



Proposal for a Bridging Fund

The mission of the California Institute for Regenerative Medicine is to advance the development of therapies and cures to benefit patients. In order to accelerate the development of stem cell therapies and to implement the recommendation of the External Review Panel to “Pave a path from fundamental to translational research, translational medicine, product development and healthcare delivery” by a “Transition to a much more proactive strategy of funding that aligns CIRM’s peer review and other processes with its mandate of delivering new treatments to the clinic as articulated in CIRM’s mission and strategic goals” CIRM proposes creation of a Bridging Fund.

- **Objective:** The objective of the Bridging Fund is to provide supplemental funding for selected existing CIRM funded projects to enable uninterrupted funding of translational activities to occur until the next applicable RFA/review is offered, another funding source is identified or the results achieved during bridging funding do not support project continuation. Projects that are proposed for bridging funding under this program must be mission critical, competitive and in ‘good standing’ (meeting mutually agreed upon milestones and on track for planned outcome). Those projects that request bridging funding would need to address their funding strategy for continued development of the project after completion of bridging funding. If the funding strategy for further development includes submission of an application to CIRM, a Bridging Funding recipient would be required to submit an application to the next applicable CIRM RFA/GWG review but would not be required to participate in a pre-application/planning award process.
- **Eligibility:** Only active CIRM funded projects, previously reviewed by the Grants Working Group and approved by the ICOC, would be eligible for Bridging funding. Specifically, only the following translational and development projects would be eligible for Bridging funds:
 - Early Translational projects targeting a Development Candidate
 - Disease Team projects
 - Clinical Development Projects

Bridging funding may not be used for patient enrollment and treatment in a clinical trial that was not within the scope of the prior grant award.

- **Award:** The maximum Bridging funding per project is up to \$3 million for a period of up to 12 months. The type of award, grant or loan, is the same as that of the prior award that is to be supplemented by the bridging funding. Bridging supplemental project funding is approvable by the President. CIRM proposes a Bridging Fund of \$12 million, subject to replenishment upon approval

by the ICOC. CIRM will report to the ICOC on Bridging Fund disbursements when requesting replenishment or at least annually.

▪ **Implementation**

- Awardee to request of CIRM to be considered for bridging supplemental funding. Upon request, an internal staff recommendation is necessary to initiate the process for supplemental funding. Staff recommendation will be based on significance to mission, competitiveness, project performance against milestones and budget and timing relative to next RFA or evidence of timing of receipt of other funding.
- Following internal recommendation and receipt from the awardee of minimally, a description of the proposed work, a detailed budget and justification, agreed upon milestones and timeline, and funding strategy subsequent to bridging funding, the project will be reviewed by SVP, R&D, other internal staff, and external expert consultants (e.g. Clinical Development Advisors) as appropriate. The SVP, R&D and staff will advise the President who will make the bridging funding decision.
- As noted above, for projects that receive Bridging funding where the funding strategy for further development includes CIRM funding, such projects would be required to submit an application to the next applicable RFA/GWG review (but would not be required to undergo pre-application/planning award review)