To: SWG for 11/13/06 Meeting

Fr: CIRM

Re: Regulations Governing the Use of Fetal Tissue

Background:

On April 4, 2006 the SWG recommend language for interim fetal tissue regulations. This language was subsequently approved by the ICOC on April 6, 2006 (see attachment 1). The approved language is in effect for 270 days and will expire on January 1, 2007. One objective for the 11/13 SWG meeting is to consider final language for fetal tissue regulations to recommend to the ICOC for its December 7, 2006 meeting.

Policy Considerations:

The interim regulations are designed to be consistent with established state and national standards for fetal tissue research. The regulations describe specific conditions that should be met for fetal tissue to be used in research. Major requirements include:

(1) Unrestricted donation: There are no restrictions on who may receive tissue;
(2) Disclosure of interest: The attending physician should disclose any interest in the research using fetal tissue;
(3) Timing of abortion: The proposed research should not influence a woman's decision to continue her pregnancy.

The issue of screening materials for safety has also emerged as a consideration. Currently, FDA regulations exist for screening tissue intend for transplantation to humans (see attachment 2). Stem cells or their products intended for transplantation are covered by these regulations. Draft language for a section (d) has been added to the fetal tissue regulations. This language references the FDA requirements.

Recommendation:

The ICOC has indicated a desire for CIRM regulations to be consistent with Federal regulations whenever possible. For example, when the issue of consent for cord blood donation was raised, the ICOC recommended consent language consistent with established state and national policy for consent. During this discussion, board members suggested any new regulations should

be designed to filling gaps in existing federal regulations but not attempt to rewrite them.

The language in the interim fetal tissue regulations is consistent with federal policy. The existing language could serve as the basis for the final regulation unless there are gaps in existing policy that SWG members feel need to be addressed with new regulation.

The SWG should consider the need for additional language regarding materials screening.