8/27/12

To: ICOC

Fr: CIRM

Re: Consideration of regulatory final amendments to the CIRM Medical and Ethical Standards

Action for ICOC Consideration:

Final Approval of amendments to CIRM Medical and Ethical Standards.

Background:

On 5/24/12, the ICOC authorized CIRM to initiate the OAL rulemaking to amend sections 100060 and 100070 of the Medical and Ethical Standards. The process was initiated and the comment period closed without submission of any comment. The proposed amendments are unchanged from that which the ICOC authorized in May, which accomplish the following:

1) § 100060: SCRO Committee Membership and Function:

   - Revises existing language to provide greater flexibility for stem cell research oversight committee operations by striking restriction on remuneration of non-scientist public member.

2) § 100070: SCRO Committee Review and Notification:

   - Revises the current regulation requiring the stem cell research oversight committee to be notified of in vitro research involving the use of individually identifiable cells and tissue. The amendment allows a designated official to be notified in lieu of a SCRO committee for in vitro research involving identifiable cells and tissue. In vitro research involving the use of individually identifiable cells and tissue must also be reviewed and approved by an institutional review board (IRB). A designated institutional official is defined as a person *designated by the chancellor, chief executive officer or person with plenary authority*.

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

§ 100060. SCRO Committee Membership and Function.

(a) A 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. A SCRO committee shall include at least one non-scientist member of the public who is not employed ~~by, or appointed to, or remunerated~~ by the relevant research institution and who is not part of the immediate family of a person who is affiliated with the institution. In addition, a SCRO committee shall include at least one patient advocate.

(b) Any member of a SCRO committee may be reimbursed for reasonable out-of-pocket expenses for attending the meeting, not including lost wages. No SCRO committee may have a member participate in the SCRO committee's initial or continuing review of any project in which the member has a conflicting interest, except to provide information to the SCRO committee.

(c) 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.

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

(e) A 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.

(f) A SCRO committee may be convened by an institution, a group of institutions, the

CIRM or other state agency.

Note: Authority cited: Article XXXV, California Constitution; and Section 125290.40(j).

Reference: Sections 125290.35, 125290.40, 125290.55, Health and Safety Code.

Amend 17 Cal. Code of Regs. section 100070 to read:

§ 100070. SCRO Committee Review and Notification.

(a) CIRM-funded research involving the procurement or use of human oocytes or the creation of human gametes may not commence without SCRO committee review and approval in writing. If CIRM-funded research involves the procurement of human oocytes from a living donor, a member of the committee with expertise in assisted reproduction shall be present. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (a)(3) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale for the need to procure or use human oocytes or create human gametes. In the case of human oocyte procurement, a justification for the number needed. If SCNT is proposed a justification for SCNT shall be provided.

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

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

(b) CIRM-funded research involving procurement, creation or use of human blastocysts or embryos may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be made to proposed research or

documentation of compliance with the requirements of subdivision (b)(3) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale for the need to create or use blastocysts or embryos including a justification for the number needed.

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

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

(c) CIRM-funded human subjects research, as defined by Title 45, Code of Federal Regulations, Part 46 (Protection of Human Subjects), revised June 23, 2005, and California Health and Safety Code section 24173, with the aim to create, from sources other than human gametes, blastocysts or embryos, or use a covered stem cell line may not commence without written notification of the SCRO committee. A statement from the designated institutional official (as defined in Title 17, California Code of Regulations section 100040, subdivision (b)(1)) may be provided in lieu of SCRO committee notification. The institutional official shall submit documentation of any required review of the proposed research by an IRB, IACUC, IBC or other mandated review. Research may include animal assays to evaluate pluripotency; however, subsequent introduction of derived covered stem cell lines in non-human animals shall be reviewed in accordance with subdivision (e) of this section. The designated SCRO committee may require the investigator to:

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

(2) Provide documentation of compliance with any required review of the proposed research by an IRB, Institutional Bioethics Committee (IBC), or other mandated review.

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

(d) CIRM-funded purely in vitro research with the aim to create or use a covered stem cell line from non-identifiable cells may not commence with out written notification of the SCRO committee. A statement from the designated institutional official pursuant to section 100040(b)(1) may be provided in lieu of SCRO committee notification if human somatic cells conform to the requirements of section 100080(a)(3); or the covered stem cell line(s) are recognized by an authorized authority. At a minimum the statement shall certify the:

(1) Human somatic cells conform to the requirements of section 100080(a)(3); or

(2) The covered stem cell lines are recognized by an authorized authority.

In addition, the institutional official shall submit documentation of any required review of the proposed research by an IRB, IACUC, IBC, or other mandated review.

Research may include animal assays to evaluate pluripotency; however, subsequent introduction of derived covered stem cell lines in non-human animals shall be reviewed in accordance with subdivision (e) of this section.

(e) CIRM-funded research introducing covered stem cell lines into non-human animals or introducing neural-progenitor cells into the brain of non-human animals at any state of

embryonic, fetal, or postnatal development may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (e)(3) of this regulation as a condition of granting its approval. The SCRO committee may establish guidelines and procedures for expedited review of animal research so that review by the entire SCRO committee is not required. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale for introducing stem cells into non-human animals.

(2) Provide assurance that all covered stem cell lines have been acceptably derived.

(3) Evaluate the probable pattern and effects of differentiation and integration of the human cells into the nonhuman animal tissues.

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

(f) CIRM-funded research introducing cells from covered stem cell lines into a live born human may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (f)(4) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific for rationale introducing stem cells into

humans.

(2) Provide assurance that all covered stem cell lines have been acceptably derived.

(3) Evaluate the probable pattern and effects of differentiation and integration of the human cells into the human tissues.

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

(g) In cases where SCRO committee approval is required, a SCRO committee shall notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure SCRO committee approval of the research activity. If the SCRO committee decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(h) SCRO committee approvals shall be reviewed no less frequently than once per year. The renewal review shall confirm compliance with all applicable rules and regulations. The SCRO committee may establish guidelines and procedures for expedited review of renewals so that review by the entire SCRO committee is not required.

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