



TO: Members of the ICOC

FROM: C. Scott Tocher, Deputy General Counsel

DATE: September 15, 2015

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

Introduction

At its December 2014 meeting, the ICOC approved interim changes to the conflict of interest policy applicable to members of the Grants Working Group. The Board also directed the CIRM team to finalize the amendments with the Office of Administrative Law. The rule-making process to finalize the amendments is nearly completed and the interim changes are now ready for final adoption by the Board.

As part of the rule-making process, CIRM circulated the proposed amendments to the public and received no comments. Except as noted below, the amendments have not materially changed from the version approved by the Board in December 2014.

Financial Conflicts of Interest

Under the current GWG policy, financial conflicts are limited to a member's financial interest in the applicant institution and the application under review. The amendments 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. Partner does not include an organization that, like the National Institutes of Health, provides research

funding to a proposed project but that does not have the right to a future financial return.

“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 \$25,000 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. Subsequent to the Board’s approval of the proposed changes, CIRM lowered the subcontractor threshold in part (b) from \$50,000 to \$25,000 to conform with the Board’s approval of the concept plan for CIRM Clinical Stage Program. In addition, the definition of “Partner” is further clarified to exclude organizations that provide co-funding for a project but which do not obtain rights to financial returns.

Professional Conflicts of Interest

Under the current GWG 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. Differences of scientific opinion, however, 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, the amendments eliminate “long-standing scientific differences” as a basis for recusal. However, to address the concerns underlying this rule, CIRM 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, CIRM has implemented a screening mechanism that permits 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 are not permitted to review the applicant’s application.

The amendments 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 GWG 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. The amendments 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, the revised policy addresses 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).

Requested Action

Recommend approval of the amendments to the Grants Working Group Conflict of Interest Policy and forward to the Office of Administrative Law for final approval.

Attachment