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

| 2 | § 100070. SCRO Review and Notification. [Recommended Revisions] |
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| 3 | (a) CIRM-funded research involving use of human oocytes or embryos in stem cell |
| 4 | research may not commence without SCRO committee review and approval in writing. The |
| 5 | designated SCRO committee may require that modification be made to proposed research or |
| 6 | documentation of compliance with the requirements of subdivision (a)(3) of this regulation as a |
| 7 | condition of granting its approval. At a minimum, the SCRO committee shall require the |
| 8 | investigator to: |
| 9 | (1) Provide an acceptable scientific rationale for the need to use oocytes or |
| 10 | embryos including a justification for the number needed. If SCNT is proposed a |
| 11 | justification for SCNT shall be provided. |
| 12 | (2) Demonstrate experience, expertise or training in derivation or culture of |
| 13 | human or nonhuman stem cell lines. |
| 14 | (3) Provide documentation of compliance with any required review of the |
| 15 | proposed research by an IRB, Institutional Animal Care and Use Committee (IACUC), |
| 16 | Institutional Bioethics Committee (IBC), or other mandated review. |
| 17 | (4) Document how resulting stem cell lines will be characterized, validated, |
| 18 | stored, and distributed to ensure that the confidentiality of the donor(s) is protected. |
| 19 | (covered in (b)). |
| 20 | |
| 21 | (b) CIRM-funded research intended to derive or create a covered stem cell line may not |
| 22 | commence without SCRO committee review and approval in writing. The designated SCRO |
| 23 | committee may require that modification be made to proposed research or documentation of3/03/061100070.oal.notice |

| 1 | compliance with the requirements of subdivision (a)(3) of this regulation as a condition of |
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| 2 | granting its approval. At a minimum, the SCRO committee shall require the investigator to: |
| 3 | (1) Provide an acceptable scientific rationale for the need to derive a covered |
| 4 | stem cell line. |
| 5 | (2) Demonstrate experience, expertise or training in derivation or culture of |
| 6 | human or nonhuman stem cell lines. |
| 7 | (3) Provide documentation of compliance with any required review of the |
| 8 | proposed research by an IRB, Institutional Bioethics Committee (IBC), or other |
| 9 | mandated review. |
| 10 | (4) Document how stem cell lines will be characterized, validated, stored, and |
| 11 | distributed to ensure that the confidentiality of the donor(s) is protected. |
| 12 | |
| 13 | (c) CIRM-funded purely in vitro research utilizing covered stem cell lines may not |
| 14 | commence without written notification to the designated SCRO Committee. At a minimum, the |
| 15 | notification shall: |
| 16 | (1) Provide assurance that all covered stem cell lines have been acceptably |
| 17 | derived. |
| 18 | (2) Provide documentation of compliance with any required review of the |
| 19 | proposed research by an IRB, IACUC, IBC, or other mandated review. |
| 20 | |
| 21 | (d) CIRM-funded research introducing covered stem cell lines into non-human animals |
| 22 | at any state of embryonic, fetal, or postnatal development may not commence without SCRO |
| 23 | committee review and approval in writing. The designated SCRO committee may require that |
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| 1 | modification be made to proposed research or documentation of compliance with the |
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| 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 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 | The SCRO may establish guidelines and procedures for expedited review of animal research so |
| 11 | that review by the entire SCRO is not required. |
| 12 | |
| 13 | (e) CIRM-funded research introducing stem cells from covered stem cell lines into live |
| 14 | born human may not commence without SCRO committee review and approval in writing. The |
| 15 | designated SCRO committee may require that modification be made to proposed research or |
| 16 | documentation of compliance with the requirements of subdivision (b)(3) of this regulation as a |
| 17 | condition of granting its approval. At a minimum, the SCRO Committee shall require the |
| 18 | investigator to: |
| 19 | (1) Provide an acceptable scientific rationale introducing stem cells into humans. |
| 20 | (2) Provide assurance that all covered stem cell lines have been acceptably |
| 21 | derived. |
| 22 | (3) Evaluate the probable pattern and effects of differentiation and integration of |
| 23 | the human cells into the human or nonhuman animal tissues. |
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| 1 | (4) Provide documentation of compliance with any required review of the |
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| 2 | proposed research by an IRB, IACUC, IBC, or other mandated review. |
| 3 | |
| 4 | Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), |
| 5 | Health and Safety Code. |
| | |

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