

NOTICE OF PROPOSED REGULATION AMENDMENTS

California Code of Regulations

Title 17. – Public Health

Division 4 - California Institute For Regenerative Medicine

Chapter 1, Section 100003

Date: March 13, 2015

Deadline for Submission of Written Comment: April 27, 2015 – 5:00 p.m.

Public Hearing Date: None Scheduled

Subject Matter of Proposed Amendments:

Conflict of Interest Rules Applicable to the Non-ICOC Members of the Scientific and Medical Research Funding Working Group

Sections Affected: The proposed regulatory action amends Chapter 1, Section 100003, of Title 17 of the California Code of Regulations.

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

Reference: Sections 125290.50, subd. (e), and 125290.60, 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 goal of CIRM is to sponsor and facilitate research in regenerative medicine that will advance scientific understanding and result in the development of therapies and treatments for a wide range of devastating diseases. To help in this task, the Act creates three working groups that draw on outside experts for advice. Each of the working groups has patient advocates, as well as outside experts, among its members.

The purpose of the Scientific and Medical Research Funding Group (“Grants Working Group” or “GWG”) is to provide recommendations to the ICOC regarding standards, criteria, requirements, funding, and oversight of grant and loan applications and awards. This purpose will be accomplished through the review of grants and loan applications, based on standards and criteria adopted by the ICOC, in order to make recommendations to the ICOC for the awarding and continued funding of training, research, therapy development, and clinical trial grants and loans. Finally, this purpose will be accomplished through oversight reviews of grantees to ensure compliance with the terms and conditions of the award in order to fulfill the mission of the Act,

and to make recommendations for subsequent actions to the ICOC or the CIRM President, as appropriate.

Because the GWG is a purely advisory body, members of the groups are not subject to the conflict of interest disclosure and disqualification laws of the Political Reform Act. (Health and Safety Code § 125290.50, subd. (e).) Nevertheless, the ICOC has taken the unprecedented step of subjecting these advisory bodies to stringent conflict of interest requirements as reflected in section 100003.

The success of the CIRM research program and its ability to maintain the confidence of the people of California depends critically upon the agency's ability to fund the highest quality research proposals, chosen without bias. Strong CIRM conflict of interest policies are thus essential. The proposed amendments strengthen the policy and make it clearer and easier to follow and understand.

Financial Conflicts of Interest

Under current policy, financial conflicts are limited to a member's financial interest in the applicant institution and the application under review. CIRM proposes to expand the scope of financial conflicts to strengthen the policy by including financial interests in subcontractors and partners. These terms are defined as follows:

“Partner” means an organization that, in exchange for the right to the opportunity for a future financial return, has (1) agreed to provide matching funds for the proposed project or (2) entered into an agreement with the applicant organization relating to the commercialization of the proposed project.

“Subcontractor” means an organization (other than the applicant organization) that is expected to: (a) contribute to the scientific development or execution of the project in a substantive, measurable way and (b) receive \$50,000 or more through the proposed project. “Subcontractor” does not include suppliers of widely available goods.

The intent of this change is to capture other financial interests that could create a conflict of interest with respect to a particular application because they are significant participants in the proposed project or stand to benefit financially if the project is successful.

Professional Conflicts of Interest

Under the current regulation, a non-ICOC member of the Grants Working Group is considered to have a conflict of interest if he or she has had long-standing scientific differences or disagreements with the applicant that are known to the professional community and could be perceived as affecting the member's objectivity. However, debate helps illuminate issues of concern. Furthermore, it is often difficult to discern when a difference of opinion crosses the line into a “long-standing scientific difference” warranting recusal. Additionally, under Prop. 71, CIRM's conflict rules must be modeled on the NIH's conflict policies, which do not include an analogous provision. Because of the difficulty of applying the rule and the absence of a similar NIH rule, the amendments propose to eliminate “long-standing scientific

differences” as a basis for recusal. However, to address the concerns underlying this rule, CIRM has added a provision requiring a member to recuse himself or herself if the member believes his or her objectivity could be compromised for any reason.

The amendments also clarify the scope of professional conflicts to ensure that the recusal requirement applies to research collaborations and other significant professional relationships, but not to more remote connections, such as when the reviewer and an applicant are two of many authors of a review article or where the reviewer and applicant each contributed a chapter to a book.

Personal Conflict of Interest

Under the existing regulation, a member is deemed to be in conflict if he or she “has had long-standing personal differences” with the applicant. As with long-standing professional differences, this provision is very difficult to apply because it is so subjective. Short of a formal dispute, it is often difficult to determine whether personal differences exist. Furthermore, the NIH does not have an analogous provision. CIRM therefore proposes to modify this provision to apply it to situations in which the reviewer and an applicant have been on opposing sides of a formal legal dispute.

Definitions

CIRM also proposes to clarify the policy by providing definitions of key terms, such as key personnel, research collaboration, subcontractor, partner and immediate family. These definitions will assist both reviewers and applicants in identifying potential conflicts and will facilitate CIRM’s administration of the regulation.

Anticipated Benefits of the Proposed Regulation:

The primary objective of the regulation is to codify the process of identifying and screening for potential conflicts of interest in the review of grant proposals for CIRM funding. The success of the CIRM research program and its ability to maintain the confidence of the people of California depends critically upon the agency’s ability to fund the highest quality research proposals, chosen without bias. Strong CIRM conflict of interest policies are thus essential. The proposed amendments strengthen the policy and make it clearer and easier to follow and understand. The amendments help to ensure that the funding process is fair to all applicants.

Consistency with Existing State Regulations:

After performing an evaluation for any other regulations in this area, CIRM has determined that these are the only regulations dealing with conflicts of interest for non-ICOC members of the Grants Working Group, and therefore the proposed regulations are neither inconsistent nor incompatible with existing state regulations.

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 April 27, 2015. 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 April 13, 2015.

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 proposed amendments do not impose new requirements on existing business operations or functions of other agencies or individuals, but implement standards identifying and screening for potential conflicts of interest during the internal review of grant applications. CIRM has made an initial determination that it is unlikely the proposed amendments will directly 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. However, to the extent that the amendments ensure a fair and thorough process for screening conflicts of interest, and thereby ensure the integrity of the grant-evaluation process, the welfare of California residents is enhanced. In addition, to the extent that the applications for funding are evaluated not on the basis of bias but on the basis of scientific merit, and to the extent that the regulation ensures that is the case, the welfare of California residents is enhanced by ensuring that only the best scientific proposals receive funding, which ultimately may lead to the reduction of suffering (and save money) if the research projects are ultimately successful and reach California patients.

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 public 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:

Amy Cheung
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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