



Funding Opportunity Concept Plan

EDUC4: Funding Opportunity for “CIRM Scholar” Research Training Program Awards (2021 Relaunch)

BACKGROUND

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

Keeping pace with the growing demand for regenerative medicine solutions in California will require the scientific training of individuals at all levels to provide a continuing supply of scientists with the knowledge and skill to lead effective research programs. The CIRM Research Training Program was developed to foster and enhance the research experience of basic and clinical scientists during the doctoral and immediate postdoctoral stages of their career.

Between 2006 and 2017, CIRM awarded Research Training grants to 18 California non-profit, academic institutions to provide critical skill sets to future scientific leaders in the stem cell community. Beyond 2020, CIRM wishes to renew its support of training programs at the pre-doctoral, postdoctoral and clinical levels by modernizing and adapting the framework of the Training Grant Program to better

suit the demands and challenges of the present day. These include a recognition that stem cell, gene therapy and related research are poised to achieve broader real-world use at a time when the ability to conduct such research and training is reeling from the COVID-19 pandemic. Furthermore, the COVID-19 pandemic and the move toward new stem cell and gene therapy treatments has heightened a keen appreciation of and sensitivity to the needs of all communities who have unmet needs, particularly those that have been traditionally under-represented in the sciences, and those who have had disproportionate access to the benefits afforded by scientific innovation. CIRM seeks to address all of these challenges in this relaunch.

OBJECTIVE

The objectives of the Research Training Program are to:

- Enable training programs that create future leaders in the stem cell, gene therapy and regenerative medicine fields.
- Foster a commitment among trainees to the goal of accelerating the delivery of treatments to patients with unmet needs.
- Broaden the participation in regenerative medicine of individuals representing the diversity of California's population.
- Provide research training in stem cell, gene therapy and related disciplines to a diverse cadre of individuals drawn from a wide variety of scientific backgrounds, including, but not limited to fundamental biology (e.g., developmental biology, neuroscience, molecular biology), engineering (e.g., bioengineering, chemical engineering, mechanical engineering, electrical engineering/computer science), clinical programs (e.g., medicine, surgery, neurology, cardiology), and other relevant areas (e.g., manufacturing process development, data science, regulatory science, bioethics, etc.).
- Promote interactions among trainees from different fields, especially those trained in basic sciences, engineering, translational research and clinical medicine.
- Prepare a workforce of skilled, stem cell ambassadors with an awareness and appreciation of inequities that impact development of therapies for all.

AWARD INFORMATION

How is the Research Training Program Structured?

Each Research Training Program award will be led by a qualified Program

Director who will be responsible for the management and coordination of all activities supported by the program as well as the appointment of qualified trainees. Each Research Training Program award will provide a single integrated program of training that is appropriate for the educational levels of its trainees and the expertise of its faculty, which may be broadened by the inclusion of additional faculty through partnerships with other qualified organizations, if desired.

What activities will CIRM fund?

CIRM funds will support the following activities under this opportunity:

- Stipends (\$36,000-\$94,000¹)
- Research and travel allowance (\$6,000-\$12,000²)
- Tuition and fees for student trainees
- Health insurance for post-doctoral/clinical trainees

- Program Expenses
 - Support for activities to develop and administer the Training Grant Program
 - Course operations, seminars, etc.
 - Support for Patient Engagement, Community Outreach activities
 - Administrative support salaries

What is the award amount and duration?

CIRM requests \$100 million to support up to 20 awards of a maximum total award amount of \$5 million per award for five years, to support comprehensive training for individuals from one or more following categories:

- **Pre-doctoral graduate students:** Trainees in this category should be supported for a minimum period of 3 years
- **Post-doctoral fellows:** Trainees in this category should be supported for a minimum period of 2 years
- **Clinical fellows:** Trainees in this category should be supported for a minimum period of 2 years

¹ Stipend allowances vary by training level.

² Research/travel allowances vary by training level.

Institutions will propose the allocation of funds to one, two or all training categories, subject to institutional capabilities and CIRM requirements.

The indirect cost rate will be set at 10%.

How will funds be awarded?

All applications for the Research Training Program will be considered in a single review cycle. 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 stipends funds upon submission of a signed Trainee 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. Stem Cell/Regenerative Medicine Relevant Coursework: All training programs must offer 1) one or more classes in stem cell/regenerative medicine and its application to health and disease; 2) a required course in the social, legal and ethical implications of stem cell/regenerative medicine research; and 3) a specialized course in another area with high relevance to the advancement of regenerative medicine approaches, such as regulatory science, cell manufacturing process development, data science, biostatistics, business of drug development, healthcare delivery/healthcare policy, etc.
- b. Patient Engagement and Community Outreach Activities to raise awareness of patient needs and to foster sensitivity around issues of access and inclusion that differentially impact communities in California, particularly those that are disadvantaged by socio-economic status and/or other factors.
- c. Mentored Laboratory Research in stem cell, gene therapy and/or regenerative medicine-related research or key supportive disciplines. Trainees must receive sustained support for research leading towards their degree, faculty position or career advancement.

d. A Diversity, Equity and Inclusion Plan that addresses

- How the implementation of the Training Program will incorporate diverse and inclusive perspectives and experience in the development and implementation of the program
- How the 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.

(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?

CIRM Research Training Program awards will be available to public colleges and universities and to non-profit academic and research institutions in California.

Institutions wishing to include training of pre-doctoral students must have an accredited graduate program in biology or biomedical sciences. CIRM will accept only one application per institution.

Who can serve as the Program Director (PD)?

To be eligible, the Program Director must satisfy the following requirements:

- Program Directors must have a Ph.D., M.D., or equivalent doctoral degree and hold, at a minimum, a faculty-level position at the applicant institution.
- Must be authorized by the applicant organization to assume the responsibilities of the Program Director
- 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 June 10, 2021
Grants Working Group (GWG) Review	Approximately 60 days post submission
ICOC Review and Approval	Approximately 90 days post submission
Award Start	Must start within 60 days of award approval (i.e., approximately 130 days post submission)