gamete
28 donors may receive reimbursement for permissible expenses as defined in California
29 Code of Regulations, title 17, section 100020, subdivision (h); and

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

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

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

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

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

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

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

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

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

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

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

14 (2) Any payments for the purchase of covered stem cell lines, somatic cells, or human
15 tissue to persons other than the original donors shall be limited to those costs identified in Health
16 & Safety Code, section 125290.35, subdivision (b)(5). Any payment for gametes and embryos,
17 to persons other than the original donors, shall be limited to necessary and reasonable costs
18 directly incurred as a result of providing materials for research, which include but are not limited
19 to expenditures associated with processing, quality control, storage, or transportation.

20 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
21 Safety Code. Reference: Sections 125290.35, 125290.40, 125290.55 and 125300, Health and
22 Safety Code.