§ 100070. SCRO Committee Review and Notification.

(a) 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 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) 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) Human subjects research with the aim to create, from sources other than human gametes, blastocysts or embryos, 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) Purely in vitro research with the aim to create or use a covered stem cell line from non-identifiable cells may not commence without written notification of the SCRO committee. A

statement from the designated institutional official pursuant to section 100040(a) 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) The introduction of covered stem cells into nonhuman mammalian blastocysts or fetuses or introducing human 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. Studies involving postnatal animals performed pursuant to a FDA Investigational New Drug (IND) or Investigational Device Exception (IDE) application are exempt from SCRO committee review and approval. 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) 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.