Study Group Working Notes #14: Human Fetal Tissue

Background:

Fetal tissue is a source for human stem cell lines or other cell lines of a pluripotent nature. National and international guidelines for the use of fetal tissue have been developed to address the unique ethical issues associated with the use of fetal tissue in research.

National and international guidelines are consistent with regards to specific conditions that should be met for fetal tissue to be used in research. Major concerns related to:

(1) Timing of abortion: The proposed research should not influence a woman's decision to continue her pregnancy;
(2) Disclosure of interest: The attending physician should disclose any interest in the research using fetal tissue.
(3) Informed consent: The donor is fully informed of (a) the potential uses of the donated tissue and (b) any risks to personal privacy;
(4) Prohibition on payments: No payment is provided for fetal tissue.

The CIRM MES Regulations already address issues 3 and 4. Section 100100 includes extensive informed consent provisions including items a & b. Section 100080(e)(2) prohibits the purchase or selling of "gametes, embryos, somatic cells, or human tissue for research purposes."

Issue 2 is conceptually consistent with Section 100090(b)(3) which requires the physician attending an oocyte donor not be the researcher. Issue 1 is currently not addressed in the CIRM MES Regulations.

Recommendation and/or Proposed Language:

Given fetal tissue is an important source for pluripotent cells and the existing CIRM MES Regulations are generally consistent with existing guidelines, it is recommended that the following revisions be made to make the MES Regulations consistent with existing NIH policy.

http://www.hhs.gov/ohrp/humansubjects/guidance/publiclaw103-43.htm

To create such consistency, the following language is recommended:

New Section 100085: Use of Fetal Tissue

Fetal tissue shall be procured in accordance with, 17 Cal. Code Regs. Sections 100080 subsections(e)(1)-(3) [see language below]. In addition research involving human fetal tissue will adhere to the following provisions:

(a) The woman who donates the fetal tissue must:

(1) Sign a statement declaring that the donation is being made for research purposes.

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(2) Not receive valuable consideration for fetal tissue donation.

(b) The attending physician must:

(1) Sign a statement that he/she has obtained the tissue in accordance with the donor's signed statement.

(2) Disclose to the donor any interest, financial or otherwise, in the research to be conducted with the tissue.

(3) Disclose any known medical risks to the donor or risks to her privacy that might be associated with the donation of the tissue and that are in addition to risks of such type that are associated with the woman's medical care.

(4) In the case of tissue obtained pursuant to an induced abortion, the physician must sign a statement stating that he/she obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used; did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and performed the abortion in accordance with applicable state and local laws.

(5) Note Pat K comment might consider barring physician from furnishing tissue directly to the researcher.

(c) The principal investigator of the research project must sign a statement certifying that he/she is aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PI must certify in writing that he/she has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy and the he/she is not the donor's attending physician.

Existing Regulatory Langauge:

§ 100080. Acceptable Research Materials. [Reference included for reference]

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

(e) Have been derived under the following conditions:

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

(2) 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;

(3) A person may not knowingly, for valuable consideration, purchase or sell gametes, embryos, somatic cells, or human tissue for research purposes pursuant to this chapter, except for donors as provided in subdivision (e)(2) of this regulation. This provision does not prohibit reimbursement for permissible expenditures as approved by a SCRO committee. "Permissible expenditures" means necessary and reasonable costs directly incurred as a result of persons, not including human subjects or donors, providing gametes, embryos, somatic cells, or human tissue for research purposes. Permissible expenditures may include but are not limited to costs associated with processing, quality control, storage, or transportation of materials.