

## **§5 SCRO Committee Review and Notification**

- (a) Research involving the procurement or use of human oocytes as part of human stem cell research may not commence without SCRO Committee review and approval in writing. For such SCRO Committee review and approval, 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 guideline 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, 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) Further requirements for research involving the procurement or use of human oocytes are provided in Section 8 below.
- (b) Covered research involving use of human 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 section 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 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, IACUC, IBC, or other mandated review.
- (c) Covered research with the aim 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 (c)(4) of this section 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.

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- (2) If SCNT is proposed as a route to generating human stem cell lines, a justification for SCNT shall be provided.
- (3) Demonstrate experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.
- (4) Provide documentation of compliance with any required review of the proposed research by an IRB, IBC, or other mandated review.
- (5) Document how stem cell lines will be characterized, validated, stored, and distributed to ensure that the privacy of the donor is protected and the confidentiality of identifiable information is maintained.
- (6) Further requirements for research involving the derivation or creation of covered stem lines are provided in Section 7 below.

(d) Clinical trials involving the use of human pluripotent cells or cells derived from human pluripotent cells may not commence without SCRO Committee review and approval in writing. In addition, clinical trials involving the transfer of non-autologous neural-progenitor stem cells to a human central nervous system shall also receive SCRO Committee review and approval before commencement. The SCRO Committee shall ensure that adequate scientific and ethical review of each protocol has taken place. The SCRO Committee may require that modification be made to proposed research, or documentation of compliance with (d)(4) of this section 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 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.
- (5) Further requirements for research involving the derivation or creation of covered stem lines are provided in Section 7 below.

(e) Purely in vitro covered research 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.

(f) Research introducing human pluripotent cells or cells differentiated from human pluripotent 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 (f)(4) of this section as a condition of granting its approval. The SCRO Committee may

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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.

(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. A SCRO Committee may revoke its prior approval of research under this section, and require modifications to the plan or design of a continuing research project before permitting the research to continue. The SCRO Committee may establish guidelines and procedures for expedited review of renewals so that review by the entire SCRO Committee is not required.