

1 **§ 100020. Definitions.**

2 As used in this chapter:

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

5 (b) “Awardee” means an organization that is the recipient of an award from CIRM and
6 that is legally responsible and accountable for their use of the funds provided and for the
7 performance of the CIRM-funded project or activity. The Awardee is the entire legal entity even if
8 a particular component is designated in the notice of award. Campuses of the University of
9 California shall be considered as separate and individual Awardees.

10 (c) “CIRM” means the California Institute for Regenerative Medicine.

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

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

19 (f) “Human subject” means a living individual about whom an investigator (whether
20 professional or student) conducting research obtains:

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

22 (2) Identifiable private information.

1 (g) “Human Subjects Research” is research defined by Title 45, Code of Federal
2 Regulations, Part 46 (Protection of Human Subjects), revised June 23, 2005.

3 (h) “Institutional Review Board” (“IRB”) is an entity established in accordance with Title
4 45, Code of Federal Regulations, section 46.107, revised June 23, 2005.

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

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

13 (k) “Somatic Cell Nuclear Transfer” (“SCNT”) means the transfer of a somatic cell
14 nucleus into an oocyte.

15 (l) “Stem Cell Research Oversight Committee” (“SCRO” committee) means a committee
16 established in accordance with Code of California Regulations, Title 17, section 100060.

17 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
18 Safety Code. Reference: Sections 125290.35, 125290.40, 125290.55, 125292.10(p) and (q),
19 Health and Safety Code.

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