11/30/05

To: SWG

Fr: CIRM

Re: Summary of SWG Comments and Revisions to the Draft CIRM Regulations

Note counsel has reviewed 100003-05 and 100008 and provided edits to language in 10/20 draft. These edits have been incorporated into the 11/29 draft.

Edits & Comments on 11/29 Existing Draft

Section 100001: Definitions

- Definition of stem cells consistent with language proposed by Grants Working Group. [staff edit]

Section 100003: Institutional Assurances of Compliance

- *Institution* is responsible for all oversight and assurances of compliance 100003(a) [staff edit]. Previous oversight language was in section 100004 ESCRO Requirements where the ESCRO was tasked with broad oversight responsibility. Since we allow joint or shared ESCROs, it seems this responsibility would be a disincentive for collaboration because (1) the ESCRO may not want to take responsibility for another institution or (2) the institution would not want to delegate responsibility to a third party. Therefore, all oversight and assurance now at institutional level which is also consistent with the Grants Administration Policy.

- Section 100003(e): Failure to comply with requirements set forth in this policy constitutes ground for non-continuation of existing, or disqualification for future, CIRM funding [staff edit]. This language was moved from section 100008. Compliance should be expected for all sections of the regulations, not just 100008.

Section 100004: ESCRO Requirements

- ESCRO provides scientific and ethical review. There was consensus that the ESCRO should consider the science and the ethics of proposed research. Previous draft did not explicitly state ethical review was performed by ESCRO. The NA Committee also agreed with this position.

- 100004(a) Membership: There was a desire to not specify the exact composition of the ESCRO but require that at least one member be drawn from outside the institution.

Section 100005: ESCRO Review & Notification

- The term "designated" as opposed to "the ESCRO" reinforces the concept that ESCROs can be shared.
- Just in time review by ESCRO ok as an initial policy [SWG comment]. Regulations are not prescribing order of ESCRO and IRB review other than saying all reviews must be complete *prior to commencing research*. Grants policy may consider special conditions when ESCRO approval is provided either (1) with the initial application or (2) prior to CIRM release of funds. CIRM will specify requirements in its grants policy.
- Grants Administration Policy requires all necessary reviews be completed as a *condition of release of funds*. Recommend that *prior to commencing research* be changed to *as a condition of release of funds* to harmonize with the Grants Administration Policy.

Section 100006: Ethically Derived Materials

- To improve this section suggestion made to start (a), (b) and (c) with the following: *For human stem cells derived* ***with CIRM funding after*** *the effective date of this chapter to be considered ethically derived, the ESCRO must determine all of the following requirements are satisfied* [SWG Comment].