

### **Pre-Application Review Process for Basic Biology RFA**

The ICOC, at its most recent meeting, considered a proposal from CIRM staff to introduce a pre-application review process, on a trial basis, for use in the upcoming Basic Biology I & II and Disease Team RFAs. The ICOC approved the proposal, subject to receiving further information from staff about the criteria that would be used for pre-application review. ICOC members also had questions about plans for evaluating the trial and the review timeline for an RFA including pre-application review.

### **Current Process: Criteria for GWG Review of Grant Applications**

In 2005, the ICOC adopted general criteria for the Grants Working Group to use for scientific review of grant applications. The criteria were incorporated into the Grants Administration Policy, which the ICOC adopted in December 2006. When the scientist members of the GWG review applications, they are required to base their scores on these criteria:

1. ***Impact and Significance.*** Whether and to what extent the proposed research: addresses an important problem; significantly moves the field forward, either scientifically or medically; moves the research closer to therapy; and changes the thinking or experimental or medical practice in the field.
2. ***Quality of the Research Plan.*** Whether and to what extent: the proposed research is planned carefully to give a meaningful result; the possible difficulties are acknowledged, with alternative plans should the proposed strategy fail; and the timetable allows for achieving significant research or clinical results. Whether appropriate milestones are used to assess progress towards the aims and goals of the proposal.
3. ***Innovation.*** Whether and to what extent the research approach is original, breaks new ground, and brings novel ideas, technologies or strategies to bear on an important problem.
4. ***Feasibility.*** Whether and to what extent the aims of the research can be reasonably achieved and the investigator has access to appropriate technology to perform the research.
5. ***Investigators.*** Whether and to what extent the investigators have the training and experience to carry out the proposed project, including the investigators' record of achievement in the areas of pluripotent stem cell and progenitor cell biology, unless the research proposal is determined to be a vital research opportunity.

6. ***Collaboration.*** Whether and to what extent the proposal supports collaborative efforts that would enhance the quality or potential of the research.
7. ***Responsiveness to RFA.*** Whether and to what extent the proposed research project or activity adequately and appropriately addresses the goals and objectives presented in the RFA.
8. ***Eligibility for Federal Funding.*** Whether and to what extent the research is ineligible or unlikely to receive federal funding. If not, whether and to what extent the research is sufficiently compelling in that it presents “a vital research opportunity” that will materially aid the objectives of CIRM.

These standard criteria are employed for all RFAs. In order to focus reviewers on the goals of a specific RFA, CIRM’s science officers prepare guidelines for how to apply the standard criteria to concepts in that RFA. All applicants are aware of these specific criteria, which are shown in the RFA itself. As examples, we have attached excerpts from several recent RFAs.

**Proposal: Criteria for Review of Pre-Applications**

Pre-application review will focus on the essential aspects of the scientific proposal, without requiring Principal Investigators (PIs) to finalize or describe detailed research plans, budgets, collaborations or personnel. This review will consider a subset of the standard GWG criteria, tailored to the level of information we will seek in the pre-application:

1. ***Impact and Significance.*** Whether and to what extent the proposed research: addresses an important problem; significantly moves the field forward, either scientifically or medically; moves the research closer to therapy; and changes the thinking or experimental or medical practice in the field.
2. ***Innovation.*** Whether and to what extent the research approach is original, breaks new ground, and brings novel ideas, technologies or strategies to bear on an important problem.
3. ***Feasibility.*** Whether and to what extent the aims of the research can be reasonably achieved in the specified timeframe of the award.
4. ***Responsiveness to RFA.*** Whether and to what extent the proposed research project or activity adequately and appropriately addresses the goals and objectives presented in the RFA.

CIRM science staff and outside scientific specialists will apply these standard criteria. As with the criteria for GWG review of full applications, science officers will prepare guidelines that describe how these criteria apply to the concept for a specific RFA. These guidelines will be published as part of the RFA, so that PIs can address them in their pre-applications.

**Proposal: Process for Pre-Application Review**

The purpose of this process is to identify the proposals shown by the review criteria to most effectively advance the goals of the RFA and CIRM, and to invite those

investigators to prepare full, detailed applications. The other PIs will be deferred, with the opportunity to revise their pre-applications for submission when the initiative is repeated in re-release of a core RFA.<sup>1</sup> This pre-application review process reflects the goal of offering a set of standard RFAs on a recurring basis. At this time, staff do not propose to employ pre-application review for unique, specialized RFAs that are issued only once.

1. Pre-applications will be evaluated by Grants Working Group specialists (scientists and clinicians from universities and companies outside California) with expertise in the specific scientific areas of the proposal.
2. Specialists will be subject to the conflict of interest policy that applies to all members of the Grants Working Group.  
<<http://www.cirm.ca.gov/faq/pdf/GrantsWG.pdf>> Science officers are subject to the conflict of interest policy for CIRM employees.  
<<http://www.cirm.ca.gov/faq/pdf/employees.pdf>> Science officers participating in pre-application review will not discuss the RFA or the review process with PIs submitting pre-applications. All inquiries will be directed to the CIRM Review Office, whose scientific members will not participate in pre-application review. The Review Office will also handle conflict checks.
3. CIRM science officers will use the recommendations from the specialists together with their own assessments to identify the top 40-60 pre-applications.<sup>2</sup> Science officers will evaluate pre-applications using the same review criteria as those used by the specialists, as outlined above. All participating science officers will then meet to discuss the pre-applications.
4. Investigators whose proposals are shown by the review criteria to most effectively advance the goals of the RFA will be invited to submit full applications. The remainder will be deferred.

### **Timeline for Basic Biology Awards I**

last week of December 2008	RFA Posted
last week of January 2009	Pre-Applications due
last week of March 2009	Invitations and deferrals sent to applicants
last week of April 2009	Full Applications due
third week of June 2009	GWG review
third week of August 2009	Present recommendations to ICOC

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<sup>1</sup> As Dr. Grieshammer explained when she presented the Basic Biology concept proposal to the ICOC, the inaugural round for the Basic Biology core initiative will be split into two RFAs. PIs will be permitted to submit pre-applications for only one of this pair of RFAs.

<sup>2</sup> That target is intended to ensure that GWG members will be able to give careful attention to all of the applications they review. This target range is based on the anticipated complexity of applications for the Basic Biology grants, so the target may be different for other RFAs.

### **Evaluating the Effect of Pre-Application Review**

The Science Office is developing qualitative and quantitative measures to evaluate the effect that pre-application review has on the review process. These measures will consider some or all of the following:

- Number of new PIs who have not previously applied to CIRM.
- Views of PIs about the expanded number submitting proposals, and the use of a shorter pre-application.
- Views of ICOC members, GWG reviewers, science officers and other stakeholders, comparing the pool of full applications submitted to the GWG on this RFA with the application pools reviewed in prior RFAs.
- Analysis of scoring ranges and distributions.