



MEMORANDUM

TO: Members of the ICOC

FROM: C. Scott Tocher, Counsel to the Chair; Gabriel Thompson, Grants Management Officer

RE: **Item 12:** Consideration of Initiating Rulemaking for Amendments to Grants Administration Policy

DATE: March 4, 2014

Executive Summary

CIRM's Grant Administration Policy for Academic and Nonprofit Institutions – the GAP -- sets out the detailed rules for management of CIRM awards. The GAP is generally modeled on the NIH's Grants Policy Statement, with differences that reflect CIRM's distinct role and mission.

The GAP was adopted by the ICOC in December 2006. In 2009 and 2012 the ICOC adopted amendments intended to further clarify certain provisions, simplify some requirements, and incorporate several modifications based on experience with the GAP.

CIRM now proposes a third round of amendments. With additional experience and feedback from grantees, we have identified various ways in which the wording or organization of the GAP may be improved. In addition, issues have arisen that are not explicitly addressed in the GAP, as described below.

We are not asking the Governing Board to consider and approve these proposed changes at this time. We are bringing this item to the Board to keep you informed about the process, and to let you know that we will be coming back to you for further input and, ultimately, approval.

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 proposals to address issues raised by Board members and commenters, and those proposed modifications would 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.

I. Proposed Amendments

A. Sabbaticals:

The GAP identifies certain circumstances where prior approval of CIRM is required, such as when a Grantee wishes to transfer an award to another institution or change the principal investigator. This policy reflects the critical role that the Grantee institution and PI maintains on the grant and affirms CIRM's ability to ensure the ability of the team to fulfill the grant's objectives. While the GAP currently speaks to "leaves of absence" from an institution, staff proposes making explicit the interpretation of that language to include sabbaticals, which will require prior approval from CIRM to continue the award.

B. PFAR – Clinical Trial Projects:

Applications approved for funding by the ICOC are reviewed by the Grants Management Office and science office to ensure that they meet all applicable CIRM funding requirements, including the submission of required public policy assurances. CIRM reviews the Application budget to ensure that all proposed costs are allowable, as specified in the GAP and pertinent RFA. In addition for clinical trials, CIRM will review the clinical protocol and any amendments, the investigator brochure, the informed consent template, the DSMB composition and charter, and various documents needed prior to award issuance.

C. Research Patient Care Costs:

When CIRM funds a grant, the amount of the grant is determined primarily by two sets of costs: *direct* and *indirect*. Generally speaking, *direct* costs are those for activities or services that benefit a specific project, e.g., salaries for project staff and laboratory supplies required for a particular grant project. Because these costs are easily traced to specific grant activities, they are charged to projects on an item-by-item basis and form the primary basis for a given budget. In contrast, *indirect* costs are those for activities or services that benefit more than one project. Their precise benefits to a specific project may be difficult or impossible to trace, such as the services of the accounting staff and research administrators. *Indirect* costs are applied as a percentage of the *direct* costs, and together with the *direct* project costs form the total budget of the grant.

There are some circumstances, however, where a given category of *direct* project cost is not subject to the additional indirect cost funding calculation – such as equipment or tuition costs that CIRM may pay for in a given grant. In the context of research patient care costs, NIH policy is to exclude these *direct* costs from *indirect* cost calculations. Thus, even where NIH pays for such activities directly in a grant, the NIH does not include the extra *indirect* funds on top. Currently, the GAP is silent on how to treat

indirect funds to patient care costs. Staff proposes CIRM align itself with NIH policy and exclude the *indirect* cost bump when CIRM funds research patient care costs directly.

D. Direct Project Costs:

Staff proposes that the GAP make clear that costs should be allocated in accordance with cost principles set forth in the federal Office of Management and Budget Circular A-21 (Cost Principles for Educational Institutions) and A-133 (Audits of States, Local Governments and Non-Profit Organizations). In determining when and how to charge a cost to a CIRM award under a particular scenario, the Grantee should consider whether the cost is allowable, allocable, reasonable and consistently treated in like circumstances. Relying on the federal cost principles explicitly is easier and more reliable than developing CIRM policies for all the various cost scenarios.

E. No-Cost Extensions:

Currently the GAP allows a one-time no-cost extension of the Project Period end date of up to one year, upon a request and justification submitted at least 30 days prior to the end date. Staff will explore the propriety of allowing for a 24 month extension for extraordinary circumstances and relaxation of the 30-day pre-end submission requirement.

F. Patent Costs:

CIRM has an ongoing patent assistance fund that provides patent support to non-profit grantees. CIRM is considering expanding that opportunity to include small for-profit companies via amendment to the GAP to allow such costs to be covered by the grant. CIRM proposes that funding levels and requirements for covering such costs to for-profits mirror those imposed on non-profit organizations.

G. GAP Consolidation:

CIRM currently has two grants administration policies that apply either to for-profit or not-for-profit organizations. To simplify administration and enable greater understanding of and compliance with these policies, staff will examine the prospect for consolidating these two policies into one coherent policy.

H. Service Contracts:

Staff proposes excluding or otherwise capping the amount of facilities and indirect costs allowed on service contracts. CIRM is funding more research projects that budget for expensive service contracts for which a Grantee can incur full facilities and indirect cost. These services happen largely outside the Grantee organization and do not require administrative costs in proportion to the size of the service contract, so excluding or otherwise capping the amount of facilities and indirect costs, similar to how we treat research subcontracts, is a more equitable calculation.

II. Requested Action

Staff requests the Board approve the commencement of a rulemaking process to amend the Not-For-Profit and For-Profit GAPS to address the issues identified above.