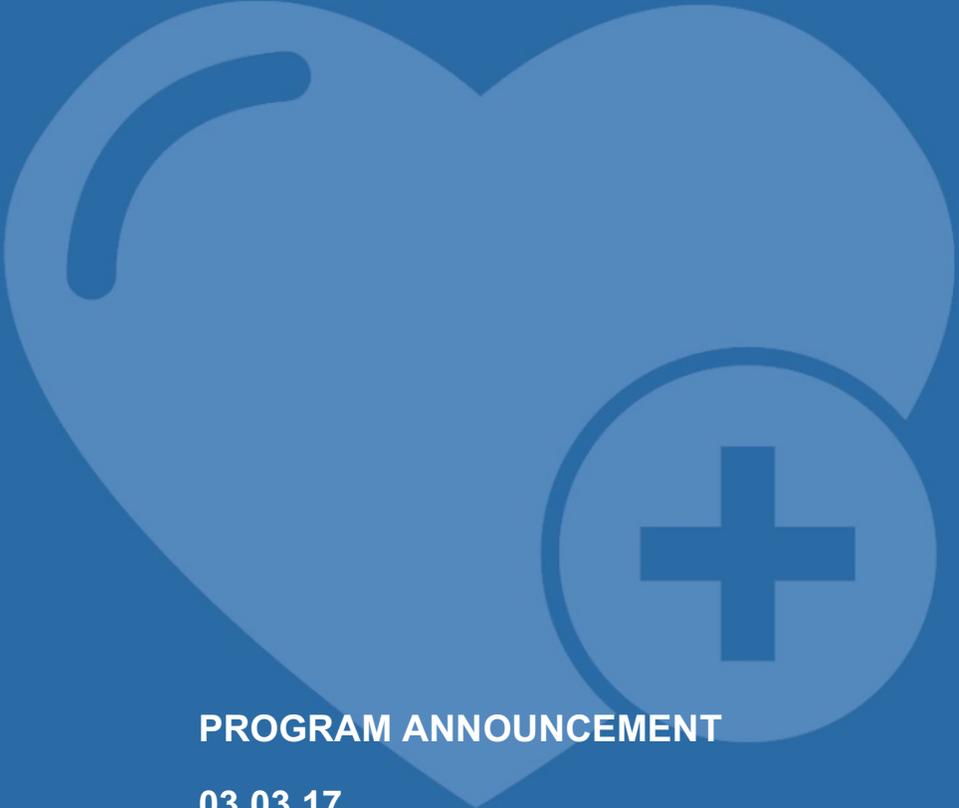


Partnering Opportunity for Stem Cell Therapy Registration Clinical Trials

CLIN3



PROGRAM ANNOUNCEMENT

03.03.17



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Partnering Opportunity for Stem Cell Therapy Registration Clinical Trials

(CLIN3)

Objective

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

The objective of this program announcement is to support new activities on active CIRM-funded clinical trial projects that will directly enable product registration with the Food and Drug Administration (FDA). This award is only available to holders of a current CLIN2 award for a trial that has been deemed by FDA to be sufficient for registration.

Under this program, CIRM will act not only as a funding agency, but will also devote significant internal resources and leverage its external team of world-class subject matter experts to actively advance the project. The result of a successful application will be the formation of a true partnership that both accelerates the program and gives it the greatest opportunity for success.



Award Information

What activities will CIRM support?

CIRM resources will support the following activities under this opportunity:

- ✓ New activities not funded under the parent award (see below) that enable the parent's award trial to be converted to a registration trial for the product
- ✓ New activities not funded under the parent award but that are required by FDA for product registration

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

- ✗ Studies for therapeutic candidate discovery
- ✗ Specific activities already funded under the parent award
- ✗ Activities not necessary to obtain FDA marketing approval
- ✗ Activities occurring after attaining marketing approval

How will funds be awarded?

CIRM will disburse funds pursuant to a Notice of Award. Awardees may elect, upon completion of their award, to treat their award as a loan pursuant to CIRM's award conversion policy. (See CLIN Grants Administration Policy, Ch. IV(C).) If an awardee does not make this election, the award will be treated as a grant. Except for the first payment issued upon initiation of an award, payments will be disbursed upon completion of specific Operational Milestones. **Costs resulting from a delay or failure to meet an Operational Milestone will be the sole responsibility of the recipient.** Successful applicants will have thoughtfully accounted for foreseeable project risks and developed contingency plans that **do not** involve additional funding from CIRM (see "Contingency Plan" under application components).

Award Cap

CLIN3 awards are capped at a maximum amount of \$20 million per award.



Eligibility

What types of projects are eligible for partnering?

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

(1) Must be ready to initiate work on the new activities within 45 days of approval

Given the urgency of CIRM's mission, all approved awardees must initiate work on the funded new activities within 45 days of approval and authorization for funding by Application Review Subcommittee of CIRM's governing board, the Independent Citizens' Oversight Committee ("ICOC").

Because of the open and ongoing nature of this Program Announcement, investigators should only apply when their project has reached the stage where all eligibility criteria are met. **CIRM reserves the right to refuse to consider an application that is submitted prior to the completion of all necessary prerequisites.**

(2) Must supplement an active CIRM-funded clinical trial that FDA has indicated could serve as a basis for marketing approval (registration)

The applicant must currently have an active CIRM-funded clinical trial award and FDA communication indicating that the existing or proposed clinical trial could serve as the basis for product registration.

(3) Must use the same therapeutic candidate as the parent CIRM-funded project

The new activities proposed must support the same therapeutic candidate as in the parent award (i.e., supporting the same IND).

(4) Must propose conversion of an existing trial to a registration trial or propose new activities to an ongoing registration trial necessary to attain product registration.

CIRM will support activities that FDA has agreed will convert an existing clinical trial to a registration clinical trial. The project plan must include the filing of a Biologic License Application (BLA) and attaining product registration with the FDA.

CIRM will also support new activities for an ongoing registration trial that FDA has indicated are required to attain marketing approval. The application must provide evidence that all proposed activities are required in order to obtain FDA registration.

(5) Must propose product registration with a stem¹ or progenitor² (collectively "stem cells") cell-based treatment

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

² 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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CIRM will support the completion of a registration trial or new activities necessary for registration of a stem cell therapy where stem cells either compose the therapy or are used to manufacture the stem cell therapy.

(5) Co-funding requirements

CIRM will require all applicants to co-fund at 50% of the total “Allowable Project Costs” (the same level required for a Phase 3 trial). Allowable Project Costs are those costs that: (1) are permitted under CIRM policies and regulations and (2) are for allowable project activities (see below). Allowable Project Costs include both direct, facilities, and indirect costs. The sum of CIRM funds requested plus co-funding contribution by the applicant make up the total Allowable Project Costs. The co-funding may come from any funding source arranged by the applicant, but may not include “in-kind” or similar types of support. 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) and by the project start date the awardee must have cash-on-hand to fund the first operational milestone. Only funds that will be spent concurrently with CIRM funds (e.g. no sooner than ICOC approval and no later than completion of the final Operational Milestone) will qualify toward this co-funding requirement.

(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) Limit to One CLIN3 Award Per Parent Award

An applicant is only eligible for a single CLIN3 award per parent award.

(8) FDA Concurrence

The applicant must provide correspondence from the Food and Drug Administration indicating that the activities are appropriate for registration.

(9) 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.

For-Profit and Non-Profit (in existence for less than five years):

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

All Applicants:

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 NIH Office of Research Integrity.



Who can apply and on what activities can funds be spent?

Only CIRM awardees with an active CIRM-funded clinical trial award (such as a Disease Team Award, Strategic Partnership Award, or Clinical Trial Stage Award [CLIN 2]) 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 and that directs and controls the award activities from California.

For a California Organization, Allowable Project Costs include:

- Costs for 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.

Non-California Organization

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 include:

- Cost of nonclinical research activities conducted wholly in California; and
- The pro rata share of costs incurred out-of-state to treat California clinical trial subjects.

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

Active Clinical Trial Costs

For applicants that apply for CIRM funding for an active clinical trial, allowable costs include the per subject share of the cost of all clinical and nonclinical research activities directly attributable to subjects enrolled on or after the date of submission of the applicant's original application.

CIRM Discretion

CIRM may determine, in its sole discretion, whether an applicant is a California organization and whether the project activities are allowable. If an applicant is a non-California organization at the time of application, but intends to become a California organization by the time this project would need to execute a CIRM award contract (~130 days from time of application), then the applicant may submit a budget that includes the Allowable Project Costs for California organizations and must describe their intentions and the timing of becoming a California organization in this application.



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Funding of Non-Allowable Project Activities

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 the same PI as the parent award.
- Must not currently have another application pending review or approval under this partnering opportunity.
- Any effort for which salary from CIRM is claimed must be expended in California.



Schedule and Deadlines

Applications Due	2:00 pm (PDT/PST) on the last business day of each month
Grants Working Group (GWG) Review	Approximately 60 days post submission
ICOC Review and Approval	Approximately 90 days post submission
Award Start	Must start within 45 days of award approval (i.e., approximately 130 days post submission)

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, scientific, or budget considerations.

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, CIRM will notify the applicant of its decision, if CIRM deems it appropriate allow an opportunity to remedy. If CIRM deems it inappropriate, or if the applicant does not timely remedy the deficiency, CIRM will terminate all further action on the application. In the event CIRM determines that the application does not meet the eligibility requirements of the program based on a subjective criterion (designated in the ELIGIBILITY section with an asterisk "*"), the applicant may request that the CIRM Grants Working Group (GWG) review the decision. This request must be submitted to CIRM no later than 14 days after the date of CIRM's notification that the application is ineligible. If the working group affirms CIRM's decision, the applicant will be notified and no further action will be taken on the application. If the GWG determines the application meets the eligibility requirements, the application will be accepted into the next available review cycle.

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

Budget Review

CIRM will review the proposed budget to assess how the proposed costs compare with established market rates for similar activities, how well the costs are justified when market rates are not established and to confirm that costs designated as



Allowable Project Costs comply with CIRM policies. When a proposed budget differs significantly from market rates, is not well justified or does not comply with Allowable Project Cost policy, adjustments to the budget will be required by CIRM prior to further review of the application. Applicants will be notified of the specific discrepancies and applications will not be forwarded for scientific review until an amended budget has been submitted and approved by CIRM. Additionally, project budgets may be subject to further adjustments prior to issuance of an award based upon assessments of the GWG, the CIRM team, or by the Application Review Subcommittee of the ICOC.

Scientific Review

Scientific merit will be assessed by the CIRM Grants Working Group (GWG), which is composed of fifteen scientific experts from outside California, seven patient advocate members of CIRM's Governing Board (ICOC), and the Chair of the Governing Board. The list of scientific members who may participate in the GWG review can be found at http://www.cirm.ca.gov/WorkingGroup_GrantsReview. The composition of the ICOC can be viewed at <http://www.cirm.ca.gov/GoverningBoard>.

The fifteen participating scientists on the GWG will evaluate the applications and score them according to scientific and technical merit, applying the review criteria described below. The GWG will score each application and make one of the following specific recommendations to the ICOC's Application Review Subcommittee: 1) fund the project based on its exceptional merit; 2) do not fund the project but allow for resubmission to address areas for improvement; or 3) do not fund the project and do not allow resubmission for 6 months. In the event the GWG recommends amendment and resubmission, the applicant may elect, prior to the ICOC's final funding decision, to amend and resubmit the application for reevaluation by the GWG.

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

Consideration of Related CIRM Award Information

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

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

Will the conduct of the proposed new activities directly enable product registration? Is the therapy for a pediatric or rare indication (i.e. FDA orphan drug designation) or, if not, is the project unlikely to receive funding from other sources?

2. Is the rationale sound?

Are all proposed new activities integral to achieving product registration? Is there evidence that pursuing registration is appropriate at this time?

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 product registration? Do the project plan and timeline demonstrate an urgency that is commensurate with CIRM's mission (i.e. Are the proposed experiments essential and do they create value that advances CIRM's mission? Is the timeline appropriate to complete the essential work without unnecessarily extending it for non-essential activities)?

4. Is the project feasible?

Are the intended objectives likely to be achieved within the proposed timeline? Is the proposed team appropriately qualified and staffed and have access to all the necessary resources to conduct the proposed activities? Does the team have a viable contingency plan to manage risks and delay?



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 application in a given review cycle.

Applications are due by 2:00pm (Pacific Time) on the last business day of each month. Applications received after the deadline will be deferred to the next monthly 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, complete a detailed activity-based budget, and provide reference materials, such as FDA correspondence that confirms the status of the project. Applicants will also be required to provide a financial contingency plan that addresses how the applicant will cover possible funding shortfalls.

The main body of the proposal contains the following sections:

1. **Program Summary**
2. **Target Product Profile:** Outline of product specifications for the aspirational goals of the commercialized product. Describe the base case and optimal safety and efficacy outcomes of the commercialized product that differentiate it from other treatments; improve upon the standard of care; and demonstrate a compelling value proposition supporting its use as a marketed product or in practice of medicine.
3. **Parent Award:** Describe of the parent award and its objectives and status.
4. **Statement of Significance and Impact:** Discuss how receipt of this award will result in achieving product registration.
5. **Phase 3 Trial Preference:** Describe how the therapy qualifies as a pediatric or orphan indication, or if it does not, why the project is unlikely to receive funding from other sources.
6. **Rationale:** Explain how the proposed activities are integral to achieving product registration and why the proposed activities are appropriate at this time.
7. **Parent Award Timeline in Gantt-Like Format**
8. **Updated Timeline in Gantt-Like Format**



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9. **Project Plan to Achieve the Program Announcement Objective:** Describe the activities that will be conducted to achieve product registration (this should annotate the updated Gantt chart). Clearly delineate whether CIRM funds are requested for each specific activity and where each activity will be conducted.
10. **Planned Preclinical Studies:** Tabular summary of planned nonclinical studies, if any are proposed.
11. **FDA Correspondence:** Summary of FDA communications indicating proposed activities are appropriate and sufficient for product registration; discussion of relevant FDA communications; and description of the plan for addressing FDA comments. Official FDA meeting minutes and/or FDA correspondence relevant to the proposed project must be provided.
12. **Manufacturing Summary:** Provide the manufacturing plan synopsis.
13. **Clinical Protocol:** Provide the Clinical protocol synopsis and draft of the full clinical protocol, if available I.
14. **Operational Plan:** Provide the clinical operations plan for the proposed clinical trial.
15. **Commercial Development Plan:** Provide plans for commercial development if funds for commercial development activities are requested.
16. **Financial Contingency Plan:** Describe potential risks, mitigation strategies, and associated costs, including a description of a viable source to cover these costs (other than CIRM and not including co-funding) to the timeline.
17. **Team Organization:** Describe team qualifications, structure, leadership and communications plan.
18. **Resources and Environment:** Describe resources available to the project and environment.
19. **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?

A specific and well-justified activities-based budget must be provided that clearly outlines the total costs of the project, including those costs not proposed to be funded by CIRM. The corresponding budget justification should provide enough detail to allow budget professionals to determine the appropriateness of the costs in relation to the activities being performed. Allowable Project Costs for research funded by CIRM are detailed in the CIRM Grants Administration Policy for Clinical Stage Programs. 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 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. 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 (administrative) overhead 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.

How does one utilize CIRM Infrastructure Programs?

CIRM has established a set of Infrastructure Programs to help CIRM applicants and Awardees prepare competitive applications and to accelerate the conduct of high quality stem cell clinical trials and research. The active Infrastructure Programs are currently composed of The Alpha Stem Cell Clinics Network and the CIRM Stem Cell Center. The Alpha Stem Cell Clinics Network is composed of 3 stem cell-focused clinics within existing medical centers that work to leverage each other's strengths to form an efficient, scalable and sustainable network that will attract and conduct high-quality clinical trials (<https://www.cirm.ca.gov/patients/alpha-clinics-network>). The CIRM Stem Cell Center is composed of the Accelerating Center and the Translating Center. The Accelerating Center is a high quality clinical research organization (CRO) with a dedicated focus on stem cell treatments that provides regulatory, operational and consultative services at a reduced, competitive rate to CIRM-funded projects to support IND submissions and clinical trials. The Center is available to help CIRM Clinical Stage applicants prepare their applications, including the proposal, budget and timeline. The Translating Center is a preclinical research organization specializing in stem cell treatments that supports activities related to stem cell process development and manufacture and preclinical research necessary to obtain an Investigational New Drug (IND) application.



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Award Administration

Issuance of Award

A CIRM award is issued via a Notice of Award Agreement, which is the formal contract that defines the terms and conditions of an award and documents the commitment of funds from CIRM.

Operational Milestones and Payment

CIRM funds under the award will be disbursed based on achievement of specific Operational Milestones established by CIRM. An “Operational Milestone” is an objective event that is indicative of project progress occurring as proposed in the application. CIRM establishes Operational Milestones for inclusion in the Notice of Award based upon information provided in the Application. Upon issuance of the award, funds budgeted to achieve the initial Operational Milestone will be disbursed. Upon the successful completion of the initial Operational milestone and each successive milestone, additional funds will be disbursed. If funds allocated to a specific Operational Milestone (including both CIRM funds and the required applicant co-funds) are exhausted prior to achievement of that milestone, the Awardee will be responsible for covering any remaining costs. CIRM expects that the applicant’s contingency plan will identify the project timeline and budget risks and will provide details for covering such costs, including the source of funding. CIRM reserves the right to make adjustments to the timeline for inclusion in the Notice of Award to ensure that funds are appropriately dispersed across Operational Milestones.

If CIRM determines, in its sole discretion, that an awardee has failed to satisfy an Operational Milestone within four months of the date that the Operational Milestone was scheduled to have been completed, or if the delay is not addressed to CIRM’s satisfaction, CIRM may permanently cease disbursements and terminate the award.

Suspension Events

CIRM reserves the right to hold or terminate disbursements if CIRM determines, in its sole discretion, that a Suspension Event has occurred. A “Suspension Event” means a pre-defined condition that triggers a hold of CIRM funding until the suspension event has been resolved, if resolvable. Following a Suspension Event, the Awardee is expected to provide CIRM with a plan to resolve the issue that triggered the Suspension Event. CIRM establishes Suspension Events for inclusion in the Notice of Award based on information provided in the Application.

Reporting

Awardees will be required to provide periodic written progress and financial reports to CIRM.

Upon approval of an award, CIRM will appoint a Clinical Advisory Panel (CAP) to partner with the Awardee. The CAP will be composed of at least one CIRM science officer, one external advisor, and a patient representative and will provide guidance and advice to foster success of the project. CAPs have the ability to enlist the help of CIRM’s external subject matter experts when needed. Awardees will have ongoing communication with the CAP throughout the duration of the award, typically meeting by teleconference on a quarterly basis and in person once a year.



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Other Requirements

CIRM Regulations

Grant or Loan 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>.

Clinical Trials

Clinical trials funded by CIRM must be listed on <http://clinicaltrials.gov/> and awardees must submit the administrative and scientific results of the trial to the clinicaltrials.gov results database within one year of completion of the studies (in compliance with FDAAA801), for the benefit of the field.

Change in Status

Applicants are required to notify CIRM of any material change in status while the application is pending review, e.g., the applicant has commenced the trial that is the subject of the award, the applicant no longer qualifies as a California Organization, etc.



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Contacts

For information about this program announcement:

Send email correspondence to Clinical@cirrn.ca.gov

or

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



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 that directs and controls 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.

“Operational Milestone” means an objective event that is indicative of project progress occurring as proposed in the application.

“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.

“Suspension Event” means a pre-defined condition that triggers a hold of CIRM funding until the suspension event has been resolved, if resolvable.