

1 Adopt 17 Cal. Code of Regs. section 100020 to read:

2 **§ 100020. Definitions.**

3 As used in this chapter:

4 (a) “Acceptably derived” means derived in accordance with the requirements of Code of
5 California Regulations, Title 17, sections 100080 and 100090.

6 (b) “CIRM” means the California Institute for Regenerative Medicine.

7 (c) “Covered stem cell line” means a culture-derived, human pluripotent stem cell
8 population that is capable of: 1) sustained propagation in culture; and (2) self-renewal to produce
9 daughter cells with equivalent developmental potential. This definition includes both embryonic
10 and non-embryonic human stem cell lines regardless of the tissue of origin. “Pluripotent” means
11 capable of differentiation into mesoderm, ectoderm, and endoderm.

12 (d) “Funded research” means research supported in whole or part by funds authorized by
13 article XXXV of the California Constitution. For the purpose of this chapter, training activities
14 supported by such funds shall be considered funded research.

15 (e) “Human subject” means a living individual about whom an investigator (whether
16 professional or student) conducting research obtains:

17 (1) Data through intervention or interaction with the individual, or

18 (2) Identifiable private information.

19 (f) “Institution” means any public or private entity or agency (including federal, state,
20 local or other agencies).

21 (g) “Institutional Review Board” (“IRB”) is an entity established in accordance with
22 Title 45, Code of Federal Regulations, section 46.107, revised June 23, 2005.

1 (h) “Permissible Expenses” means necessary and reasonable costs directly incurred as a
2 result of donation or participation in research activities. Permissible expenses may include but
3 are not limited to costs associated with travel, housing, child care, medical care, health insurance
4 and actual lost wages.

5 (i) “Research” means a systematic investigation, including research development, testing
6 and evaluation, designed to develop or contribute to generalizable knowledge. Activities which
7 meet this definition constitute research for purposes of these regulations, whether or not they are
8 conducted or supported under a program which is considered research for other purposes.

9 (j) “Somatic Cell Nuclear Transfer” (“SCNT”) means the transfer of a somatic cell
10 nucleus into an oocyte.

11 (k) “Stem Cell Research Oversight Committee” (“SCRO” committee) means a
12 committee established in accordance with Code of California Regulations, Title 17, section
13 100060.

14 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
15 Safety Code. Reference: Sections 125290.35, 125290.40, 125290.55, 125292.10, subds. (p)(q),
16 Health and Safety Code.

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