

1/9/08

To: ICOC
Fr: CIRM
Re: Consideration of Final Adoption MES Amendments Package: Sections 100080, 100085, 100090, 100100 and Regulations Section 100120: Record Keeping

Action Required:

ICOC approval of final regulations Sections 100080, 100085, 100090, 100100 and 100120 as noticed with the Office of Administrative Law (OAL). Final recommended language is attached.

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 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 in 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 Administrative Activities:

Sections 100080, 100085, 100090, 100100

On October 26, 2007 CIRM in accordance with the California Administrative Procedure Act CIRM provided [notice](#) and posted 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. The proposed amendments

incorporated the SWG recommended amendments and the ICOC-mandated clarification to regulation 100080.

Section 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 California Administrative Procedure Act, CIRM posted [revisions](#) to section 100120 for an additional 15-day public comment period.

Public Comments:

Sections 100080, 100085, 100090, 100100

Public comments were received and modifications were made to Sections 100080, and 100100. CIRM provided [notice](#) with the OAL for an additional 15 days, and no additional public comments were received.

Section 100120

No public comments were received on section 100120 prior to the 12/5/07 deadline. Comments were received on 12/13/07 and CIRM is preparing a response to these comments in accordance with the California Administrative Procedure Act. No further modifications are recommended based on these comments.