DISCOVERY

CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

DISC0 (Foundation Awards): Funding Opportunity for Discovery Stage Research

PROGRAM ANNOUNCEMENT

3.27.25

DISC0 (Foundation Awards): Funding Opportunity for Discovery Stage Research

Objective

The mission of the California Institute for Regenerative Medicine (CIRM) is to accelerate world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world.

The expected outcome of a **DISC0 Foundation Award** is the achievement, within three years or fewer, of a novel discovery or technology that addresses a knowledge gap in human biology and/or disease pathology. Projects funded through the Foundation Awards should propose impactful or innovative research that culminates in a discovery or technology that would:

- Advance our understanding of the biology or application of stem or progenitor cells[1] (collectively, "stem cells") that is relevant to human biology and disease; or
- Advance the application of genetic research[2] that is relevant to human biology and disease and pertains to stem cells or regenerative medicine[3]; or
- Advance the development or use of human stem cells as tools for biomedical innovation; or
- Extend the applicability of regenerative medicine discoveries to the full spectrum of affected populations.

Beyond the unique contributions of individual innovators, CIRM recognizes the value of team science in making scientific breakthroughs that would not be achievable by individual investigators within an award period. The DISC0 Foundation Awards capitalize on both approaches by supporting two types of programs. The Single PI Track supports projects with discrete objectives that are achievable under the leadership of a single investigator. The Team Track supports multidisciplinary collaborations of 2-3 investigators that bring specific knowledge and skills to a project to create a unique advantage or synergy, where diverse perspectives drive innovation and creativity in the regenerative medicine field.

Contact

For information and assistance with this program announcement please send email correspondence to discovery@cirm.ca.gov.

---

[1] Under Proposition 14, progenitor cells are "multipotent or precursor cells that are partially differentiated, but retain the ability to divide and give rise to differentiated cells." Progenitor cells may include directly reprogrammed cells if they meet the criteria in the above definition.

[2] For the scope of this solicitation, CIRM considers genetic research to mean research that alters genomic sequences of cells (edits, removes, or adds DNA sequences) or introduces or directly manipulates nucleic acids (such as mRNAs, antisense oligonucleotides) in cells.

[3] For the scope of this solicitation, CIRM considers regenerative medicine to mean therapeutic approaches that are intended to replace, regenerate or repair the function of aged, diseased, damaged or defective cells, tissues, and/or organs.

Table of Contents

Award Information

The **Expected Outcome of a Foundation Award** is to achieve, within three years or fewer, a novel discovery or technology that addresses a knowledge gap in human biology and/or disease pathology.

The DISC0 Foundation Awards will support basic research projects via two tracks:

1) **Single PI Track:** projects led by a single principal investigator.
2) **Team Track:** projects led by a team of 2-3 co-investigators (with 1 applicant PI) where synergistic, multidisciplinary collaboration justifies larger scale projects of critical or unique value.

This program announcement includes detailed descriptions of the Single PI Track and the Team Track, each with distinct award characteristics, budget, and eligibility criteria. An applicant PI may a) select only one award track in their application and b) may submit only one DISC0 application as PI.

What is the award amount and duration?

CIRM will fund direct project costs of up to:

- $1,500,000 per Single PI Track award; award duration is up to 3 years, OR
- $3,000,000 per Team Track award (1 PI + 1-2 Co-I) award; award duration is up to 3 years.

The amount of direct project costs requested must be adequately justified. The requested amount is subject to adjustments prior to the issuance of an award based on assessments by the Grants Working Group (GWG), the CIRM team, or by the Application Review Subcommittee of CIRM's Governing Board, the Independent Citizens' Oversight Committee ("ICOC"). The proposed project period must not exceed 3 years from the award start date (approximately 90 days after the date of ICOC approval).

If the proposed budget is equal to or exceeds:

- $600,000 direct project costs in a single budget year for a Single PI Track award, OR
- $1,200,000 direct project costs in a single budget year for a Team Track award,

strong justification will be required, and the GWG will be instructed to consider that budget rationale in their scoring.

Please refer to *Additional budget considerations for multi-institutional collaborations (pg. 15)* for additional budget information that may impact Team Track projects and other projects that include subcontracts.

How will funds be awarded?

Awards will be made in the form of a grant. Funds will be disbursed pursuant to a CIRM Notice of Award. The first payment will be issued upon initiation of an award and subsequent payments will be disbursed on a regular interval at CIRM's option. Continued funding is contingent upon timely progress, as outlined in the project or milestones and timeline established under the Notice of Award, and, when applicable, the ongoing ability of the applicant to fund its operations and to satisfy its co-funding commitment.

What activities will CIRM fund?

DISC0 funding is explicitly for foundational and/or mechanistic research projects. Importantly, DISC0 projects should be grounded in human biology and/or disease pathology. CIRM's goal is that these efforts will ultimately create new avenues and provide a rigorous foundation for translational and clinical development work.

For DISC0 projects that will generate datasets requiring bioinformatics, CIRM strongly encourages the inclusion of computational biology expertise within team leadership.

CIRM funds **will** support the following activities under this opportunity:

- ✓ Basic research into stem cell mechanisms as they relate to human biology

- ✓ Investigating stem cells or their derivatives as tools for discovering and/or enabling therapeutic or other innovations, e.g., for studying or modeling disease. Laboratories in search of expertise, infrastructure, or support with human stem cell manipulation, stem cell-based modeling experiments, or model analysis are encouraged to check the CIRM Network of Shared Resources Labs (SRL) for offerings that may contribute to their proposals (see Appendix).
- ✓ Basic genetic research relevant to human biology and as it pertains to stem cells or regenerative medicine
- ✓ Research or tools for extending or validating the applicability of regenerative medicine discoveries to affected populations (e.g., use of human induced pluripotent stem cell (hiPSC) lines or omics analyses from individuals with differing genetic backgrounds, target diseases or disease subtypes
- ✓ Basic research or tool discovery to address bottlenecks in the development of stem cell-based and gene therapies, such as cell/tissue targeting, immunogenicity and toxicity, in vivo gene therapy delivery, engineering human pluripotent stem cells (hPSC) to evade the immune system
- ✓ Studies of primary human tissues (healthy and/or diseased) to obtain ground truth knowledge that is critical for validating in vitro stem cell-based models or to improve regenerative medicine approaches (e.g., omics and other profiling for human cell/tissue atlases). A human stem cell/regenerative medicine component (wet lab and/or data-related) must be included in the project
- ✓ Auxiliary research activities that support regenerative medicine science (e.g., biomarker discovery, genome and epigenome editing tools, imaging tools, mechanism of disease to enable rational design of stem cell- or gene therapy-based treatments, data science and computational approaches). A human stem cell / regenerative medicine component (wet lab and/or data-related) must be included in the project
- ✓ Reverse translation studies related to stem cell- or gene therapy-based regenerative medicine therapies

Activities should focus on human cells but may include supportive studies using nonhuman cells provided that human cells are also investigated; or activities may focus on nonhuman cells if a strong justification is provided that the proposed research is of immediate relevance to human biology / disease but cannot be conducted using human cells. Studies of human cells transplanted into animals are considered human cell studies.

CIRM funds **will also** support:

- ✓ Activities intended to better understand the effects of genetic and/or environmental factors on project findings
- ✓ Activities associated with sharing data and knowledge from the study

CIRM resources **cannot** be used to support the following activities under this opportunity:

- ✘ Activities that in sum, are designed to produce the Expected Outcome of a DISC2 (Quest) award, i.e., a project deliverable that is a therapeutic or biomarker candidate that can immediately progress to translational activities (see DISC2 (Quest) Program Announcement on CIRM's Funding Opportunities for Discovery Stage Research page).
- ✘ Translational stage and development activities targeted by TRAN and CLIN programs (see www.cirm.ca.gov)
- ✘ Projects that propose solely or mainly to derive new pluripotent stem cell lines from somatic cells or embryos
- ✘ Activities already budgeted or paid for under a prior, existing or future CIRM award

Eligibility

What types of projects are eligible for funding?

To be eligible the proposed project must satisfy the following requirements:

(1) The applicant must

a) Define a key knowledge gap (including bottlenecks in the field) (i) in our understanding of the biology or application of stem cells, or (ii) in the application of genetic research as it pertains to stem cells or regenerative medicine;

b) Propose research that addresses this knowledge gap; and

c) Validate any discoveries made using nonhuman cells with a relevant human cell equivalent.

(2) Projects that generate molecular omics data must include an experienced Data Project Manager on the team.

To ensure effective and collaborative sharing and management of data, (see What is required for the Data Sharing and Management Plan?), a dedicated Data Project Manager must be part of the team (minimum 15% effort) in projects that collect substantial omics data, such as genomics, transcriptomics, epigenomics, proteomics, metabolomics, lipidomics, etc. This individual must have demonstrated experience in data handling and is responsible for interfacing with a data management team(s), interfacing with CIRM's planned data infrastructure, reporting progress on data management and sharing as well as maintaining the integrity of data during ingestion.

(3) The applicant 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 (ARS) of CIRM's governing board, the Independent Citizens' Oversight Committee (ICOC).

(4) Co-funding is not required.

If the project does, however, require 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).

(5) For-profit organizations must demonstrate solvency.

For-profit organizations must provide documentation that shows cash on hand or funding from committed sources that will cover the organization's expenses for 180 days from the date of application submission. These funds must be distinct from, and in addition to, funds for meeting the co-funding requirement (if applicable) for the term of the project. The determination of solvency will be made at CIRM's sole discretion.

(6) The application must be accurate and complete.

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

(7) The applicant must be in "good standing".

Applicants must represent and certify that they are in good standing, as follows:

a) The applicant organization's Chief Executive Officer, Chief Financial Officer, and Principal Investigator must not have been convicted of, nor currently be under investigation for, crimes involving fraud/misappropriation;

b) The applicant organization must have accounting systems in place that are capable of tracking CIRM funds in accordance with the policies and regulations set forth by CIRM;

c) The Principal Investigator or Key Personnel named in the application 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; and

d) The applicant must describe, in the application, the following:

(i) any pending legal proceedings to which the applicant organization (or any of its affiliates or subsidiaries) is a party or of which any of their products or property is the subject of the proceeding;

(ii) any governmental investigation, or any administrative or judicial proceeding arising under any Federal, State, or local provisions, involving the applicant organization or any of its affiliates or subsidiaries; and

(iii) any outstanding UCC, federal or state tax judgment liens.

For-profit applicants must provide a certified copy of a Certificate of Good Standing dated within 60 days of the date of their CIRM application from the jurisdiction in which the applicant organization is incorporated.

Who can apply?

Only California Organizations are eligible to apply for this opportunity.

The applicant organization must be a California organization per CIRM's definition, below, at the time of application.

A "California Organization" is a for-profit or non-profit organization or is a California-domiciled wholly owned subsidiary of a non-California organization (any entity that does not qualify as a California Organization) that meets all of the following criteria:

a) Employment and Payroll:

(i) Employs at least one W-2 employee; and

(ii) More than 50% of its W-2 employees, whether part-time or full-time, who are paid in any manner (e.g., wage, salary, commission, equity), must be domiciled full-time in California and be required to file California state income taxes due to their employment with the organization.

b) Management of Award Activities: The Principal Investigator (PI) must be physically located in California while overseeing all project activities.

c) Intellectual Property Rights: In the case of a California-domiciled wholly owned subsidiary of a non-California organization, the subsidiary must retain exclusive rights to any intellectual property arising out of the CIRM-funded project as well as any pre-existing IP rights held by the parent organization.

Allowable Project Costs include:

✓ Costs for research activities conducted wholly in California.

✓ Costs for research activities conducted outside of California, provided that the California Organization exercises direction and control over the activities.

Unallowable Project Costs include:

✘ The costs of activities performed by a separate out-of-state organization that retains intellectual property or independent publication rights in any intellectual property (e.g., invention, technology, data) arising out of the CIRM-funded project.

✘ Project costs incurred before the date the ICOC approves the application for funding, which can be as early as 90 days post application submission.

Who can serve as the Principal Investigator (PI)?

To be eligible, the PI 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 15 percent 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 conduct the research and assume the responsibilities of the PI;
- Must not currently have another application pending review or approval under this funding opportunity; and
- Must not currently have another application that is substantially similar or has overlapping activities pending review or approval under any CIRM opportunity.

Who can serve as a Co-Investigator (Co-I) on a Team Track Award?

To be eligible, each Co-I (up to two) must satisfy the following requirements:

- Must be an employee of a California-based organization or be accountable for the conduct of the proposed project to their California-based organization through a formal contract;
- Must commit at least 10 percent effort to working on the project. Any effort for which salary from CIRM is claimed must be expended in California;
- Must not currently have another application that is substantially similar or has overlapping activities pending review or approval under any CIRM opportunity; and
- Must not currently be part of the same lab as the PI.

Application Review Information

What is the process for evaluating an application?

Pre-submission Consultation

In accordance with CIRM's mission, the Agency is committed to helping develop promising stem cell-based technologies and genetic therapies by partnering with world-class investigators. Therefore, prospective applicants are encouraged to contact CIRM before applying with questions or to discuss their project's eligibility. To start a consultation please email discovery@cirm.ca.gov.

Eligibility Review

CIRM will assess whether the proposed project meets eligibility requirements sought under this program. If CIRM determines, in its sole discretion, that an application does not meet the eligibility requirements of the program or that the submitted application is incomplete or contains false or inaccurate information, CIRM will notify the applicant of its decision and, if CIRM deems it appropriate, allow an opportunity to remedy. If CIRM deems it inappropriate, or if the applicant does not remedy the error in a timely manner, CIRM will terminate all further action on the application.

CIRM may exercise its authority to make eligibility determinations at any time before an award is executed.

Scientific Review

The scientific merit of each application will be assessed by the GWG, which is composed of fifteen subject matter experts from outside California, seven patient advocate or nurse members of the ICOC (called "GWG Board Members"), and the Chair of the ICOC. The list of scientific members who may participate in the GWG review can be found at https://www.cirm.ca.gov/WorkingGroup_GrantsReview. The composition of the ICOC can be viewed on the CIRM website https://www.cirm.ca.gov/board-and-meetings/board/.

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

Positive Selection

CIRM anticipates that the number of applications submitted will be very high for this competition. When the number of applications received in a cycle is significantly in excess of the number that can be reviewed by the GWG panel, the GWG members conduct the review in two stages.

In the first stage, GWG members (including scientific members and GWG Board Members) will conduct a pre-review of applications (called "Positive Selection") to identify applications that the panel believes are most responsive to the funding opportunity and hold the most potential for impact. Applications that are not selected are examined by the CIRM scientific team and CIRM President to determine whether any additional applications merit a full GWG review. The remaining non-selected applications are deemed to be denied. Since the selection process is focused on quickly identifying promising proposals rather than identifying deficiencies in applications, no reviewer comments are collected at this stage. Positively selected applications advance to the second stage of review, which involves assignment to specific reviewers on the panel, a full discussion at review meeting, and scoring by the GWG.

Consideration of Past CIRM Award Information (If Applicable)

The GWG may consider information from a previously funded and related CIRM award as part of its review. CIRM will provide the GWG with objective information regarding a related award that CIRM, in its sole discretion, deems relevant, including but not limited to achievement of specific milestones, data, and outcomes for a related CIRM award or awards.

A “related CIRM award” includes: (1) an award for which the applicant PI served as the PI, a co-PI, a co-investigator, or otherwise substantially participated in the conduct of the award; (2) an award involving the same research project or product; or (3) an award that includes overlapping team members.

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).

Change in Status

Applicants are required to notify CIRM of any material change in status while the application is pending review, e.g., a change in PI or Data Project Manager, or any changes that could compromise the applicant organization’s status as a CA organization per CIRM’s definition.

How will the scientific merit of an application be evaluated?

Scientific GWG and GWG Board Members will evaluate applications and the scientific members will score them based on the following key questions:

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

- Does the project hold the potential to resolve a key knowledge gap (i) in our understanding of the biology or application of stem cells that is relevant to human biology and disease, or (ii) in the application of genetic research that is relevant to human biology and disease as it pertains to stem cells or regenerative medicine, or (iii) in the development or use of human stem cells as tools for biomedical innovation?
- Do proposed collaborations (particularly for Team Track projects) offer a unique synergy or advantage that augments the potential impact of the project?

2. Is the rationale sound?

- Is the proposed project based on a sound scientific rationale?
- Is the rationale supported by the body of available data?

3. Is the project well planned and designed?

- Is the project appropriately planned and designed to give meaningful results?
  - Are any specific studies using non-human cells adequately justified and necessary?
- Is there a well-constructed plan for team communications and management of all aspects of the project, particularly if collaborations are proposed?
- Are potential pitfalls identified and alternative approaches presented?

4. Is the project feasible?

- Does the team have the appropriate leadership and expertise to carry out the proposed activities?
- Does the team have access to all the resources and staff necessary to conduct the proposed activities?
- Are the budget and timeline appropriate for the research proposed?
  - For projects shorter than 3 years and that propose annual budgets above $600,000 (single PI) / $1.2M (Team), are the budget and timeline appropriately justified?

5. Does the project include considerations for maximizing the impact of successful outcomes across affected populations?

- Does the project plan and design adequately address and account for the influence of genetic, environmental and/or other external factors that may impact research findings?
- Would the project outcomes extend or validate the applicability of regenerative medicine discoveries to additional affected populations, patients or communities?
- Has the applicant described prior efforts or proposed plans for outreach, partnership, or educational activities to inform the development of the research project?

What is the review schedule?

Visit CIRM's Funding Opportunities for Discovery Stage Research page to find the most updated version of this PA, the application submission deadline, and planned dates for GWG review and final funding decisions. Funded projects must commence within 90 days of final funding decisions.

Application Components and Submission

How does one apply?

Applications must be completed and submitted online using the CIRM Grants Management Portal at https://grants.cirm.ca.gov. Any prospective PI must create a login in the system to access application materials and apply. Applications are available in the system only to the PI. A PI may submit only one (1) Foundation Award application in a given review cycle.

What components does an application include?

CIRM's online application is designed to collect information for CIRM staff to assess eligibility, for Grants Working Group reviewers to evaluate the project, and for CIRM to rapidly initiate an award if the project is approved for funding.

In the online portal, applicants must fill out an eligibility form, indicate Key Personnel involved in the project, describe how the proposal addresses the objective of the funding opportunity, provide an overview of proposed activities, and prepare and justify an appropriate budget.

The online application also includes the **Positive Selection Preview Page** – a section to be utilized by reviewers to prescreen applications and select a subset to move forward to the second and final stage of review. The Positive Selection Preview includes these subsections:

- Knowledge Gap/Bottleneck/Outcome
- Project Summary
- Areas of Impact
- Consideration of genetic, environmental or other external factors in project design and execution

The application uploads page provides templates and guidelines for writing the DISC0 proposal, biosketches, project timelines and other key components of the application. Applicants must use the provided templates.

What are the contents of the proposal?

The proposal comprises the bulk of detailed information on the project and is central to evaluation by the Grants Working Group if an application is selected for full review. It includes these sections:

1. **Resubmission Statement:** If this application is a resubmission, then the applicant will provide a brief statement on how this application addresses the reviewers' critiques.
2. **Statement of Significance and Impact:** Description of how the proposed research, if successful, could a) address a critical basic knowledge gap in the biology of stem cells or regenerative medicine approaches that is relevant to human biology or disease, or b) advance the development or use of human stem cells as tools for biomedical innovation, addressing a major bottleneck to the discovery, development or use of stem cell-based or gene therapies, or c) lead to the greater applicability of regenerative medicine discoveries to the full spectrum of affected populations. Applicants may highlight the impact of the approach and collaboration proposed, as well as public resources and datasets that would become available to the research community as a result of this work.
3. **Population Impact:** Statement describing how the project will help broaden or extend the impact or relevance of scientific discoveries to the relevant spectrum of affected California patients or populations.
4. **Objective and Specific Aims:** A concise description of the project objective, project aims, and criteria for success.
5. **Rationale:** Description of the scientific rationale for the proposed research and the preliminary data.

6. **Research Plan:** A concise but detailed description of methods and techniques to be employed to achieve aims, and potential pitfalls and alternative approaches.
7. **Data Sharing Overview:** A description of how raw data, processed data and metadata produced from the project will be made available to the research community consistent with FAIR (Findability, Accessibility, Interoperability, and Reusability) data sharing principles.
8. **Principal Investigator and Team:** A description of the PI, co-Investigators (Team Track) and most relevant Key Personnel, highlighting the team's expertise and experience relevant to the execution of the proposed study. Team members that fulfill the project needs for relevant bioinformatic or computational expertise (encouraged by CIRM) must be highlighted here.
9. **Project Organization and Management Plan:** Overview of the organizational structure of the project including subprojects, significant subcontracts, collaborations, partnerships and assigned leads for each. This section should include a communication plan and a detailed description of how the collaborative effort will be managed.
10. **Resources and Environment:** A brief description of the resources available to the project and environment.
11. **References:** Sources cited in the proposal.

How does one address population impact?

Applicants must address how the proposed project will broaden or extend the impact or relevance of scientific discoveries to representative or relevant affected populations. Applicants should describe how the overall study plan and design has considered the influence of genetic, environmental and geographic factors that may impact their findings. For example, the plan could incorporate the use of models and tools that account for population differences (e.g., HLA types, sex, genomics data, cell models **– see Resources**). Applicants should explain how the project outcomes might extend or validate the applicability of regenerative medicine discoveries to broader affected populations of patients. Applicants should also describe the research team's prior efforts or proposed plans for outreach, partnership, or educational activities to inform the development of the research project, including, for example, developing partnerships with patient organizations, acquiring training in cultural competence, utilizing institutional resources, and allocating funds and/or personnel to incorporate these considerations.

The GWG and CIRM's governing board will evaluate these statements as a review criterion in making funding recommendations. Priority will be given to projects with the highest quality plans in this regard.

What is required for the Data Sharing and Management Plan (DSMP)?

The sharing of data and knowledge produced from CIRM-funded projects is key to advancing the field of regenerative medicine and accelerating the discovery, validation and development of treatments for patients. CIRM requires awardees to manage and preserve raw data, processed data, and metadata, and make applicable data and metadata available to the broader scientific community. CIRM also requires applicants to allocate funds in their proposed budget for personnel and/or activities related to managing and sharing data produced from the funded project.

To ensure data processing steps can be replicated and data can be reused by other researchers, CIRM requires sharing of data in accordance with FAIR data principles, using established repositories where possible. CIRM requires that applicants provide a Data Sharing Overview in their proposal, and awardees develop and execute a detailed **Data Sharing and Management Plan (DSMP).** The data repositories selected and other information about deposited data must be reported to CIRM during and after the project period. To promote FAIR data sharing and open science, CIRM may publicly share information about CIRM-funded data, including what types of data were generated and where data are deposited.

Application stage – Data Sharing Overview

A general overview of a plan for sharing data produced in the proposed project **(Data Sharing Overview)** must be included in the application and is subject to evaluation by the GWG. Applicants must allocate funds in their proposed budget for personnel and/or activities related to managing and sharing data produced from the funded project. For guidelines, please refer to the Data Sharing Budget Justification Guidelines.

Pre-funding administrative review for awarded projects – DSMP

For omics and/or flow cytometry data, a completed DSMP, using templates provided, must be submitted to CIRM as Just in Time (JIT) material during pre-funding administrative review (PFAR). CIRM will review DSMPs and work with awardees to optimize the DSMP, including negotiation of milestones and budget. Awardees must agree with CIRM on a DSMP and associated milestones and budget prior to CIRM issuing a Notice of Award. Guidance to complete the DSMP for Omics and Flow Cytometry Data can be found here.

Specific instructions for preparing the DSMP for Omics and Flow Cytometry Data will be provided by CIRM during PFAR. For **data from other types of experiments** (e.g., imaging, electrophysiology, etc.), CIRM may work with the awardee to establish data sharing milestones prior to CIRM issuing a Notice of Award.

Active award stage

Grantees will report on their data sharing and management activities during regularly scheduled progress reporting and will work with CIRM staff to adjust the DSMP and other data-related milestones as necessary and align data sharing processes with other initiatives at CIRM.

Who are Key Personnel?

In the application, we ask you to identify by name pertinent Key Personnel and their specific roles on the project. Key Personnel are defined as (1) the Principal Investigator or program director; or (2) any other person, including an independent consultant or an employee of a Subcontractor or Partner, who is expected to contribute to the scientific development or execution of the project in a substantive, measurable way *and* who is expected to: (a) receive or has been promised income, or anything else of value, of $10,000 or more per year for his or her contribution to the project or (b) contribute one percent (1%) or more effort to the proposed project. “Key Personnel” does not include a person who is expected to be involved in the proposed project but who does not satisfy conditions (1) or (2).

Individuals who do not meet the definition of Key Personnel may be supported with CIRM funds but should **not** be identified by name in the application. Such unnamed personnel may be referenced indirectly by their role on the project (e.g., technician). The budget includes a line item for requesting support for unnamed personnel.

What should one know before preparing the budget?

Budgets must be justified in detail, including all subcontracts and consulting fees, including, if applicable, any additional costs that would be funded from another source. Allowable Project Costs for research funded by CIRM are detailed in the CIRM Grants Administration Policy for Discovery, Translation and Education Projects. Generally, project costs for personnel, supplies, travel, equipment, data sharing/management and subcontracts may be claimed. Limits for specific cost categories must be observed.

What are Direct Facilities Costs and how much can an applicant claim?

Direct Facilities Costs are the general operating costs of the awardee’s facilities attributable to housing all elements of the CIRM-funded project or activity. Facilities costs for non-profit applicant organizations are limited to the current applicable, federally negotiated rates for the organization as defined by the Office of Management and Budget (OMB) Circular A-21 or A-122. Facilities rates for for-profit applicant organizations are limited to 35% of the direct project costs. The facilities rate is applied to direct project costs exclusive of the costs of equipment, tuition and fees, research patient care costs, as well as the costs of each

individual subcontract, consultant, and service agreement in excess of $25,000. The facilities rates approved and in place at the time of the application are to be applied to the entire award project period.

What are indirect costs and how much can an applicant claim?

Indirect costs are administrative costs of the awardee incurred for common or joint objectives, which cannot be readily and specifically identified with a particular project. For-profit organizations cannot claim indirect costs. For non-profit organizations, indirect costs will be limited to 20% of allowable direct research funding costs awarded by CIRM (i.e., project costs and facilities costs), exclusive of the costs of equipment, tuition and fees, research patient care costs, as well as the costs of each individual subcontract, consultant, and service agreement in excess of $25,000. The indirect cost rate budgeted at the time of application is to be applied to the entire award project period.

Additional budget considerations for multi-institutional collaborations

Co-Is and collaborators that are based at a different organization than the applicant institution and that are requesting CIRM funds, will be considered “subcontracts” to the primary applicant organization. Direct project costs of subcontracts **AND** all associated overhead costs (facilities costs and indirect costs) requested by the subcontracted organization(s) will be applied to the award Direct Project Cost limit.

Applicant teams are encouraged to align with their institutions to adjust overhead requests to maximize direct research support offered by this grant.

Award Administration

Issuance of Award

A CIRM award is issued via a Notice of Award (NOA), which is the formal contract that defines the terms and conditions of an award and documents the commitment of funds from CIRM. CIRM reserves the right to modify or establish funded project activities and the associated budget prior to issuance of the Notice of Grant Award, including, when applicable, optimizing Data Sharing and Management Plans (DSMPs) submitted as Just in Time (JIT) material during pre-funding administrative review (PFAR). CIRM also establishes project milestones, DSMP milestones, success criteria and timelines at its sole discretion after consultation with the PI and based on information provided in the application and DSMP. CIRM may consult with Data Advisors towards optimizing the DSMP and implementing corresponding milestones as part of the NOA. CIRM may also review key contracts/agreements that are critical to the success of the project for compliance with CIRM's policies and regulations.

Milestones and Payment

Upon execution of the NOA, CIRM will issue an initial payment; subsequent disbursements will be made as outlined in the NOA. Continued CIRM funding is contingent upon timely scientific progress against specific aims or milestones, DSMP milestones, and timeline established under the NOA. Where project and/or DSMP milestones are not timely met, CIRM reserves the right to either redirect resources to maximize the project outcome or, at its sole discretion, to suspend payment and/or terminate the project.

Reporting

Grantees will be required to provide periodic written progress and financial reports to CIRM. CIRM will partner with the grantee to foster the success of the project. Grantees will have ongoing communication with the CIRM Science Officer throughout the duration of the award, typically meeting by teleconference and periodically in person.

No-Cost Extensions

Timely progress on funded projects is of critical importance to CIRM. Therefore, CIRM will consider a one-time, No-Cost Extension (NCE) request of no more than 6 months, submitted at least 30 days before the project end date. Such requests should properly justify how such an extension will advance the project towards its expected outcome, but Grantees should not assume CIRM will approve a NCE request.

Acknowledgement of Funder

CIRM grantees must acknowledge CIRM support of research findings in publications, announcements, presentations, and press releases by the grantees. An example of an acknowledgement is: "The research was made possible by a grant from the California Institute for Regenerative Medicine (Grant Number _____). The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of CIRM or any other agency of the State of California." Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.

CIRM Regulations

Grant awards made through this PA will be subject to all applicable CIRM regulations. These regulations can be found at https://www.cirm.ca.gov/our-funding/cirm-stem-cell-grant-regulations.

Resources

For more information about this and CIRM's other Discovery stage programs, please visit our Current Funding Opportunities page to access DISC-specific program announcements, webinar materials and FAQs. For scientific questions that are not addressed in the above resources, send email correspondence to discovery@cirm.ca.gov.

For questions related to application review, send email correspondence to review@cirm.ca.gov.

For questions related to budgets or allowable project costs, please consult the Grants Management FAQ on CIRM's website under "For Researchers > Grants > Managing your Grant."

CIRM iPSC Repository

As a resource to the regenerative medicine community, CIRM has funded the creation of an Induced Pluripotent Stem Cell Repository, a large, genetically diverse collection of stem cells produced from thousands of individuals representing various diseases of interest and healthy controls. The 2600+ lines were uniformly derived, have undergone rigorous quality control, and include demographic and clinical data. The CIRM Repository is managed by Fujifilm Cellular Dynamics, Inc., who have made the lines available for purchase at https://www.fujifilmcdi.com/cirm-ipsc-products/. SNP data for 2166 CIRM lines and whole genome sequence data for 299 of the CIRM iPSC donors is available at dbGaP. A list of CIRM lines with WGS data can be found here.

Applicants who are interested in using iPSCs to investigate mechanisms of disease, develop novel tools, discover therapeutic targets, or increase diversity in their experimental design are encouraged to explore the CIRM iPSC Repository or request additional information from CIRM Science Officers at discovery@cirm.ca.gov using the subject line "DISC0 application - iPSC Repository."

Please note, cells in the CIRM iPSC Repository are for research use only and are not eligible nor consented for clinical use.

CIRM Shared Resources Labs for Stem Cell-Based Modeling

CIRM is supporting a network of Shared Resources Laboratories (SRLs) for Stem Cell-Based Modeling across California. These are core laboratories that provide access to expertise and infrastructure for conducting and analyzing stem cell-based modeling experiments. The first 4 SRLs are slated to open for business in January 2025, and their offerings can be found at https://cirmhub.cirm.ca.gov. Applicants are encouraged to engage with SRLs as potential partners in their DISC0 applications. Synergies may arise for stem cell-based modeling-experienced labs in need of expertise with additional models or analyses, and for labs that do not have expertise in stem cell-based modeling but wish to test hypotheses using this technology.

Resource and Data Sharing Limitations

Proposals that include plans for prospective collection of human biosamples (including for derivation of novel hiPSC lines for research use) or plan work with existing human biosamples/cell lines should ensure that resources and data generated from these samples can be broadly shared across the scientific community. All applicants must consider:

- Obtaining comprehensive donor informed consent for planned prospective collections. Applicants should reach out to CIRM staff to learn more.
- Prioritizing the use of existing cell lines/biosamples that are consented for broad utility and data-sharing or re-consenting original donors of samples that were not suitably consented.

During pre-funding administrative review, CIRM Science Officers will work with awardees to review any limitations on resource and data use.

Standards in Stem Cell Research

CIRM has a strong interest in promoting the highest quality standards in human stem cell research. In 2023, the International Society for Stem Cell Research (ISSCR) published a document (https://www.isscr.org/standards-document) that identifies quality standards and outlines basic principles for the laboratory use of human stem cells and the in vitro models derived from them. CIRM strongly encourages all awardees to adhere to the recommended characterization and reporting practices outlined in this document to ensure rigor and reproducibility of human stem cell research. CIRM science officers will work with all awardees to ensure quality standards are taken into consideration.

Definitions

"For-profit organization" means: a sole-proprietorship, partnership, limited liability company, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. Such organizations also are referred to as "commercial organizations".

"Non-profit organization" means: (1) a governmental entity of the state of California; or (2) a legal entity that is tax exempt under Internal Revenue Code section 501(c)(3) and California Revenue and Taxation Code section 23701d.

"Partner" means an organization that, in exchange for the right to the opportunity for a future financial return, has (1) agreed to provide matching funds for the proposed project or (2) entered into an agreement with the applicant organization relating to the commercialization of the proposed product.

"Subcontractor" means an organization (other than the applicant organization) that is expected to: (a) contribute to the scientific development or execution of the project in a substantive, measurable way and (b) receive $25,000 or more through the proposed project. "Subcontractor" does not include suppliers of widely available goods.

Revision

Revision Date	List of Changes
3/27/25	• Addition of population impact. • Added link to CIRM Hub.
10/03/24	• Removed review timeline information; refer to CIRM's website for expected dates.
08/09/24	• Specified Team Track and Single PI Track awards; associated updates to budget, budget guidance, proposal sections, and review criteria. • Updated definitions of 'good standing' and 'CA-based organization'. • Described new 'Project Organization and Management Plan' section of the proposal. • Additional resources added: 'CIRM Shared Resources Labs for Stem Cell-Based Modeling', 'Resource and Data Sharing Limitations' and 'Standards in Stem Cell Research'. • Noted CIRM's Grants Administration Policy (GAP) requirements for notice of change in status and acknowledgement of funder.
08/11/23	• Clarified fundable activities • Clarified expectations for addressing diversity, equity, and inclusion • Revised requirements for Data Sharing and Management Plan Overview and full plan
09/11/22	• Emphasized CIRM's interest in investigating disease mechanisms of CNS disorders • Clarified the activities CIRM will support under DISC0 • Clarified review criterion 1