11/22/06

To: ICOC

Fr: CIRM

Re: Revisions to MES Section 100120 & 100130 in Response to OAL Comments

On August 2, 2006 the ICOC approved final CIRM Medical and Ethical Standards (MES) regulations. On October 10 2006, the Office of Administrative Law (OAL) informed CIRM that sections 100010-100110 of the MES regulations have been adopted and became effective November 22, 2006.

Sections 100120-100130 of the regulatory package approve by the ICOC were withdrawn by CIRM in response to comments from OAL. There were a number of concerns identified with the original language of section 100120 which deals with record keeping. CIRM has subsequently revised section 100120 to address these concerns. Section 100130 deals with sharing of cells and other research materials. CIRM proposes deleting section 100130 because it is redundant with CIRM's intellectual property regulations.

Included below is a mark-up version of section 100120 with modifications identified. A clean version is also included at the end of this document. For this regulation to be submitted to OAL for final adoption, the ICOC must approve regulatory language.

Adopt 17 Cal. Code of Regs. section 100120 to read:

§ 100120. Record Keeping.

(a) In addition to any other reporting or record retention obligations required by the CIRM, each grantee's institution shall also maintain records documenting: ~~Each grantee's institution shall maintain records of all CIRM-funded research activities. At a minimum, the institution shall maintain a research registry that includes, but is not limited to, documentation of:~~

~~(a) CIRM-funded stem cell research conducted by the institution;~~

(1b) ~~Any required r~~Review or notification requirements as described in Title 17, California. Code of Reg'~~.~~s, section 100070;

~~(c) The methods utilized to characterize and screen the materials for safety;~~

~~(d) The conditions under which the materials have been maintained and stored;~~

~~(e) Any additional requirements set forth in any other regulations under this title;~~

(2f) Every gamete, somatic cell, embryo donation or product of SCNT that has been donated, created or used. This record should be sufficient to determine ~~the~~ ~~provenance~~whether such materials comply with section 100080, subdivision (e), and should document the final ~~and~~ disposition of such materials.

(b) Such records shall be made available at CIRM's request.

§ 100120. Record Keeping.

(a) In addition to any other reporting or record retention obligations required by the CIRM, each grantee's institution shall also maintain records documenting: (1) Review or notification requirements as described in Title 17, California. Code of Reg's, section 100070;

(2) Every gamete, somatic cell, embryo donation or product of SCNT that has been donated, created or used. This record should be sufficient to determine whether such materials comply with section 100080, subdivision (e), and should document the final disposition of such materials.

(b) Such records shall be made available at CIRM's request.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.