INFRASTRUCTURE

CIRM
CALIFORNIA'S STEM CELL AGENCY

# INFR7: CIRM Patient Support Program Services

**REQUEST FOR APPLICATIONS**

**06.06.23 (revised 08.11.23)**

# INFR7: CIRM Patient Support Program Services

## Objective

The mission of the California Institute for Regenerative Medicine (CIRM) is to accelerate world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world.

The objective of this funding opportunity is to support the establishment and operations of a CIRM Patient Support Program (PSP). CIRM seeks to identify a meritorious organization to implement patient support services that will enhance the accessibility of patients to CIRM-funded clinical trials, particularly for underserved populations.

The regenerative therapies supported by CIRM are designed to address unmet medical needs and may be curative with a single or limited treatment course in some cases.

Clinical trials for cell and gene therapies are demanding for patients throughout the entire clinical trial process, from screening and enrollment to treatment and subsequent long-term follow-up. In particular, increasing financial expenditures by enrolled study participants require added support beyond routine costs for patients and their families. As a result, service providers (for-profit and non-profit) have emerged to provide a range of services to support patients in meeting the new demands of cell and gene therapy trials. CIRM-funded programs have relied on variable approaches to cover patient costs and services. The goal of a CIRM-funded PSP is to create consistent, efficient, streamlined, and reliable access to resources and support across all the different types of CIRM-funded programs.

PSPs have grown into highly successful operations that place greater emphasis on providing services to patients throughout the course of their treatment plan. Evidence indicates a positive impact of PSPs on clinical trial accrual rates, more diverse study participation by minority groups, trial adherence, humanistic outcomes, reduction in healthcare utilization costs, and quality of life. Best-in-class PSPs also provide services related to the needs of the whole patient and may include support with financial stressors and psychosocial, practical, and emotional support. FDA-approved medicines will not be commercially launched in the U.S. without a PSP.

In addition to providing direct patient support, these programs increase both the likelihood and timeliness of trial enrollment, completion of CIRM-supported clinical trials, and protecting California investment in this research. Due to the high demands of clinical trials, dropout rates can be as high as 30%, which may be attributed to financial costs, long-distance traveling, family commitments, and lack of incentives for study completion. Currently, 85% of clinical trials fail to retain sufficient patients[1], 37% are terminated before testing even begins due to under-enrollment[2], 11% fail to recruit a single patient[3], and 30% of patients who enroll will drop out before the trial is

[1] BiopharmaDive. Decentralized clinical trials: are we ready to make the leap? January 29, 2019. https://www.biopharmadive.com/spons/decentralized-clinical-trials-are-we-ready-to-make-the-leap/546591/. Accessed April 4, 2022.
[2] Coalition for Clinical Trial Awareness; About Us. http://cctawareness.org/about-us/. Accessed April 4, 2022.
[3] Cytel. Interview with Ken Getz: exploring challenges of clinical trial operations part 1. April 5, 2018. Accessed December 31, 2021. https://www.cytel.com/blog/interview-kengetz-challenges-clinicaltrial-operations. Accessed April 4, 2022.



complete[4]. Today, patients enrolled in gene and cell-edited therapies require support specifically customized to their treatment.

Proposition 71, the California Stem Cell Research and Cures Initiative (November 2004), enacted the California Stem Cell Research and Cures Act. This established CIRM for the purpose of making grants and loans for stem cell research and research facilities and appropriated $3 billion in general obligation bonds to be governed by the Independent Citizens Oversight Committee (ICOC), a distinguished body appointed by California constitutional officers and public university chancellors.

Proposition 14, the California Stem Cell Research, Treatments, and Cures Initiative (November 2020), authorized an additional $5.5 billion in new bonds to continue CIRM funding of stem cell and other medical research and training, stem cell therapy, and delivery of treatments to patients, research facility construction and administrative expenses.

Under these Propositions, CIRM grantees have revenue-sharing requirements for funds they receive from licensing of or royalties from inventions or technologies that arise from CIRM-funded research. Proposition 14 requires that these revenues be deposited into an interest-bearing account in the General Fund to be spent on "offsetting the costs of providing treatments and cures arising from institute-funded research to California patients who have insufficient means to purchase such treatment or cure, including the reimbursement of patient-qualified costs for research participants." This Patient Assistance Fund (PAF) will continue to grow as CIRM programs progress and trigger revenue-sharing returns to the state. Currently, the PAF has a balance of $15.6 million derived from royalty payments.

## Contact

For information about this program announcement, send email correspondence to:

PSPinfo@cirm.ca.gov

## Award Information

### How Is the Program Structured?

This program will award an organization having suitable expertise to provide patient support services. This program will address the financial and logistical bottlenecks often experienced by patients and their family members enrolling in or participating in CIRM-funded cell and gene therapy trials. The awardee is expected to have demonstrated expertise in implementing patient support programs and must include four required operational activities. These activities must comply with all state and federal regulations, and the applicant should document their awareness and experience in describing the activities below.

**1. Maintain a Patient Support Center**

- Direct patients to CIRM-funded clinical trials as appropriate.
- Provide live support to handle inbound service requests during normal program hours. At a minimum, the PSP shall operate Monday through Friday

[4] Clinical Leader. Considerations for improving patient recruitment in trials. https://www.clinicalleader.com/doc/considerations-for-improving-patient-0001. Accessed April 4, 2022.



from 8:00 a.m. to 5:00 p.m. Pacific Time, exclusive of recognized State of California holidays.

- Provide individualized customer service to callers pursuant to the business rules documents (BRDs), standard operating procedures (SOPs), and specific operational process flows (PFs).
- In coordination with the clinical trial sponsor, CIRM Alpha Clinic or other clinical site the service provider will verify patient and/or health care provider authorization for participation in the program using CIRM- approved language that is consistent with applicable regulations.
- Manage patient referrals from the CIRM-funded programs and clinical sites (including but not limited to the CIRM Alpha Clinics Network), from CIRM (where inquiries come in on a daily basis), from community groups, community physicians, and other healthcare and provider entities, as well as community members themselves who are aware of CIRM clinical trials and programs.

**2. Assessing Patient/Family Financial Eligibility**

- The PSP will work with the sponsor or clinical trial sites to evaluate the patient/family eligibility and need for financial support for permitted reimbursement services or products associated with CIRM-funded trials and directing reimbursements based on financial criteria.
- The PSP service provider will utilize BRDs to determine eligibility for permitted reimbursements associated with patient participation in a CIRM-funded trial.

**3. Providing Reimbursement for Eligible Expenses**

Administer the distribution of payments from PAF. The PAF is dedicated to offsetting the cost for patients deemed eligible for support in activity #2 (Assessing Patient/Family Financial Eligibility). Covering patient costs associated with travel, childcare support, meals, or other expenditures incurred as a result of participating in CIRM-funded clinical trials.

**4. Coordination with CIRM and Trial Sponsors to Maintain Accounting and Assurance of Non-duplication of Permitted Reimbursements**

- Sponsors of CIRM-funded clinical trials may also provide permitted reimbursements to enrolled patients regardless of financial means. The PSP service provider will establish BRDs to work with CIRM-funded sponsors to assure CIRM that there is non-duplication of permitted reimbursements for eligible patients receiving reimbursement from the PAF. Upon CIRM's request, the PSP service provider will be subject to compliance audits.
- The PSP service provider shall provide CIRM with access to standard and customized reports. At a minimum, such reports should provide an accounting of all disbursements from the PAF. The PSP **service provider** should also maintain systems sufficient to document no duplication of permitted reimbursements for eligible patients in CIRM-funded trials. Access to the reports should be available to CIRM 24/7/365 through internet access.

After granting the award, the service provider will prepare appropriate BRD, SOPs, PFs, compiling educational materials, creating standard metric reports, and staff recruitment and training. When the operational system, BRD, SOPs, PFs are in place, system testing will be implemented to assess operational readiness.

**Phase 1** services will be activated through post-testing and staff training. The program will be communicated and advertised through Alpha Clinics, the CIRM

website or other clinical site. Real-time monitoring will occur at the time of activation to identify any gaps or opportunities for additional services.

**Phase 2** of the program will include further expansion of patient services and initiation of additional patient financial services based on real-time metrics reporting provided by the PSP service provider, ongoing internal gap analysis, and patient experience surveys. Metrics reporting and real-time gap analysis results for trial participants will be provided to CIRM and made available to the Accessibility and Affordability Working Group (AAWG) members.

### What activities will CIRM fund?

The CIRM award will provide support to implement the four required operational activities described above, including costs related to:

- ✓ Clinical trial support to guide patients to appropriate clinical trials. Clinical trial support will include partnerships with Alpha Stem Cell Clinics or other clinical sites.
- ✓ Assessing patient/family needs regarding financial support and administering supplemental reimbursements.
- ✓ Preparing BRD, SOPs, PFs, educational materials, standard metric reports, staff recruitment and training in coordination with CIRM. Performing system testing to assess operational readiness.
- ✓ Data gathering and analysis, metrics reporting, gap analyses and patient surveying to inform development, testing, implementation, and expansion of the Patient Support Program services.
- ✓ Activities intended to promote and uphold principles of Diversity, Equity, and Inclusion (DEI) in the conduct of the study
- ✓ Activities associated with sharing data and knowledge from the study

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

- ✗ The conduct of a clinical trial
- ✗ Activities and costs already supported under another CIRM award

### What is the award amount and duration?

The CIRM Governing Board has allocated up to $2.5 million for one award for a duration of up to 5 years. CIRM will not fund indirect costs for awards issued under this funding opportunity.

The amount of total project costs requested must be adequately justified and is subject to adjustments prior to issuance of an award based upon assessments of the Accessibility and Affordability Working Group (AAWG), the CIRM team, or by CIRM's Governing Board.

### How will funds be awarded?

Awards will be made in the form of a grant. Funds will be disbursed pursuant to a CIRM Notice of Award. The first payment will be issued upon initiation of an award,

and subsequent payments will be disbursed on a regular interval at CIRM's option. Continued funding is contingent upon timely progress, as outlined in the project milestones and timeline established under the Notice of Award.

***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 "Plans for Risk Mitigation & Financial Contingency" under application components).

## Eligibility

### What types of projects are eligible for funding?

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

**(1) Must be ready to initiate work on the funded project within 120 days of approval**

Given the urgency of CIRM's mission, the approved awardee must initiate work on the funded project within 120 days of approval and authorization for funding by CIRM's governing board, the Independent Citizens' Oversight Committee ("ICOC").

**CIRM reserves the right to refuse to consider an application that is submitted prior to the completion of all necessary prerequisites.**

**(2) Must have a California operating location**

At the time of the application deadline, the applicant organization must have an operating location in California and must have proof of their legal right to conduct business in California.[5]

**(3) Must provide evidence of certification or license in best practices for patient support**

The applicant must provide evidence of best practices for patient support programs. Evidence may include certification by an organization such as the Utilization Review Accreditation Commission (URAC), International Standards Organization, American Health Information Management Association, the American Medical Association, or the American Academy of Professional Coders in ICD-10 training and Clinical Documentation Improvement or other appropriate body or standard.

**(4) Must have at least five years of experience in patient support services**

Applicants must provide evidence that the applicant organization has at least five years of relevant experience in patient support services.

**(5) For-profit organizations must demonstrate solvency**

For-profit organizations must provide documentation that shows 180 days cash on hand from date of application submission and the financial ability to meet the

[5] CIRM expects that program management and oversight will be performed by employees paid in California. In addition, in order to ensure that the majority of activities occur in CA, the operational systems, business rules documents, standard operating procedures, operational project flows, educational materials, metric reports and knowledge sharing shall be developed and managed by employees paid in California. It is also expected that the Grantee's California management shall develop relationships with the CIRM team and the California clinical trial sites.



contingency requirements for the term of the project. The determination of solvency will be made at CIRM's sole discretion.

**(6) Application must be accurate and complete**

All required components of the application must be completed and may not contain false or inaccurate information.

**(7) Applicant must be in "good standing"**

Applicants must certify that they are in good standing, as follows:

- The applicant' Chief Executive Officer, Chief Financial Officer, or Chief Operational Officer must not have been convicted of, or currently under investigation for, crimes involving fraud/misappropriation;
- The applicant must have accounting systems in place that are capable of tracking CIRM funds; and
- The applicant or key personnel named in the application must not be currently under investigation for research misconduct by the applicant institution or a funding agency and must not be currently debarred by HHS Office of Research Integrity.

## Who can apply?

***Organizations Eligible to Apply for this Opportunity***

California and non-California organizations are eligible to apply; however, applicants must have an appropriate California operating license and a California operating location. Applicants must conduct program management and oversight by employees paid in California from a facility permanently located within California that is adequately equipped to provide the required services.

***Unallowable Costs***

Unallowable Project Costs include the costs of activities performed by a separate out-of-state organization that retains intellectual property or independent publication rights in any intellectual property (e.g., invention, technology, data) arising out of the CIRM funded project. Unallowable costs also include project costs incurred before the date the ICOC approves the application for funding, which can be as early as 90 days post application submission. CIRM has the sole and absolute discretion to determine additional unallowable costs during contracting and the award management process.

***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 the time of application), then the applicant may submit a budget that includes the Allowable Project Costs for California organizations and must describe its intentions and the timing of becoming a California organization in this application.

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### Who can serve as the Program Director (PD)?

To be eligible, the PD 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 propose a level of effort on the project consistent with achieving the project's objectives and not less than 20% on average over the project period. (Note: "project" includes both the CIRM-funded and applicant co-funded components.) Any effort for which salary from CIRM is claimed must be expended in California.
- Must be authorized by the applicant organization to conduct the work and assume the responsibilities of the PD.
- Must ***not*** currently have another application pending review or approval under this funding opportunity.
- Must ***not*** currently have another application that is substantially similar or has overlapping activities pending review or approval under any CIRM opportunity.

### Additional Requirements

***Addressing the Needs of Underserved Communities in CIRM-Funded Projects***

All applicants will be required to provide a statement describing:

- How the proposed project activities will improve access to CIRM-funded clinical trials by underserved and disproportionately affected populations
- How the project team will bring diverse and inclusive perspectives and experience to the implementation of proposed activities
- Activities for building cultural sensitivity and knowledge on the team and/or at partner institutions
- How well the project team demonstrates a successful track record for promoting and valuing diversity, equity, and inclusion (DEI)

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# Application Review Information

***Schedule and Deadlines***

| | |
|---|---|
| Applications Due | 2:00 pm (PDT/PST) on October 31, 2023 |
| Accessibility and Affordability Working Group (GWG) Review | Approximately 60 days post submission |
| ICOC Review and Approval | Approximately 120 days post submission |
| Award Start | Must start within 120 days of award approval |

## What is the process for evaluating an application?

***Pre-submission Consultation***

Prospective applicants are encouraged to contact CIRM before applying with questions or to discuss their project's eligibility or budget considerations.

***Eligibility Review***

CIRM will assess whether the proposed project meets eligibility requirements. 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 and if CIRM deems it appropriate, allow an opportunity to remedy. If CIRM deems it inappropriate, or if the applicant does not remedy the deficiency in a timely manner, CIRM will terminate all further action on the application.

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

***Merit Review***

The merit of each application will be assessed by the AAWG, which is composed of (1) five members of the ICOC; (2) an individual who has private sector experience in innovative therapy medical coverage terms, qualifications, and the process for reimbursement; (3) an expert or a highly knowledgeable individual with experience in federal therapy coverage, qualifications, and process for reimbursement; (4) an expert or a highly knowledgeable individual with experience in California's public insurance program (currently Covered California), coverage, qualifications, and the process for reimbursement of innovative therapies; (5) two (2) representatives from hospitals in California that are participating in stem cell clinical trials or that are treating patients with federal Food and Drug Administration (FDA) approved stem cell or genetic therapies; (6) a representative from a philanthropic organization who has experience assisting patients with clinical trial access and affordability or with access to, and the affordability of, innovative therapies; (7) two representatives from patient advocacy organizations who have technical expertise or experience in coverage, qualifications, and the process for reimbursement of innovative therapies; (8) a health care economist with experience in advising or negotiating with private insurers, government insurers, or corporate self-insurance programs on coverage for innovative therapies or human trials; (9) a patient navigator with training and



experience helping patients obtain financial support from private insurers, public support, or nonprofit support, and helping patients obtain social science support to facilitate their participation in FDA approved human trials or qualification for access and financial assistance for innovative therapies; and; (10) the Chairperson and Vice Chairperson of the ICOC.

The sixteen participating members of the AAWG will evaluate the applications and score them according to technical merit, applying the review criteria described below. The AAWG will score each application and make one of the following specific recommendations to the ICOC:

1) fund the project based on its exceptional merit;
2) do not fund the project but allow resubmission to address areas for improvement if the ICOC has not approved an application for funding following the AAWG's review; or
3) do not fund the project and do not allow resubmission.

The ICOC will make final funding decisions giving consideration to the AAWG's recommendations and any CIRM team recommendations.

***Consideration of Related 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 AAWG 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 merit of an application be evaluated?**

Members of the AAWG will evaluate and score applications based on the following five review criteria:

**1. Does the application offer a meaningful value proposition to improve access and retention to CIRM-funded clinical trials through its proposed patient support services?**

Will establishment of the proposed services successfully accomplish the goals of the Patient Support Program, including improved patient access to CIRM-funded clinical trials? Are the proposed services likely to overcome recognized challenges and barriers to patient access and participation in clinical trials? Does the proposal leverage collaboration opportunities with appropriate partners such as CIRM Alpha Clinics Network? Are the proposed operational elements scalable should there be a

need to increase capacity? Are the budgeted project costs appropriate for the activities proposed and do they represent a good value for CIRM?

**2. Is the project well planned and designed?**

Is the project appropriately planned and designed to meet the objective of the Patient Support Program and to achieve meaningful outcomes? Does the applicant have adequate plans to set up effective documentation, procedures, and processes to conduct required activities, including assessment of patient/family financial eligibility? Does the applicant have appropriate plans to partner with CIRM, Alpha Clinics, and other clinical sites to support effective implementation? Has the applicant developed appropriate mechanisms to minimize patient costs or provide patient reimbursement for eligible expenses in a timely and efficient manner? Does the applicant have appropriate and compliant infrastructure to maintain accounting and assurance of non-duplication of permitted reimbursements? Do the project plan and timeline demonstrate an urgency that is commensurate with CIRM's mission?

**3. Is the project feasible?**

Are the intended objectives likely to be achieved as proposed within the proposed timeline? Does the applicant organization have the necessary resources, technologies, facilities, and established partnerships to carry out the proposed services and activities? Is the proposed team appropriately structured and do team members have the necessary qualifications, expertise, and experience to perform the proposed activities? Does the team have a viable contingency plan to manage risks and delays?

**4. Does the project uphold principles of Diversity, Equity, and Inclusion (DEI)?**

Has the applicant developed effective services, resources, and partnerships to support and facilitate study participation by underserved and disproportionately affected populations in CIRM-funded clinical trials? Do the proposed activities effectively address barriers (e.g., logistical, communication, cultural) that impact access and participation by underserved populations? Does the project team bring diverse and inclusive perspectives and experience to the implementation of proposed activities? Does the project team demonstrate a successful track record for promoting and valuing diversity, equity and inclusion (DEI)? Are activities for building cultural sensitivity on the team proposed and are they well-matched to the needs of the project?

## 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 applicant must create a login in the system to access application materials and apply. Applications are available in the system only to the PD and their designee. A PD may submit only a single application.

### What components does an application include?

CIRM's online application is designed to collect information for CIRM staff to assess eligibility, for the AAWG reviewers to evaluate the project, and for CIRM to rapidly initiate an award if the project is approved for funding.

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### What are the contents of the Proposal?

**Project Summary:** An overview of the proposed activities and significant features of the program.

**Value Proposition:** A description of the overall value of the proposed services and activities towards achieving the objective of the CIRM Patient Support Program.

**Experience and Capabilities of the Organization:** Description of the applicant organization's management and operational expertise with implementing patient support programs in general and direct experience in the four required operational activities. A description of the applicant's approach to developing and maintaining effective partnerships and collaborations with other organizations.

**Project Plan:** Description of all proposed activities detailing how each of the four required operational activities will be accomplished and how the objective of the CIRM Patient Support Program will be met. Description of the technology platforms and solutions (i.e., trial locator technology, integration capabilities, automation sophistication) that will be used for this program. Summary of all data/reporting capabilities related to automation, frequency, and metrics for service level expectations with details of opportunities for sharing data with CIRM.

**Timeline:** Timeline for all proposed activities.

**Resources and Partnerships:** Description of the operating location and resources that will be dedicated to this program. Description of partnerships that have been established or will be forged for the proposed project.

**Team Organization:** Description of the team structure, management oversight, and scalability of staff. Description of the qualifications and experience of team members.

**Budget Description and Justification:** Description and justification of overall project costs including but not limited to set-up fees, ongoing costs (program management, FTEs, shared staff, and IT support).

**Diversity, Equity, and Inclusion (DEI):** Description of the applicant's plan for program engagement, helping sites with retention into the clinical trial process, and implementing assistance programs to address barriers to program participation faced by underserved populations. Description of the applicant's experience and track record in addressing DEI. A description of activities to build cultural sensitivity on the team and/or partner institutions.

**Plans for Risk Mitigation & Financial Contingency:** Potential risks, mitigation strategies, associated costs, and non-CIRM sources of contingency funding.

### 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 their 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 Projects (https://www.cirm.ca.gov/sites/default/files/files/funding_page/CIRM_Grants_Administration_Policy_for_Clinical_Stage_Projects.pdf). 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 will not be funded under this RFA.

### What are indirect costs and how much can an applicant claim?

Indirect Costs will not be funded under this RFA.

## 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 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

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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.

***CIRM Regulations***

Awards made through this program announcement will be subject to all applicable CIRM regulations. These regulations can be found on CIRM's website at https://www.cirm.ca.gov/our-funding/cirm-stem-cell-grant-regulations.

***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 no longer qualifies as a California Organization, etc.

A list of frequently asked questions regarding managing a CIRM award can be found at https://www.cirm.ca.gov/researchers/managing-your-grant.

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## RFA 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.

"**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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## Revisions

| Revision Date | List of Changes |
|---|---|
| **08/11/23** | • Updated submission deadline to October 31, 2023 |
| **07/20/23** | • Clarified patient support activities under the first category of operational activities on pages 3 and 4<br>• Clarified language related to cost reimbursements under the third operational activity on page 4<br>• Provided additional information on what activities CIRM funds can support<br>• Updated award amount information to remove requirement that limited total project costs to $500,000 per year<br>• Clarified that activities conducted in California include program management and oversight of employees paid in California.<br>• Clarified that evidence of patient support best practices may include certification/license from organizations other than URAC<br>• Updated submission deadline to August 29, 2023 |
| **06/06/23** | • Clarified that applicants must have a California operating location rather than must be located in California in the eligibility section on page 6<br>• Clarified an inconsistency that projects must start within 120 days after approval in the Schedules and Deadlines table on page 9 |