Agenda Item # 16 4/6/06 ICOC Meeting CIRM MES Regulations – Additional Item

4/3/2006
To: ICOC
Fr: CIRM
Re: Consensus Recommendation CIRM MES Regulations

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). In addition research involving human fetal tissue will adhere to the following provisions:

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

(1) That the donation is being made for research purposes, and

(2) The donation is made without any restriction regarding the identity of individuals who may be the recipients of materials derived from the tissue; and

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(3) She did not receive valuable consideration for the 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 for research; 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.

(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 he/she is not the donor's attending physician.

(d) *Tissue or tissue-based products (as defined in 21 CFR 1271.3(d)) intended for transplantation into a human recipient, shall conform with current good tissue practice requirements CFR 1271.145-1271.320.*