



MEMORANDUM

To: Independent Citizen's Oversight Committee

Fr: Paul Stein; Scott Tocher; James Harrison

Re: Amendments to Conflict-of-Interest Rules for Non-ICOC Members of the Grants Working Group

Date: September 27, 2013

I. SUMMARY AND REQUESTED ACTION:

In April 2013, CIRM reported to the Legislature that it intended to modify its conflict-of-interest rules for non-ICOC members of the Grants Working Group to clarify certain provisions in an effort to prevent future conflicts from arising. To that end, CIRM has prepared a set of proposed amendments to the regulations, and now seeks the Board's consent to initiate a formal rulemaking process.

CIRM aims to clarify the circumstances which may give rise to a personal, professional, or financial conflict. By doing so, CIRM intends to: (1) reduce the risk that conflicts will occur in the future; (2) make our conflict-of-interest rules more objective, understandable, and easier to apply for Grants Working Group members, CIRM staff, and the public; (3) streamline the conflict screening process CIRM undertakes in advance of each meeting of the Grants Working Group; and (4) only screen reviewers for personal, professional, or financial interests that could genuinely be deemed material.

The proposed amendments drafted by CIRM are shown in red-line on Attachment A to this memo. *We are not asking the Board to approve these amendments at this time.* Rather, Staff drafted these amendments to initiate the process of obtaining public comment, and shaping a final recommendation to the Board. As part of the rulemaking process, the amendments will be posted for public review and comment and refined as needed before Staff returns to the Board to request final approval.

II. BACKGROUND:

The Grants Working Group (GWG) is an advisory body composed of expert scientific members, patient advocate members of CIRM's Board, and the chairperson of CIRM's Board. The GWG reviews applications for research funding based on scientific

merit and makes recommendations to the Board, which has final decision-making authority. In addition to making funding recommendations, the GWG is charged by Proposition 71 with: (1) recommending criteria, standards, and requirements for considering funding applications and for awarding grants and loans; (2) recommending standards for the scientific and medical oversight of awards; (3) conducting peer group reviews of grantees to ensure compliance with the terms of CIRM awards; and (4) recommending standards and requirements governing the conduct of CIRM awards, including but not limited to reporting requirements.

Non-ICOC members of the GWG are subject to conflict-of-interest and economic disclosure requirements adopted by the ICOC.¹ Because the state's chief conflict-of-interest law, the Political Reform Act, would not otherwise apply to the GWG, Proposition 71 required CIRM to adopt its own conflict of interest rules for scientific members of the GWG. Indeed, the ICOC's conflict rules for the GWG go beyond, and are more restrictive than, the Political Reform Act in that they prohibit not only financial conflicts, but also personal and professional conflicts. A GWG member is prohibited from participating in the review of any application for CIRM funding in which the member has a personal, professional, or financial conflict, as defined in the regulations.

Prior to each meeting of the GWG, CIRM staff work extensively with grant reviewers to identify potential conflicts and ensure that any reviewer with a conflict is recused from the application in question. If, during or after the review, CIRM discovers that a violation of the rules has occurred, it is required to provide a report to the Legislature, together with a review of corrective actions taken to prevent future occurrences.

A confirmed conflict under the rules has occurred on only two occasions, most recently in April 2013. In each of these cases, the reviewer had a personal or professional relationship with someone involved in the applicant's research team who stood to receive a very small amount of salary from the grant – so small as to be immaterial. The violations were both inadvertent and highly technical. Although CIRM applied its rules strictly in each case, we believe situations such as these were not intended to trigger a conflict. We are also concerned that, by causing prospective reviewers to be flagged for a technical conflict, when in fact they have no financial or other interest that could realistically compromise the quality or integrity of the review process, strict application of the rules could hamstring the GWG's ability to attract the nation's leading scientific and medical experts. In order to prevent both the reality and appearance of a conflict,

¹ GWG members who also sit on the ICOC are subject to separate conflict-of-interest rules found in Proposition 71 (Health and Safety Code § 125290.30(g)) and the ICOC's bylaws. We are not proposing changes to the ICOC's bylaws.

while preserving CIRM's ability to attract the best reviewers available, the rules should flag only those interests that could genuinely be deemed material.

The amendments address this by establishing a monetary threshold for personal and professional conflicts of \$5,000 per year in salary or consulting fees. Under this approach, GWG members who have personal or professional ties to specified members of the applicant's research team who stand to receive less than \$5,000 per year in salary or consulting fees from the grant being reviewed would not be required to report a conflict.

This new monetary threshold for personal and professional conflicts is consistent with the way the rules presently address "financial benefits" which a GWG member may receive from the applicant institution, but which are unrelated to the proposal in question. Under the current rules, a financial benefit unrelated to the proposal of \$5,000 or more per year triggers a conflict. The proposed amendments would leave this \$5,000 threshold intact, but substitute the term "financial interest" for financial benefit, and clarify when such a financial interest exists.

A more detailed summary of the proposed amendments follows.

III. SUMMARY OF PROPOSED AMENDMENTS:

CIRM proposes to modify the definition of each type of conflict under the rules: financial, professional, and personal.

A. Financial Conflicts.

Presently, a non-ICOC member of the GWG has a financial conflict if s/he is an employee of the applicant institution; is under active consideration for a position at the applicant institution; stands to receive a financial benefit of any amount from the application under review; or has received or "could receive" a financial benefit of any type from the applicant institution that is "unrelated to the proposal" being reviewed. Further, a financial conflict exists not only if the GWG member has a prohibited financial interest in his or her own right, but also if "his or her spouse, or any other person *with whom the member has a common financial interest,*" has such an interest. Some aspects of these requirements may be subject to different interpretations by reviewers, as well as CIRM staff.

For example, the rules do not explicitly define whether a member has a "common financial interest" with someone sufficient to trigger a conflict. CIRM proposes to clarify the regulation by providing that a financial conflict exists where either: (1) a member has a prohibited interest in his or her own right; or (2) someone in the GWG member's "immediate family" has a prohibited interest. (See Att. A, § 100003(b)(1).) Consistent with state conflict-of-interest laws, "immediate family" means spouse, domestic partner, or dependent children.

CIRM also proposes to broaden the “employment” trigger for a financial conflict such that a conflict would exist where a GWG member or someone in the member’s immediate family is either an employee of the applicant institution, the Principal Investigator, or Co-Principal Investigator, or “has received, or has been promised, income of \$5,000 or more, or gifts of \$500 or more, in the past year” from the applicant institution, the Principal Investigator, or Co-Principal Investigator. (See Att. A, § 100003(b)(1).)

CIRM also proposes to clarify the circumstances in which an investment or other financial interest in the applicant institution triggers a conflict. Presently, a conflict exists if a GWG member has received or “could receive” a financial benefit of any type of over \$5,000 per year from the applicant institution that is “unrelated to the proposal” being reviewed. To clarify this provision, CIRM proposes to prohibit reviewers from having a “financial interest in the applicant institution of \$5,000 or more,” including but not limited to “current stock holdings, equity interest, [and] intellectual or real property interest” (See Att. A., § 100003(b)(4).) Finally, it should be noted that: (1) the rules presently ban GWG members from participating where they stand to receive a financial benefit of *any* amount from the application under review; and (2) that prohibition is not affected by the proposed amendments.

B. Professional Conflicts.

Presently, a conflict exists where a GWG member and a “primary member of the applicant’s research team” are engaged in, or are planning to be engaged in, collaboration. CIRM proposes a more objective screen to determine which people on the applicant’s research team must be checked for present or future collaborations. Specifically, a conflict would arise where a GWG member is collaborating or plans to collaborate with any “person listed on the grant application as Principal Investigator or Co-Principal Investigator or someone who will receive salary or consulting fees of \$5,000 or more per year from the grant.” (See Att. A, § 100003(c)(2).) The same \$5,000 per year threshold would also apply to conflicts based on professional ties between a GWG member and certain members of the applicant’s research team. In addition, in order to clarify the rule, the term “professional associate” has been defined more precisely to mean someone who has been a “research collaborator, a former student, post-doctoral fellow, or someone with whom the member has co-authored a publication, within the past three years.” (See Att. A, § 100003(c)(1).)

CIRM proposes similar changes to the rule prohibiting professional conflicts based on “long-standing scientific differences or disagreements or disagreements that are known to the professional community and could be perceived as affecting the member’s objectivity.” Presently, this prohibition is triggered where a GWG member and the “applicant” are determined to have such differences or disagreements. CIRM proposes to screen not the “applicant,” which is typically an academic institution or a company, but

rather those persons “listed on the grant application as Principal Investigator or Co-Principal Investigator or someone who will receive salary or consulting fees of \$5,000 or more per year from the grant.” (See Att. A, § 100003(c)(3).)

C. Personal Conflicts.

CIRM proposes similar changes to the regulatory language governing “personal” conflicts. Instead of screening members to determine whether any close family member or personal friend is an “applicant,” the rule would require a check into whether any such person is “listed on the grant application as Principal Investigator or Co-Principal Investigator or someone who will receive salary or consulting fees of \$5,000 or more per year from the grant.” (See Att. A, § 100003(d)(1)-(2).)

D. Economic Disclosures.

The regulations presently require disclosures of specified economic interests that GWG members may have in their own right, as well as any interests held by their “spouses, or others with whom the member has a common financial interest.” As above, in order to provide greater clarity and ease of administration, CIRM proposes to require disclosure of specified economic interests held by the member and anyone in the member’s immediate family, rather than anyone with whom the member may have an undefined “common financial interest.” (See Att. A, § 100003(e)(1)-(6).)

ATTACHMENT A

Adopt 17 Cal. Code of Regs. section 100003 to read:

§ 100003. Conflicts of Interest – Non-ICOC Members of the Scientific and Medical Research Funding Working Group.

(a) Prohibition: Except as provided otherwise in this regulation, a non-ICOC Grants Review Working Group member may not participate in a decision of the working group in which the individual has a conflict of interest. A conflict of interest exists when a non-ICOC Grants Review Working Group member has a real or apparent interest in the outcome of an application such that the member is in a position to gain financially, professionally or personally from either a positive or negative evaluation of the grant proposal.

(b) “Financial: Conflict of Interest - Defined: A non-ICOC member has a financial conflict of interest if:

(1) ~~The member, his or her spouse, or any other person with whom the member has a common financial interest, or a member of his or her immediate family is an employee of either the applicant institution, or the Principal Investigator, or the Co-Principal Investigator on an application, or has received, or has been promised, income of \$5,000 or more, or gifts worth \$500 or more, in the past year from the applicant institution, the Principal Investigator, or the Co-Principal Investigator.~~

(2) ~~The member or a member of his or her immediate family, his or her spouse, or any other person with whom the member has a common financial interest, is under active consideration for a faculty or administrative position at an applicant institution.~~

(3) ~~A member or a member of his or her immediate family, his or her spouse, or any other person with whom the member has a common financial interest, stands to receive a financial benefit of any amount from an application under review.~~

(4) ~~A member or a member of his or her immediate family has a financial interest in the applicant institution of \$5,000 or more. A “financial interest” includes, his or her spouse, or any other person with whom the member has a common financial interest, has received or could receive a financial benefit of any type from an applicant institution or organization unrelated to the proposal, of over \$5,000 per year. This total includes honoraria, fees, stock and other benefits. It also includes current stock holdings, equity interest, intellectual property or real property interest, but does not include an interest held through a -diversified mutual funds.~~

(c) “Professional” Conflict of Interest - Defined: A non-ICOC member has a professional conflict of interest if:

(1) ~~A person listed on the grant application as Principal Investigator or Co-Principal Investigator, or someone who will receives salary or consulting fees of \$5,000 or more per year from the grant, has been a research collaborator is a professional associate, such~~

as, a former student, or post-doctoral fellow, or someone with whom the member has co-authored a publication, within the last three years.

(2) The member and a person listed on the grant application as Principal Investigator or Co-Principal Investigator, or someone who will receive salary or consulting fees of \$5,000 or more per year from the grant,~~primary member of the applicant's research team~~ are engaged in, or are planning to be engaged in, collaboration.

(3) A person listed on the grant application as Principal Investigator or Co-Principal Investigator, or someone who will receive salary or consulting fees of \$5,000 or more per year from the grant,~~An applicant is someone a person~~ with whom the member has had long-standing scientific differences or disagreements that are known to the professional community and could be perceived as affecting the member's objectivity.

(d) "Personal" Conflict of Interest - Defined: A non-ICOC member has a personal conflict of interest if:

(1) A close family member or close personal friend is a person listed on the grant application as Principal Investigator or someone who will receive salary or consulting fees of \$5,000 or more per year from the grant~~an applicant~~.

(2) A person listed on the grant application as Principal Investigator or someone who will receive salary or consulting fees of \$5,000 or more per year from the grant~~An applicant is someone a person~~ with whom the member has had long-standing personal differences.

(e) Disclosure: A non-ICOC working group member shall disclose confidentially and under penalty of perjury the following financial interests: 10/01/06 3 100003

(1) Income of \$5,000 or more, or gifts worth \$500 or more, received by the member or a member of his or her immediate family from a~~All~~ California-based academic or non profit research institution in the past years from which members, their spouses, or others with whom the member has a common financial interest, receive income or other benefit of \$5,000 or more.

(2) Income of \$5,000 or more received by the member or a member of his or her immediate family from ~~All a~~ publicly-held biotechnology ~~and or~~ pharmaceutical companies from which members, their spouses, or others with whom a member has a common financial interest, receive current income or other benefit, or hold an investment, of \$5,000 or more.

(3) An investment worth \$5,000 or more held by the member or a member of his or her immediate family in a publicly-held biotechnology or pharmaceutical company.

(34) Income received by the member or a member of his or her immediate family in a~~All~~ privately held biotechnology companies in which reviewers, their spouses, or others with whom a member has a common financial interest, have an equity interest.

(5) An investment held by the member or a member of his or her immediate family in a privately held biotechnology company.

(46) An interest worth \$2,000 or moreReal property interests in California held held by the members or a member of his or her immediate family in real property in California; their spouses, or others with whom a member has a common financial interest.

(f) Disqualification: A non-ICOC member is required to report to the CIRM staff any conflict of interest of which he or she is aware, including, but not limited to, those described in subdivisions (b) through (e) of this regulation. Any member of the Grants Review Working Group who has a real or apparent conflict of interest with respect to an application may not review or vote on the application and must leave the room when that application is discussed. In exceptional cases, the President of the CIRM may decide that the need for special expertise of the reviewer outweighs any possible bias posed by a real or apparent conflict of interest. Under these circumstances, the CIRM staff shall publicly disclose the working group member's interest before the meeting and the working group member shall be permitted to participate in the discussion but will not be permitted to vote on the application or participate in the scientific scoring.

(g) All non-ICOC members must sign a pre-review statement indicating any possible conflicts of interest that they have in advance of a review, and must also sign a post-review statement certify that they did not participate in the discussion or review of any application for which they might have a conflict of interest, or shall indicate permission to participate was granted by the President pursuant to subdivision (f) of this regulation.

(h) Record-Keeping: All financial disclosure documents shall be kept confidential by the CIRM staff and preserved for purposes of review by the State Auditor or another independent auditor and any other audit as required by law. Records of the working group indicating those members who participated in or voted on particular recommendations shall be maintained by the CIRM staff. If the CIRM or an auditor discovers a violation of these conflict of interest provisions, a report will be made to the Legislature along with a review of corrective actions taken by the CIRM to prevent future occurrences.

(i) For purposes of this section, "immediate family" means spouse, domestic partner, and dependent children.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.50, subd. (e), 125290.60, Health and Safety Code.