TO: Members of the ICOC

FROM: Gabriel Thompson, Director of Portfolio Operations and Performance

DATE: December 13, 2016

RE: **Items 7:** Consideration of Initiating Rulemaking for Amendments to Grants Administration Policy for Clinical Stage Projects

Executive Summary

In furtherance of CIRM's mission to accelerate the development of stem cell therapies to patients with unmet medical needs, CIRM seeks to continuously improve upon its policies and procedures to ensure a more streamlined, predictable process for awarding and administering grants. As part of that goal, we propose to initiate a new round of amendments to the Grants Administration Policy for Clinical Stage Projects (Clinical GAP). The Clinical GAP sets out the detailed rules for management of CIRM awards issued under program announcements for clinical stage projects.

With this item the CIRM team seeks Board approval to begin the regulatory amendment process to make the improvements discussed in this memorandum. The proposed changes reflect the evolution of agency policy since the Board first approved the Clinical GAP, as well as the identification of additional opportunities for clarification.

To begin the formal rulemaking process, CIRM will publish the proposed changes and solicit feedback from Board members, grantees, and members of the public. CIRM staff may then modify the proposed amendments to address issues raised by Board members and commenters; any proposed modifications will also be published for public review and comment. We will notify Board members when the proposed amendments and any further modifications are published. Once that process is complete, the amendments will go to the Board for final approval, which is estimated to be in the summer of 2017.

I. Proposed Changes

The following changes are presented for your review. With the exception of these

proposed amendments, the remainder of the Clinical GAP will remain in effect.

A. Allowable and Unallowable Project Costs

These sections describe the types of direct project costs CIRM funding may and may not support. CIRM proposes generally to follow the NIH Grants Policy Statement on allowable costs and highlight areas of common interest to our Awardees as follows:

Allowable

- Insurance that is deemed necessary and specific to the project not otherwise covered by Facilities or Indirect costs, including clinical trial insurance and medical liability (malpractice) insurance when the project involves human subjects.

Unallowable

- Legal costs incurred in defending or prosecuting claims, whether equitable or monetary.
- Intellectual property costs including, but not limited to, invention, copyright, patent, licensing or royalty costs, filing fees, translation costs, examination fees, annuity costs and grant fees, and related attorney's fees.
- Routine, patient standard of care costs or any cost of care covered by a 3rd party provider.

B. Clinical Trial Registration Requirement

CIRM proposes to add a requirement for all CIRM-funded clinical trials to be registered and submit the results of the trial in accordance with FDAAA 801 requirements. These requirements include registering the trial no later than 21 days after the 1st patient is enrolled in the trial and publishing the results no later than 12 months after completion of the trial.

C. Delete Description of Scoring

CIRM proposes to remove the paragraph in Section II.E. Application Review that describes clinical application scoring. The current statement is inconsistent with the GWG bylaws, which modified the definition of a Tier 3 score. Given the existing conflict and the potential for future inconsistencies if the Board approves future changes to the GWG bylaws regarding scoring, CIRM suggests removing this language from the Clinical GAP.

D. Prior Approval Request – Change in Calfornia Organization Eligibiliy

CIRM proposes to add a requirement for a CIRM-funded Awardee to immediately

report whether their organization's status as a California-based or Non-California-based organization has changed in light of the fact that such status will determine the scope of allowable project costs.

If a California-based Organization becomes a Non-California-based organization, we will propose to reduce the remainder of the award effective the date the organization's status changed to only cover the allowable project costs available to Non-California-based organizations. If a Non-California-based organization becomes a California-based organization, we propose to maintain the existing award amount as approved by the ICOC, but allow the Awardee to reallocate remaining funds to also cover any additional allowable project costs available to California-based organizations.

II. Recommendation

The CIRM team requests the Board approve the commencement of a rulemaking process to amend the Grants Administration Policy for Clinical Stage Projects to address the issues identified above.