Agenda Item # 11
8/8/07 ICOC Meeting

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

8/01/2007

To: Independent Citizens Oversight Committee (ICOC)
From: Scientific and Medical Accountability Standards Working Group (SWG)
Re: Recommendations from July 27 SWG Meeting

Background:

On 7/27/07 the SWG met to consider three issues related to the existing Medical and Ethical Standards.

1. **Use of cell lines derived under *Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells***
2. **Limitations on payment for cells**
3. **Requirements for use of somatic cells and human tissue**

Each issue and the SWG's recommendation are summarized below.

1. Use of Cell Lines Derived Under *Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells*

Background:

In May 2007, the SWG requested that CIRM staff review the *Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells* for consistency with the MES regulations. The purpose of this evaluation was to consider whether stem cell lines derived under the *Japanese Guidelines* may be designated as acceptable "research materials." Such a designation would enable the Japanese lines to be utilized without additional reviews by a stem cell research oversight committee.

Recommendation:

The SWG recommends that the Japanese guidelines be included a acceptable research materials provided the MES regulations are modified to require that all covered stem cell lines designated as acceptable research materials conform to California Health and Safety code 125290.35(b)(6) which sets time limits for extracting cells from blastocysts to 12 days.

2. Limitations on Payment for Cells

Background:

In the California Health and Safety Code regulations governing CIRM-funded research there are two separate provisions limiting payments to third-parties for cell lines. One provision is contained in the California Stem Cell Research and Cures Initiative (Proposition 71) California Health and Safety code 125290.35(b)(5). The second provision is contained in the CIRM MES regulations California Health and Safety code 10080(e)(3). The existence of two separate regulations governing related issues creates ambiguity for CIRM grantees.

Recommendation:

The SWG recommends that the existing language in the MES regulations be deleted and replaced with language that references the original language in the initiative California Health and Safety code 125290.35(b)(5) provided the scope of the language is expanded to include payments for gametes, embryos, somatic cells, human tissue or covered stem cell lines. Note the recommended modification only affects payments to third-parties and does not affect existing restrictions on payments for donors.

3. Requirements for Use of Somatic Cells and Human Tissue

Background:

The existing MES regulations require that when CIRM-funded research is designed to derive covered stem cell line all donors of cells and genetic material provide informed consent in accordance with the exact consent requirements detailed in section 100100. As a consequence, existing somatic cell lines may not be available for reprogramming experiments unless consent was obtained in accordance with the exact requirements of section 100100.

At least one CIRM funded institution has a number of investigators who have been studying epigenetic control of gene expression for many years and their work often utilizes commercially available human somatic cell lines. This same institution has proposed reprogramming experments that have been approved for funding by the ICOC. Under the current requirements of section 100090, continuation of this work with the intent to derive ES-line cell is not feasible.

Recommendation:

The SWG recommends a more flexible standard for use of somatic cells consistent with federal Office for Human Research Protections (OHRP) guidance for research with existing biological materials. The recommended language below, 100080(b)(2), is consistent with OHRP guidance designed to ensure the identity of cells cannot be readily ascertained by the investigator. Under the recommended standard, CIRM-funded research intended to derive a covered stem cell line from somatic cells must conform to federal standards.

Draft Language to Support Item #3

§ 100080. Acceptable Research Materials

(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 cells have no codes or linkers maintained by anyone that would identify to the investigator(s) the donor of the specimens, or, if such codes or linkers exist, that the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the specimens pertain because, for example:
    (A) the key to decipher the code is destroyed before the research begins;
    (B) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased;
    (C) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
    (D) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

§ 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.