



M E M O R A N D U M

October 14, 2012

From: Ellen G. Feigal, M.D., Senior Vice President, Research and Development
To: Independent Citizens Oversight Committee (ICOC)
Subject: Budgetary Review for CIRM Research Awards

The topic of budgetary review for CIRM research awards was conceptually discussed at the July 25, 2012 science subcommittee, and the recommendation was to return to the science subcommittee in advance of the ICOC October meeting to have a more in-depth discussion of the issues. At the July discussion, the science subcommittee strongly recommended against incorporating budgetary considerations into the scoring for a project, which they felt should remain focused on the scientific merit, unless the budget directly impacted on the design and feasibility of the project. The science subcommittee suggested the budget considerations during the GWG session follow as a separate discussion item from the scoring of each application, with comments to be captured as part of the summary. The science subcommittee noted the ICOC should explicitly allow the CIRM officers to have the flexibility and discretion, to consider these comments and other appropriate changes, in their negotiations with the applicants at the time of the prefunding administrative review.

At the October 8, 2012 science subcommittee, the discussion in general was very favorable towards having budget consideration during the GWG session, and a suggestion was made to consider an option of defining a specific weight (e.g., 10% or some multiple) to the scientific score for those applications in which the proposed budget raised serious concerns about the design of the research, or the feasibility to conduct the research.

Currently, the Grants Working Group (GWG) scientific members' discussion and scoring on submitted applications to CIRM's initiatives have focused primarily on the scientific merits of each application, and do not reflect budgetary and other financial matters. The budget considerations are indirectly brought into the scoring on the principal investigator component of the overall score for a proposal if the GWG thinks the budget adversely impacts on the design or feasibility of accomplishing the objectives of the research. Otherwise, the budget and financial considerations on GWG recommended and ICOC approved or ICOC approved awards are assessed by CIRM scientific officers and CIRM grants management staff during the prefunding administrative review (PFAR). At this

stage, however, it is often challenging to make substantive changes to the budget, based on appropriateness of study activities and costs, given the ICOC approval at a given budget amount.

In recognition of CIRM's responsibility to be good stewards of taxpayer dollars, we propose augmenting our current procedures to increase budget scrutiny as part of the primary review process. All applications for CIRM awards should be carefully examined for budgetary appropriateness, particularly CIRM's translational initiatives, and the large, complex and expensive Early Translation and Disease Team awards. They all merit increased and focused attention on the budget, during the GWG discussion, by the appropriate expertise, to ensure appropriate and reasonable alignment with the project objectives and activities.

Understandably, as we have reviewed increasing numbers of larger awards, GWG reviewers and CIRM officers have identified shortcomings in some recent applications. Examples include:

- Budget does not align with the program deliverables and milestones. For example, the budget includes activities not relevant to project objective(s) or that are out of scope.
- Budget does not contain adequate expenses for known costs. For example, an applicant may budget \$100,000 for a GMP manufacturing run of a biologic in which it is generally accepted knowledge that the actual expenses are typically much greater.
- Budget item significantly exceeds a known cost or seems excessive without adequate justification. For example, an applicant may propose a surgical expense of \$100,000 per patient for a procedure with Medicare reimbursement set at \$15,000.
- Cost allocations are not done properly. For example, an applicant is developing the same therapeutic candidate for 3 indications, and is applying for CIRM funding for 1 of the 3, but is charging CIRM for the cost of the entire manufacturing run.

Unless budget and financial issues along with their potential resolution are explicitly addressed in the GWG review summaries, it may be difficult at times for CIRM officers to address and negotiate such issues post-ICOC approval.

Recommendation

As part of CIRM's responsibility to be good stewards of taxpayer dollars, we propose augmenting the current review procedures to increase budget scrutiny as part of the primary review process. This policy would apply to all reviews of the "Disease Team," "Early Translational – Development Candidate" and "Strategic Partnership" RFAs, and any new RFAs as deemed appropriate. We propose the following for consideration at the upcoming Science Subcommittee meeting:

- To assist GWG review, appropriate expertise on budget and financial matters (e.g., this could be in the form of a specialist reviewer, or can also be assigned to a GWG reviewer with the appropriate background and expertise), will review applications for sound budgeting and provide comments or questions to the GWG for consideration by the reviewers before the reviewer's final scores are entered.
- If the financial/budgetary matter potentially directly impacts on the design or feasibility of conducting the project, the GWG may consider this issue in the scoring (from the October 2012 science subcommittee, a suggestion was made to provide a specific weight, e.g, 10% or some multiple, to the scientific score for budget proposals that raise serious concerns); otherwise, budgetary and financial issues and questions will not contribute to the scientific score.
- As appropriate, review summaries sent to the ICOC will identify scientific as well as budget or other issues. To the extent endorsed by the GWG, the review summaries will also identify potential resolution should the ICOC approve a given award with budget issues.
- CIRM officers should be provided explicit discretion to consider the budget comments, as well as the non budget recommendations, in their negotiations with the applicants.

Increasing the importance of budgetary review will encourage applicants to propose rigorous, realistic and vetted budgets, and will further our mission to be good stewards of taxpayer dollars. These additions will not significantly increase the workload burden on GWG members, and explicitly acknowledges that program goals, scientific plans, accurate budgeting and prudent spending are inextricably linked.