

Funding Opportunity For “CIRM Scholar” Research Training Program Awards

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REQUEST FOR APPLICATIONS
04.01.21



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Objective

The mission of California Institute for Regenerative Medicine (CIRM) is to accelerate stem cell treatments to patients with unmet medical needs.

The overall objective of the CIRM Research Training Program is foster and enhance the research experience of basic and clinical scientists during the doctoral and immediate postdoctoral stages of their career. Specific objectives 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.

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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 is the award amount and duration?

The CIRM Governing Board has allocated \$100 million to support up to 20 awards of a maximum total award amount of \$5 million each (including indirect costs) and a project period of five years. The indirect cost rate will be set at 10%. Awards will support comprehensive training for individuals from one or more following categories:

- **Predoctoral graduate students:** Trainees in this category should be supported for a minimum period of 3 years
- **Postdoctoral trainees:** Trainees in this category should be supported for a minimum period of 2 years
- **Clinical trainees:** Trainees in this category should be supported for a minimum period of 2 years

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 funds upon submission of a signed Trainee Appointment Form for an eligible trainee.

What activities will CIRM fund?

1. Trainee Funds

The award will provide up to the following amounts per trainee per year:

- a. Stipends – annual amounts based on the level of training.
 - i. Predoctoral - \$36,000
 - ii. Postdoctoral - \$51,000 to \$74,000 depending on years of experience
 - iii. Clinical - \$74,000 to \$94,000 depending on years of experience
- b. Tuition and fees – up to 100% of the first \$4,500 incurred for annual Tuition and Fees and 60% thereafter up to a maximum of \$16,000 for predoctoral trainees to cover enrollment in their institutional degree program.



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- c. Research and travel allowance – up to \$6000 (or \$12,000 if postdoctoral or clinical level) for annual research supplies, travel, books.
- d. Health insurance – up to \$5,000 for postdoctoral and up to \$12,000 for clinical trainees annually

2. Program Administration Funds

Up to \$69,000 per year may be requested to develop and administer the required training activities. Funds may be used for administrative support salaries, planning and implementing activities focused on patient and healthcare engagement, community outreach, administrative support salaries, course operations and delivery, or seminars. Up to \$17,250 may be requested for salary support for the Program Director. Adequate justification for all Program Administration expenses must be provided.

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 the following:
 - One or more classes in stem cell/regenerative medicine and its application to health and disease
 - A required course in the social, legal and ethical implications of stem cell/regenerative medicine research
 - 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 Research Training Program will promote diversity, equity, and inclusion 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; and
- What the applicant institution has done previously to support DEI.

See additional details on DEI Plan requirements on page 9 in the section, “What is required to prepare a complete application?”

(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 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?

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 predoctoral 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 PD 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	June 10, 2021, 2:00pm Pacific Time
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 150 days post submission)

Application Review Information

What is the process for evaluating an application?

Eligibility Review

CIRM will assess whether the applicant and proposed program meets eligibility requirements under this RFA. If CIRM determines, in its sole discretion, that an applicant or proposed program does not meet the eligibility requirements, CIRM will notify the applicant of its decision, and the application will not be reviewed.

Scientific Review

The scientific and educational merit of each application will be assessed by the CIRM Grants Working Group (GWG), which is composed of fifteen subject matter experts from outside California, seven patient advocate members of the Independent Citizens Oversight Committee (ICOC), and the Chair of the ICOC. The list of scientific members who may participate in the GWG review can be found at http://www.cirm.ca.gov/WorkingGroup_GrantsReview. The composition of the ICOC can be viewed at <http://www.cirm.ca.gov/GoverningBoard>.

The fifteen participating scientists on the GWG will evaluate the applications and score them according to scientific and technical merit, applying the review criteria described below. The patient advocate members of the GWG will score the applications specifically on the Diversity, Equity and Inclusion Plan and the full GWG will make funding recommendations to the ICOC's Application Review Subcommittee.

The ICOC's Application Review Subcommittee will make final funding decisions giving consideration to the GWG recommendations and any CIRM team recommendations.



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Confidentiality

CIRM's confidentiality and conflict screening rules apply to everyone who will have access to applications or who will attend any review meeting in which confidential information is discussed, including but not limited to CIRM team members, reviewers and members of the ICOC. (Per Gov. Code §6254.5(e) non-public records may be disclosed to government agencies under confidentiality agreements.)

How will the educational and technical merit of an application be evaluated?

Scientific members of the GWG will evaluate and score applications based on the following key criteria:

1. Does the proposed program hold the necessary significance and potential for impact?

Is the proposed training program likely to have a meaningful, positive impact on trainees' career development in stem cell science or gene therapy and awareness of therapy development and patient needs? Is the program likely to foster a commitment among trainees to the CIRM Mission of accelerating the delivery of stem cell-based treatments to patients with unmet medical needs? Is the program likely to impact trainees representing the broad diversity of California's population?

2. Is the training program well planned and designed?

Is the training program appropriately planned and designed to provide all trainees a quality, first-hand experience in stem/progenitor cells, gene therapy and/or other critical laboratory research relevant to understanding or treating a human condition? Does the program propose suitable coursework from qualified instructors to create a unified experience? Are there robust plans in place to support all required core training activities including patient/healthcare engagement and community outreach? Does the program provide a suitable mentoring and career development plan for all trainees and alumni that enables career advancement? Have adequate mechanisms and procedures been established for tracking trainee progress after completing the program? Does the program propose a well-considered diversity, equity and inclusion plan?

3. Is the proposed program practical and achievable?

Does the program have access to all the necessary resources to implement and carry out the proposed training program, including personnel, key partnerships, and the requisite infrastructure for research training in the areas of stem cell research, gene therapy and regenerative medicine? Is the program director (and leadership team if applicable) appropriately qualified to manage and lead the training program? Does the institutional commitment and track record support achievement of program objectives, including the ability to recruit and train the proposed numbers of trainees at the proposed level of training? Are appropriate mechanisms established for the recruitment of qualified students with diverse backgrounds?



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Application Components and Submission

How does one apply?

Applications must be completed online using the CIRM Grants Management Portal at <https://grants.cirm.ca.gov>. Any prospective Program Director (PD) must create a login in the system to access application materials and apply. Applications are available in the system only to the PD. A PD may submit only a single application in response to this RFA.

Applications are due by 2:00 PM (Pacific Time) on June 10, 2021.

What is required to prepare a complete application?

The Grants Management Portal provides instructions for completing all the necessary components and submitting a final application. The application is designed to collect information necessary to appropriately evaluate the proposal and for CIRM to rapidly initiate an award if approved for funding. Applicants are required to indicate key personnel involved in the program, describe how the program will address the RFA objectives, provide a detailed plan of proposed activities, summarize trainee lab opportunities and include letters confirming support and commitment of the applicant institution and any partnering organizations.

The main body of the proposal contains the following sections:

- 1. Program Summary and Overall Program Design:** Description of the proposed program of training including the level of training, the numbers of trainees, the scientific curriculum, the spectrum of scientific disciplines or backgrounds from which trainees may be drawn, and the strengths of the institution's stem cell research and/or regenerative medicine programs.
- 2. Stem Cell/Regenerative Medicine Research Expertise:** Description of how the strengths of the institution's stem cell, regenerative medicine and other relevant research programs will contribute to the training of the scientists at each of the trainee levels to be offered under the proposed program.
- 3. Prior Program Track Record and Outcomes:** Description of prior CIRM Research Training Programs or other similar programs including quantitative information about program outcomes.
- 4. Trainee Selection and Laboratory Placement:** Description of how trainees will be recruited and selected for the program and how trainees will be placed in mentored labs.
- 5. Patient and Healthcare Engagement Activities:** Description of planned activities including specific details about scope and duration of activities and nature of trainee involvement.
- 6. Community Outreach and Education Activities:** Description of activities focused on educating diverse California communities and groups about stem cell biology and regenerative medicine.
- 7. Coursework:** Description of required coursework in 1) stem cell/regenerative medicine and its application to health and disease; 2) the ethical, legal and social implications of stem cell research; and 3) a specialized course in another subject with high relevance to the advancement of regenerative medicine approaches.



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8. Mentoring, Advising and Trainee Assessment: Description of how trainees and alumni will be mentored, advised and assessed for progress.

9. Program Leadership and Administration: Summary of the program leadership including qualifications of the Program Director as well as any key members of the leadership team (e.g., program coordinator)

10. Institutional Resources and Environment: Provide a description of the facilities and environment in which the training activities will be done, and the resources available for training in stem cell/regenerative medicine research.

11. Diversity, Equity and Inclusion Plan: A description that addresses the following elements.

- How the Research Training Program will promote diversity, equity, and inclusion 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, trainees who: (a) grew up in low-income families or come from socioeconomically disadvantaged communities; (b) are the first in their family to attend college; or (c) have overcome educational, economic, physical (e.g., disability), or other barriers to opportunities; and
- What the applicant institution has done previously to support DEI, including:
 - (a) how the applicant institution has demonstrated awareness of inequities and challenges faced by traditionally underrepresented communities;
 - (b) the applicant institution's demonstrated commitment to tangibly promote a culture where diversity, equity, and inclusion are valued; and
 - (c) the applicant institution's track record of supporting activities that reduce barriers in research for traditionally underrepresented communities, including in prior CIRM-funded training programs.

Because CIRM is prohibited from taking race, ethnicity, national origin and gender into account in making grant decisions, applicants should refrain from focusing exclusively on race, ethnicity, national origin, or gender in describing their program or DEI plan. Applications that respond to this section solely by addressing the racial, ethnic, gender, or national origin of their research program or their DEI plan will not be scored in this category.

Who are Key Personnel?

In the application, we ask you to identify by name pertinent Key Personnel and their specific roles in the program. Key Personnel include the Program Director and any key administrative personnel. Do not include prospective trainee mentors or advisory committee members in this section.

What should one know before preparing the budget?

All budgetary requests must be indicated on the online application form. Limits for each budget category are indicated above (Award Information: What Activities Will CIRM Fund?) and must be observed. Budget justification for "Program Administration Funds" should provide sufficient detail to allow evaluation of the appropriateness of the costs in relation to the activities proposed. Budget justification for "Trainee Funds"



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is not required; however number and type of trainee positions should be justified in the "Program Summary and Overall Program Design" section of the proposal.

How much can an applicant claim for indirect costs?

Indirect costs will be limited to 10% of the total direct costs (Trainee Funds and Program Funds) less the costs for tuition and fees. For this program, CIRM will not allow the applicant institution to incur additional Indirect Costs on any subcontract costs proposed for the project.

Award Administration

Issuance of Award

A CIRM Research Training Program award is issued via a Grant, which is the formal contract that defines the terms and conditions of an award and documents the commitment of funds from CIRM.

CIRM will adjust the award start date for a Research Training Program award to coordinate with the academic year calendar of the applicant institution.

Reporting

Grantees will be required to provide annual written progress and financial reports to CIRM. Research Training Programs also will be required to submit Trainee Appointment Forms describing the planned laboratory placement, mentor and research activities/project for each trainee prior to start of the appointment. CIRM will only disburse trainee funds upon submission of a signed Trainee Appointment Form for an eligible trainee.

Fund Carry-forward and No-Cost Extensions

CIRM allows carry-forward of any obligated trainee funds from one grant year to the next. All unobligated trainee funds at the end of each year must be returned to CIRM and cannot be used to fund additional appointments, additional program administration funding or for any other purpose unless specifically approved in advance by CIRM for exceptional circumstances. CIRM will allow carry-forward of unobligated program administration funds from one grant year to the next in order to allow use of those funds in a way that best serves the trainees.

No-cost extensions (NCEs) are only permitted under exceptional circumstances, where an extension would facilitate the completion of a trainee's normal appointment term; such an extension would require specific approval by CIRM.



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Contacts

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