

# Partnering Opportunity for Discovery Stage Research Projects: The Inception Awards

DISC 1



PROGRAM ANNOUNCEMENT

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# Partnering Opportunity for Discovery Stage Research Projects: **The Inception Awards**

## DISC 1

### Objective

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

The Discovery Program provides partnering opportunities to support exploratory research leading to the discovery of novel stem cell technologies and related technologies to improve patient care.

The Inception Awards mechanism described in this document is a seed funding opportunity. Its objective is to initiate exploratory research by funding studies designed to test new, potentially transformational ideas that could greatly impact the field of human stem cell research, but will require the generation of additional data to be competitive for larger funding opportunities through CIRM or other sources.



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## Award Information

### **What activities will CIRM support?**

CIRM resources will support the following activities under this opportunity:

- ✓ Exploratory research studies using human stem<sup>1</sup>/progenitor<sup>2</sup> or directly reprogrammed cells designed to test new, potentially transformational ideas that could lead to further discovery and translation of stem cell based innovations.
- ✓ Activities may include supportive studies using nonhuman model systems provided that human stem/progenitor or directly reprogrammed cells are also investigated.

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

- ✗ Research that does not require stem/progenitor or directly reprogrammed cells for achieving the project goal.
- ✗ Research that solely uses nonhuman cells/systems.
- ✗ Activities directly supported under CIRM's translation or clinical stage program announcements (see [www.cirm.ca.gov](http://www.cirm.ca.gov)), i.e., critical path activities to support defined stem cell technologies (candidates) that have already progressed towards early or later stages of development.

### **How much will CIRM provide to cover the cost of proposed activities, and for what duration?**

CIRM will fund direct project costs of up to \$150,000 per award, over the period of time it takes to test the hypothesis as proposed by the applicant. Successful applicants will propose a timeline that is commensurate with the urgency of CIRM's mission.

<sup>1</sup> Under Proposition 71, stem cells are "capable of self-renewal and have broad potential to differentiate into multiple adult cell types."

<sup>2</sup> Under Proposition 71, progenitor cells are "multipotent or precursor cells that are partially differentiated, but retain the ability to divide and give rise to differentiated cells."



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## Eligibility

### **What types of projects are eligible for partnering?**

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

**(1) The applicant must propose exploratory research studies that test a new idea with human stem/progenitor or directly reprogrammed cells.**

The applicant must clearly indicate in the application that the proposed activities use human stem/progenitor or directly reprogrammed cells.

**(2) The applicant must be ready to initiate work on the funded project within 120 days of approval.**

Given the urgency of CIRM's mission, all approved awardees must initiate work on the funded project within **120** 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.

### **Who can apply and on what activities may funds be spent?**

**Only California Organizations are eligible to apply.** A California Organization is a for-profit or non-profit organization that employs and pays more than 50% of its employees in California.

#### **Allowable Project Costs include:**

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

#### **Allowable Project Costs do NOT include:**

- 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

The applicant must demonstrate by the application deadline a commitment of funds from other sources for non-allowable project activities that are necessary to achieve the goals of the application.



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**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. For-Profit and Non-Profit (in existence for less than five years):
  - (i) The applicant’s Chief Executive Officer, Chief Financial Officer, and Principal Investigator must not have been convicted of, nor 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. All Applicants:
  - (i) The Principal Investigator 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 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 10 percent effort to working on the project
- Must be authorized by the applicant organization to conduct the research and assume the responsibilities of the PI

## Schedule and Deadlines

<b>Applications Due</b>	August 4, 2017 at 2pm PDT. For future application offerings, due date will be posted at <a href="http://www.cirm.ca.gov">http://www.cirm.ca.gov</a> .
<b>Grants Working Group (GWG) Review</b>	Approximately 90 days post submission
<b>ICOC Review and Approval</b>	Approximately 150 days post submission
<b>Award Start</b>	Must start within 120 days of award approval



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## 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.

#### **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, allow an opportunity to remedy, and if not remedied in a timely manner satisfactory to CIRM, terminate all further action on the application.

#### **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 members of the 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](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.

If the number of applications received in any given cycle is significantly in excess of the number that the GWG can review in a single session, GWG members will conduct the review in two stages. In the first stage, reviewers will conduct a pre-review of applications to advance a subset of applications to second stage, the full GWG review described below. Those applications that are not advanced to the second stage will not be recommended for funding.

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

#### **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.



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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 scientific merit of an application be evaluated?**

Scientific and patient advocate members of the GWG will evaluate applications and the scientific members will score them based on the key questions below. The goal of the review will be to identify new ideas that hold the greatest potential to impact human stem cell research, but that require additional data to be competitive for larger funding opportunities.

### **1. Does the application propose a new idea that could impact the field of human stem cell research?**

Does the proposal explore a new, potentially transformational idea that is worth testing? Will the outcome ultimately benefit patients by accelerating stem cell research and/or accelerating development of stem cell based treatments?

### **2. Is the scientific premise valid?**

Is the new idea to be tested based on a reasonable scientific premise? Is a clear rationale provided for the use of stem/progenitor or directly reprogrammed cells in meeting the objective of the program announcement?

### **3. Is the experimental plan adequately designed to test the idea?**

### **4. Is the project duration commensurate with the proposed experimental plan and requested budget?**

## **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 and his or her designee. A PI may submit only a single Inception Award application in a given review cycle.

### **What components does an application include?**

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 project, describe how the proposal addresses the objective of the partnering opportunity, provide a detailed plan of proposed activities, and prepare and justify an appropriate budget.



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The main components of the application include the following key sections:

1. **Project Idea:** A description of the new idea to be explored and the hypothesis proposed to test this idea.
2. **Impact:** A vision for how this idea, if successfully tested, could accelerate human stem cell research and/or development to benefit patients.
3. **Scientific Validity:** Summary of scientific basis underlying the new idea to be tested.
4. **Experimental Plan:** A concise description of methods and techniques used to test the new idea and generate data for follow on studies.
5. **Project Duration:** Provide justification that the project duration is commensurate with the proposed experimental plan and requested budget.
6. **References**

### 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 3<sup>rd</sup> party subcontracts and consulting, as well as, 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 Stage Projects. Generally, project costs for personnel, supplies, travel, equipment, and subcontracts may be claimed. Limits for specific cost categories must be observed.

### 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, or non-profit organizations that do not have federally negotiated rates, 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,





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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.

## 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. The duration of the award will be determined based on the project period defined in the application and in the NOA.

No-cost extensions **are not permitted** for Inception Awards.

### **Payments and Reporting**

Upon execution of the NOA, CIRM will issue an initial payment; subsequent disbursements will be made as outlined in the NOA.

Awardees will be required to provide periodic written progress and financial reports to CIRM as defined in the NOA.

## Contacts

For information and assistance with this program announcement send email correspondence to [Discovery@cirm.ca.gov](mailto:Discovery@cirm.ca.gov)



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## 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 project.

“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.

## Appendix

### **CIRM Regulations**

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