7/26/2007

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

To: SWG
Fr: CIRM
Re: Draft Language to Support Item #3 7/27/07 SWG Meeting

The draft language below is intended to support agenda item #3 (with the exception of 100080(a)(5) which supports item #1). Language for consideration is in blue with double underlining. Draft language is provided so the SWG and the public may more clearly evaluate the policies under consideration.

§ 100080. Acceptable Research Materials.

(a) All covered stem cell lines used in CIRM-funded research must be "acceptably derived." To be "acceptably derived," the stem cell line must:

(1) Be approved by the National Institutes of Health; or

(2) Be deposited in the United Kingdom Stem Cell Bank; or

(3) Be derived by, or approved for use by, a licensee of the United Kingdom Human Fertilization and Embryology Authority; or

(4) 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

(5) Be derived in accordance with the Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells; or

(6) Be derived under the following conditions:

(A) Donors of gametes, embryos, somatic cells or human tissue gave voluntary and informed consent; and

(B) Donors of gametes, embryos, somatic cells or human tissue did not receive valuable consideration. This provision does not prohibit reimbursement for permissible expenses as determined by an IRB; and

(C) Donation of gametes, embryos, somatic cells or human tissue was overseen by an IRB (or, in the case of foreign sources, an IRB-equivalent); and

(D) Individuals who consented to donate stored gametes, embryos, somatic cells or human tissue were not reimbursed for the cost of storage prior to the decision to donate.

(b) Covered stem cell lines used in CIRM-funded research derived from somatic cells that do not meet any of the requirements of subdivision (a) of this regulation are nevertheless "acceptably derived" provided:

(1) the derivation did not require the transfer of a somatic cell nucleus into a human oocyte (SCNT) or the creation or use of a human embryo; and

(2) the resulting cells have no codes or linkers of any sort maintained, either by the CIRM-funded researcher or a third party, that would permit access to identifiable private data or information about the living individual from whom the material was obtained.

§ 100090. Additional Requirements for CIRM-Funded Derivation.

(a) If CIRM funds are to be used to derive a covered stem cell line from (1) human gametes, (2) human embryos or (3) human cells necessary for SCNT, then the SCRO committee must determine that both the requirements of Code of California Regulations, title 17, section 100080, subdivision (a)(6), and the requirements of Code of California Regulations, title 17, section 100100, subdivision (b), are met.

(b) This section does not apply to research intended to derive a covered stem cell line from human somatic cells provided the derivation (1) does not require SCNT or (2) the creation or use of a human embryo.

(c) This section does not apply to the modification of an existing covered stem cell line.