

July 26, 2006

To: ICOC

Fr: Medical and Ethical Standards Working Group (SWG)

Re: Final Recommended from the CIRM Scientific and Medical Accountability Standards Working Group (SWG)

**Objective:**

The SWG is pleased to submit for your consideration its final recommendations for Medical and Ethical Standards regulations. The recommended regulations have been prepared in accordance with Proposition 71 (Health and Safety Code Section 125290.10-125290.70) and the California Administrative Procedure Act. To initiate Office of Administrative Law (OAL) review of the proposed regulations, the ICOC must approve regulatory language and supporting documentation described below.

**History:**

On 2/10/06 the ICOC approved the CIRM Medical and Ethical Standard (MES) regulations recommended by the Standards Working Group (SWG). Subsequently the MES regulations were noticed with the Office of Administrative Law (OAL) for the purpose of receiving formal public comment. Through an iterative process of public comment and revision (Box 1), including a specific recommendation by the ICOC with regard to CIRM policy on consent for cord blood donation, final recommended MES regulations have been drafted for ICOC adoption.

**Box 1: MES Rulemaking Process**

- ▶ Proposition 71 grants authority for the ICOC to adopt regulations;
- ▶ 2/10/06 ICOC approves recommended MES regulations;
- ▶ 3/17/06 CIRM submits initial statement of reasons, rulemaking record is open and 45 day public comment period begins;
- ▶ 5/03/06 SWG meets to review public comments and make changes to the regulations;
- ▶ 5/09/06 CIRM second posting of proposed changes for 15 day public comment;
- ▶ 6/02/06 ICOC recommends policy on consent for cord blood donation;
- ▶ 6/15/06 CIRM third posting of proposed changes for 15 day public comment;
- ▶ 7/06/06 CIRM fourth posting of proposed changes for 15 day public comment;
- ▶ 7/19/06 SWG meets to recommend final language to ICOC for section 100095;
- ▶ 8/02/06 ICOC considers recommended language for section 100095, complete regulatory language and supporting documentation.

**Documents for ICOC Consideration:**

There are four documents for ICOC consideration; each is described below.

1. *Final Compiled Proposed CIRM MES Regulations*: This document contains the final recommended language for the CIRM MES regulations.
2. *Optional Language for CIRM MES Regulations Section 100095*: This document contains three options for language that were posted for public comment on 7/19/06. Dr. Bernard Lo, co-chair of the SWG, will describe each option. On 7/19/06 the SWG voted 12-0 to approve a motion to recommend optional language #3 to the ICOC for approval and incorporation into the final recommended MES regulations. Public comments to the ICOC with regard to this section are also attached.
3. *Summary and Response to Public Comment for the Proposed CIRM MES Regulations*: This document summarizes the public comment and the response to comments on a section-by-section basis. Included are all changes to accommodate or reasons for rejection. Note some responses included reference to supporting materials contained in the public record.
4. *Original Basis for CIRM MES Regulations*: This document provides specific references for the origin of or basis for each provision. It is intended to support the final statement of reasons and provide transparency by clearly identifying the basis for each provision.

**Motions Required to Continue Rulemaking:**

1. Motion to adopt language for CIRM MES Regulations Section 100095.
2. Motions to adopt final regulatory package – documents 2-4 above.
3. Motion to Repeal Emergency MES Regulations, Title 17, Division 4, of the California Code of Regulations, Sections 100140 – 100150, upon effective date of the permanent MES regulations.