



TO: Members of the ICOC

FROM: Gabriel Thompson, Director of Portfolio Operations and Performance

DATE: September 15<sup>th</sup>, 2016

RE: Consideration of Amendments to, and Final Adoption of, Grants Administration Policy for Discovery, Translational and Education Projects

### **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. 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 a Grants Administration Policy (GAP) to support our program announcements for Discovery, Translation, and Education Projects. This GAP sets out the detailed rules for management of CIRM awards issued under these initiatives.

In January of this year, the Board adopted a prior version of the attached policy on an interim basis to permit time to seek approval from the Office of Administrative Law. Since then, the CIRM team has been working to further refine the policy. Substantively, this draft is virtually the same as the draft reviewed in January. However, we have modified the policy to align with our new programs, to clarify how funds will be disbursed and how they can be spent, and to streamline reporting requirements.

#### **I. Proposed Changes**

In drafting the final GAP, the CIRM team reviewed each aspect of the existing policy through the lens of the new Discovery, Translation and Education Programs. 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. Part II.A.2. Organizational Eligibility (p.13)

This section broadly describes an applicant organization's eligibility to apply for and receive a CIRM award. The amendments state an applicant's qualification as a California or Non-California organization and refers to the relevant program announcements to determine the allowable project costs for each type of organization.

B. Part II.H. Policy on Collection and Use of Personal Information (p. 16)

This section describes CIRM's need to collect and use personal information to perform its duties and its responsibility to keep such information confidential and secure unless such information is not protected from disclosure under a California Public Record Act.

Given the program requirement for CIRM-funded trainees to publish about their training-related activities, the amendment requires individuals to seek a Principal Investigator's permission before they publicly communicate about unpublished data.

C. Part IV.C. Award Conversion/Loan Election Policy (p. 28)

On May 21, 2015, the Board approved the loan election policy for clinical stage projects as well as therapeutic translational stage projects and delegated the responsibility for determining the appropriate rate of return to the IP & Industry Subcommittee. Under the policy approved by the Board, an awardee may elect to treat its award as a loan if it makes the election by the earlier of ten years from the date of the award or (10) business days after the Food and Drug Administration notifies the awardee that it has accepted its application for marketing authorization.

The amendment references the existing Award Conversion section in the Grants Administration Policy for Clinical Stage Projects given the policy also applies to therapeutic translational stage programs.

D. Part V.A. Payment and Use of Funds (p. 31)

CIRM Awardees have always been allowed to accrue interest on the balance of their CIRM funds. This allowance has traditionally been set forth in the Notice of Award, but is now being added to the Grants Administration Policy to make it more explicit. Any accrued interest as a result of a CIRM funds must be spent to further the CIRM-funded project.

E. Part V. E. Unallowable Project Costs and Activities (pp. 32-33)

This section describes costs and activities that cannot be charged to CIRM funding nor accounted for in an Awardee's co-funding.

The amendment adds to the list of unallowable project costs the following items: equity compensation, fines or penalties not related to costs incurred to comply with the terms of the award, and attorneys' fees related to litigation and patent defense.

F. Part V.F. Allowable Facilities Costs (p. 33)

This section describes the allowable facilities costs awardees can incur with CIRM funds. The proposed amendment clarifies that non-profit Awardees that do not have a federally-negotiated Facilities and Administrative rate agreement are limited to a 35% cap on Facilities costs and must use rates consistent with facilities rates applied to similar research awards at their organization.

G. Part V.K.4. Prior Approval Requirements: Change in PI or Project Manager Status or Percent Effort (p. 37)

This section describes the scenarios in which an awardee must seek CIRM's prior approval before proceeding with a change of Principal Investigator, a change in a Principal Investigator's status or change in the Principal Investigator's effort below the minimum required by the program announcement.

Our clinical and translational stage programs also require a Project Manager with certain experience and a minimum percent effort devoted to the CIRM project. The amendments add to this section the requirement for an awardee to also seek CIRM's prior approval before proceeding with a change in Project Manager or a change in the Project Manager's effort below the minimum required by the program announcement.

H. Part V.K.5. Prior Approval Requirements: Progress Event Report and Award proposal (pp. 37-38)

This section describes the mechanism and requirements by which an Awardee can request a Progression Award as described in the Partnering Opportunity for Discovery Stage Research Projects: The Quest Award.

I. Part V.O.2. Reporting Requirements: Progress Report (p. 40)

The amendment clarifies that CIRM will only collect a public summary of progress in the final progress report for the award rather than at the end of every year of the award period.

J. Part VI.D.4. Requirements for Training Grants (pp. 46-48)

The amendments clarify that (1) carryforward of obligated funds from one budget period to the next does not require CIRM's prior approval, (2) individual trainees are no longer required to complete an annual progress report, but rather a final progress report at the end of their training period and (3) awardees of training grants will receive CIRM payment for their trainee-related costs upon submission of a trainee appointment form.

## **II. Recommendation**

The CIRM Team requests that the Board approves the amendments and final adoption of the Grants Administration Policy for Discovery, Translational and Education Stage Projects.

1 Add 17 Cal. Code of Regs. section 100504 to read:

2 **§ 100504. Grants Administration Policy for Discovery, Translation and Education Projects.**

3 (a) All recipients of a grant, loan or guarantee from the California Institute for Regenerative  
4 Medicine (“CIRM”) for Discovery, Translation and Education Projects agree to be bound by the terms  
5 and conditions of the CIRM Grants Administration Policy for Discovery, Translation and Education  
6 Projects incorporated herein by reference as identified below.

7 (b) The CIRM Grants Administration Policy for Discovery, Translation and Education Projects  
8 is incorporated by reference herein in its entirety as to Sections “II” through and including “VI”. As to  
9 Section “I,” only parts “I.B.,” (“Abbreviations”), “I.C.,” (“Defined Terms”), “I.D” (“Types of Support”)  
10 and “I.E.” (“Roles and Responsibilities”) are incorporated by reference.

11 (c) Amendments to this regulation and the policy incorporated herein will be applied to already  
12 active grants on the start date of the next budget period after the effective date of this regulation's  
13 amendment.

14 (d) The CIRM's right to enforce the provisions of the policy incorporated herein shall survive  
15 the end of the term of the grant and, should CIRM no longer exist, those rights may be enforced by the  
16 State of California.

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

19 Reference: Sections 125290.30, 125290.40, 125290.60 and 125292.10, Health and Safety Code.