



MEMORANDUM

TO:	ICOC Science Subcommittee
FROM:	Gil Sambrano, Director of Portfolio Development and Review
RE:	Proposed Updates to CIRM 2.0 Concept Plans
DATE:	November 20, 2015

Background

On December 31, 2014, we launched CIRM 2.0 with three new program announcements to offer funding opportunities for stem cell projects in the late preclinical to clinical trial stages. Since then, the Board has adopted concept proposals for CIRM's discovery and translation programs. Despite our best effort to put forth flawless concepts, we understood that in practice there would be much to learn and that adjustments would be necessary to ensure our programs are effective and efficient. The clinical program has been in place for close to one year and overall implementation has been a success. However, there are adjustments to the concept that we believe would improve the clinical program as well as the other CIRM 2.0 programs. This memorandum summarizes two key changes for which we seek your approval.

Proposed Changes

1. Include Past Performance as CIRM Awardee in Review Criteria. CIRM began issuing research awards in 2006 and has awarded grants to hundreds of unique investigators. As a result, CIRM has significant experience with

many applicants, some of whom may apply for a new award or a continuation of a program that has received previous funding from CIRM. Frequently, members of the Grants Working Group request information about an applicant's past performance as a CIRM awardee. In order to ensure that we have a uniform process in place to provide such information, we propose to include "past performance as a CIRM awardee, if applicable" as a review criterion for all CIRM 2.0 programs, as follows:

Consideration of Past Performance as CIRM Awardee (If Applicable):

The GWG may consider an applicant's past performance in connection with a related CIRM award as part of its review. CIRM will provide the GWG with objective information regarding a related award that CIRM, in its sole discretion, deems relevant, including but not limited to performance against milestones, data, and outcomes for a related CIRM award or awards.

A "related CIRM award" includes: (1) an award for which the applicant PI served as the PI, a co-PI, a co-investigator, or otherwise substantially participated in the conduct of the award; (2) an award involving the same research project or product; or (3) an award that includes overlapping team members.

2. Include Accuracy and Completeness of Application in Eligibility Criteria.

Applicants for CIRM funding are currently required to attest to the accuracy and completeness of the information submitted in an application. In order to ensure that CIRM has a mechanism in place to address concerns regarding the accuracy or completeness of an application, we propose to include the accuracy and completeness of an application as an eligibility criterion for all CIRM 2.0 programs.

Pursuant to this change, if CIRM were to determine, in its sole discretion, that the application includes a material misstatement or omission, CIRM would discontinue its review of the application and communicate its determination to the applicant, who would have the opportunity to

resubmit its application or explain why it has decided not to address CIRM's concerns. If the applicant were either to resubmit an application that satisfactorily addressed CIRM's concerns or satisfactorily explain why CIRM's determination was erroneous, review of the application or revised application would proceed. If the applicant were to elect not to resubmit the application or CIRM is not satisfied with the explanation or revised submission, the applicant would have the ability to appeal CIRM's eligibility determination to the GWG.

Requested Action:

Recommend Board approval of modifications to concept plans for CIRM 2.0 programs.