

## **Key Questions from CIRM 2.0 Webinar**

### **We are located in California, but our partners are in other states. Are we eligible for all costs associated with the project?**

If the applicant is a California based organization (i.e., has >50% of its employees located and paid in the State of California and manages the award activities from the California location), then CIRM will cover Allowable Project Activities conducted in and outside California. “Allowable project activities” means those activities that are conducted in California, and for activities outside of California, those activities over which the California Organization exercises direction, supervision and control, including activities performed by a wholly owned subsidiary of the California Organization outside of California. It does not include activities undertaken by a separate organization outside of California that retains intellectual property or publication rights in connection with the performance of those activities, including a research collaboration in which the research is conducted outside of California.

Non-California organizations cannot use CIRM funds for any costs incurred outside California.

Both California and Non-California organizations are subject to the co-funding requirements specified in the Program Announcements. For a California based organization this means that the co-funding amount may contribute to costs both in and outside California. For a Non-California organization, the co-funding provided by the applicant contributes only to the costs incurred in California.

### **Do you have a pathway for Allograft Studies to receive funding?**

If the proposed allograft is dependent on the metabolic activity of a stem cell for its primary mechanism of action, then such a project is eligible for funding from CIRM. An allograft that meets this criterion, however, is not one that the FDA would consider a “361 allograft”, but instead a “351 allograft”, which is subject to the requirements of an IND and ultimately premarket approval through the BLA process before it’s allowed into the market. Therefore, an allograft that falls under the FDA’s designation of a “361 allograft” would not be eligible for CIRM funding.

### **How likely is CIRM to fund start-up companies?**

As with any applicant, it depends on the quality of your application and also on your ability to demonstrate solvency of your company.

### **What role is there for international collaborations with CIRM 2.0?**

With CIRM 2.0, we do not discriminate other than whether an applicant is in or outside California.

**Is CIRM finally ready to consider working with companies that have technologies that work?**

Yes, that's what CIRM is after. However, it all depends on demonstrating the value and quality of your technology in the application you submit to CIRM.

**Will CIRM fund technologies that enhance activity of stem cells to improve bone marrow transplants?**

Yes, this has generally been within scope of CIRM funding. Under the current Program Announcements, projects that involve hematopoietic stem cell transplantation are eligible. However, unmodified hematopoietic stem cells are eligible only if being developed as a novel method of addressing a rare or unmet need unlikely to receive funding from other sources.

**Will it be possible to submit to the current CIRM 2.0 RFAs applications that had been rejected by CIRM in the past?**

If the proposal meets all the eligibility requirements of the new Program Announcement then it may be submitted using the new application forms. However, if the proposal is not substantially better than what was previously submitted then it is unlikely to receive a favorable review.

**When do you anticipate accepting proposals for basic, translational, & discovery-based research?**

CIRM is committed to funding the entire continuum from early stage discovery research to clinical trials. Programs in discovery and translational research are under development and will begin in 2015.

**How many submissions can a PI have "active" or "in review" at one time?**

A PI can only have one application under consideration at one time. If you have more than one eligible project, you should pick the best one to submit to CIRM.

**Are private-public partnerships encouraged?**

Yes, CIRM encourages partnerships that will enhance the likelihood of getting a therapy to patients. For example, an academic institution that develops a technology for eventual clinical application will benefit greatly from partnering with a private entity that can commercialize and realize its potential.

**When you state that the applicant must be able to start within 45 days of the award, are you including IRB or SCRO approvals without contingencies? Usually institutions take 6 weeks-2 months to review and approve applications.**

If the proposed project plan includes initial start-up activities such as acquiring or finalizing IRB approval, we will consider these to be part of the project and therefore do not need to be completed within the 45 days. CIRM requires its Grantees to have protocol approvals in place before CIRM funds can be used for activities requiring such approvals.

**What is the “right” amount of funds to ask for to maximize our chances of being awarded a grant?**

CIRM is looking for proposals that demonstrate to CIRM that the applicant has a very good understanding of what it takes to conduct the proposed activities, such as a clinical trial, and knows the costs associated with these activities. Applications will undergo a budget review by external experts that will assess the proposed costs. If the proposed budget does not fall within a reasonable amount of established market rates, the application will not go forward to scientific review until the budget has been appropriately corrected and justified by the applicant.

**Will budget reviewers and/or scientific reviewers be named, or anonymous? To what extent will their comments be shared with applicants?**

CIRM intends to partner with at least two distinct CROs to conduct the budget review. Currently, Quintiles has joined with CIRM to develop the budget review process and serve as the initial budget review group. Scientific review is conducted by the CIRM Grants Working Group whose membership includes approximately 200 individuals appointed by our governing board and recognized for their expertise in areas ranging from stem cell research to clinical development and regulatory affairs. A roster of the GWG membership is available on our website at: [XXXXXX](#)

Following the budget and scientific review of each application, applicants will receive an overall score and a summary of key recommendations as well as key strengths and weaknesses of the proposed project.

**Is it possible to have other funding sources in addition to CIRM for the same clinical trial?**

Yes. Co-funding of the project can come from any source, but may not include “in-kind” services or similar types of support. Where co-funding is not specifically required (e.g., Phase 1 trial for academic applicant), co-funding is still encouraged and it demonstrates commitment from you and/or your partners to the project.