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

§ 100070. SCRO Review and Notification. [Recommended Revisions]

(a) CIRM-funded research involving use of human oocytes or embryos in stem cell research 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 (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 use oocytes or embryos including 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.

(4) ~~Document how resulting stem cell lines will be characterized, validated, stored, and distributed to ensure that the confidentiality of the donor(s) is protected.~~ (covered in (b)).

(b) CIRM-funded research intended to derive or create a covered stem cell line 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 (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 derive a covered stem cell line.

(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 Bioethics Committee (IBC), or other mandated review.

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

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

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

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

(d) CIRM-funded research introducing covered stem cell lines into 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 (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 assurance that all covered stem cell lines have been acceptably derived.

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

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

The SCRO may establish guidelines and procedures for expedited review of animal research so that review by the entire SCRO is not required.

(e) CIRM-funded research introducing stem cells from covered stem cell lines into 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 (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 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 or 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.

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

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