HEALTH AND SAFETY CODE - HSC

DIVISION 106. PERSONAL HEALTH CARE (INCLUDING MATERNAL, CHILD, AND ADOLESCENT) [123100 - 125850] *(Division 106 added by Stats. 1995, Ch. 415, Sec. 8.)*

PART 5. HEREDITARY DISEASES/CONGENITAL DEFECTS [124975 - 125292.10] *(Part 5 added by Stats. 1995, Ch. 415, Sec. 8.)*

CHAPTER 3. California Stem Cell Research and Cures Bond Act [125290.10 - 125292.10] *(Chapter 3 added November 2, 2004, by initiative Proposition 71, Sec. 5, a bond act.)*

ARTICLE 3. Definitions [125292.10- 125292.10.] *(Article 3 added November 2, 2004, by initiative Proposition 71, Sec. 5.)*

125292.10. Definitions

As used in this chapter and in Article XXXV of the California Constitution, the following terms have the following meanings:

(a) “Act” means the California Stem Cell Research and Cures Bond Act constituting Chapter 3 (commencing with Section 125290.10) of Part 5 of Division 106 of the Health and Safety Code.

(b) “Adult stem cell” means an undifferentiated cell found in a differentiated tissue in an adult organism that can renew itself and may, with certain limitations, differentiate to yield all the specialized cell types of the tissue from which it originated, including a cell that is committed to make all of the functional cells of the tissue or organ where it resides and regenerates but that is itself undifferentiated.

(c) “Basic research” means the investigation of basic mechanisms underlying stem cell biology, cellular plasticity, cellular differentiation, and other vital research opportunities.

(d) “Capitalized interest” means interest funded by bond proceeds.

(e) “Committee” means the California Stem Cell Research and Cures Finance Committee created pursuant to subdivision (a) of Section 125291.40.

(f) “Constitutional officers” means the Governor, Lieutenant Governor, Treasurer, and Controller of California.

(g) “Early development” means discovery of promising new stem cell-based technologies that could be translated to enable broad use and ultimately improve patient care.

(h) “Facilities” means buildings, building leases, or capital equipment.

(i) “Floating-rate bonds” means bonds which do not bear a fixed rate of interest until their final maturity date, including commercial paper notes.

(j) “Fund” means the California Stem Cell Research and Disease Cures Fund created pursuant to Section 125291.25.

(k) “Grant” means a grant, loan, or guarantee.

(l) “Grantee” means a recipient of a grant from the institute. All University of California grantee institutions shall be considered as separate and individual grantee institutions.

(m) “Human reproductive cloning” means the practice of creating or attempting to create a human being by transferring the nucleus from a human cell into an egg cell from which the nucleus has been removed for the purpose of implanting the resulting product in a uterus to initiate a pregnancy.

(n) “Indirect costs” mean the recipient’s costs in the administration, accounting, general overhead, and general support costs for implementing a grant or loan of the institute. NIH definitions of indirect costs will be utilized as one of the bases by the Scientific and Medical Research Standards Working Group to create a guideline for recipients on this definition, with modifications to reflect guidance by the ICOC and this act.

(o) “Institute” means the California Institute for Regenerative Medicine.

(p) “Interim standards” means temporary standards that perform the same function as “emergency regulations” under the Administrative Procedure Act (Government Code, Title 2, Division 3, Part 1, Chapter 3.5, Sections 11340 et seq.) except that in order

to provide greater opportunity for public comment on the permanent regulations, remain in force for 270 days rather than 180 days.

(q) “Life science commercial entity” means a firm or organization, headquartered in California, whose business model includes biomedical or biotechnology product development and commercialization.

(r) “Medical ethicist” means an individual with advanced training in ethics who holds a Ph.D., MA, or equivalent training in the biological sciences or the field of clinical medicine or clinical ethics and who spends or has spent substantial time (1) researching and writing on ethical issues related to medicine, and (2) administering ethical safeguards during the clinical trial process, particularly through service on institutional review boards.

(s) “Pluripotent cells” means cells that are capable of self-renewal, and have broad potential to differentiate into multiple adult cell types. Pluripotent stem cells may be derived from somatic cell nuclear transfer or from surplus products of in vitro fertilization treatments when such products are donated under appropriate informed consent procedures. These excess cells from in vitro fertilization treatments would otherwise be intended to be discarded if not utilized for medical research.

(t) “Progenitor cells” means multipotent or precursor cells that are partially differentiated but retain the ability to divide and give rise to differentiated cells.

(u) “Quorum” means at least 65 percent of the members who are eligible to vote.

(v) “Research donor” means a human who donates biological materials for research purposes after full disclosure and consent.

(w) “Research funding” includes interdisciplinary scientific and medical funding for all stages of research, including, but not limited to, stem cell discovery research, early development, translational research, therapy development, and the development of treatments through clinical trials, including, without limitation, the reimbursement of patient-qualified costs for research participants and their caregivers pursuant to paragraph (4) of subdivision (b) of Section 125290.35; the operations of the working groups, including the costs associated with the expert review of applications; the costs of advisory groups and consultants established or retained to evaluate and advise the governing board, the working groups, and awardees; and research conferences. When a facility’s grant or loan has not been provided to house all elements of the research, therapy development, and/or clinical trials, research funding shall include an allowance for a market lease rate of reimbursement for the facility. In all cases, operating costs of the facility, including, but not limited to, library and communication services, utilities, maintenance, janitorial, and security, shall be included as direct research funding costs. Legal costs of the institute incurred in order to negotiate standards with federal and state governments and research institutions; to implement standards or regulations; to resolve disputes; and/or to carry out all other actions necessary to defend and/or advance the institute’s mission shall be considered direct research funding costs.

(x) “Research participant” means a human enrolled with full disclosure and consent, and participating in clinical trials.

(y) “Research program” means research projects that are designed to advance the same ultimate goal along the research continuum and that are conducted by the same or overlapping investigators.

(z) “Revenue positive” means all state tax revenues generated directly and indirectly by the research and facilities of the institute are greater than the debt service on the state bonds actually paid by the General Fund in the same year.

(aa) “Stem cells” mean nonspecialized cells that have the capacity to divide in culture and to differentiate into more mature cells with specialized functions.

(ab) “Stem cell discovery research” means basic research, early development, and the discovery, evaluation, or improvement of tools and technologies in the fields of stem cell and genetic research and other vital research opportunities.

(ac) “Vital research opportunity” means scientific and medical research and technologies, including, but not limited to, genetics, personalized medicine, and aging as a pathology, and/or any stem cell research not actually funded by the institute under paragraph (3) of subdivision (c) of Section 125290.60 which provides a substantially superior research opportunity, vital to advance medical science as determined by at least a two-thirds vote of a quorum of the members of the Scientific and Medical Research Funding Working Group and recommended as such by that working group to the ICOC, or as determined by the vote of a majority of a quorum of members of the ICOC. Human reproductive cloning shall not be a vital research opportunity.

(Amended November 3, 2020, by initiative Proposition 14, Sec. 25. Effective on December 16, 2020. Note: This section was added on Nov. 2, 2004, by initiative Prop. 71.)