

Partnering Opportunity to Create a CIRM Accelerating Center

INFR 1



REQUEST FOR APPLICATIONS

03.01.16



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Partnering Opportunity to Create a CIRM Accelerating Center

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Objective

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

The objective of this partnering opportunity is to create the CIRM Accelerating Center, a top quality clinical research organization (CRO) with a dedicated focus on stem cell treatments. Operating from a facility permanently located within California, the Accelerating Center will provide regulatory, operational and consultative services to clinical trial sponsors in order to accelerate the regulatory review process and the conduct of high quality clinical trials using stem cell treatments. The Accelerating Center will initially focus on CIRM-funded projects¹, but must include a business plan to extend the services to other clients so as to ensure Center sustainability.

The Accelerating Center is one of multiple coordinated Infrastructure Programs that CIRM is establishing to overcome obstacles and accelerate the progression of stem cell treatments through translational, preclinical, and clinical research to demonstrate clinical proof of concept.² Other Infrastructure Programs include the CIRM Translating Center and the CIRM Alpha Clinics Network.

The CIRM Translating Center is a stem cell preclinical research organization that will be launched later this year. The Translating Center will support process development, manufacturing, and preclinical research activities that are necessary to support regulatory filings (e.g., Investigational New Drug Applications (IND) with the Food & Drug Administration (FDA)). The Accelerating Center will develop service contracts with the Translating Center and act as the lead organization in interactions with the FDA in support of regulatory submissions. The existing Alpha Clinics Network provides clinical trial sites and Accelerating and Value Add Resources (AVARs). The Accelerating Center will facilitate utilization of the Alpha Clinics Network by aiding the conduct of clinical trials, by bringing additional trials to the network, and by facilitating use of the (AVARs). Together, these CIRM Infrastructure Programs will support CIRM-funded translational, preclinical, and clinical projects to develop stem cell treatments for patients with unmet medical needs.

These centers are intended to address common concerns raised by **both researchers and regulatory officials**, making them particularly valuable tools to increase the quality and speed of clinical and translational stage projects.

¹ CIRM-funded projects are defined as current and future CIRM Translational Program, Clinical Program, and Alpha Clinic Program projects.

² See Beyond CIRM 2.0: 2016 Strategic Plan p. 26 -30.

https://www.cirm.ca.gov/sites/default/files/files/agenda/151217_Agenda_7_CIRM_StratPlan_final_120815.pdf



Award Information

What is the CIRM funding allocation and project term?

Under this RFA, a single applicant organization will be supported to develop and operate the Accelerating Center within California. The award will provide up to \$15M in funding over a five-year period.

What activities must be performed under the CIRM award?

The Accelerating Center will assist sponsors with the development of a comprehensive regulatory strategy. It must provide the following Core Services for stem cell-based projects under the CIRM award:

- ✓ **Regulatory management services.** Regulatory support, including planning and consultative services necessary to develop supportive preclinical packages; compile and submit successful regulatory applications; design clinical protocols that support clinical development of stem cell treatments, and manage regulatory requirements and interactions necessary to conduct those trials.
- ✓ **Clinical trial operations and management services.** Services that include site selection; patient recruitment and management; logistical support across multiple sites, and coordination of vendors and third party organizations necessary for the efficient conduct of high quality stem cell clinical trials.
- ✓ **Data management, biostatistical and analytical services.** Data management (EDC) systems, biostatistics and analytics to enable the generation of high quality, reliable, and statistically sound data from clinical trials. Make available aggregated knowledge to inform researchers and the stem cell community of the best path forward for delivering stem cell treatments to patients.

For translational and preclinical stem cell projects, the Accelerating Center will act as the lead organization to manage and coordinate the filing of strong IND or IDE applications and to support interactions with the FDA or other relevant regulatory bodies.

For clinical stage stem cell projects, the Accelerating Center will accelerate clinical development of stem cell treatments by managing successful IND/IDE preparation and submission and providing clinical trial management services. The Accelerating Center will evaluate and implement an optimal configuration of services proportional to the needs of specific trials. The scope of services may range from complete reliance, where the client is dependent on Center's infrastructure and capacities, to facilitation, where the Accelerating Center facilitates the sponsor's use of CIRM's infrastructure programs including the Alpha Clinic Network resources. Service contracts will be scaled to meet the needs of a specific program, sponsor or site.



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What activities will CIRM not fund?

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

- ✘ Activities already paid for by CIRM under a prior or existing award , i.e., double billing³
- ✘ Discovery or translational research projects (i.e., projects that have not held a pre-IND meeting)
- ✘ Construction or renovation of physical facilities
- ✘ Activities to be performed by the CIRM Translating Center
- ✘ Subsidizing direct costs of core services provided to non-CIRM funded projects

What are the expected outcomes of the proposed CIRM Accelerating Center?

The CIRM Accelerating Center is intended to accelerate clinical development of stem cell treatments to patients by creating a focused clinical research organization specializing in stem cell products.

Integration with CIRM Infrastructure Programs. The Accelerating Center will achieve a coordinated and efficient work-flow with the Translating Center to best serve the overarching objective of accelerating stem cell treatments to patients with unmet medical needs. Collectively, these assets are described as Mission Critical Infrastructure in CIRM’s Strategic Plan

[\[https://www.cirm.ca.gov/sites/default/files/files/agenda/151217_Agenda_7_CIRM_St_ranPlan_final_120815.pdf\]](https://www.cirm.ca.gov/sites/default/files/files/agenda/151217_Agenda_7_CIRM_St_ranPlan_final_120815.pdf).

The Accelerating Center will coordinate with the Alpha Clinics Network to bring new stem cell clinical trials to the network and leverage, improve upon, and scale up the services and unique resources provided by the Alpha Clinics Network, so called AVARs (Accelerating and Value Added Resources) . It should facilitate the dissemination of AVARs to support stem cell clinical trials throughout the state. Access to AVARs by sponsors may be facilitated through the administration of subcontracts and licenses.

The Accelerating Center Director will serve on a newly formed joint Translating Center/Accelerating Center/ CIRM Steering Committee and the Alpha Clinics Network Steering Committee to oversee the coordination of CIRM’s Infrastructure Programs (the Accelerating Center, the Translating Center and the Alpha Clinics Network).

Business and Sustainability Plan. The Accelerating Center will develop organizational assets through the aggregation of regulatory, clinical and operational knowledge. The Accelerating Center is expected to develop a sustainability plan designed to leverage these assets in the context of CIRM’s Infrastructure Programs. The aim of this leveraging strategy is to create a sustainable platform for ongoing acceleration of stem cell treatments to patients.

³ As discussed below, the Center is expected to use CIRM funds to subsidize the services provided to CIRM-funded projects.



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The Accelerating Center must utilize the CIRM funding in order to provide a competitive, reduced rate for services provided to all CIRM-funded projects during the term of the award.

While CIRM funds can only be used for CIRM-funded projects, the Accelerating Center may charge commercially reasonable fees to support other non-CIRM funded projects. However, the Accelerating Center may not use CIRM funds to subsidize the direct costs of services provided to non-CIRM funded projects.

This Business and Sustainability plan for the organization must be designed to (i) maximize broad access to clients throughout the state who are developing stem cell treatments, (ii) increase the probability of creating a sustainable business enterprise and (iii) minimize competing interests to support business development.

How will funds be awarded?

CIRM will disburse funds pursuant to a Notice of Grant Award (NGA) and based on 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** require additional funding from CIRM.



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Eligibility

What are the eligibility requirements for partnering with CIRM?

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

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

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

(2) Must have a California operating location

Applicants must conduct a majority of the Accelerating Center's operations from a facility located within California that is equipped to provide the required core services. The Center Director and a majority of the Center's dedicated staff must work out of the California facility and any effort for which salary is claimed must be expended in California.

(3) Applicants must demonstrate solvency

Applicants must provide documentation that shows 180 days' cash on hand from date of application submission to fund operations and the financial ability to meet the contingency requirements for the term of the project. The determination of solvency will be made at CIRM's sole discretion.

(4) 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 serve as the Center Director (CD)?

To be eligible, the CD 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 100 percent effort to the Center for the first three years of CIRM-funding and no less than 80 percent effort thereafter for the duration of the award.



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Schedule and Deadlines

Applications Due	2:00 PM PT, April 15, 2016
Grants Working Group (GWG) Review	Q2 2016
ICOC Review and Approval	Q3 2016
Award Start	Must start within 45 days of award approval

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 ensure the submission of high quality applications. 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.

Budget Review

A team of budget professionals will review the proposed budget regarding how the proposed costs compare with established market rates for similar activities (or how well the costs are justified when market rates are not established). When a proposed budget differs significantly from market rates, 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

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. The GWG will score each applications and the highest scoring application will be recommended for funding to the ICOC's Application Review Subcommittee.

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

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 and patient advocate members of the GWG will evaluate applications and the scientific members will score them based on the following key questions:

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

How likely is the proposed center to accelerate the progression of projects from the late preclinical to clinical stage and the conduct of safe, efficient, and effective stem cell clinical trials? Is the proposed center positioned to be sustainable beyond five years? Does the proposed center offer a sufficient, impactful, and practical value proposition for trial sponsors, patients and/or health care providers?



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2. Has the applicant developed a plan designed to successfully establish and operationalize the center?

Is the operation of the center appropriately planned and designed to provide meaningful, accelerating, and impactful resources (including the required core services) to stem cell clinical trials? Do the project plan and timeline for establishing the center demonstrate an urgency that is commensurate with CIRM's mission? Is an effective plan proposed to provide optimal access and support for CIRM-funded projects while the Center builds its business with non-CIRM funded projects? How competitive is the proposed fee plan for CIRM-funded projects?

3. Is the proposal feasible?

Is the proposed center likely to be established within the proposed timeline? Is the proposed team appropriately qualified and staffed? Does the team have access to all the necessary resources to establish, equip, operate, and maintain the center? Will the center have the capability and resources to provide the required core services? Does the team have a viable contingency plan to manage risks and delays?



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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 CD must create a login in the system to access application materials and apply. Applications are available in the system only to the CD. A CD may submit only a single application.

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 objectives of the partnering opportunity, provide a detailed plan of proposed activities, complete a detailed budget, and provide reference materials 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:** A brief description of the overall program.
2. **Statement of Significance and Impact:** Describe how the core services will serve to address obstacles affecting the speed, probability and sustainability of delivery of stem cell treatments to patients. Describe the contribution the core services will make towards:
 - a. Accelerating advancement of CIRM projects from the preclinical stage to IND or IDE filing and clinical trial initiation.
 - b. Accelerating the safe and efficient conduct of stem cell clinical trials generally and within the Alpha Clinics Network.
 - c. Providing a sustainable (beyond the five-year award period) value proposition for trial sponsors, patients, and/or health care providers by positively affecting the delivery of stem cell treatments to patients.
3. **Project Plan:** Describe how core services will be provided to achieve the objective of the RFA.
4. **Operational Plan:** Describe the plan to operationalize the Accelerating Center and describe how the plan will result in establishment of the Accelerating Center within proposed timelines.
5. **Business Plan & Sustainability:** Describe how the Accelerating Center will provide services based on the requirements set forth in this RFA and build a business sustainable beyond the five-year award period. Describe how the Accelerating Center will:
 - a. Attract CIRM-funded projects (sponsors). Propose a marketing plan that (1) describes how the collective resources and capacities (organizational experience and assets, will be marketed to attract sponsors, and (2) provides a formula illustrating how CIRM funding will be utilized to allow a competitive rate for cores services to be provided.



- b. Describe how the Accelerating Center will leverage and provide synergy with CIRM Infrastructure Programs (the CIRM Translating Center and Alpha Clinics Network). How will the Center interact with, support and leverage and, where appropriate, import critical resources developed and offered by the CIRM Alpha Clinics Network such as, for example, reciprocal IRB approval mechanisms and established patient registries for cohort identification and trial recruitment, nursing “best practices” for support of stem cell clinical trials. Describe how the Accelerating Center would serve as the “lead” in assisting the sponsor with IND preparation and submission. How will the Accelerating Center work with the sponsor and the planned Translating Center (see Translating Center Concept Plan) to drive a regulatory strategy and to import the datasets and materials required for IND assembly and submission.
 - c. Forecast and align capacity with demand for services for clients across the state. Describe how the Center will optimally support the CIRM pipeline of projects while building a business that includes non-CIRM funded projects.
 - d. Remain sustainable after the award period.
 - e. Create data management systems and tools to track the effectiveness of the clinical trial and regulatory services provided by the Center in coordination with the other infrastructure programs.
6. **Timeline:** Provide an activities-based timeline for set up and operations in Gantt chart-like format.
7. **Organizational Experience and Assets**
 - a. Describe relevant experience in project management of preclinical IND-enabling programs and provide a summary table of these activities indicating the: (1) therapeutic area; (2) investigational product and (3) project outcomes (e.g., IND filed and clinical trial initiated 30 days post filing).
 - b. Describe the experience of the applicant in FDA regulated clinical research involving CBER-regulated biologics and/or cell-based therapeutics. Provide a summary table of clinical trial experience indicating the: (1) therapeutic area; (2) investigational product (3) clinical trial phase; (4) number of clinical sites; (5) trial size and (6) project outcome (e.g., clinical trial enrolled as projected).
 - c. Describe the experience of the applicant in clinical trial data management, biostatistics and analytics.
 - d. Discuss any specialized assets the applicant brings that may be deployed to accelerate preclinical programs and/or clinical trials involving stem cell treatments.
8. **Core Service Capacity, Resources, and Environment:** This award will support the provision of core systems and services. Describe the resources, facilities and infrastructure the applicant will dedicate to:
 - a. Regulatory support and management services.
 - b. Clinical operations and management.



c. Data management, biostatistics and analytics.

For each of core service, describe how the available resources, facilities, and infrastructure will be leveraged to achieve the plan in the timeline provided and with the proposed and required core services.

9. **Team Organization:** Describe the team structure (including proposed subcontractors (external CROs or CMOs)), leadership, and communications plan. Describe how the team will coordinate with the Translating Center team to best serve sponsors to achieve a successful IND or IDE and with the Alpha Clinics Network to facilitate initiation of new clinical trials, entry of new clinical projects and sites to the Alpha Clinics Network and development and scale up/scale out of the Networks AVARs.
10. **Contingency Plan:** Summary of potential risks, costs associated with those risks, and mitigation strategies, together with a financial contingency plan outlining viable funding sources in the event that costs exceed the amount of funding disbursement.
11. **References:** List all references used in the body of the proposal.

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 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 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 the rules for spending CIRM funds outside of California?

Awardees 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 those activities conducted outside of California, provided that: (a) the Awardee exercises direction, supervision and control over the activities and (b) a separate out-of-state organization that performs project activities does not retain intellectual property or publication rights in any intellectual property (e.g., invention, technology, data) arising out of the CIRM funded project.



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What are Direct Facilities Costs?

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 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.



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Award Administration

Issuance of Award

A CIRM award is issued via a Notice of Award (NOA) 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 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.

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

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



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Contacts

For information about this RFA or the review process:

Send email correspondence to Infrastructure@cirm.ca.gov

or

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



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Definitions

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

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

“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.



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Appendix

CIRM Regulations

The award made pursuant to this RFA 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>. The CIRM Grants Administration Policy for Clinical Stage Programs will govern this award.