

Funding Opportunity Concept Plan

EDUC5: Funding Opportunity for Creating Opportunities through Mentorship and Partnership Across Stem Cell Science (COMPASS)

BACKGROUND

CIRM's mission is to accelerate world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world.

Rapid advances and technological innovations in stem cell biology and gene therapy have led to increased opportunities and demands for regenerative medicine solutions that can address unmet medical needs. At the same time, recent events including the COVID19 pandemic have made it clear that the benefits of scientific discovery are not always accessible or even applicable to communities that most need them. CIRM is committed to tackling these challenges by creating a diverse and dedicated workforce that can meet the technical demands of translating novel treatment paradigms to reality, while engendering the necessary appreciation for and sensitivity to the perspectives and participation of communities that have been historically under-represented in the biomedical sciences.

To date, CIRM has supported three major and complementary training programs to develop a pipeline of qualified workers that can contribute to its mission: The Research Training (or CIRM Scholar Program), which equips predoctoral, postdoctoral and clinical fellows to become future leaders and innovators in the regenerative medicine field; the Bridges Program, which connects undergraduate and masters level students in state universities and community colleges to world-

class research training opportunities in the biotechnology and academic sectors; and the SPARK program, which introduces and inspires high school students to consider careers in regenerative medicine through summer laboratory internships. Despite these efforts, there remains a critical need for skilled research practitioners who understand and contribute at all levels in the translation of science to medicine-from bench scientist to thought leader- for which foundational research training is a necessity and can also serve as a gateway to leadership roles. CIRM intends to address this gap by developing a new training program that seeks out and fosters untapped talent amongst diverse undergraduate students in California universities and colleges who are open to a variety of career possibilities in regenerative medicine- students whose innate talents and creativity may go unrecognized due to a lack of opportunity or due to circumstances beyond their control, yet whose perspectives and experiences are critical to ensuring the promise of regenerative medicine will be afforded to all who would need it.

The COMPASS Training program will target a unique niche that is unlikely to receive timely or sufficient funding from other sources such as NIH. While undergraduate research training programs are not unique, the majority are geared towards students with predetermined aspirations towards graduate school, medical school or a specific discipline. Furthermore, most programs, even those focused on supporting students representing underserved communities, use selection criteria to prioritize acceptance (e.g., grade point average, class rank, SAT scores, etc.) that miss this promising student niche. The COMPASS Program will support the development and management of novel and alternative strategies to recognize and foster talent that can lead to new and valuable perspectives that are specific to the challenges of regenerative medicine, and that will create new paths to careers that are not always apparent to students in the academic, undergraduate environment. This new program will be complementary to but not competing with CIRM's Bridges program, which serves a different but equally important population of trainees, nor is it likely to compete for the same pools of students that would be most likely to receive support through the major NIH initiatives such as MARC and RISE.

OBJECTIVE

The objective of the COMPASS Training Program is to prepare a diverse cadre of undergraduate students for careers in regenerative medicine through the creation of novel recruitment and support mechanisms that identify and foster untapped talent within populations that are historically under-represented in the biomedical sciences, and by combining hands-on research opportunities with strategic and structured mentorship experiences to enhance transition of students to successful careers. This program will afford interested and open-minded students the opportunity to explore a variety of ways in which their research skills can be applied towards improving human health through career paths in both the public and private sectors. A parallel objective is to foster greater awareness and appreciation of diversity, equity and inclusion in trainees, mentors, and other program participants.

Specifically, this program will:

- Create novel mechanisms to identify and cultivate untapped talent amongst undergraduate populations representing the depth and diversity of California's population
- Provide foundational knowledge in stem cell/regenerative medicine and related science through coursework and hands-on research internships in cutting edge regenerative medicine laboratories and/or biotech companies
- Create Mentorship Programs to foster an environment of inclusivity and awareness, to guide program participants through their educational experience, and to facilitate their progression to successful and rewarding careers in regenerative medicine
- Produce a cadre of stem cell scientists and regenerative medicine practitioners with an awareness and appreciation of inequities that impact development of therapies for all.

AWARD INFORMATION

How is the Program Structured?

Each COMPASS Program will be led by a team that includes a qualified Program Director, who will oversee all activities supported by the program; a Mentorship Facilitator (MENFAC), who will design and execute a Mentorship Program to ensure all trainees receive customized, appropriate and meaningful mentorship throughout their time in the program; and a Diversity and Outreach Coordinator (DIVOC), who will strategize and evaluate efforts to recruit diverse and qualified students from under-represented and disadvantaged populations and bring value to CIRM's mission. The COMPASS Program must be integrated within a bachelor's degree program at the applicant institution and provide resources and opportunities for students to participate in hands-on research in stem cell biology, gene therapy, or related regenerative medicine activities, either at the applicant institution or with a partnering "host" institution, which may be biotech or pharmaceutical companies, research universities or institutes. Trainees, including those who may be recent transfers from community colleges, should be supported as "COMPASS Scholars" for two to three years while they complete required coursework and participate in research internships and Mentorship Program; they will continue to have access to the Mentorship Program to the time of graduation and will be encouraged to participate further as peer mentors.

What activities will CIRM fund?

CIRM funds will support the following activities under this opportunity:

- Trainee Related Expenses Including:
 - Stipends during appointment (academic year) and laboratory internship (summer or other)
 - Tuition and fees for core program requirements
 - Research related funds for laboratory internship period
 - Program-related travel expenses
 - Accessibility Funds (conditional)
- Program Related Expenses Including:
 - Developing and administering a Mentoring Program
 - Developing and administering an Adaptive Outreach and Recruitment Plan
 - Support for Patient Engagement and Community Outreach activities
 - Administrative support salaries and mentorship incentives
 - Funds for general education course/workshop development

What is the award amount and duration?

CIRM requests \$58.3 million to support up to 20 awards of a maximum of \$ 2.91 million per award, for five years. Each award will provide direct project costs of up to \$2.7 million as detailed below, plus 10% indirect costs on eligible expenses for the five-year period.

- **1. Trainee Funds** The award will support undergraduate trainees for two to three appointment periods (years), at the following amounts per trainee:
 - a) Trainee Stipends Up to \$18,000 per year comprising
 - Up to \$9000 (\$1000/month) during academic year and Mentor Program activities
 - Up to \$9000 (\$3000/month) for laboratory research internship. The research internship can take place over a summer, an academic quarter, or may be distributed on a part time basis over several months to a year, as is most suitable to the program and/or individual trainee.
 - b) Tuition and Fees up to 100% of the first \$3,000 incurred Core Program Requirement courses, and 60% thereafter up to a maximum of \$9600 (to the institution)

- c) Research Related Funds up to \$2,200 for research project costs to the internship host laboratory
- d) Program Related Travel expenses up to \$1000, including attendance at a CIRM sponsored conference

2. Program Administration Funds

Up to \$200,000/year may be requested to develop and administer the program including the Adaptive Outreach and Recruitment Plan, the Mentorship Program and associated activities, key personnel and administrative support salaries, activities focused on patient engagement and community outreach, and developing a general education course or workshop on Diversity in Science. Adequate justification for all Program Administration expenses must be provided.

3. Accessibility Fund

Up to \$30,000/year (based on 10 trainees, \$3000/year) to be used conditionally, at Program Director's discretion, to enable a trainee to join or stay in program if a specific hardship arises and can be addressed.

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. The first payment will be issued upon initiation of an award and continued funding will be contingent upon timely progress, as outlined in the project milestones and timeline established under the Notice of Award. In addition, CIRM will only disburse stipend-related funds upon submission of a signed 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. Foundational coursework in stem cell/regenerative medicine that is integrated within a trainee's bachelor's degree curriculum. Foundational coursework must include some introduction to:
 - FAIR principles of data sharing
 - Good research habits (planning, documentation, time management)

- Principles of translational research
- Specialized options of value, for example computational biology, bioengineering, data science or analysis, statistics, etc.
- b. A structured **Mentoring Program**, led by Mentorship Facilitator who will identify and train a small team of individual(s) including external advisors that will serve as role models for students, and who will bring culturally aware knowledge and perspectives representing the targeted student groups that may not be present in the resident faculty of the academic institution. The Mentoring Program must include:
 - Individual development plans for students
 - Formal mentor training for research advisors, including implicit bias training and access to any institutional courses or resources relating to promoting DEI in the scientific and broader community
 - Development of mentoring agreements between students and research mentors, including preparation and presentation of a culminating Capstone Project (see below)
 - Cohort-wide activities to guide personal and professional growth such as life skills workshops, resume/interview workshops, and networking events
 - Activities to develop soft skills such as presentation and scientific writing
 - Career counseling and introduction to diverse opportunities for applying regenerative medicine skillsets in the workforce such as manufacturing, quality control and assurance, regulatory affairs, entrepreneurship and business development, scientific communications, etc.
 - Sharing of Mentorship Program approaches and outcomes within and outside of the institution (applicable to other education programs)
- c. An Adaptive Outreach and Recruitment Plan (AORP), to identify and foster talent within students that may otherwise go unrecognized, and that is targeted to students who are open to and interested in variety of alternative career possibilities in regenerative medicine besides graduate or medical school. The AORP will be developed and executed by a dedicated Diversity and Outreach Coordinator and must include:
 - Defined goals and expected outcomes of the AORP and COMPASS Program
 - Novel approaches to identify and select scientifically talented students in lieu of typical practices that have relied on highest SAT scores, grades, educational pedigree, etc.
 - Regularly scheduled assessment and analysis of disparities within the applicant institution's STEM programs
 - Adaptive strategies to address program-specific disparities in representation of socioeconomically disadvantaged groups, first

- generation college students and/or other underserved populations through increased outreach and other targeted approaches
- Regularly scheduled assessment and analysis of the success of AORP strategies in meeting the goals and expected outcomes of the program, including consultation with members of underrepresented communities (Advisory Committee) to gain perspective and insight on outreach and recruitment strategies
- d. Laboratory Research Internships 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. Internships will take place under the direction of a laboratory mentor within the applicant institution or at a partnering, host institution and culminate in a poster presentation at a CIRM-hosted event. Research internships must be the equivalent of 2-3 months full time work and can take place over the summer or can be distributed as part time effort over an extended or different period as suits program and individual.
- e. A Capstone Project to be developed under the guidance of mentor(s), highlighting training outcomes including any co-authorship of publications as part of the research team.
- f. 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
- g. An Alumni Tracking and Engagement Plan to enable annual assessment and reporting on post-graduate employment positions taken by program alumni, and to encourage their continued participation in the Mentorship Program to inspire and motivate future COMPASS Scholars
- h. A Diversity, Equity and Inclusion Plan that addresses:
 - How the COMPASS Program will promote diversity, equity, and inclusion in the development and implementation of the program;
 - What the applicant institution has done previously to support DEI;
 - How the applicant team will include perspectives from communities that are systematically underrepresented in STEM to inform recruitment and outreach strategy (Advisory Committee);
 - How the program will provide trainees with access to coursework and resources within their institution that relate to promoting DEI in scientific research and in the broader community
- (2) Must be ready to initiate work on the funded project within 90 days of approval

Given the urgency of CIRM's mission, all approved awardees must initiate work on the funded project within 90 days of approval and authorization for funding by the Application Review Subcommittee of the Independent Citizens' Oversight Committee.

(3) Must include a Mentorship Facilitator

The project team must include a Mentorship Facilitator with experience in developing and executing mentorship programs, knowledge and skill in working with people from targeted underrepresented populations, and who able to devote at least 10% percent effort to the program.

(4) Must include a Diversity and Outreach Coordinator

The project team must include a Diversity and Outreach Coordinator who is knowledgeable about issues of diversity, equity and inclusion in an academic environment, who has appropriate qualifications to design and execute effective outreach to persons from targeted, underrepresented populations, and who is able to devote at least 10% percent effort to the program.

(5) Co-funding is not required

However, if the project requires funding over and above that which CIRM provides, documentation demonstrating the commitment of funds to cover the proposed co-funding amount must be provided at the time of application submission (e.g., copy of executed term sheet showing amount of co-funding, conditions, and source).

(6) Application must be accurate and complete

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

(7) 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 Principal Investigator 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 and 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 and have an accredited bachelor's degree program in biology, bioengineering, biomedical sciences, or other STEM disciplines relevant to regenerative medicine.

Applicant institutions intending to host research internships internally must include participating faculty with federally or CIRM supported research programs in regenerative medicine-related disciplines. Applicant institutions without this necessary research infrastructure may partner with another organization, such as a research university or institute or appropriate biotechnology/pharmaceutical company, to provide appropriate internship opportunities.

Applicant institutions that currently have an active CIRM Bridges Award that supports undergraduate level students must clearly differentiate between the two programs to be eligible. Applicants will be expected to outline differences in program goals and targeted student population, as well as demonstrate the capacity of the institution to recruit and support both programs.

CIRM will accept only one application per institution.

Who can serve as the Program Director (PD)?

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

- Must be an employee of the applicant organization or be accountable for the conduct of the proposed project to the applicant organization through a formal contract.
- Must commit at least 5% effort to working on the project. Any effort for which salary from CIRM is claimed must be expended in California.
- Must be authorized by the applicant organization to assume the responsibilities of the PD.
- Must <u>not</u> currently have another application pending review or approval under this funding opportunity.
- Must <u>not</u> currently have another application that is substantially similar or has overlapping activities pending review or approval under any CIRM opportunity.

SCHEDULE AND DEADLINES

Applications Due	May 2022
Grants Working Group (GWG) Review	Approximately 60 days post submission
ICOC Review and Approval	Approximately 90 days post submission
Award Start	Must start within 90 days of award approval (i.e., approximately 180 days post submission)