

8/4/08

To: ICOC

Fr: CIRM

Re: Consideration of SWG Recommendation for Regulatory Amendment Authorizing a Procedure for Designating hESC lines derived before 11/22/06 as Acceptably Derived

Action for ICOC Consideration:

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

Background:

CIRM regulations require hESC lines derived prior to November 22, 2006 – the date the MES regulations took effect – to (1) be recognized by an authorized authority or (2) conform to specific regulatory criteria. hESC lines that do not meet either standard are not eligible for use in CIRM-funded research.

On [7/25/08](#) CIRM presented an example to the Standards Working Group (SWG) of a scientifically significant hESC line derived before November 22, 2006 in accordance with the prevailing ethical standard of care at the time. The line, however, does not conform to the exact regulatory criteria set forth in the CIRM regulations. The MES regulations have the effect of applying requirements retroactively to hESC lines.

SWG Sense of the Committee:

It was the sense of the SWG that for lines derived before the effective date of the regulations, there is a need for a “grandfathering” process to evaluate materials for use in CIRM-funded research. This evaluation process should include the following:

- ▶ Consideration of the informed consent from the woman or couple in IVF (and a lack of any indication that original donor would have objected to use for research);
- ▶ Consideration of documentation related to the approval of the donation protocol by an Institutional Review Board;
- ▶ Consideration of compliance with prevailing ethical and legal standards in place at the time of derivation in the jurisdiction where the derivation was carried out;
- ▶ Documentation of the scientific or medical significance of the hESC line.

The evaluation process would be initiated with a request to CIRM. Staff would review the request and make a recommendation to the ICOC. The ICOC would consider the request in a public meeting.

Attachment 1 contains language designed to support the recommendation of the Standards Working Group.