NOTICE OF PROPOSED REGULATION AMENDMENTS

California Code of Regulations
Title 17. – Public Health
Division 4 - California Institute For Regenerative Medicine
Chapter 5, Section 100500

Date: August 8, 2014
Deadline for Submission of Written Comment: September 22, 2014 – 5:00 p.m.
Public Hearing Date: None Scheduled

Subject Matter of Proposed Amendments:
Grant Administration Policy for Academic and Non-Profit Institutions

Sections Affected: The proposed regulatory action amends the document incorporated by reference into Chapter 5, Section 100500, of Title 17 of the California Code of Regulations, and makes technical non-substantive amendments to section 100500.

Authority: Article XXXV of the California Constitution and Health and Safety Code Section 125290.40, subdivision (j).

Reference: Sections 125290.30, 125290.35, 125290.40, 125290.45, 125290.50, 125290.60, 125290.70, 125292.10, Health and Safety Code.

Informative Digest/Policy Statement Overview:
The California Institute for Regenerative Medicine ("Institute" or "CIRM") was established in 2005 after the passage in 2004 of Proposition 71 (the "Act"), the California Stem Cell Research and Cures Initiative. The statewide ballot measure established a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities. The Independent Citizens' Oversight Committee ("ICOC") is the 29-member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry. The Act charges the ICOC with developing standards and criteria to make grant awards and to develop standards and criteria for proper oversight of awards. (§ 125290.50.) To that end, CIRM adopted the CIRM Grants Administration Policy for Academic and Non-Profit Institutions ("Non-Profit GAP"). The Office of Administrative Law approved the Policy and it is now codified in the California Code of Regulations under Title 17, Division 4, Chapter 5, Section 100500. This Policy states the rights and responsibilities of academic and non-profit recipients of CIRM research funding. Principal investigators, program directors, and organizational officials with grants management responsibilities may refer to pertinent sections for answers to questions that arise concerning the award and administration of the grants. By accepting a CIRM grant award, grantees agree to comply with the provisions set forth in the policies for the entire project period of the grant, and thereafter.

The proposed amendments to the Non-Profit GAP include non-substantive changes without regulatory effect, changes made for clarity and substantive changes. The proposed amendments

in this rulemaking action interpret, clarify and make specific the regulations in Section 100500. The amendments are to the document incorporated by reference through subdivision (a) of Section 100500 entitled "CIRM Grants Administration Policy for Academic and Non-Profit Institutions" with a footer that now dates the document as "Non-Profit and Academic Institution Grants Administration Policy (Rev. April 28th, 2009)". The amendment to subdivision (a) of Section 100500 will now reference a footer that dates the document as "Non-Profit and Academic Institution Grants Administration Policy (Rev. November 2014)." The amendments facilitate the award and management of research funds as authorized by Proposition 71 for use in California by California researchers and affiliated entities. The amendments further the purposes of the Proposition to find procedures, treatments and cures for major diseases, injuries and orphan diseases and to establish the appropriate regulatory standards for research development. The proposed amendments are not inconsistent or incompatible with existing state regulations.

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, CIRM proposes making explicit the interpretation of that language to include sabbaticals, which will require prior approval from CIRM to continue the award.

B. Allocation of Research Patient Care Costs:

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

C. Direct Project Costs:

CIRM 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). Relying on the federal cost principles is consistent with federal grants and lead to more efficient administration.

D. 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. CIRM will explore the propriety of allowing a no-cost extension greater than 12 months for awards that fund clinical trials and pivotal IND-enabling activities in extraordinary circumstances and subject to additional review including Presidential approval.

E. 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, CIRM will examine the prospect for consolidating these two policies into one coherent policy.

F. Service Contracts:

CIRM 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.

G. Appeals Process:

CIRM proposes elaborating on existing provisions for appeals by grant applicants of Scientific Reviews. CIRM also proposes adding additional grounds and procedures for lodging appeals of scientific reviews, describes the grounds and timelines for doing so, and the process by which CIRM will resolve such appeals.

DISCLOSURES REGARDING THE PROPOSED AMENDMENTS:
CIRM has made the following initial determinations:

Mandate on local agencies and school districts: None.

Submittal of Comments:

Any interested party may present comments in writing about the proposed amendments to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on September 22, 2014. Comments regarding this proposed action may also be transmitted via e-mail to GAPComments@cirm.ca.gov or by facsimile transmission to (415) 396-9141.

Public Hearing:
At this time, no public hearing has been scheduled concerning the proposed regulations. If any interested person or the person's representative requests a public hearing, he or she must do so in writing no later than September 8, 2014.

Effect on Small Business:
CIRM has determined that the proposed amendment will have no impact on small businesses. The regulation implements conditions on awarding and administering grants for stem cell research. This research is conducted almost exclusively by large public and private nonprofit institutions. As such, the amendments to the regulation are not expected to adversely impact small business as defined in Government Code Section 11342.610.

Impact on Local Agencies or School Districts:
CIRM has determined that the proposed amendments do not impose a mandate on local agencies or school districts, nor do they require reimbursement by the state pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code because the amendments do not constitute a "new program or higher level of service of an existing program" within the meaning of Section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed amendments.

Costs or Savings to State Agencies:
CIRM has determined that no savings or increased costs to any agency will result from the proposed amendments.

Effect on Federal Funding to the State:
CIRM has determined that no costs or savings in federal funding to the state will result from the proposed amendments.

Effect on Housing Costs:
CIRM has determined that the proposed amendments will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:
CIRM has made an initial determination that the proposed amendments will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:
CIRM has made an initial determination that the adoption of these amendments will not have a significant cost impact on representative private persons or businesses. CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed amendments.

Results of Economic Impact Analysis:
The above analysis is based on that fact that the proposed amendments do not impose new requirements on existing business operations or functions of other agencies or individuals, but implement standards for seeking and using state grant funds for scientific research. In most cases, such grants include funds to cover overhead and other indirect costs of the research, including most compliance activities. CIRM has made an initial determination that it is unlikely the proposed amendments will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California, nor directly impact the health and welfare of California residents, worker safety, and the state's environment.

Consideration of Alternatives:
In accordance with Government Code Section 11346.5, subdivision (a)(13), CIRM must determine that no reasonable alternative it considered, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of the law than the proposal described in this Notice. CIRM invites interested persons to present statements or arguments with respect to alternatives to the proposed amendments at the scheduled hearing or during the written comment period.

Availability of Statement of Reasons and Text of Proposed Regulations:
CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed amendments, all of the information upon which the amendments are based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:
After holding the hearing and considering all timely and relevant comments, CIRM may adopt the proposed amendments substantially as described in this notice. If CIRM makes modifications that are sufficiently related to the originally proposed text of the amendments, it will make the modified text (with the changes clearly indicated) available to the pubic for at least 15 days before it adopts the regulations as amended. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact:

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the amendments; and inquiries regarding the rulemaking file may be directed to:

Scott Tocher
Counsel to the Chairman, ICOC
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
(415) 396-9100

Questions on the substance of the proposed regulatory action may be directed to:

Gabe Thompson, Grants Management Officer
California Institute for Regenerative Medicine
(415) 396-9100

The Notice of Proposed Regulatory Amendment, the Initial Statement of Reasons and any attachments, and the proposed text of the amendments and existing regulation are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons:
Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code Section 11346.9, subdivision (a), may be obtained from the contact person named above.

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