



CALIFORNIA'S STEM CELL AGENCY

Funding Opportunity Concept Plan

EDUC2: Funding Opportunity for Bridges to Stem Cell Research and Therapy Awards - 2021 Relaunch

BACKGROUND

The mission of CIRM is to accelerate stem cell treatments to patients with unmet medical needs.

Under Proposition 71, CIRM ran a very successful Bridges to Stem Cell Research and Therapy Awards (Bridges) Training Program that has trained over 1500 undergraduates and graduate students to date, the majority of whom have obtained successful positions in academic or biotechnology laboratories, or have been accepted into PhD, MD or other professional degree programs. CIRM intends to launch a revised version of the Bridges Program under Proposition 14 incorporating changes that will a) better serve a diverse cohort of trainees to succeed in the fast-paced real-world environment of stem cell, gene therapy and

regenerative medicine research, development and commercialization; and b) broaden the extent and geographic reach of the program to better serve communities throughout California. This concept plan describes the first call under this relaunch.

OBJECTIVE

The overall objective of the Bridges Training Program is to produce well-trained, committed and “ready-to-start” laboratory professionals for both academia and industry to accelerate the discovery, development and delivery of stem cell, gene therapy and related technologies for improving human health. Specific objectives are to:

- Enable training that will significantly enhance the technical skills, knowledge, and experience of a diverse cohort of undergraduate and master’s level students from California’s state universities and community colleges
- Foster a commitment among trainees to the goal of accelerating the delivery of stem cell-based and gene therapy treatments to patients with unmet needs
- Broaden the participation in regenerative medicine of individuals representing the diversity of California’s population
- Create a cadre of technically skilled, stem cell ambassadors with an awareness and appreciation of inequities that impact development of therapies for all
- Promote trainees’ efficient transition to careers in the life sciences and regenerative medicine by directly linking educational programs to organizations and companies focused on stem cell and gene therapy research and related disciplines

AWARD INFORMATION

How is the Bridges Training Program Structured?

Each Bridges Training Program will be led by a qualified Program Director based at the awardee, “home” institution, which will be responsible for the management and coordination of all activities supported by the program as well as outreach to and the recruitment of diverse and qualified students. The Bridges program must be integrated into a degree or certificate program at the home institution. Research internships, which are a central component of these programs, will

take place at partner or “host” institutions, which are biotech or pharmaceutical companies, research universities or institutes.

What activities will CIRM fund?

CIRM funds will support the following activities under this opportunity:

- Trainee Expenses including:
 - Stipends during internship period
 - Tuition and fees during internship period
 - Research-related funds
 - Techniques course fees
 - Travel expenses for program-related travel

- Program Expenses
 - Support for activities to develop and administer the Bridges Program
 - Support for Patient and Healthcare Engagement activities
 - Support for Educational Enhancement activities
 - Support for Community Education and Outreach activities
 - Administrative support salaries

What is the award amount and duration?

CIRM requests \$65 million to support up to 18 awards for a duration of five years. Each award will provide direct project costs of up to \$3.32M plus 10% indirect costs on eligible expenses, for a total of up to five years. Each award will support up to 10 trainees per year.

How will funds be awarded?

Awards will be made in the form of a grant. CIRM will disburse funds pursuant to a Notice of Award. CIRM will only disburse trainee internship funds upon submission of a signed Intern Appointment Form for an eligible trainee.

ELIGIBILITY

What types of projects are eligible for funding?

(1) To be eligible, the proposed program must include the following components:

- a. Patient (or Patient Advocate) and Healthcare Engagement Activities designed to engage trainees with patients/patient advocates and provide insights into the challenges of developing new cell therapies and drugs. One component of these activities will be a required course on the regulatory pathway and therapy development process.
- b. Internships at host laboratories, where trainees participate in hands-on, regenerative medicine-related research involving stem cells, gene therapy and/or other critical research relevant to understanding or treating a human condition or disease.
- c. Educational Enhancement Activities that prepare students for internship research and augment the internship experience.
- d. Community Outreach and Education Activities in which trainees participate in educating diverse California communities about stem cells, gene therapy and regenerative medicine, and gain awareness of socio-economic issues and disparities around health care and access.
- e. Advanced Cell Culture Techniques Course that will provide all trainees with hands-on training in methods for working with human stem cells and/or other therapeutically relevant human cell types.
- f. Advising and Career Development Activities to equip and assist trainees and Bridges Training Program alumni in advancing to jobs and further opportunities in regenerative medicine for themselves and others.
- g. A Diversity, Equity and Inclusion Plan that addresses:
 - How the implementation of the Bridges Training Program will incorporate diverse and inclusive perspectives and experience in the development and implementation of the program.

- How the grantee institution will conduct outreach and recruit qualified persons for training who are representative of the diverse California population, including, for example, those from different socio-economic backgrounds and those who are the first in their family to attend college.

(2) Must be ready to initiate work on the funded project within 60 days of approval

Given the urgency of CIRM’s mission, all approved awardees must initiate work on the funded project within 60 days of approval and authorization for funding by the Application Review Subcommittee of the Independent Citizens’ Oversight Committee or upon end date of a preceding Bridges grant.

(3) Application must be accurate and complete

All required components of the application must be completed and may not contain false or inaccurate information.

(4) Applicant must be in “good standing”

In order to be eligible to apply for CIRM funding, an applicant must certify that it is in good standing, as follows:

- a. Non-Profit (in existence for less than five years):
 - (i) The applicant’s Chief Executive Officer, Chief Financial Officer, and Program Director must not have been convicted of, or currently under investigation for, crimes involving fraud/misappropriation; and
 - (ii) The applicant must have accounting systems in place that are capable of tracking CIRM funds.
- b. The Program Director or key personnel must not be currently under investigation for research misconduct by the applicant institution or a funding agency, and must not be currently debarred by HHS Office of Research Integrity.

Who can apply?

Applicant institutions must be California public universities or colleges or private, non-profit academic institutions, which did not receive a CIRM-funded Major Facility or Shared Research Laboratory Award under Proposition 71. Each eligible applicant institution may submit only a single application.

Who can serve as the Program Director (PD)?

To be eligible, the PD must satisfy the following requirements:

- Must be a full-time faculty member of the applicant organization or be accountable for the conduct of the proposed project to the applicant organization through a formal contract
- Must commit a minimum of 5% effort to the program.
- Must be authorized by the applicant organization to assume the responsibilities of the PD
- Must not currently have another application pending review or approval under this funding opportunity

SCHEDULE AND DEADLINES

Applications Due	2:00 pm (PDT/PST) on April 22, 2021
Grants Working Group (GWG) Review	Approximately 60 days post submission
ICOC Review and Approval	Approximately 90 days post submission
Award Start	Within 60 days of award approval (i.e., approximately 130 days post submission) or end of preceding Bridges grant