

§ 2. Definitions

(e) "covered stem cell line" means a culture-derived, human pluripotent cell stem cell population derived from an embryo or product of SCNT that is capable of: 1) sustained propagation in culture; and (2) self-renewal to produce daughter cells with equivalent developmental potential. "Pluripotent" means capable of differentiation into mesoderm, ectoderm, and endoderm.

§ 5. SCRO Committee Review and Notification (*track changes version in separate document*)

- (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....
- (d) Clinical trials involving the use of pluripotent cells or cells derived from pluripotent cells may not commence without SCRO Committee review and approval in writing.
- (f) Research introducing pluripotent cells or cells differentiated from pluripotent cells into non-human animals, or

§ 6. Acceptable Research Materials

All covered stem cell lines used in research must be "acceptably derived."

- (a) To be "acceptably derived," the stem cell line must meet one of the following three criteria:
 - (1) The stem cell line is recognized by an authorized authority. To be recognized by an authorized authority the stem cell line must:
 - A. Be approved by the National Institutes of Health; or
 - B. Be deposited in the United Kingdom Stem Cell Bank; or
 - C. Be derived by, or approved for use by, a licensee of the United Kingdom Human Fertilization and Embryology Authority; or
 - D. Be 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. Be derived in accordance with the Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells; or
 - F. Be derived in accordance with California Code of Regulations, title 17, section 100081

- (2) The stem cell line is derived from human gametes, embryos, somatic cells, or tissue under the following conditions:
 - A. Donors of human gametes, embryos, somatic cells or tissue gave voluntary and informed consent; and
 - B. Donors of human gametes or embryos did not receive valuable consideration. This provision does not prohibit reimbursement for permissible expenses as defined in section 2(k), as determined by an IRB; and
 - C. Donation of human gametes, embryos, somatic cells or tissue was overseen by an IRB (or, in the case of foreign sources, an IRB-equivalent); and
 - D. Individuals who consented to donate stored human gametes or embryos were not reimbursed for the cost of storage prior to donation.
- (3) The stem cell line has been derived from human gametes, embryos, somatic cells, or tissue under the following conditions:
 - A. The lines were derived in accordance with Section 6(a)(2)(A), (B), and (D); and
 - B. The line was derived prior to the publication of the NAS guidelines (2005); and
 - C. A SCRO has determined that the investigator has provided sufficient scientific rationale for the need for use of the line. This should include establishing that the proposed research can not reasonably be carried out with covered lines that did have IRB approval.

§ 7 Additional Requirements for Covered Research Deriving New Human Stem Cell Lines

When reviewing proposals to derive new human embryonic stem cell lines, the SCRO committee must confirm that the donors of gametes, embryos, somatic cells or human tissue have given voluntary and informed consent.