CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INITIAL STATEMENT OF REASONS FOR THE PROPOSED ADOPTION OF SECTION 100006: CONFLICTS OF INTEREST FOR NON-ICOC MEMBERS OF THE TREATMENTS AND CURES ACCESSIBILITY AND AFFORDABILITY WORKING GROUP

HEARING DATE: None scheduled.

CLOSE OF PUBLIC COMMENT: March 13, 2023

SUBJECT MATTER OF PROPOSED REGULATIONS: Conflict of Interest Rules Applicable to the Non-ICOC Members of the Treatment and Cures Accessibility and Affordability Working Group

SECTIONS AFFECTED: The proposed action adds Section 100006 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 TREATMENTS AND CURES ACCESSIBILITY AND AFFORDABILITY 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 non-ICOC members of the Treatment and Cures Accessibility and Affordability 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 circumstance identified therein is self-explanatory and is the logical and most likely source for a potential professional 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. Current regulations require similar disclosures for CIRM working groups. Cal. Code Reg. tit. 17, §§ 100001-100005.

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 under the rule of necessity.

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 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 working group. The interests identified take into account the context of possible types of awards. As a result, the term includes interests as a result of a member's (or Immediate Family member's) employment or potential employment with the applicant institution, subcontractor or partner; if there is any potential for receiving any financial benefit from the applicant institution under the award, or indirect benefit of more than $5,000, or similar investment.

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.

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 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 THE REGULATION:

Because the Treatment and Cures Accessibility and Affordability 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 existing CIRM regulations, Title 17 Sections 100001-100005. Pursuant to Propositions 71 and 14, this regulation is necessary to provide conflict of interest rules to members of review committees, such as this 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:

CIRM relied upon the statutes cited in the authority and reference sections for the regulations.

ClRM also modeled this regulation on conflict of interest rules for working groups as described in sections 100000 through 100005 of Title 17 of the California Code of Regulations.

In addition, CIRM consulted the following conflict of interest standards for the National Institutes of Health and the National Academy of Sciences:

- Conflicts of lnterest Policy for Institutional Oversight and Non-Advisory Program Activities, The National Academies: National Academy of Sciences, National Academy of Engineering, Institute of Medicine, National Research Council (Last updated April 18, 2011).
- National Institutes of Health, Policy for Managing Conflict of lnterest in the Peer Review of Concepts and Proposals for Research and Development Contract Projects, Notice No. NOT-OD-14-069 (Mar. 20, 2014).

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 REGULATORY ACTION THAT WOULD BE LESS BURDENSOME AND EQUALLY EFFECTIVE IN ACHIEVING THE PURPOSES OF THE REGULATION IN A MANNER THAT ACHIEVES THE PURPOSES OF THE STATUTE OR OTHER LAW BEING IMPLEMENTED:

CIRM believes that there are no reasonable alternatives to the proposed regulations. However, CIRM invites and will consider all public comments on alternatives to the regulation.

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 GOVERNMEND CODE SECTION 11346.3, SUBDIVISION (b)

CIRM does not anticipate that this proposed regulation will have any economic impact, including any impact on jobs or businesses within the State of California or any impact on the expansion of business in the state of California, nor any impact on the health and welfare of California residents, worker safety, and the state's environment. This analysis is based on that fact that the proposed regulation does not impose new requirements on existing business operations or functions of other agencies or individuals but implements a conflict of interest policy for members of the working group that will ensure that members of the Treatment and Cures Accessibility and Affordability Working Group abide by rigorous conflict of interest rules as

intended by the voters. The regulation will impose no costs on these members, other than a de minimis period of time spent completing the required disclosure.

DOES THE PROPOSED REGULATORY ACTION CONTAIN FACTS, EVIDENCE, DOCUMENTS TESTIMONY, ON WHICH THE AGENCY RELIES TO SUPPORT AN INITIAL DETERMINATION THAT THE ACTION WILL NOT HAVE A SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS?
No.

REGULATIONS MANDATED BY FEDERAL LAW (11346.2(c))

The proposed regulatory action does not contain any regulations that are identical to any corresponding federal regulation.

All initial statement of reasons requirements for the proposed regulations have been satisfied.