# Community Care Centers of Excellence (CCCE): Infrastructure Funding Opportunity

## Summary

| AWARD FEATURES | |
|---|---|
| **Objective** | Expand **geographically diverse** centers of excellence across California to enhance patient access to regenerative medicine treatments by:<br>(1) **Expanding** the **reach** and **delivery** of clinical trials and approved therapies, and<br>(2) Developing a **skilled workforce** to support the delivery of regenerative medicine treatments and ensure **broad accessibility**, particularly in **underserved communities**. |
| **Scope** | Conduct FDA-authorized clinical trials involving stem cell-based or genetic regenerative medicine therapies, make approved regenerative medicine treatments broadly available to California patients, and develop the regenerative medicine workforce |
| **Program Recurrence** | This is a one-time funding opportunity |
| **AWARD DETAILS** | |
| **Maximum Award Amount** | $9,000,000 |
| **Maximum Award Duration** | Five years |
| **ELIGIBILITY REQUIREMENTS** | |
| **Applicant Organization** | Must meet CIRM's definition of a California Organization |
| **Program Director** | The PD must commit a minimum of 30% effort |
| **Matching Funds** | Preferred but not required |
| **SCHEDULES AND DEADLINES** | |
| **Application Due Date** | July 2025 |
| **GWG/FWG Review** | Approximately 90 days post submission deadline |
| **Award Approval** | Approximately 120 days post submission deadline |
| **Start Date** | Must be ready to start award activities within 120 days of award approval |
| **CONTACT AND ADDITIONAL RESOURCES** | |
| **https://www.cirm.ca.gov/researchers/funding-opportunities-infrastructure-projects/**<br>For additional information on the program or applications, contact ccce@cirm.ca.gov. For questions related to the review and approval of applications, contact review@cirm.ca.gov.<br>Additional requirements and definitions may be found in **CIRM Funding Opportunities: Common Requirements and Definitions,** and are incorporated herein by reference. | |

# Background

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. Consistent with this mission, the California Stem Cell Research, Treatments, and Cures Initiative of 2020 (Proposition-14) mandates the establishment of the Community Care Centers of Excellence (CCCE) Program to promote access, across the state, to clinical trials, treatments, and cures arising from CIRM-funded research.

In September 2024, the CIRM Board approved the Strategic Allocation Framework Recommendations. These recommendations include strengthening clinical infrastructure connectivity to ensure enhanced referral, enrollment and retention of California patients in clinical trials. CIRM has performed a state-wide needs assessment and recognizes that achieving this goal will require approaches attuned to social determinants that vary both geographically and within sub-populations. Further, there is a need for additional operational capacities to conduct clinical trials and deliver approved therapies to patients across the state.

# Objective

The objective of this funding opportunity is to expand geographically diverse centers of excellence across California to provide and enhance access to regenerative medicine treatments to patients by:

1. Expanding the reach and delivery of clinical trials and approved therapies, and
2. Developing a skilled workforce to support the delivery of regenerative medicine treatments and ensure broad accessibility, particularly in underserved communities.

A strategic aim is to achieve population representation in clinical research by enhancing the geographic distribution of medical centers capable of delivering regenerative medicine treatments and addressing social determinants that currently limit patient participation.

# Scope and Structure

The operational objective of CCCE program is to establish geographically diverse and culturally responsive centers of excellence to (1) conduct FDA-authorized clinical trials involving cell, gene and/or approved regenerative medicine treatments, (2) make these treatments broadly available to California patients, and (3) enhance California's regenerative medicine workforce. CCCEs must demonstrate the following capabilities:

- **Clinical Operations:** Have licensed and certified healthcare facility with a demonstrated capacity to conduct human subjects' protocols consistent with FDA guidelines in a health research context. Have a demonstrated track record of conducting clinical research protocols (clinical trials). If adequate technical capabilities exist, must not exclude delivery of cell-based therapies derived from human embryonic or other pluripotent stem cells, gene therapies or other cellular or tissue-based products.
- **Health Equity and Access:** Have a demonstrated capacity to perform patient outreach, engagement and education necessary to achieve population representation in clinical trials.
- **Workforce / Career Development:** Have a demonstrated capacity to conduct education, training and career development of physicians, nurses, research coordinators, community health workers or other health/medical professionals with the aim of expanding the availability of regenerative medicine treatments throughout California.
- **Community-based Partnerships:** Have the capacity to initiate community-based partnerships to support the objectives of this program.
- **New Capacities:** Implement evidence-based approaches for evaluating the effectiveness of proposed clinical, career development and education/engagement programs. Drawing on this

evidence centers should propose new community centered capacities, consistent with CCCE program objectives, to improve program effectiveness.

- **Knowledge Sharing:** Develop plans to capture and disseminate operational information vital to evaluating or replicating (1) core competencies, (2) training programs, and (3) outreach and engagement efforts.
- **Organizational Integration and Infrastructure Interconnectivity:** Integrate with clinical operations beyond the award period and develop synergies between Alpha Clinic Network sites and other CIRM Infrastructure and Research Programs.

### *Program Activities*

CIRM **will fund** the following activities under this opportunity:

| ALLOWABLE ACTIVITIES | |
|---|---|
| ✓ | Hiring and salary for team members necessary to conduct clinical trials involving cell, gene and/or regenerative medicine treatments |
| ✓ | Development of systems or deployment of technologies integral to performing the clinical, career development or engagement and outreach objectives of this program |
| ✓ | Contracts with existing CIRM programs or other service providers to enable the implementation of clinical, career development or engagement and outreach programs |
| ✓ | Partnerships with community-based organizations to support clinical research, career development, and/or community engagement |
| ✓ | Personnel and activities related to managing and sharing knowledge |
| ✓ | Acquisition of equipment or renovation of facilities necessary for the delivery of investigational product to patients in clinical trials, if applicable |
| ✓ | Acquisition or deployment of equipment or renovation of facilities necessary for the delivery of approved regenerative medicine products to patients, if applicable |
| ✓ | Acquisition or deployment of equipment or renovation of facilities necessary to navigate, screen or follow up with patients who are participating in clinical trials, if applicable |

CIRM **will not fund** the following activities under this opportunity:

| UNALLOWABLE ACTIVITIES | |
|---|---|
| ✗ | Costs associated with the operation of individual clinical trials |
| ✗ | Project costs incurred before the date the ICOC approves the application for funding, which can be as early as 90 days post application submission. |
| ✗ | Activities already budgeted or paid for under a prior, existing or pending CIRM award or which are already supported by another funder |

### *Award amount and duration*

The maximum amount of funding that may be requested for a CCCE Award is $9,000,000 The maximum award duration is five (5) years. The requested amount must be adequately justified and is subject to adjustments prior to the issuance of an award based on assessments by the Grants Working Group, the Facilities Working Group, the CIRM team, or by the Application Review Subcommittee of the ICOC.

Pursuant to Proposition 14, CIRM shall prioritize CCCE applications that offer matching funds or verified in-kind support, consistent with the highest medical standards, as established by the CIRM governing board.

### *Provisional timetable*

The CCCE funding opportunity will follow the provisional timeline below:

| PROVISIONAL TIMETABLE | |
|---|---|
| **Applications open** | June 2025 |
| **Application Due Date** | July 2025 |
| **Grants Working Group Review** | Approximately 90 days post submission deadline |
| **Facilities Working Group Review, if needed** | Approximately 90 days post submission deadline |
| **Application Review Subcommittee Award Approval** | Approximately 120 days post submission deadline |
| **Award Start** | 120 days after award approval |

## Eligibility

All the following requirements must be fully satisfied for an application to be accepted and considered for funding by CIRM. Requirements marked with a * incorporate by reference the requirements and definitions described in **CIRM Funding Opportunities: Common Requirements and Definitions.**

| ELIGIBILITY REQUIREMENTS | |
|---|---|
| **1** | The applicant organization must have demonstrated ability to perform human clinical trials |
| **2** | The applicant organization must not currently have an active award funded under CIRM's Alpha Clinics (INFR4) Program |
| **3** | The applicant must propose at least one partnership with a community-based organization or organizations to support clinical research, career development or engagement |
| **4** | The applicant must **not** provide direct to consumer fee for service interventions involving "stem cell therapies" subject to the notice requirements of CA Bus & Prof Code § 684 (2018) |
| **5** | The applicant must be ready to initiate work on the funded project within 120 days of award approval |
| **6** | The Program Director must commit a minimum of 30% effort and adhere to CIRM's requirements* |
| **7** | The application must be complete and accurate |
| **8** | The applicant organization must be a non-profit organization and meet CIRM's definition of a California Organization* |
| **9** | The applicant must be in "good standing"* |