BOARD OPTION TO REQUEST ADDITIONAL ANALYSIS

Background

At the July 20, 2010 Science Subcommittee meeting, members of the Subcommittee discussed a proposal to permit the Board to request that an application be referred for additional analysis under limited circumstances. The Subcommittee did not reach a conclusion regarding the proposal but agreed to consider further public input and to reconsider the proposal at its next meeting.

The Subcommittee met again on September 29, 2010 to consider a draft proposal. By a vote of 9 to 0, the members of the Scientific Subcommittee approved a motion to recommend that the Board adopt this proposal for a trial period of 18 months; upon expiration of this period of time, the policy will be subject to reconsideration by the Board. The proposal is intended to create a procedure whereby the Board can conditionally deny an application and request further analysis of specific questions under a narrow set of circumstances. The details of the proposal follow:

Proposal

When a material dispute of fact exists and the Board is unable to resolve the issue at the meeting at which the application is considered, the Board may conditionally deny funding for the application, subject to a limited analysis of the factual issue or issues identified by the Board. The option for additional analysis is not a reconsideration of the application as a whole, but is limited to consideration of the issue or issues identified by the Board. This option should be reserved only for those circumstances in which the Board is unable to reach a decision at meeting at which the application is presented because of the factual dispute or question. Programmatic issues, such as whether the agency's portfolio is well-balanced among diseases, should not be a justification for additional analysis, nor should clear errors in the review of an application that have been identified by staff and presented to the Board during the meeting at which the application is considered. The procedure for the limited additional analysis of an application should consist of the following:

- The factual issue or issues identified by the Board should be referred to the Chair of the Grants Working Group and the Review Chair of the Grants Working Group (i.e., the scientific member of the GWG who was designated to act as Chair for the review meeting at which the application was considered).

- If the Chair and the Review Chair of the GWG agree that the question or questions may be resolved through their own research or research conducted by staff (e.g., consulting publicly available research resources, such as PubMed), then they may conduct such research or request that staff conduct such research and report back to the Chair and the Review Chair of the GWG, who shall recommend whether, in their view, the new information warrants reconsideration of the Board's conditional decision not to fund the application. If the Chair and

the Review Chair of the GWG concur, their recommendation shall be reported to the Board for its consideration. If the Chair and the Review Chair of the GWG do not agree, then the process described in the next paragraph shall be used to resolve the question.

- If the Chair and the Review Chair of the GWG agree that the question or questions warrant additional expert research or analysis, or if they cannot reach consensus on this issue or on their recommendation of whether the new information warrants reconsideration of the Board's conditional decision not to fund, then the Chair and the Review Chair of the GWG shall each designate one scientific member of the GWG (excluding members who participated in the initial review of the application) to serve with the Chair and the Review Chair of the GWG to consider the issue or issues presented. The Chair and Review Chair of the GWG may seek assistance from CIRM staff or outside specialists to assist in analyzing the scientific issues referred to it by the Board. Both of the Vice Chairs of the GWG, the Board Chair, and another Patient Advocate from the GWG, with the priority for the Patient Advocate who represents the disease type that is the target of the proposal (if applicable) will be invited to participate in the consideration of the issue or issues presented. The scientific members of the panel will present a summary of their analysis of the question to the panel. The panel members will have an opportunity to discuss the analysis and recommendation and the panel (excluding the Chair of the Board) will vote on a motion addressing whether, in their view, the new information or analysis warrants reconsideration of the Board's conditional decision not to fund the application. The outcome of this motion, along with any minority report, will be presented to the Board for its consideration.

- CIRM's conflict rules will apply to this process. In the event that the Chair or the Review Chair of the GWG has a conflict with respect to the application, another scientific member of the GWG (excluding members who participated in the initial review), selected by lot, shall be invited to act in his or her place.

- The recommendation of the Chair and the Review Chair of the GWG, or in the case of a question that warrants further research or analysis, the recommendation of the panel, shall be placed on the Board's consent calendar at the next meeting of the Board; however, any member of the Board who does not have a conflict may request that the matter be pulled from the consent calendar and considered as a stand-alone item.