

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

**INITIAL STATEMENT OF REASONS FOR THE
PROPOSED AMENDMENTS OF THE SECTION 100003: CONFLICTS OF INTEREST FOR
NON-ICOC MEMBERS OF THE SCIENTIFIC AND MEDICAL RESEARCH FUNDING WORKING
GROUP**

HEARING DATE: None scheduled.

CLOSE OF PUBLIC COMMENT: April 27, 2015

SUBJECT MATTER OF PROPOSED REGULATIONS: Conflict of Interest Rules Applicable to the Non-ICOC Members of the Scientific and Medical Research Funding Working Group

SECTIONS AFFECTED: The proposed amendments are to Chapter 1 and Section 100003 of Title 17 of the California Code of Regulations.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH AMENDMENT:

SECTION 100003. CONFLICTS OF INTEREST – NON-ICOC MEMBERS OF THE SCIENTIFIC AND MEDICAL RESEARCH OF FUNDING WORKING GROUP.

Purpose:

To ensure that working group members do not participate in decisions in which they have a conflict of interest, this regulation describes the disclosure and disqualification rules applicable to members of the Grants Review Working Group.

Subdivision (a) contains the prohibition against participating in a decision of the working group in which the member has a conflict. The second sentence elaborates on the circumstances that may comprise a conflict of interest, identifying three types of interests – financial, professional and personal.

Subdivision (b) defines what constitutes a “financial interest” that gives rise to a conflict of interest for a working group member. The four types of interests are self-explanatory and are the logical and most likely sources for a potential conflict of interest.

Subdivision (c) defines what constitutes a “professional” conflict of interest. The three circumstances identified therein are self-explanatory and are the logical and most likely sources for a potential conflict of interest.

Subdivision (d) defines what constitutes a “personal” conflict of interest. The two circumstances identified therein are self-explanatory and are the logical and most likely sources for a potential conflict of interest.

Subdivision (e) requires working group members to disclose confidentially and under penalty of perjury the financial interests enumerated therein. The subparts require disclosure of academic, non-profit, biotechnology, pharmaceutical and real property interests above a certain threshold held by the member and his or her spouses and anyone else with whom the member shares a common financial interest.

Subdivision (f) requires each non-ICOC member to report to CIRM staff any conflict of interest that may arise, including those identified in subdivisions (b) through (d) of the regulation. The regulation requires a member under these circumstances to leave the room when the particular application in question is discussed. The member is prohibited from participating in any manner in either the discussion or the vote on the matter. Because of the unique and highly specialized expertise required in order to inform and advise the ICOC in its decisions regarding which grants to fund, the President may, in exceptional cases, allow an otherwise ineligible member to participate in the discussion only of a particular matter, but not vote. This provision can be analogized to the allowance under the Political Reform Act for public officials with a conflict of interest to nevertheless participate in the process as a member of the public would under certain circumstances. By publicly disclosing the working group members' interests before the meeting one ensures that the public is informed of the particular member's participation and allows for public monitoring of the circumstances surrounding the use of the exception.

Subdivision (g) requires each non-ICOC member to sign a pre-review statement indicating any possible conflicts of interest the person may have and must also sign a post-review statement that they did not participate in the review of any application for which they might have had a conflict of interest. Where the member's participation in the discussion only by virtue of permission granted by the President, that information will be disclosed on the post-review form.

Subdivision (h) requires the voting, disclosure and participation records of the working group be preserved for audit purposes and requires the CIRM or auditor to report violations of these rules to the Legislature and describe the CIRM's corrective actions.

Rationale:

This regulation is necessary to ensure the success of the CIRM research program and its ability to maintain the confidence of the people of California, which 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.

Subdivision (a) provides the necessary rule prohibiting participation by working group members who have a conflict of interest in an applicant before the working group. Unlike the Political Reform Act, which focuses its ethics provisions solely at financial interests, this subdivision broadens the scope of the regulation to include professional and personal circumstances that may give rise to a conflict of interest.

Subdivision (b)'s specificity in defining the term "financial" conflict of interest is necessary to provide clear guidance as to the scope of interests intended to be covered by the regulation. These interests are common-sense and logical sources of potential conflicts of interests for members of the Grants Working Group. The interests identified take into account the context of

research grants. As a result, the term includes interests as a result of a member's (or spouse's) employment with the grantee institution or status as its principal investigator, is under consideration for a faculty position with the applicant institution, if there is any potential for receiving any financial benefit from the grantee institution, or indirect benefit of more than \$5,000.

Subdivisions (c) and (d) are necessary to give specificity to the terms "professional" and "personal" conflicts of interest and give clear guidance as to the scope of interests subject to the regulation's prohibition.

The groups identified in subdivision (e) of the regulation are targeted as the most logical sources from which a conflict of interest likely would arise. Accordingly, these entities are required to be disclosed under penalty of perjury, which will ensure the diligence of the disclosures. The disclosure under penalty of perjury is consistent with existing requirements of individuals who file a Statement of Economic Interests pursuant to the Government Code.

Just as the Political Reform Act contains separate disclosure and disqualification requirements, proposed subdivision (f) defines the circumstances under which a working member is required to disqualify himself or herself from the decision-making process of the working group. Because of the unique and highly specialized expertise required in order to inform and advise the ICOC in its determination of what grants to fund, the President may, in exceptional cases, allow an otherwise ineligible member to participate in the discussion only of a particular matter, but not vote. This provision can be analogized to the allowance under the Political Reform Act for public officials with a conflict of interest to nevertheless participate in the process as a member of the public would under certain circumstances. By publicly disclosing the working group members' interests before the meeting one ensures that the public is informed of the particular member's participation and allows for public monitoring of the circumstances surrounding the use of the exception.

Subdivision (g)'s provisions for pre- and post-review certification demonstrate the vigilance CIRM staff and working group members will maintain to ensure bias-free decision-making with regard to the research grant recommendations. By examining before each grant session all of the potential sources of conflicts of interest, the members are assured being best able to identify grant applications for which the member may have a conflict of interest. The assurance under penalty of perjury further assures that all pre- and post-reviews will be done with the utmost diligence.

Health and Safety Code section 125290.50, subdivision (f), exempts most working group records from disclosure. Nevertheless, subdivision (h) of the regulation requires that confidential disclosure documents would be maintained to ensure that auditors would be able to confirm that working group members have complied with the conflict of interest provisions applicable to them by virtue of these regulations. The regulation goes beyond typical provisions of the Political Reform Act and requires the CIRM to notify the Legislature in the unlikely event the rules are violated and requires a review of corrective actions taken by CIRM to ensure compliance in the future. This ensures that the Standards Working Group will have the strictest ethical guidelines of any state advisory group otherwise exempt from the Political Reform Act.

SPECIFIC PURPOSE OF REGULATION AND FACTUAL BASIS FOR AMENDMENTS TO REGULATION:

Because the Grants Working Group 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, CIRM has taken the unprecedented step of subjecting these advisory bodies to stringent conflict of interest requirements as reflected in section 100003. Pursuant to Proposition 71, this regulation is necessary to provide conflict of interest rules to members of scientific review committees, such as the Grants Working Group.

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.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS:

A. Documents or Laws:

None.

B. Public Input:

None.

Copies of the documents referenced above are available at the offices of CIRM located at 210 King Street, San Francisco, California, 94107. Alternatively, transcripts and agendas for public meetings identified above are available on CIRM's website, www.cirm.ca.gov.

MANDATE FOR SPECIFIC TECHNOLOGIES OR EQUIPMENT:

The proposed amendments do not mandate the use of specific technologies or equipment.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES:

In view of information currently possessed, no reasonable alternative considered would be more effective in carrying out the purposes for which the amendments are proposed, or would be as effective as the amendments proposed.

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.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THAT WOULD LESSON ANY ADVERSE IMPACT ON SMALL BUSINESS:

CIRM has made the initial determination that the proposed amendments will not have an adverse impact on small business. This regulation applies to members of an internal advisory body who make funding recommendations to CIRM's governing board. As such, no private conduct or commercial activity by a business of any size is being regulated.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS:

CIRM has made the initial determination that the proposed amendments will not have a statewide adverse economic impact. This action is not expected to have a direct impact on the creation or elimination of jobs, nor the creation of new businesses or elimination of existing businesses, nor the expansion of business currently doing business within the State of California because the amendments affect only internal operations. The use of grant funds is required neither by law nor these regulations. To the extent the regulations facilitate use of the funds and encourage development of intellectual property and return to the state as required by law, and to the extent California institutions apply for and receive research funds, such requirements are indirectly attributable to increased economic activity spurred by the investment research funds in the state and resultant positive business and employment development. Also, to the extent the amendments makes it possible for the expenditure of research funds in the state, and to the extent that research results in medical treatments and cures for chronic disease and injury, the amendments indirectly benefit the health and welfare of California residents who will benefit from such treatments and cures.

ECONOMIC IMPACT ANALYSIS REQUIRED BY GOVERNMENT CODE SECTION 11346.3, SUBDIVISION (b)

Action: The regulatory action amends the existing conflict of interest regulation for non-ICOC members of the Grants Working Group (section 100003 et seq.). The amendments refine the scope and source of potential conflicts of interest for an internal advisory panel that makes funding recommendations to CIRM's Board, the Independent Citizens Oversight Committee. The action does not regulate a commercial or private activity of any individual or institution but reaches only administrative functions of an internal panel in connection with the conduct of the review of grant applications.

Impact:

Under section 3 of the "California Stem Cell Research and Cures Act," which established the California Institute for Regenerative Medicine, funds for this agency are continuously appropriated without regard to fiscal year and not subject to budgetary control. The Act requires CIRM adopt rules to apply to the Grants Working Group, which must be modeled on the NIH's conflict policies.

CIRM has determined that that proposed regulatory action has no impact on small businesses. The members of the Grants Working Group are out-of-state researchers and their participation in a grant review is not a business activity otherwise performed by a small business in the state of California.

This action is not expected to have a direct impact on the creation or elimination of jobs, nor the creation of new businesses or elimination of existing businesses, nor the expansion of business currently doing business within the State of California because the amendments affect only administrative requirements regarding use of grant funds. The proposed amendments govern the treatment of conflicts of interest in the internal function of evaluating grant proposals, and do not govern a business activity in the state. 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.

TECHNICAL, THEORETICAL, and/or EMPIRICAL STUDY, REPORTS, OR DOCUMENTS RELIED UPON:

None.

Copies of the documents referenced above are available at the offices of CIRM located at 210 King Street, San Francisco, California, 94107.