

12/3/07 DRAFT

To: Members of the ICOC

Fr: CIRM

Re: Consideration of Final Adoption MES Amendments Package: Sections 100080, 100085, 100090, 100100 and 100120

Action Required:

Approval of amendments to MES regulations: Sections 100080, 100085, 100090, 100100 and 100120, as noticed with the Office of Administrative Law (OAL).

Background:

Sections 100080, 100085, 100090, 100100

On [8/8/07](#) the ICOC considered the [recommendations](#) from the 7/27/07 Standards Working Group (SWG) meeting. Dr. Lo presented the recommended amendments to the CIRM Medical and Ethical Standards (MES) regulations addressing:

1. Use of cell lines derived under *Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells*
2. Limitations on payment for cells
3. Requirements for use of somatic cells and human tissue

The ICOC [approved](#) the recommendations described by Dr. Lo provided the standard setting a limit on the time during which cells may be extracted from blastocysts was clarified in the final regulation (section 100080).

Section 100120: Record Keeping

On [8/8/07](#) the ICOC approved revised language for [regulation 100120](#). The language approved on 8/8/07 referenced requirements in section 100080 of the MES regulations. The amendments to section 100080 (described above) resulted additional changes to the section numbering of this regulation. Regulation 100120 has been [modified](#) to reflect the changes approved by the ICOC on 8/8/07.

CIRM Activities:

Sections 100080, 100085, 100090, 100100

On October 26, 2007, in accordance with California's Administrative Procedure Act (APA), CIRM [noticed](#) and posted an update to the [proposed amendments](#) affecting sections 100080, 100085, 100090 and 100100 of Title 17 of the California Code of

Regulations for a 45-day public comment period. With the ICOC's approval, the regulations will be submitted to the OAL for final adoption.

Sections 100120

The proposed regulation comprising the Medical and Ethical Standards Regulations, proposed section 100120, was [originally](#) published by the Office of Administrative Law on March 17, 2006. After numerous public comment periods, the regulations were forwarded to the Office of Administrative Law for approval and publication. During the review process, the CIRM withdrew regulations 100120 to reflect the changes approved by the ICOC to section 100080 on 8/8/07.

On November 20, 2007 In accordance with the APA, CIRM posted [revisions](#) to section 100120 for an additional 15-day public comment period. The public comment period has concluded and the regulations are now ready for final adoption by the ICOC. With the ICOC's approval, the regulations will be submitted to the OAL for final adoption.