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M E M O R A N D U M

To: Members, Application Review Task Force
California Institute for Regenerative Medicine

From: James C. Harrison

Date: November 21, 2012

Re: Summary of Discussion at October 24, 2012 Meeting (Our File No.: 2297-0)

The Application Review Task Force met on October 24, 2012 to discuss the Extraordinary Petition policy and the policy concerning consideration of material disputes of fact and material new information. Although the agenda also included consideration of a policy to govern ex parte communications, the Task Force did not have time to discuss this topic. Members of the Task Force who participated in the meeting included Bert Lubin, Anne-Marie Duliege, Jeff Sheehy, Os Steward, Kristiina Vuori, and Jonathan Thomas. From CIRM staff, Alan Trounson, Ellen Feigal, Pat Olson, Gil Sambrano, and Maria Bonneville participated.

Jon Thomas explained that the Governing Board had adopted revisions to the Extraordinary Petition policy and criteria for consideration of a material dispute of fact or material new information following the Board's consideration of applications for Disease Team II awards. During its review of the Disease Team II applications, the Board referred several applications to a subset of the Grant Working Group to consider new information. Although the new policies address some of the concerns raised regarding the referral of applications back to the Grants Working Group, the Board felt that it was important to take a closer look at the policies to ensure that they reflect best practices. Dr. Thomas then asked Board counsel to summarize the current policies.

Board counsel explained that CIRM currently has an appeals process, which is set forth in the Grants Administration Policy, and a separate policy for Extraordinary Petitions. Pursuant to the Grants Administration Policy, an applicant may file an appeal alleging that a member of the Grants Working Group had a conflict of interest under the Grants Working Group's conflict of interest rules. The appeal must be filed within 30 days of receiving the Grants Working Group's review. Upon receipt of an appeal, the President is charged with

reviewing the conflict of interest allegation and determining whether a conflict existed and whether it adversely affected the review. If the President concludes that a conflict of interest existed and that it adversely affected the review, the application is referred back to the Grants Working Group for a new review, excluding the conflicted member.

Under the Extraordinary Petition policy, an applicant may submit written comments, limited to three pages, to the Board addressing the Grants Working Group's recommendation, provided that the comments are submitted at least five working days before the first Board meeting at which the application is considered. Unlike the appeals process, there are no restrictions on the grounds for an Extraordinary Petition.

The Board also adopted a policy to govern new information and material disputes of fact submitted as part of an extraordinary petition. Pursuant to this policy, the Board may refer an application to a subset of the Grants Working Group (three members) for additional analysis if it determines that the applicant has established that there is a material dispute of fact or has submitted material new information.

To demonstrate that a material dispute of fact exists, an applicant must establish that: (1) the dispute involves the accuracy of a statement in the review summary; (2) the disputed fact was significant in the scoring or recommendation of the GWG; (3) the dispute pertains to an objectively verifiable fact, rather than a matter of scientific judgment or opinion; (4) the discrepancy cannot be resolved at the meeting at which the application is being considered; and (5) resolution of the dispute could affect the outcome of the Board's funding decision.

To establish that the applicant has material new information, the applicant must show that the information: (1) is verifiable through external sources; (2) has arisen since the Grants Working Group meeting at which the application was considered; and (3) responds directly to a specific criticism or question identified in the Grants Working Group's review. The policy offers examples of information that would qualify, including approval by the Food and Drug Administration to initiate a clinical trial; a documented, enforceable agreement between the applicant and a commercial partner; a final court decision or administrative action; and documentation confirming that a manuscript has been accepted for publication in final form. The policy specifies that new scientific data will not be considered "new information" unless it has been peer reviewed and published.

After Board counsel completed his summary of current policies, the Chair of the Task Force, Bert Lubin, asked for input from members of the Task Force, CIRM staff, and the public. Generally, participants stressed the importance of public comment and the consideration of pertinent new information, the need for the Board to exercise discipline in its review of applications, and the need to provide clarity to applicants and the public regarding the parameters of CIRM's application review policies.

Gil Sambrano, CIRM's Senior Review Officer, explained that applicants perceive the Extraordinary Petition policy as another form of appeal and suggested that the Task Force consider creating a single appeals process. Anne-Marie Duliege suggested that CIRM staff and members of the Grants Working Group should advise the Board whether an applicant has met the criteria for a material dispute of fact or material new information, or that Extraordinary Petitions be presented to the Grants Working Group before coming to the Board. Jeff Sheehy added that deferring consideration of an application for which an Extraordinary Petition was submitted could help address the concern that the submission deadline (five business days before the Board meeting) does not leave sufficient time for review. Participants expressed general agreement that the policies should be crafted in a manner that avoids putting the Board in a position in which it is asked to assess new information on the fly without the benefit of full scientific analysis.

The members also discussed the appropriate number of members of the Grants Working Group to conduct additional analysis. Os Steward suggested that a follow-up meeting of the full Grants Working Group could be scheduled to consider new information that was deemed to be pertinent to the Grants Working Group's recommendation. Alan Trounson, CIRM's President, and Gil Sambrano responded that the appropriate number of members would depend upon the scope of the question asked – for example, a narrow issue could be reviewed by three members – but expressed concern about the difficulty of scheduling a second meeting of the full Grants Working Group.

Jeff Sheehy proposed that, for large awards, the Grants Working Group could engage in a more interactive process with the applicants to respond to questions and to provide greater clarity in the review, or alternatively, that CIRM could use a process similar to the Clinical Development Advisory Panel to award increments of funding based on milestones rather than approving a very large award at the outset. Ellen Feigal, CIRM's Senior Vice-President for Research and Development, responded that CIRM currently has the ability to terminate funding if a grantee is not meeting its scientific milestones.

Bert Lubin closed the meeting by acknowledging the need for the Task Force to maintain momentum and to continue exploring the use of criteria to guide decisions regarding new information.