

Compiled Draft for Public Comment

1 Adopt 17 Cal. Code of Regs. section 100010 to read:

2 **§ 100010. Scope of Chapter 2 – Stem Cell Research.**

3 The standards set forth in this chapter apply to all institutions, as defined by Title 17,
4 California Code of Regulations, section 100020, subdivision (g), performing research, as defined
5 in Title 17, California Code of Regulations, section 100020, subdivision (d), funded by the
6 California Institute for Regenerative Medicine (CIRM) as authorized by Article XXXV of the
7 California Constitution.

8 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
9 Health and Safety Code.

10 Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

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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 17 Cal.
5 Code Regs. 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 stem cell population that is
8 capable of: 1) sustained propagation in culture; 2) differentiation along multiple cell lineages;
9 and 3) self-renewing to produce daughter cells with equivalent developmental potential. This
10 definition includes both embryonic and non-embryonic human stem cell lines regardless of the
11 tissue of origin.”

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” is an entity established in accordance with Title 45,
22 Code of Federal Regulations, section 46.107, revised June 23, 2005.

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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 cell nucleus from a
10 somatic cell into an oocyte from which the nucleus has been removed.

11 (k) “Stem Cell Research Oversight Committee” (SCRO committee) means a committee
12 established in accordance with 17 Cal. Code Regs. section 100060.

13 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
14 Health and Safety Code.

15 Reference: Sections 125290.35, 125290.40, 124290.55, 125292.10, subds. (p)(q), Health and
16 Safety Code.

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1 Adopt 17 Cal. Code of Regs. section 100030 to read:

2 **§ 100030. Activities Not Eligible for CIRM Funding.**

3 The following activities are not eligible for CIRM funding:

4 (a) Human reproductive cloning, as defined in California Health and Safety Code
5 Section 125292.10. subdivision (k), or reproductive uses of SCNT prohibited by article XXXV
6 section 3 of the California Constitution.

7 (b) The culture in vitro of (i) any intact human embryo or (ii) any product of SCNT,
8 parthenogenesis or androgenesis, after the appearance of the primitive streak or after 12 days
9 whichever is earlier. The 12 day prohibition does not count any time during which the embryos
10 and/or cells have been stored frozen.

11 (c) The introduction of stem cells from a covered stem cell line into nonhuman primate
12 embryos.

13 (d) The introduction of any stem cells, whether human or nonhuman, into human
14 embryos.

15 (e) Breeding any animal into which stem cells from a covered stem cell line have been
16 introduced.

17 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
18 Health and Safety Code.

19 Reference: Sections 125290.35, 125290.40, 124290.55, 125292.10, Health and Safety Code.

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1 Adopt 17 Cal. Code of Regs. section 100040 to read:

2 **§ 100040. Institutional Assurance of Compliance.**

3 (a) All research institutions shall be responsible for providing written assurance
4 satisfactory to CIRM that CIRM-funded research complies with the requirements set forth in this
5 chapter.

6 (b) Each institution shall:

7 (1) Designate an institutional official responsible for oversight of and
8 documentation of compliance for CIRM-funded research;

9 (2) Designate one or more SCRO committee(s) established in accordance with
10 the requirements of 17 Cal. Code Regs section 100060;

11 (3) Designate one or more Institutional Review Boards;

12 (4) Ensure that clinical personnel who have a conscientious objection not be
13 required to participate in providing donor information or securing donor consent for research use
14 of gametes or embryos. That privilege shall not extend to the care of a donor or recipient.

15 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
16 Health and Safety Code.

17 Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

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1 Adopt 17 Cal. Code of Regs. section 100050 to read:

2 **§ 100050. Compliance.**

3 Grantees must report promptly to CIRM any failure to comply with the terms and
4 conditions of an award. Depending on the severity and duration of the non-compliance, CIRM
5 actions may include, but are not limited to, the following:

6 (a) Temporary withholding of payment;

7 (b) Placing special conditions on awards;

8 (c) Conversion to a reimbursement payment method;

9 (d) Precluding the grantee (principal investigator (PI) or grantee organization, as
10 appropriate) from obtaining future awards for a specified period;

11 (e) Debarment from receipt of further CIRM funds;

12 (f) Recovery of previously awarded funds;

13 (g) Civil action, including referring the matter to the Office of the Attorney General of
14 the State of California for investigation and enforcement;

15 (h) Other available legal remedies.

16 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),

17 Health and Safety Code.

18 Reference: Sections 125290.40, 124290.55, Health and Safety Code.

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Adopt 17 Cal. Code of Regs. section 100060 to read:

§ 100060. SCRO Membership and Function.

(a) An SCRO committee shall be comprised of persons with expertise in, including but not limited to, developmental biology, stem cell research, molecular biology, assisted reproduction, and ethical issues in stem cell research. An SCRO committee shall include at least one representative of the public who is not employed by, appointed to, or remunerated by the relevant research institution. In addition, an SCRO committee shall include at least one patient advocate. No SCRO committee member may have a financial conflict of interest in the research under review.

(b) The designated SCRO committee shall provide scientific and ethical review of CIRM-funded research consistent with the requirements of Section 100070 and other applicable CIRM requirements.

(c) The SCRO committee shall facilitate education of investigators with applicable requirements of this chapter.

(d) An SCRO committee may provide oversight for two or more funded research institutions, provided the SCRO committee has oversight authority consistent with the requirements of this chapter.

(e) An SCRO committee may be convened by an institution, a group of institutions, the CIRM or other state agency.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

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1 Adopt 17 Cal. Code of Regs. section 100070 to read:

2 **§ 100070. SCRO Review and Notification.**

3 (a) CIRM-funded research involving derivation of covered stem cell lines or use of
4 human oocytes or embryos in stem cell research may not commence without SCRO committee
5 review and approval in writing. The designated SCRO committee may require that modification
6 be made to proposed research or documentation of compliance with the requirements of
7 subdivision (a)(3) of this regulation as a condition of granting its approval. At a minimum, the
8 SCRO committee shall require the investigator to:

9 (1) Provide a scientific rationale for the need to derive a new human stem cell
10 line. When such research involves the use of oocytes and embryos, a justification for the
11 number needed for derivation shall be provided. If SCNT is proposed as a route to
12 generating human stem cell lines, justification for SCNT shall be provided.

13 (2) Demonstrate experience, expertise or training in derivation or culture of
14 human or nonhuman stem cell lines.

15 (3) Provide documentation of compliance with any required review of the
16 proposed research by an IRB, Institutional Animal Care and Use Committee (IACUC),
17 Institutional Bioethics Committee (IBC), or other mandated review.

18 (4) Document how stem cell lines will be characterized, validated, stored, and
19 distributed to ensure that the confidentiality of the donor(s) is protected.

20 (b) CIRM-funded research introducing covered stem cell lines into human or non-human
21 animals at any state of embryonic, fetal, or postnatal development may not commence without
22 SCRO committee review and approval in writing. The designated SCRO committee may require

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1 that modification be made to proposed research or documentation of compliance with the
2 requirements of subdivision (b)(3) of this regulation as a condition of granting its approval. At a
3 minimum, the SCRO Committee shall require the investigator to:

4 (1) Provide assurance that all covered stem cell lines have been acceptably
5 derived.

6 (2) Evaluate the probable pattern and effects of differentiation and integration of
7 the human cells into the human or nonhuman animal tissues.

8 (3) Provide documentation of compliance with any required review of the
9 proposed research by an IRB, IACUC, IBC, or other mandated review.

10 (c) CIRM-funded purely in vitro research utilizing covered stem cell lines may not
11 commence without written notification to the designated SCRO Committee. At a minimum, the
12 notification shall:

13 (1) Provide assurance that all covered stem cell lines have been acceptably
14 derived.

15 (2) Provide documentation of compliance with any required review of the proposed research by
16 an IRB, IACUC, IBC, or other mandated review. Note: Authority cited: California Constitution,
17 article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

18 Reference: Sections 125290.40, 124290.55, Health and Safety Code.

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1 Adopt 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 To be “acceptably derived,” the stem cell line must:

5 (a) Have been approved by the National Institutes of Health, or

6 (b) Been deposited in the United Kingdom Stem Cell Bank, or

7 (c) Been derived by, or approved for use by, a licensee of the United Kingdom Human
8 Fertilization and Embryology Authority, or

9 (d) Been derived in accordance with the Canadian Institutes of Health Research
10 Guidelines for Human Pluripotent Stem Cell Research under an application approved by the
11 National Stem Cell Oversight Committee, or

12 (e) Have been derived under the following conditions:

13 (1) Donors of gametes, embryos, somatic cells or human tissue gave voluntary
14 and informed consent.

15 (2) Donors of gametes, embryos, somatic cells or human tissue did not receive
16 valuable consideration. This provision does not prohibit reimbursement for permissible
17 expenses as determined by an IRB;

18 (3) A person may not knowingly, for valuable consideration, purchase or sell
19 gametes, embryos, somatic cells, or human tissue for research purposes pursuant to this
20 chapter, except for donors as provided in subdivision (e)(2) of this regulation. This
21 provision does not prohibit reimbursement for permissible expenditures as approved by a
22 SCRO committee. “Permissible expenditures” means necessary and reasonable costs

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1 directly incurred as a result of persons, not including human subjects or donors,
2 providing gametes, embryos, somatic cells, or human tissue for research purposes.
3 Permissible expenditures may include but are not limited to costs associated with
4 processing, quality control, storage, or transportation of materials.

5 (4) Donation of gametes, embryos, somatic cells or human tissue was overseen
6 by an IRB (or, in the case of foreign sources, an IRB-equivalent):

7 (5) Individuals who consented to donate stored gametes, embryos, somatic cells
8 or human tissue were not reimbursed for the cost of storage prior to the decision to
9 donate.

10 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
11 Health and Safety Code.

12 Reference: Sections 125290.35, 125290.40, 124290.55, 125300, Health and Safety Code.

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

2 **§ 100090. Additional Requirements for CIRM-Funded Derivation.**

3 Where CIRM funds are to be used to derive new human stem cell lines, in addition to the
4 requirements of 17 Cal. Code Regs section 100080, subdivision (e), the SCRO must confirm that
5 the following additional requirements have been met:

6 (a) Donors of gametes, embryos, somatic cells or human tissue have given voluntary and
7 informed consent in accordance with 17 Cal. Code Regs section section 100100;

8 (b) When procurement of oocytes are required for derivation, the following conditions
9 have been met:

10 (1) For a woman providing oocytes for research and clinical infertility treatment
11 (either for herself or another woman), research shall not compromise the optimal
12 reproductive success of the woman in infertility treatment.

13 (2) The funded institution has agreed to assume the cost of any medical care
14 required as a direct and proximate result of oocyte donation for research.

15 (3) The physician attending to any donor and the principal investigator shall not
16 be the same person unless exceptional circumstances exist and an IRB has approved an
17 exemption from this requirement.

18 (4) The physician performing oocyte retrieval shall not have a financial interest in the outcome
19 of the research.

20 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
21 Health and Safety Code.

22 Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

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1 Adopt 17 Cal. Code of Regs. section 100100 to read:

2 **§ 100100. Informed Consent Requirements.**

3 (a) All CIRM-funded human subjects research shall be performed in accordance with
4 Title 45 Code of Federal Regulations, Part 46 (Protection of Human Subjects), revised June 23,
5 2005, and California Health and Safety Code section 24173. In accordance with existing law,
6 California Health and Safety Code section 24173 does not apply to a person who is conducting
7 research as an investigator within an institution that holds an assurance with the United States
8 Department of Health and Human Services pursuant to Title 45 Code of Federal Regulations Part
9 46, revised June 23, 2005, and who obtains informed consent in the method and manner required
10 by those regulations.

11 (b) CIRM-funds may not be used for research that violates the documented preferences
12 of donors with regard to the use of their donated materials. To ensure donors are fully informed
13 of the potential uses of donated materials, researchers shall disclose, in addition to the general
14 requirements for obtaining informed consent, all of the following, unless a specific item has been
15 determined by the SCRO or IRB to be inapplicable.

16 (1) Derived cells or cell products may be kept for many years.

17 (2) Whether the identity(ies) of the donor(s) will be ascertainable to those who
18 work with the resulting cells or cell products. If the identity(ies) of the donor(s) are
19 retained (even coded), CIRM-funded researchers must discuss any plans for recontact of
20 donors of materials used to derive cell lines and obtain consent for recontact. This
21 requirement includes both recontacting donors to provide information about research

1 findings and recontacting donors to ask for additional health information. Donors may be
2 recontacted in the future only if they consent to recontact at the time of donation.

3 (3) Researchers may use cell lines for future studies, some of which may not be
4 predictable at this time.

5 (4) Derived cells or cell products may be used in research involving genetic
6 manipulation.

7 (5) Derived cells or cell products may be transplanted into humans or animals.

8 (6) Derived cells or cell products are not intended to provide direct medical
9 benefit to the donor(s), except in the case of autologous donation.

10 (7) The donation is being made without restriction regarding who may be the
11 recipient of transplanted cells, except in the case of autologous donations.

12 (8) That neither consenting nor refusing to donate materials for research will
13 affect the quality of any future care provided to potential donors.

14 (9) That the results of research may be patentable or have commercial potential,
15 and that the donor will not receive patent rights and will not receive financial or any
16 other benefits from future commercial development.

17 (c) Researchers shall offer donors an opportunity to document their preferences
18 regarding future uses of their donated materials. Researchers may choose to use materials only
19 from donors who agree to all future uses.

20 (d) For CIRM-funded research involving the donation of oocytes, the following
21 additional requirements apply:

1 (1) The description of foreseeable risk shall include but not be limited to
2 information regarding the risks of ovarian hyperstimulation syndrome, bleeding,
3 infection, anesthesia and pregnancy.

4 (2) The physician must disclose his or her relationship to the research or
5 researcher/s to the egg donor.

6 (3) Steps shall be taken to enhance the informed consent process. Measures to do
7 so shall include, but are not limited to, an adequate period of time, as determined by an
8 IRB, to deliberate about the decision to donate. In the case of such periods of
9 deliberation, researchers may not solicit potential donors until they have initiated
10 recontact with the researchers.

11 (4) The researcher shall ascertain that the donor has understood the essential
12 aspects of the research. Researchers may meet this requirement by following a process
13 that is approved by the designated Institutional Review Board or SCRO committee.
14 Understanding the essential aspects of the research includes understanding at least that:

15 (i). Their eggs will not be used for reproductive purposes.

16 (ii). There are medical risks in oocyte donation, including the risks of ovarian
17 hyperstimulation syndrome, bleeding, infection, anesthesia, and pregnancy.

18 (iii). The research will not benefit them or any other individuals directly at this
19 time.

20 (iv). Whether stem cell lines will be derived from their oocytes through
21 fertilization, SCNT, parthenogenesis, or some other method.

1 (v). Stem cell lines developed from their oocytes will be grown in the lab and
2 shared with other researchers for studies in the future.

3 (vi). If stem cells are to be transplanted into patients, researchers might recontact
4 the donor to get additional health information.

5 (vii). Donors receive no payment beyond reimbursement for permissible
6 expenses.

7 (viii). Stem cell lines derived as a result of their oocyte donation may be patented
8 or commercialized, but donors will not share in patent rights or in any revenue from the
9 patents.

10 (e) For CIRM-funded research involving the donation of embryos for stem cell research,
11 the informed consent process shall include a statement that embryos will be destroyed in the
12 process of deriving embryonic stem cells.

13 (f) For CIRM-funded research involving the donation of the umbilical cord, cord blood
14 or the placenta, consent shall be obtained from each known legal parent, guardian or progenitor.
15 Informed consent shall include a statement as to whether the donated cells may be available for
16 autologous treatment in the future.

17 (g) For CIRM-funded research involving the donation of somatic cells for SCNT, informed
18 consent shall include a statement as to whether the donated cells may be available for autologous
19 treatment in the future.

20 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
21 Health and Safety Code.

22 Reference: Sections 24173, 125290.35, 125290.40, 124290.55, 125315, Health and Safety Code.

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1 Adopt 17 Cal. Code of Regs. section 100110 to read:

2 **§ 100110. Fairness and Diversity in Research.**

3 CIRM grantees shall comply with the California Health Research Fairness Act, California Health
4 and Safety Code, Sections 439.900-439.906, and Inclusion of Women and Minorities in Clinical
5 Research Act, Health and Safety Code, Sections 100237-100239.

6 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
7 Health and Safety Code.

8 Reference: Sections 439.900-439.906, 100237-100239, 125290.40, 124290.55, Health and
9 Safety Code.

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1 Adopt 17 Cal. Code of Regs. section 100120 to read:

2 **§ 100120. Record Keeping.**

3 Each grantee's institution shall maintain records of all CIRM-funded research activities.

4 At a minimum, the institution shall maintain a research registry that includes, but is not limited

5 to, documentation of:

6 (a) CIRM-funded stem cell research conducted by the institution;

7 (b) Any required review or notification requirements as described in 17 Cal. Code of

8 Reg.s section 100070;

9 (c) The methods utilized to characterize and screen the materials for safety;

10 (d) The conditions under which the materials have been maintained and stored;

11 (e) Any additional requirements set forth in any other regulations under this title;

12 (f) Every gamete, somatic cell, embryo donation or product of SCNT that has been donated,
13 created or used. This record should be sufficient to determine the provenance and disposition of
14 such materials.

15 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
16 Health and Safety Code.

17 Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

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1 Adopt 17 Cal. Code of Regs. section 100130 to read:

2 **§ 100130. Materials Sharing.**

3 Stem cell lines and biomedical materials developed with CIRM funding at academic, commercial
4 research and development organizations shall be broadly disseminated. CIRM-funded research
5 institutions shall comply with any CIRM-Intellectual Property regulations intended to ensure
6 data and materials sharing.

7 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
8 Health and Safety Code.

9 Reference: Sections 125290.30, subd.(h), 125290.40, 124290.55, Health and Safety Code.