

GESCR PROCEDURE: USE OF OUTSIDE HUMAN EMBRYONIC STEM CELL LINES

Office of Origin: Human Research Protection Program

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I. Introduction

The Human Gamete, Embryo and Stem Cell Research (GESCR) Committee functions as the Stem Cell Research Oversight (SCRO) Committee for the University of California, San Francisco (UCSF).

II. Purpose

This document describes the conditions under which the GESCR Committee may approve the use at UCSF of human embryonic stem cell (hESC) lines that have been derived at another institution.

III. Review Process for Outside Human Embryonic Stem Cell Lines and Requirements

A. Acceptable Research Materials

The GESCR Committee may approve the use at UCSF of hESC lines that satisfy the requirements described in Section A.1, Section A.2, Section A.3 or Section A.4:

1. The hESC line has been:
 - (a) Approved by the National Institutes of Health; or
 - (b) Deposited in the United Kingdom Stem Cell Bank; or
 - (c) Derived by, or approved for use by, a licensee of the United Kingdom Human Fertilization and Embryology Authority; or
 - (d) Derived in accordance with the Canadian Institutes of Health Research Guidelines for Human Pluripotent Stem Cell Research under an application approved by the National Stem Cell Oversight Committee; or
 - (e) Derived in accordance with the Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells¹.
2. The hESC line was found to be “acceptably derived”, within the meaning of Title 17, Section 100081 of the California Code of Regulations, by the Independent Citizens’ Oversight Committee, the governing board of the California Institute for Regenerative Medicine.
3. The derivation of the hESC line was reviewed and approved by an organization in accordance with its procedures for the review of hESC research and:
 - (a) The GESCR Committee has determined that the procedures are substantially equivalent to its own procedures for review of hESC research; and
 - (b) The standards recognized by the relevant jurisdiction for the derivation of the hESC line that were in force when the hESC line was derived incorporated then-current “core ethical standards²”.
4. The GESCR Committee has approved the hESC line for use at UCSF by determining that:
 - (a) Donors of biological materials used to derive the hESC line gave voluntary and informed consent, in compliance with standards recognized by the relevant jurisdiction that were in force when the materials were donated; and
 - (b) The procedures for obtaining biological materials used to derive the hESC line complied with standards recognized by the relevant jurisdiction that were in force when the biological materials were obtained; and

- (c) The standards recognized by the relevant jurisdiction for the derivation of the hESC line that were in force when the hESC line was derived incorporated then-current core ethical standards; and
- (d) No payment beyond reimbursement for reasonable expenses was provided for human gametes, embryos, somatic cells or tissue used to derive the hESC line, with the exception of payments to gamete donors in excess of "permissible expenses" connection with the creation of an embryo for reproductive purposes prior to August 13, 2008³; and
- (e) An Institutional Review Board (IRB)⁴ or, in the case of donations taking place outside the United States, a substantially equivalent oversight body, reviewed and approved the protocols for obtaining the biological materials used to derive the hESC line; and
- (f) The institution at which the biological materials used to derive the hESC line were obtained had a current and valid Federalwide Assurance at the time that the biological materials were obtained.

B. Deemed Satisfaction of Requirements

1. The requirements described in Section A.4, above, may be deemed satisfied if the GESCR Committee receives a letter that meets all of the following requirements, subject to the exception described in Section B.2, below. The letter must:
 - (a) Be addressed to the Chair of the GESCR Committee; and
 - (b) Be signed by:
 - (i) For lines derived at an institution within the United States, the Chair of the Stem Cell Research Oversight Committee that reviewed and approved the derivation of the hESC line or an official or administrator authorized by the institution at which the hESC line was derived to verify such information; or
 - (ii) For lines derived at an institution outside of the United States, the presiding officer of the oversight body that reviewed and approved the derivation of the hESC line or an official or administrator authorized by the institution at which the hESC line was derived to verify such information; and
 - (c) Attest that each of the requirements described in Section A.4 was satisfied in connection with derivation of the hESC line.
2. Where the hESC line was derived from a human embryo, the GESCR Committee must receive and review a sample of the consent form that was provided to the embryo donors.

C. Exceptional Approval

The GESCR Committee will consider protocols involving the use of an hESC line that has been derived at another institution, where the line does not satisfy the requirements described in Section A.1, A.2, A.3 or A.4, above, on a case-by-case basis. The GESCR Committee may approve the use of such hESC lines as an exception to this Policy.⁵

D. Committee Discretion

The GESCR Committee may, in its sole discretion, impose conditions on its approval for use of an hESC line derived at another institution that otherwise satisfies the requirements described in Section A, above, where ethical or other concerns have been raised.

In exceptional circumstances, the GESCR Committee may, in its sole discretion, disapprove use of an hESC line that satisfies the requirements described in Section A.1, A.2, A.3 or A.4, above, where ethical or other concerns have been raised.

¹ See California Code of Regulations (CCR), Title 17, Section 100080(a).

² Examples of such “core ethical standards” include the International Society for Stem Cell Research *Guidelines for the Conduct of Human Embryonic Stem Cell Research* and the National Academies’ *Guidelines for Human Embryonic Stem Cell Research*.

³ See Title 17 CCR Section 100080(a)(2)(B), (D); 17 CCR Section 100082; California Department of Health Guidelines for Human Stem Cell Research, Section 6(e)(2), (3), (5). “Permissible expenses” has the same meaning as the term defined in Title 17 CCR, Section 100020: necessary and reasonable costs directly incurred as a result of donation or participation in research activities. Permissible expenses may include but are not limited to costs associated with travel, housing, child care, medical care, health insurance and actual lost wages.

⁴ “IRB” has the same meaning as the term defined in Title 17, California Code of Regulations, Section 100020(g): an entity established in accordance with the Code of Federal Regulations, Title 45, Section 46.107.

⁵ For discussion of factors to consider when granting an exception, please see “Importing Human Pluripotent Stem Cell Lines Derived at Another Institution: Tailoring Review to Ethical Concerns”, Bernard Lo, M.D., et al., *Cell Stem Cell*, Volume 4, Issue 2, 115-123, 6 February 2009.