

May 31, 2006

To: ICOC

Fr: CIRM Medical and Scientific Accountability Standards Working Group (SWG)

Re: Update on Proposed CIRM Medical and Ethical Standards (MES) Regulations

This memo provides an update on the development of the CIRM MES regulations approved at the February 10 meeting.

**Summary of Recent Activities:**

On March 17 the regulations were officially noticed with the Office of Administrative Law, triggering an initial 45 public comment period. Approximately 50 unique public comments were received from individuals, research institutions, women's health organizations and other public interest groups.

On May 3, 2006 the Standards Working Group convened to discuss selected comments where issues of clarity, consistency and necessity were raised. Additional public comments were received at the meeting. Revisions were recommended by the SWG in the areas of: definitions, SCRO committee membership and operations, additional protection of oocyte donors and informed consent.

On May 9, 2006 these revisions were noticed with the OAL opening an additional 15 day public comment period. During the additional 15 day public comment period we received a number of additional comments in each of these areas. Many of the comments are from the regulated institutions concerning issues of clarity and consistency.

**Revised Plan for Development of Final Recommendations:**

The SWG had originally planned to present final recommendations to the ICOC at today's (6/2/06) meeting. However, the SWG believes it is critical to provide the best product not only to the Office of Administrative Law but also to the regulated community. It is particularly important that the parties that implement these regulations are clear on what is expected of them. Therefore, we recommend making additional revisions to the regulations limited to the four areas mentioned previously. These revisions are intended to improve the clarity and consistency of the regulations.

The consequence is that the revisions will be subject to an additional 15 days of public comment. The public comment periods have served these regulations well and resulted in a greatly improved document. Therefore, we are recommending a revised implementation schedule for the CIRM MES regulations with the final regulatory package be considered by the ICOC for approval at the August 2, 2006 meeting. The final package will include the Final Recommended CIRM MES Regulations and a response to every public comment received.