10/19/09

To: ICOC

Fr: CIRM

Re: Consideration of regulatory amendments to the CIRM Medical and Ethical Standards

Action for ICOC Consideration:

Amended regulatory language (Attachment 1) so CIRM may proceed with rulemaking under the Administrative Procedure Act.

Background:

On 3/12/09, the ICOC approved a motion to initiate the rulemaking (OAL) process to amend CIRM Medical and Ethical Standards regulations. These amendments, which were approved on 3/12/09, were designed to support iPS experiments using somatic cells and utilization of certain embryos for CIRM-funded research.

On 5/22/09, CIRM provided public notice of the proposed regulatory amendments and received public comment. 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 (SCRO) committees;
2. Authorize the use of embryos donated by IVF patients where the gamete donors received compensation for reproductive purposes and the use of somatic cells for which donors have received IRB-approved compensation for inconvenience, provided that CIRM funds have not been used;
3. Provide additional clarification of regulatory requirements in response to public comment.

SWG Sense of the Committee:

It was the sense of the SWG that the ICOC should consider the following new revisions:

- Revise the oversight (SCRO) requirements consistent with Attachment 2;
- Authorize the use of embryos created for reproductive purposes (IVF-embryos) for which a gamete donor was paid;
- Maintain restriction on the use of CIRM funds to compensate any gamete, embryo or somatic cell donor in excess of allowable out-of-pocket expenses.