

DISC0: Discovery Stage Research Funding Opportunity for Foundation Awards



PROGRAM ANNOUNCEMENT

9.11.22



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

DISC0: Discovery Stage Research Funding Opportunity for Foundation Awards

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 objective of the **DISC0 Foundation Awards** is to support rigorous studies addressing critical basic knowledge gaps in the biology of stem cells and regenerative medicine approaches and to advance stem cell-based tools. 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 of stem or progenitor cells¹ (collectively, “stem cells”) that is relevant to human biology and disease; or
- Advance the application of genetic research² that is relevant to human biology and disease and pertains to stem cells or regenerative medicine³; or
- Advance the development or use of human stem cells as tools for biomedical innovation; or
- Lead to the greater applicability of regenerative medicine discoveries to communities representing the full spectrum of diversity.

As part of implementing the new Strategic Plan, CIRM is in the process of developing concepts for focused research consortia that are designed to accelerate stem cell and gene therapy research through coordinated and collaborative efforts. While this Program Announcement for Foundation Awards broadly re-initiates CIRM funding of basic stem cell science and genetic research, future DISC0 Program Announcements will be adjusted to align with collaborative infrastructure needs.

Since Proposition 14 dedicates more than a quarter of funds to support research and development of treatments for diseases and conditions of the brain and central nervous system (CNS), **CIRM encourages the submission of proposals focused on increasing our understanding of the fundamental biology of CNS disorders.**

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.



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

Table of Contents

<i>Objective</i>	2
<i>Award Information</i>	4
What is the award amount and duration?	4
How will funds be awarded?	4
What activities will CIRM fund?	4
<i>Eligibility</i>	6
What types of projects are eligible for funding?	6
Who can apply?.....	7
Who can serve as the Principal Investigator (PI)?	7
<i>Application Review Information</i>	8
What is the process for evaluating an application?	8
How will the scientific merit of an application be evaluated?	9
What is the review schedule?	10
<i>Application Components and Submission</i>	11
How does one apply?	11
What components does an application include?.....	11
What are the contents of the Proposal?	11
How does one address Diversity, Equity and Inclusion (DEI)?	12
What is required for the Data Sharing and Management Plan (DSMP)?.....	12
Who are Key Personnel?	13
What should one know before preparing the budget?	13
What are Direct Facilities Costs?.....	14
How much can an applicant claim for indirect costs?.....	14
<i>Award Administration</i>	15
Issuance of Award	15
Payments and Reporting.....	15
No-Cost Extensions	15
<i>Definitions</i>	16
<i>Appendix</i>	17



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

Award Information

What is the award amount and duration?

CIRM will fund direct project costs of up to \$1,000,000 per award. Direct project costs must be adequately justified and are subject to adjustment 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 proposed project period must not exceed 3 years.

If the project period is less than three years with an annual proposed budget above \$400,000, a strong justification will be required, and the GWG will be instructed to consider that budget rationale in their scoring.

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.

Note: CIRM encourages the submission of proposals focused on increasing our understanding of the fundamental biology of CNS disorders.

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 – In particular, CIRM is interested in:
 - Investigating disease mechanisms of CNS disorders with stem cells or their derivatives as tools for discovering and/or enabling therapies or other innovations
 - Modeling human CNS diseases with stem cells or their derivatives as tools for discovering and/or enabling therapies or other innovations
- ✓ Basic genetic research relevant to human biology and as it pertains to stem cells or regenerative medicine – In particular, CIRM is interested in:
 - The application of genetic research as a tool for discovering and/or enabling therapies or other innovations in CNS disorders
- ✓ Research or tools related to diversity, equity and inclusion in science, i.e., extending or validating the applicability of regenerative medicine discoveries to underserved populations (e.g., use of human induced pluripotent stem cell



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

(hiPSC) lines or omics analyses from diverse groups of individuals, target diseases or disease subtypes more frequently experienced by underserved groups)

- ✓ 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 to better understand primary human cells and tissues (healthy and/or diseased) as ground truth for 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.

CIRM funds **will also** support

- ✓ Activities intended to promote and uphold principles of Diversity, Equity, and Inclusion (DEI) in the conduct of the study
- ✓ 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 achieve the Expected Outcome of DISC2, i.e. a therapeutic or technology candidate that is ready for translation (see [DISC2 Program Announcement](#))
- ✗ 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



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

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 in 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 contribution of data to selected data platforms (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 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) and reporting data progress 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 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 180 days cash on hand from date of application submission and the financial ability to meet 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) 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."



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

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

- a. 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;
- b. The applicant must have accounting systems in place that are capable of tracking CIRM funds; and
- 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.

Who can apply?

Only California Organizations are eligible to apply for this opportunity.

A California Organization is a for-profit or non-profit organization that employs and pays more than 50% of its employees in California and that directs and controls the award activities from California.

Allowable Project Costs include:

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

Unallowable Costs

Allowable Project Costs do **not** 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. Unallowable costs also include 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 20 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.
- Must not currently have another application that is substantially similar or has overlapping activities pending review or approval under any CIRM opportunity.



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

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 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 http://www.cirm.ca.gov/WorkingGroup_GrantsReview. The composition of the ICOC can be viewed on the CIRM website <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 Application Review Subcommittee 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



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

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).

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 define and address 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?

Does the project define and address a major bottleneck to the discovery, development and/or use of stem cell-based or genetic therapies that is relevant to human biology and disease?

If successful, would the project have a major impact on either scientific knowledge in the stem cell/regenerative medicine field, or potential applications of stem cell or genetic research to regenerative medicine?

For projects that are descriptive or resource-generating rather than hypothesis-driven: Will the proposed outcome enable the research community to formulate and test novel hypotheses that could advance the field of regenerative medicine?

2. Is the rationale sound?

Is the proposed project based on sound scientific rationale? Are preliminary data compelling and supportive of the proposed project? Is the project significantly relevant to human biology and disease?

3. Is the project well planned and designed?

Is the project appropriately planned and designed to give meaningful results? Are potential pitfalls identified and alternative approaches presented? Do the project plan and timeline demonstrate an urgency that is commensurate with CIRM's mission?



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

For projects shorter than 3 years and that propose annual budgets above \$400,000, is the budget appropriately justified?

4. Is the project feasible?

Are the proposed aims and expected project outcome logical and likely to be achieved within the proposed timeline? Is the proposed team appropriately qualified and staffed? Does the team have access to all the necessary resources to conduct the proposed activities? Is the budget appropriate for the research proposed?

5. Does the project uphold the principles of diversity, equity and inclusion (DEI)?

Does the project plan and design adequately address and account for the influence of race, ethnicity, sex, gender, and age diversity? Would the project outcomes extend or validate the applicability of regenerative medicine discoveries to underserved populations, including underserved racial/ethnic communities? Has the applicant described prior efforts or proposed plans for outreach, partnership, or educational activities to inform the development of DEI within 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 and the application submission deadline(s). Applicants learn the final funding decisions approximately 120 days post submission. Funded projects must commence within 90 days of final funding decisions.

Schedule and Deadlines

Applications Due	One or two cycles per year
Grants Working Group (GWG) Review	Approximately 90 days post submission
ICOC Review and Approval	Approximately 120 days post submission
Award Start	Must start within 90 days of award approval (i.e., approximately 210 days post submission)



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

Application Components and Submission

How does one apply?

Applications must be completed and submitted online using the CIRM Grants Management Portal at <http://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 a single 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
- Area of Impact
- Consideration of diversity, equity and inclusion in project design and execution

The application uploads page provides templates and guidelines for writing the DISCO Proposal, Data Sharing and Management Plan, and other key components of the application.

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 ten 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 communities representing the full spectrum of diversity.



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

3. **Statement of Diversity, Equity and Inclusion:** Statement describing how the project will help fulfill the unmet medical needs of the diverse California patient population. See full description below.
4. **Objective and Specific Aims:** A concise description of the project objective and 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. **Timeline:** Activities-based timeline for achieving project aims.
8. **Principal Investigator and Team:** A description of the PI and team's expertise and experience.
9. **Resources and Environment:** A brief description of the resources available to the project and environment.
10. **References**

How does one address Diversity, Equity and Inclusion (DEI)?

Applicants must address how the proposed project upholds the principles of diversity, equity and inclusion (DEI). The DEI section of the DISC0 Proposal has two parts:

Part A. A statement describing how the overall study plan and design has considered the influence of race, ethnicity, sex, gender and age diversity, for example by use of models and tools that account for population diversity (e.g. HLA types, gender, genomics data, cell models – **see Appendix: Other Resources**). An explanation of how the project outcomes might extend or validate the applicability of regenerative medicine discoveries to underserved populations, including underserved racial/ethnic communities.

Part B. A description of the research team's prior efforts or proposed plans for outreach, partnership, or educational activities to inform the development of DEI within the research project, including, for example, developing partnerships with patient organizations, acquiring training in cultural competence and/or DEI, utilizing institutional resources for DEI, and allocating funds and/or personnel to address DEI.

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 treatments to patients. CIRM requires applicants to develop and execute a Data Sharing and Management Plan that includes management and preservation of data and making applicable data 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. CIRM requires sharing of data in accordance with [FAIR](#) data principles (Findability, Accessibility, Interoperability, and Reusability) through established repositories including, but not limited to, specialized repositories, generalist repositories, cloud platforms and institutional repositories.



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

The Data Sharing and Management Plan (DSMP) must be included in the application and the plan is subject to evaluation by the Grants Working Group. Reviewers will be asked to comment on the quality of the Data Sharing and Management Plan and advise CIRM on any improvements they recommend. CIRM staff will review plans with Data Advisor(s) with the goal of arriving to the best DSMP which can be appropriately incorporated into project milestones during the pre-funding administrative review (PFAR).

Guidelines to complete this section (with examples) can be found [here](#). The DSMP must address all of the following:

- a. Data types (i.e., the type(s) and quantity of data expected to be produced, what data will be preserved and shared, a justification for not sharing certain data, and what metadata and other relevant data will be made accessible),
- b. Related tools, software and/or code needed to access or manipulate shared scientific data,
- c. The standards that will be applied to the data and associated metadata,
- d. Data preservation (i.e., repository(ies) where shared data and metadata will be archived), access (how will shared data be findable and identifiable) and associated timelines,
- e. Considerations of factors affecting access, distribution, or reuse of shared data by others,
- f. The approach and personnel for oversight of data management and sharing, and
- g. Expected costs and budget justification.

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.



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

What are Direct Facilities Costs?

Direct Facilities Costs are the general operating costs of the grantee'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. Facilities rates are 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 cost rates approved and in place at the time of the application are to be applied to the entire award project period.

How much can an applicant claim for indirect costs?

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.



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

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, establishing project milestones, success criteria and timelines at its sole discretion after consultation with the PI and based on information provided in the application. CIRM may also review key contracts/agreements that are critical to the success of the project for compliance with CIRM's policies and regulations.

Payments and Reporting

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.

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.

Upon approval of an award, CIRM will consult with Data Advisors towards optimizing the Data Sharing and Management Plan and implement DSMP milestones as part of the NOA.

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.



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

Definitions

“California organization” means: An entity, regardless of profit status, that has >50% of its employees located in, and paid in, the state of California, and conducts the award activities from the California location.

“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.



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

Appendix

CIRM Regulations

Grant awards made through this PA will be subject to all applicable CIRM regulations. These regulations can be found at <http://www.cirm.ca.gov/reg/default.asp>.

Other Resources

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.

Contact

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



CIRM

CALIFORNIA'S
STEM CELL
AGENCY

Revisions

Revision Date	List of Changes
09/11/22	<ul style="list-style-type: none">• Emphasis on CIRM's interest in investigating disease mechanisms of CNS disorders.• Clarifications on the activities CIRM will support under DISC0.• Clarifications on review criterion 1.