



MEMORANDUM

TO: Members, Governing Board

FROM: James Harrison, Scott Tocher, Gil Sambrano and Becky Jorgenson

RE: Proposed Adoption of Interim GWG Conflict of Interest Policy for Review of Clinical Stage Applications

DATE: December 3, 2014

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Introduction

The Governance Subcommittee met on November 24, 2014, to consider proposed amendments to the Grants Working Group (GWG) Conflict of Interest Policy and, after a lengthy discussion, recommended Board approval of the amendments. We request that the Board adopt the proposed amendments to the GWG Conflict of Interest Policy on an interim basis for purposes of the review of applications submitted pursuant to the concept plan for clinical stage programs. Under Prop. 71, the interim policy will remain in effect for 270 days. During this period of time, we will initiate the rule-making process to adopt the amendments to the policy for all purposes.

Background

At its October 14, 2013 meeting, the Board considered a proposal to amend the GWG Conflict of Interest policy (Cal. Code Regs., tit. 17, section 100003). Some members of the Board expressed concerns about the proposed amendments and the Board directed the CIRM team to reconsider the proposed changes and to present them to the Governance Subcommittee. We have considered the comments made by members of the Board, including members Sheehy and Juelsgaard, at the October 14, 2013 meeting. In addition, we have reviewed the National Institutes of Health (NIH) conflict rules, and considered whether our policy is sufficiently clear and objective to capture conflicts of interest. Based on these considerations, we have proposed substantial changes to the policy. The proposed changes are included in a redlined version of the current policy, which is attached to this memorandum. Below, we summarize the most significant proposed changes.

Financial Conflicts of Interest

Under our current policy, financial conflicts are limited to a member's financial interest in the applicant institution and the application under review. We propose 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 our current policy, 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. As member Juelsgaard explained, however, differences of scientific opinion are common, and indeed healthy, because scientific 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, our 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, we propose to eliminate “long-standing scientific differences” as a basis for recusal. However, to address the concerns underlying this rule, we have 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. In addition, we plan to introduce a screening mechanism that would permit applicants to identify up to a total of three individuals (including labs and companies) whom the applicants believe could be biased (whether for personal, professional, competitive, or any other reasons).

Individuals identified by applicants pursuant to this screening mechanism would not be permitted to review the applicant's application.

We also propose to 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 conflict of interest policy, 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. We therefore propose 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. In addition, as discussed above, we propose to address the concerns regarding personal differences by requiring members to recuse themselves when they believe their objectivity may be compromised and by allowing applicants to identify up to a total of three individuals (including labs and companies) whom the applicant believes may be biased (whether for personal, professional, competitive, or any other reasons).

Definitions

We also propose 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 policy.

Requested Action

Recommend approval of the amendments to the Grants Working Group Conflict of Interest Policy as an interim policy, effective January 31, 2015, applicable to the review of clinical stage applications, and that CIRM initiate the rule-making process to adopt the amendments for all purposes.

Attachment

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: (the “Grants 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, or a member of his or her spouse, or any other person with whom the member has a common financial interest,~~ Immediate Family is an employee of either the institution or the Principal Investigator on an applicant organization, a Subcontractor, or a Partner, or has received, or has been promised, income or anything else of value, of \$5,000 or more, or gifts worth \$500 or more, in the past year from the applicant institution, a Subcontractor, a Partner, or a person listed in the application as Key Personnel.

(2) ~~The member, or a member of his or her spouse, or any other person with whom the member has a common financial interest,~~ Immediate Family is under active consideration for a faculty or administrative position employment at the applicant institution organization, a Subcontractor, or a Partner.

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

(4) ~~A member, or a member of his or her spouse, or any other person with whom the member Immediate Family has a common financial interest, has received or could receive a financial benefit of any type from an 10/01/06 2-100003- in the applicant institution or organization unrelated to the proposal,~~ a Subcontractor, or a Partner of over \$5,000 per year. This total includes honoraria, fees, stock and other benefits. It also or more. A “financial interest” includes current stock holdings, equity interest, intellectual property or real property interest, but does not include an interest held through a diversified mutual fundsfund.

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

(1) ~~A person listed on in the grant application as Principal Investigator or someone who receives salary from the grant is~~ Key Personnel has been a professional associate, such as

~~Research Collaborator, a former student/trainee, or post-doctoral fellow, or someone with whom a mentor of the member has co-authored a publication, within the last three years.~~

(2) ~~The member and a primary member of the applicant's research team~~ person listed in the application as Key Personnel are currently engaged in, or are planning to be engaged in, collaborative Research Collaboration.

(3) ~~An applicant is someone 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~~ An Immediate Family member or close personal friend is an applicant.

(2) ~~An applicant is someone with whom a person listed in the member has had long-standing personal differences~~ application as Key Personnel.

(2) The member and a person listed in the application as Key Personnel have been on opposing sides in a lawsuit, arbitration or mediation.

(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) ~~All~~ 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 California-based academic or non-profit research institutions 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 organization in the past year.

(2) ~~All~~ Income of \$5,000 or more received by the member or a member of his or her Immediate Family from a publicly-held biotechnology and/or pharmaceutical company.

(3) ~~An~~ 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 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, not including an investment, of \$5,000 or more, held through a diversified mutual fund.

(3) ~~All~~ (4) Income received by the member or a member of his or her Immediate Family from a privately held biotechnology companies in which reviewers, their spouses, or others with whom a member has a common financial interest, have an equity interest. company.

~~(4) Real~~ (5) An investment held by the member or a member of his or her immediate family in a privately held biotechnology company.

(6) An interest worth \$2,000 or more held by the member or a member of his or her Immediate Family in real property interests in California held by members, 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 (ed) of this regulation. ~~Any, and any application as to which the Member believes his or her objectivity could be compromised. A non-ICOC member of the Grants Review Working Group who has a real or apparent conflict of interest, as described in subdivisions (b) through (d) of this regulation, or who believes that his or her objectivity could be compromised, 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~~ indicate 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, the following terms have the following meanings:

(1) "Immediate Family" member means a non-ICOC member's spouse, domestic partner, and dependent children.

(2) "Key Personnel" means (1) the principal investigator or program director; or (2) any other person, including an independent consultant or an employee of a Subcontractor or Partner, who is expected to contribute to the scientific development or execution of the

project in a substantive, measurable way and who is expected to: (a) receive or has been promised income, or anything else of value, of \$10,000 or more per year through the proposed project or (b) contribute one percent (1%) or more effort to the proposed project. "Key Personnel" does not include a person who is expected to be involved in the proposed project but who does not satisfy paragraphs (1) or (2).

(3) "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.

(4) "Research Collaborator" or "Research Collaboration" means participation as Key Personnel on the same research project or effort to advance or publish research results or the commercial development of a product. The terms do not include passive associations such as belonging to the same scientific society or contributing to the same review article or textbook.

(5) "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.

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.