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MEMORANDUM

To: Members, Governing Board
California Institute for Regenerative Medicine

From: James C. Harrison

Date: October 15, 2012

Re: Proposed Amendments to Grants Working Group Bylaws (Our File No.: 2297-0)

INTRODUCTION

At the request of the Chairman of the Governing Board and the President of CIRM, we have prepared the attached description of the roles and responsibilities of the various participants in the Grants Working Group. The intent of this document is to clearly delineate the roles and responsibilities of the Scientist and Patient Advocate members of the Grants Working Group, along with the President and CIRM staff. Given the need to add new scientific members to the Grants Working Group to obtain the necessary expertise for the review of applications, a detailed description of the roles and responsibilities of the participants in the peer review process will also be helpful in educating new members of the Grants Working Group.

After reviewing the proposal internally, we presented the draft to the Science Subcommittee on July 25, 2012, which recommended it for approval by a vote of 10 to 1. On September 12, 2012, we presented the proposal to the Grants Working Group for its consideration. The Grants Working Group also recommended the Board's approval of the statement of roles and responsibilities.

RECOMMENDATION

Approve the statement of the roles and responsibilities of the participants in the Grants Working Group process and direct staff to incorporate the statement into to the Grants Working Groups bylaws.

Attachment

Proposed Addition to GWG Bylaws

Role of Scientist Members and Scientific Review

Scientist members of the GWG are full members and participate in all aspects of the GWG's review of applications. They provide the essential scientific expertise to inform the recommendations of the full GWG and the funding decisions made by the Governing Board.

Scientific Review is led by the Review Chair, a scientist member. During scientific review, scientist members of the GWG are responsible for assessing the scientific merit of each application, according to the criteria stated in the RFA, based on their own scientific expertise and the expert opinion of the other scientific reviewers. In written critiques and during review meetings, they should be willing to explain their reasoning to assist patient advocates in fulfilling their responsibilities on the GWG and the Governing Board, to allow CIRM scientific staff to prepare summaries for the Governing Board, applicants and the public, and to provide guidance that will be useful in the management of approved awards. During scientific review, scientist members may ask questions, probe the views expressed by other participants, and express their own views. Scientist members are expected to consider the views expressed by other participants, but their confidential scores should reflect their own independent scientific judgment.

During programmatic review, scientist members of the GWG join the patient advocate members to make and vote on programmatic motions and funding recommendations to the Governing Board.

Role of Patient Advocates and Programmatic Review

Patient Advocate members of the GWG are full members and participate in all aspects of the GWG's review of applications, except for assigning scores during scientific review. They represent the patients whose needs drive all CIRM-funded research. As members of the Governing Board, they provide a continuum for the flow of information and insights between the two bodies.

During scientific review, patient advocate members may ask questions, probe the views expressed by other participants, and express their own views.

Programmatic review is led by one of the GWG Vice Chairs, who is a patient advocate, or a patient advocate member designated by the Vice Chairs. During programmatic review, patient advocate members of the GWG join the scientist members to make and vote on programmatic motions and funding recommendations to the Governing Board. Programmatic review is intended to allow consideration of issues beyond scientific merit, such as disease representation and societal impact. In making funding recommendations to the Governing Board, GWG members consider the scientific merit of each application, as reflected in the scientific score, as well as any programmatic issues raised.

Recommendations may include specific conditions, such as removal of an element of the proposal or a reduction in the budget.

Role of CIRM President

CIRM's President serves on the GWG as a non-member participant in all GWG discussions, but does not assign scientific scores, make motions, or vote. As the leader of CIRM's scientific and professional staff, the President may ask members to consider how an application will address scientific or programmatic issues that have come up in the field or in the execution of CIRM-funded research, respond to questions by GWG members on science matters, and provide information within his/her expertise.

The President should alert the GWG and ICOC of matters that have been found to be inconsistent/incorrect in the review of a grant application. The President should provide the ICOC, on their request, any recommendations from CIRM staff on one or more of the grant applications under consideration.

Role of CIRM Scientific Staff

Members of CIRM's scientific staff, under the leadership of the President, support the GWG, by managing and coordinating the review process, including but not limited to tracking conflicts of interest, ensuring observance of confidentiality rules, setting the schedule of review, and ensuring that applications are appropriately evaluated and scored. To this end, the scientific staff provides guidance and information regarding CIRM's programs, portfolio and procedures, including explaining the scope and requirements of the request for applications and the review criteria and responding to requests for information regarding awards or applications that aid the GWG in making informed evaluations. The scientific staff ensures that review criteria, priorities and requirements are appropriately applied to the evaluations and discussions of applications, and help the Review Chair ensure that all GWG members contribute to the proper evaluation and scoring of applications. Scientific staff should, on request of the Review Chair, provide information to the GWG in their areas of expertise.

The scientific staff are responsible for monitoring scientific progress of CIRM-funded research projects, and may be called upon to report on that progress if it is relevant to the review of an application before the GWG. They are responsible for summarizing, for the Governing Board, applicants and the public, the reasoning behind the scientific scores and GWG recommendations. Accordingly, scientific staff may ask members to clarify their views or address specific issues in order to present a complete and useful report.

Prior to Governing Board consideration of GWG recommendations, the President and scientific staff should consider whether there are applications which they believe warrant particularly close review by the Board, or whether specific modifications may be needed to successfully execute a particular proposal.

Role of Chair of the GWG

From Art. IV, § 9 (proposed additional language in italics):

The Chair of the GWG shall preside over public meetings of the GWG and all other GWG business that has not been assigned to a Review Chair pursuant to Section 9.5 of this Article. *The Chair shall also work collaboratively with the Vice Chairs and the Review Chair to support and enhance the relationship between the scientist members and the patient advocate members of the GWG.*