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**MEMORANDUM**

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<b>TO:</b>	Members, Science Subcommittee, Governing Board California Institute for Regenerative Medicine
<b>FROM:</b>	GABRIEL THOMPSON, DIRECTOR OF GRANTS MANAGEMENT
<b>SUBJECT:</b>	CONSIDERATION OF ADOPTION OF THE INTERIM GRANTS ADMINISTRATION POLICY FOR DISCOVERY, TRANSLATION, AND EDUCATION PROJECTS
<b>DATE:</b>	JANUARY 5 <sup>TH</sup> , 2016

**Executive Summary**

In furtherance of CIRM's mission to accelerate the development of stem cell therapies to patients with unmet medical needs, CIRM is overhauling the manner in which it does business, referred to as "CIRM 2.0" in previous communications with the Science Subcommittee and the Board. As part of the process to implement a more streamlined, predictable process for awarding and administering grants, and in order to support the new features of our funding mechanisms, we are proposing an Interim Grants Administration Policy (GAP) to support our most recent program announcements for Discovery, Translation, and Education Program awards. This GAP sets out the detailed rules for management of CIRM awards issued under these initiatives.

The CIRM team regards this proposed interim GAP as the starting point for drafting a final policy that will govern discovery, translation and education projects. In light of the fact that the ICOC is scheduled to approve new "Bridges to Stem Cell Research and Therapy Awards" this month, and to ensure that rules are in place to govern the award administration process, CIRM must avail itself of its statutory authority to

adopt the GAP on an interim basis, to be followed by the permanent regulatory adoption procedure as administered by the Office of Administrative Law. With the approval of this interim policy by the ICOC, the CIRM team will initiate the formal rulemaking process. Accordingly, this subcommittee and the ICOC will have additional occasions to review and comment upon the final GAP.

## **I. Proposed Changes**

In drafting the interim GAP, the CIRM team started with the approved GAP for Clinical Stage Projects and then reviewed each aspect of the policy through the lens of the new Discovery, Translation and Education program announcements. The result is a policy designed to attract more high quality applications, reduce the cycle time from application to project start, accelerate progression of funded projects, and provide for more efficient administration of the projects. The following changes are presented for your consideration:

### **A. Project Milestones and Suspension Events (p. 10)**

CIRM employs the use of milestones on its awards as a marker of a project's progress during the duration of the Award. For clinical stage awards, CIRM establishes Operational Milestones – objective events that when achieved trigger the disbursement of additional funds. CIRM will use Operational Milestones for all Translation awards.

For Discovery awards, CIRM will use a newly defined term, Project Milestones. Project Milestones are objective events established by CIRM. Although funds will be disbursed based on time rather than the accomplishment of a Project Milestone, CIRM may, at its sole discretion, revise project activities, re-allocate resources, suspend further payments, and/or terminate the project if an awardee fails to accomplish a Project Milestone within a reasonable period of time.

CIRM has also removed the use of the term Suspension Events. For clinical stage awards, Suspension Events are a pre-defined condition that triggers a hold of CIRM funding until the Suspension Event has been resolved, if resolvable. Examples for clinical stage awards would be a clinical hold by the FDA. Given the nature of the discovery and translational awards, CIRM will not establish Suspension Events for these types of projects.

B. Application Review and Scoring (p. 15)

The previous GAP explained the meaning of each tier of the application scoring system designated by the GWG. The new language simplifies this description by specifying the GWG will designate an application either as recommended for funding or not recommended for funding. As you will recall, the Board approved amendments to the GWG bylaws, which specify the scoring system for non-Clinical Program applications. Therefore, it is not necessary to include this level of detail in the GAP.

In addition, we have aligned the language in the GAP to match the revisions we have already made to patient advocate participation in GWG and application scoring.

C. Unallowable Costs: Membership Dues (p. 28)

CIRM has removed membership dues from the list of unallowable costs. In conducting financial compliance site visits, CIRM team members have often discovered that Awardees erroneously use CIRM funds to charge membership dues to professional scientific organizations. Though CIRM has required these charges be reimbursed, there are instances where charging the CIRM award for these membership dues would be appropriate given the benefits provided to the member. Often, membership in a professional organization is automatically provided upon registration to an affiliated meeting and/or provides a heavy discount to the meeting registration fees.

CIRM will allow Awardees to charge membership dues to professional organizations for individuals working on a CIRM project and whose member benefits are reasonably allocable to the CIRM project.

D. Post-Project Allowable Costs (p. 30)

For clinical stage projects, CIRM allows Awardees who have remaining CIRM funds at the expiration of their Award, to use those funds to either (1) reduce the actual co-funding to an amount no lower than the original required by the Award; (2) fund project(s) at the Awardee organization that further CIRM's mission, subject to CIRM regulations and audit; or (3) return the funds to CIRM within 30 days of the deadline for submission of the final financial report.

CIRM will follow this same policy for all Translation and Discovery.

E. Failure of Compliance: Consideration of Past Performance

The failure of compliance section specifies actions CIRM may take if the Awardee or PI violate one or more of the conditions of a CIRM award, if the Awardee or PI engages in research misconduct or if the Awardee fails to achieve an Operational Milestone within 6 months of the target date or which CIRM determines, in its sole discretion, cannot be cured.

We proposed to expand this list to include consideration of past performance by the Awardee or PI during review of subsequent applications for CIRM funding. This language aligns the policy with modifications to CIRM 2.0 concept plans approved by the Board in December.

**II. Recommendation**

The CIRM Team requests the Science Subcommittee recommend that the Board adopt the Interim Grants Administration Policy for Discovery, Translation, and Education Projects.