



MEMORANDUM

TO: Members, Governance Subcommittee

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

RE: Proposed Amendments to GWG Conflict of Interest Policy

DATE: November 21, 2014

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Introduction

At its October 14, 2013 meeting, the Board considered a proposal to initiate the rule-making process for proposed amendments to the Grants Working Group 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. 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 that the Board approve initiating the administrative rule-making process for the proposed amendments to the Grants Working Group conflict of interest policy.

Attachment