

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**

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Objective

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

The 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, transformational ideas that hold the potential to 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, progenitor, or directly reprogrammed cells designed to test new, 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), 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.



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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?

California Organizations

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

For a California Organization, Allowable Project Costs include:

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

Non-California Organizations

A Non-California Organization is a for-profit or non-profit organization that employs and pays 50% or less of its employees in California.

For a Non-California Organization, Allowable Project Costs are limited to the cost of research activities conducted wholly in California.

Unallowable Costs

For both California Organizations and Non-California Organizations, Allowable Project Costs do **NOT** include the costs of activities performed by a separate out-of-state organization that retains intellectual property or publication rights in any



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intellectual property (e.g., invention, technology, data) arising out of the CIRM funded project.

CIRM may determine, in its sole discretion, whether an applicant is a California organization and whether the project activities are allowable.

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.

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.
- Must not have more than one application submitted as PI under a given review cycle of this Funding Opportunity.

Schedule and Deadlines

Applications Due	Annually in mid-January Next deadline: January 20, 2017
Grants Working Group (GWG) Review	Approximately 3 months post submission
ICOC Review and Approval	Approximately 5 months post submission
Award Start	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. 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 transformational 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 project hold the necessary significance and potential for impact?

Does the proposal explore a novel idea that if successfully realized, would accelerate or increase the likelihood of discovering a stem/progenitor cell-based (or directly reprogrammed cell) product or technology that could ultimately be translated? How well has the applicant presented the likely or ideal progression from a successful pilot study to the next stage(s) for the realization of this technology?

2. Is the rationale sound?

Is the proposed project based on sound scientific rationale that supports a role for stem/progenitor or directly reprogrammed cells in meeting the objective of the program announcement? If preliminary data is provided (not required), is it supportive of the rationale?

3. Is the project well planned and designed?

Is the project appropriately planned and designed to meet the objective of the program announcement and achieve meaningful outcomes? Are potential pitfalls identified and alternative approaches presented? Is the proposed timeline appropriate?

4. Is the project feasible?

Are the specific aims 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?



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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.

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

1. **Application Preview Page:** This section will serve as the primary basis for the first stage of review, in which GWG members select a subset of applications to advance to the second and final stage of review.
 - Project Summary
 - Statement of Impact
 - Vision for Progression
2. **Objective and Specific Aims:** A concise description of the scientific goals of the proposal
3. **Rationale:** Summary of the scientific rationale for the proposed research including preliminary data, if available
4. **Research Plan:** A concise but detailed description of methods and techniques to be employed to achieve Specific Aims, criteria for success, and potential pitfalls and alternatives approaches
5. **Timeline:** Activities-based timeline for achieving project aims
6. **Principal Investigator and Team:** A description of the PI and team's expertise and experience
7. **Resources and Environment:** A brief description of the resources available to the project and environment
8. **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,



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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 3rd 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 the rules for spending CIRM funds outside of California?

California Based Organizations

California organizations may use CIRM funds for Allowable Project Activities conducted both in California and outside of California. "Allowable Project Activities" means those activities that are conducted in California, and for activities outside of California, those activities over which the California organization exercises direction and control, including activities performed by a wholly owned subsidiary of the California organization outside of California. It does not include activities undertaken by a separate organization outside of California that retains intellectual property or publication rights in connection with the performance of those activities, including a research collaboration in which the research is conducted outside of California.

Non-California Based Organizations

Non-California organizations cannot use CIRM funds for any costs incurred outside California.

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, 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.



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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, 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 Notice of Award.

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

Payments and Reporting

The first payment will be issued upon execution of the award agreement and will comprise 75% of the awarded funding. The remaining funds will be disbursed upon award closeout.

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



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Contacts

For information and assistance with this program announcement please contact:

Send email correspondence to Discovery@cirm.ca.gov

or

Call our main line at 510-340-9101 and select "Funding Opportunities" then "Discovery"



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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>.