

1/28/10

To: ICOC
Fr: CIRM
Re: Consideration of Final Adoption MES Amendments: Sections 100080 & 100090

Action Required:

ICOC approval of final regulation, Sections 100080 and 100090. Proposed language recommended by the Standards Working Group and revised in response to public comment is attached.

Background:

On [9/18/09](#) and [10/12/09](#), the Standard Working Group met to consider regulatory amendments in response to public comments. These amendments are designed to accomplish the following:

1. Revise the review requirements of stem cell research oversight committees;
2. Authorize the use of embryos donated by IVF patients where the gamete donors received compensation for reproductive purposes;
3. Authorize the use of somatic cells for which donors have received IRB-approved compensation for inconvenience, provided that CIRM funds have not been used;
4. Provide additional clarification of regulatory requirements in response to public comment.

CIRM Administrative Activities:

On [10/27/09](#), the ICOC approved a motion to initiate the rulemaking (OAL) process to amend CIRM Medical and Ethical Standards regulations sections 100080 and 100090. In accordance with the California Administrative Procedure Act, CIRM provided notice of proposed amendments effecting sections 100080 and 100090 of Title 17 of the California Code of Regulations for public comment. These administrative activities were performed according to the following schedule:

Section 100080

On [11/27/09](#) CIRM provided public [notice](#) of the proposed regulatory [amendments](#) to section 100080 and received public comment in response to the notice. Comments were supportive of the proposed amendments and no revisions were required.

Section 100090

On [10/30/09](#) provided a second public [notice](#) (first public notice was [5/22/09](#)) of the proposed regulatory [amendments](#) to section 100080 and received public comments. In response to public comments, CIRM provided a third public [notice](#) on [11/18/09](#) of proposed regulatory [amendments](#) to section 100080.

Public Comments:

CIRM received public comments on sections 100080 and 100090. The proposed amendments incorporate CIRM's response to public comments. A summary of public comments and CIRM's response is attached.

Recommendation: Staff recommends the ICOC adopt Section 100080 and 100090.