1/26/09

To: ICOC

Fr: CIRM

Re: Consideration of regulatory amendments to the CIRM Medical and Ethical Standards regulations, including oversight and consent requirements for use of blastocysts and somatic cells

Action for ICOC Consideration:

Approval of recommended regulatory language (Attachment 1) so CIRM may initiate rulemaking action under the Administrative Procedure Act.

Background:

On 12/12/08 the Standards Working Group (SWG) met to consider MES revisions to support iPS research using somatic cells and to consider final recommendations for regulations governing consent for and utilization of embryos for CIRM-funded research.

SWG Sense of the Committee:

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

- Clarify that the oversight (SCRO) committee requires notification for *in vitro* iPS research;
- Revise the standard for use of somatic cells in iPS experiments to allow somatic cells obtained under IRB-approved consent protocols.

It was the sense of the SWG that the ICOC should consider the making permanent the existing interim regulations. These regulations

- Authorize the use of IVF-embryos (created prior to August 2008) for which a gamete donor was paid;
- Authorize the use of embryos donated for research, where consent was obtained prior to enactment of the CIRM regulations, provided the consent conformed to the prevailing standard at time of donation.

Attachment 1 contains language designed to support the revisions described above.