



**June 4, 2007**

**Subject / Title:**

CIRM Medical and Ethical Standard Regulation Section 100085 Use of Fetal Tissue

**Action Required:**

ICOC approval of final regulation as noticed with the Office of Administrative Law (OAL).

**Administrative History:**

1. April 4, 2006 Standards Working Group recommends interim regulation.
2. April 6, 2006 ICOC approves recommended interim regulation.
3. November 13, 2006 Standards Working Group recommends final regulation.
4. December 7, 2006 ICOC approves final regulations.
5. January 26, 2007 regulatory notice, comment period opens.
6. March 12, 2007 comment period closed, no comments received, no changes made to regulation noticed with OAL.

**Digest / Policy Statement:**

Fetal tissue is a source for human stem cell lines or other cell lines of a pluripotent nature. As such, principles for the use of fetal tissue have been developed in other jurisdictions and federal regulations to address the unique ethical issues associated with the use of fetal tissue in research. This regulation is designed to compliment and be consistent with policies in other jurisdictions for fetal tissue research, and describe specific conditions that should be met for fetal tissue to be used in research. Specifically, the regulation embodies five principles:

- (1) Unrestricted donation: There are no restrictions on who may receive tissue;
- (2) Disclosure of interest: The attending physician should disclose any interest in the research using fetal tissue;
- (3) Timing of abortion: The proposed research should not influence a woman's decision to continue her pregnancy.
- (4) Medical management of abortion: No alteration of the timing, method, or procedures used to terminate the pregnancy should be made solely for the purposes of obtaining the tissue; and

- (5) Legality of abortion: The abortion should be performed in accordance with applicable State and Federal law.

**Regulatory Language:**

1 Adopt 17 Cal. Code of Regs. section 100085 to read:

**§ 100085. Use of Fetal Tissue.**

*Fetal tissue shall be procured in accordance with 17 Cal. Code Regs. section 100080, subdivisions (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*

*(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 financial interest that the attending physician has 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 principal investigator 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.*

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 125290.55, 125300, Health and Safety Code.