INFRASTRUCTURE

CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INFR8: CIRM Community Care Centers of Excellence

Request for Applications

May 2, 2025

Summary

AWARD FEATURES	
Award Objective	Expand clinical research centers of excellence across California to enhance patient access to regenerative medicine treatments by: (1) **Expanding** the geographic **reach** of centers capable of delivering clinical trials and approved therapies, and (2) Developing a **skilled workforce** to support the delivery of regenerative medicine treatments and ensure **broad accessibility** to California patients.
Scope of Award	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 non-profit California Organization
Program Director	The PD must commit a minimum of 30% effort and adhere to CIRM's requirements*
Matching Funds	Preferred but not required
SCHEDULES AND DEADLINES	
Application Due Date	July 8, 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	
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. ***Additional requirements and definitions are available in CIRM Funding Opportunities: Common Requirements and Definitions are incorporated here by reference.**	

Table of Contents

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. CCCE sites are expected to collaborate within CIRM's broader Clinical Infrastructure.

CIRM's Clinical Infrastructure consists of three core programs: The Alpha Clinics Network, the CIRM Patient Support Program and Community Care Centers of Excellence. The Alpha Clinics Network consists of nine academic medical centers in California. Each has expertise and experience conducting clinical trials for regenerative medicine therapeutic candidates. The majority of CIRM-funded clinical trials (CLIN2 programs) enroll patients at one or more Alpha Clinic sites. The Patient Support Program provides logistical and financial support for California patients to increase enrollment and retention in clinical trials. Please see "Resources" section for more information on these programs.

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. Achieving broad representation in clinical trials is vital for a complete scientific evaluation of new treatments. CIRM has performed a state-wide needs assessment and recognizes achieving enhanced participation requires additional operational capacities to conduct clinical trials and deliver approved therapies. Currently, there is an insufficient number of centers available to sponsors that are capable of meeting potential demand for regenerative medicine products. Further, reaching patients across the state requires approaches attuned to unique needs of Californians that vary geographically and within sub-populations.

Objective

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

(1) **Expanding** the geographic **reach** of centers capable of delivering FDA-regulated regenerative medicine therapeutic candidates in clinical trials and approved regenerative medicine therapies, and
(2) Developing a **skilled workforce** to support the delivery of regenerative medicine treatments and ensure **broad accessibility** to California patients

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

A future funding opportunity, expected to open in early 2026, will fund CCCEs which propose to support patient access to regenerative medicine treatments or clinical trials via outreach, screening, enrollment, and pre/post-treatment evaluation.

Scope and Structure

CCCEs must demonstrate the following capabilities, or develop these capabilities, to meet the objective described above:

- **Clinical Operations:** If not already in place at application submission, CCCEs must establish all capabilities and obtain all regulatory approvals and certifications required to deliver regenerative medicine therapeutic candidates in the context of FDA-regulated clinical trials. CCCEs must also

have the ability to deliver FDA-approved regenerative medicine therapies to patients. If adequate technical capabilities exist, the developed CCCE 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.

- **Patient Access:** Perform patient outreach, engagement and education necessary to achieve representation of affected populations in clinical trials.
- **Workforce / Career Development:** 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:** Initiate and administer community-based partnerships to support the objectives of the CCCE program.
- **Knowledge Sharing and Evaluation Science:** Using structured, evidence-based methods, regularly self-evaluate operations, iterate to optimize them, and disseminate operational information vital to evaluating or replicating the centers' (1) core competencies, (2) training programs, and (3) outreach and engagement efforts with other CCCE.
- **Organizational Integration and Infrastructure Interconnectivity:** Integrate and develop clinical operations synergies with Alpha Clinic Network sites and other CIRM Clinical Infrastructure and Research Programs during and beyond the award period. Please see "Resources" on pg. 15 for additional information on relevant Clinical Infrastructure and Research programs.

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

ALLOWABLE ACTIVITIES	
✓	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 conduct clinical trials involving cell, gene and/or regenerative medicine treatments and to manage and share 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 funds **cannot be used** to support the following activities under this opportunity:

UNALLOWABLE ACTIVITIES	
✗	Costs associated with the operation of individual clinical trials
✗	Costs incurred before the date of ICOC approval

✘	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.

Matching fund contributions (optional)

Eligible matching fund contributions must take the form of cash funds or in-kind contributions. Expense categories may include salary for full-time personnel, supplies and resources uniquely dedicated to this project, facilities with existing recharge rates and third-party subcontracts. Expenses covered by matching funds must be described in the Proposal and detailed in the application budget. Matching fund contributions must come from a non-CIRM source.

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 3, 2025
Application Due Date	July 8, 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.

(1) The applicant organization must have demonstrated ability to perform clinical trials.

The applicant organization must have licensed and certified healthcare facility with a demonstrated capacity to perform clinical trials consistent with FDA guidelines. Applicants can demonstrate this capacity by describing and identifying specific clinical trials performed by the organization. Descriptions should include the research aims and findings, a description of the participant population, and how review and oversight of the study was performed.

(2) The applicant organization must not currently have an active award funded under CIRM's Alpha Clinics (INFR 4) 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.

A "community-based organization" means a public or private non-profit organization of demonstrated effectiveness that is representative of a community or significant segments of a community and provides educational or related services to individuals in the community. A community-based organization provider must be a public or private non-profit organization with a 501(c)(3) status or a fiscally sponsored entity of a 501(c)(3) non-profit organization.

All applicants must allocate a minimum of $562,500 ($112,500 per year average) from the total award amount to community-based partnerships. Use of community-based partnership funds is restricted solely for this purpose and cannot be expended for any other purpose. Unexpended community-based partnership funds must be returned to CIRM.

(4) The applicant must not provide direct to consumer fee for service interventions involving "stem cell therapies" subject to the notice requirements of CA Business and Professional Code § 684.

(5) The applicant must be ready to initiate work on the funded project within 120 days of award approval.

Given the urgency of CIRM's mission, all approved awardees must initiate work on the funded project within 120 days of approval and authorization for funding by the Application Review Subcommittee of the Independent Citizens' Oversight Committee.

(6) The Program Director must commit a minimum of 30% effort and adhere to CIRM's requirements.

The Program Director (PD) must adhere to general eligibility requirements described in CIRM Funding Opportunities: Common Requirements and Definitions and must propose a level of effort on the project consistent with achieving the project's aims and not less than 30% on average over the project period. Any effort for which salary from CIRM is claimed must be expended in California.

(7) The application must be complete and accurate.

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

(8) The applicant organization must meet CIRM's definition of a California Organization.

The applicant organization must be a California organization per CIRM's definition described in CIRM Funding Opportunities: Common Requirements and Definitions at the time of application

(9) The applicant must be in "good standing."

Applicants and their affiliates must represent and certify that they are in good standing, as described in CIRM Funding Opportunities: Common Requirements and Definitions.

Application Submission Process and Components

Consultation

Before applying, prospective applicants are encouraged to contact CIRM with questions or to discuss their project's eligibility or budget considerations.

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 Grants Working Group reviewers to evaluate the project, and for CIRM to rapidly initiate an award if the project is approved for funding.

The application Uploads page provides templates and guidelines for writing the Scientific and Facilities Proposal, Budget, Budget Justification, Biosketches, Letters of Support, Letters of Matching Funds Commitment, Project milestone and timelines, and other key components of the application. Applicants **must** use the provided templates.

What are the contents of the Scientific Proposal?

The Scientific Proposal comprises the bulk of detailed information on the project, organized within the following sections. Page limits and formatting information will be provided on the actual Proposal template.

Program Summary: Provide a brief description of the overall structure, capabilities, services, and objectives of the proposed Community Care Center of Excellence.

Value Proposition: Describe how the CCCE will add value to CIRM's Clinical Infrastructure and Research programs. Include description of how the proposed center is uniquely positioned to achieve the CCCE RFA's objective to address barriers to clinical trial participation, enhance California patients' access to regenerative medicine clinical trials and approved treatments, including any novel capabilities the center will bring to enhance CIRM's clinical infrastructure, and develop California's regenerative medicine workforce.

Capabilities Development Plan:

a) Clinical Operations:

- Describe the organization's clinical research capabilities and experience conducting clinical trials. Describe how the proposed center will expand referrals and access to clinical trials or regenerative medicine treatments.
- Describe the level of clinical support you aim to provide and develop over the award period (e.g. on site manufacturing capabilities, cohort identification, patient screening, enrollment, pretreatment evaluation or work up, therapeutic and therapeutic candidate delivery, post-intervention follow-up and monitoring, and evaluation of outcomes).
- Describe how you plan to acquire any new capabilities required to deliver investigational regenerative medicine products or approved regenerative medicine treatments. Describe how you will ensure the clinical team will satisfy any certification or accreditation requirements for the delivery of cell or gene therapies. See "Resources" on pg. 15 for examples of accreditations.
- Discuss how the center's clinical operations will be responsive to any unique needs of the populations being served.

b) Career Development:

- Describe how the proposed center will support career development programs to advance the knowledge of physicians, nurses, research coordinators, community health workers or other health care professionals that are integral to education, navigation or the delivery of regenerative medicine

clinical trials or treatments. Consider how health education or delivery occurs among populations in the catchment area.

- Describe how the center will collaborate with the Alpha Clinics or CIRM Education programs to adapt, expand, or otherwise utilize established training opportunities. Propose placement programs for trainees participating in CIRM-funded Education Programs.

c) Outreach and Engagement:

- Describe how your outreach and engagement activities will enable awareness and informed access to clinical trials and regenerative medicine treatments. Explain how the program will address barriers or conditions that currently limit access to treatments. CIRM recommends a logic model structure to describe outreach and engagement activities. Please see "Resources" on pg. 15 for additional information.
- Propose at least one partnership with a community-based organization or organizations to support clinical research, career development, and/or engagement. Discuss how the partnership(s) will build trust, respect, and benefit for impacted populations, and the existing gaps or barriers the partnership(s) will address. Address how you propose to manage partnership agreements to ensure successful outcomes, including ensuring community partners have appropriate field competency and appropriate training.

Organizational Experience, Capacity, and Resources:

- Describe the organization's experience conducting human subjects research, implementing a human subjects protection program, maintaining IRB review of clinical protocols, performing safety monitoring, and other required oversight activities.
- Describe the proposed service area of the center (include a map if available) and populations served. Include any satellite or affiliated sites that can be utilized to achieve the objectives of this program. Discuss how your proposed configuration of sites and collaborators increases the likelihood of patients enrolling in clinical trials or accessing approved products.
- Describe available organizational capacities and resources that will enable the team to successfully implement the proposed project plan.
- Describe matching funds or in-kind support that will contribute to the proposed center activities. Additional verification of sources of matching funds or in-kind support must be provided as Letters of Support uploaded to the online application.

Overcoming Barriers to Participation:

- Describe how the center will support and facilitate outreach and study participation by all affected populations to ensure enhanced referral, enrollment and retention of California patients in clinical trials.
- Describe how the assembled center team and community-based partners are experienced to successfully implement the proposed activities to overcome barriers to participation.
- Describe the organization and team's track record for achieving broad representation in clinical research.

Evaluation and Knowledge Sharing Plan:

- Describe plans to measure and evaluate operational information vital to optimize the center's operations or replicate the center's core clinical competencies, training programs, and outreach and engagement efforts.
- Describe capacities to collect and report data related to patient referral, recruitment and accrual. Propose metrics to measure the success of interventions aimed at expanding referrals to clinical

trials or increasing participation rates of affected patients. Include approaches for returning results to other CCCE, study participants, community-based partners, policy makers and the public.

- Describe how the knowledge sharing plan will identify opportunities for efficiency and promote collaboration. Include qualitative and quantitative methodologies and dissemination methods that are accessible to all participants. Note that applicants are encouraged to allocate funds in their proposed budget for personnel and/or activities related to managing and sharing knowledge gained from program implementation.

Network Integration Plan:

- Describe any proposed collaborations with Alpha Clinic sites or other CCCE applicants and how these collaborations will advance the CCCE program objectives.
- Describe how the proposed center would expand the value of the CIRM's Clinical Infrastructure Network. Describe how the center will leverage the Patient Support Program to expand enrollment in clinical trials during and beyond the award period.

Timeline: Provide an activities-based timeline inclusive of all operational project activities in Gantt chart format. Include facilities activities if applicable.

Project Team:

- Describe the qualifications and staffing of the Program Director, Key Personnel, and proposed Key Collaborators that will support the establishment, operation, and/or maintenance of the center according to the proposed project plan and timelines. Key Personnel are defined in CIRM Funding Opportunities: Common Requirements and Definitions.
- Describe the team structure, leadership, and communications plan.

Contingency Plan: Summarize 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.

References: List all references used in the body of the Scientific Proposal.

What are the contents of the Facilities Proposal?

The main body of the optional Facilities Proposal contains the following sections. Note, this section is optional and is only required if building (facilities) renovation(s) are proposed for performing the required activities.

Executive Summary of Renovation/Facility Improvements Project: Briefly summarize the overall CCCE to be developed. Describe how any proposed CCCE renovation supports the CCCE core activities, including expanding access to clinical trials or regenerative medicine treatments. Describe how the proposed facility renovation will leverage existing capacity or infrastructure.

Basic Site Information: Provide the site address, location, and square footage of the proposed facility for which renovation or major equipment costs are requested. Describe building construction type, age, any known historic significance or other pertinent site details. Describe how access to the building is secured (owned or leased) and whether the space is shared with another entity. If the building is leased, describe the lease tenure. Describe uses of adjacent buildings, regulatory jurisdiction (Authority Having Jurisdiction or AHJ), and storage/use of any proposed chemical/hazardous materials.

Facilities Project Team: Describe the organization and qualifications of the team that will be responsible for executing the proposed renovation/facility improvement project, such as the design personnel (e.g., Architect of Record (AOR), Engineer of Record), construction personnel (e.g., General Contractor), and any other pertinent team members. Facilities Project Team members who meet the requirements of Key

Personnel, as defined in CIRM Funding Opportunities: Common Requirements and Definitions, should be named.

Design Narrative: Describe the proposed scope of renovation, equipment, and layout of the facility to be used for CCCE activities. Discuss how the spaces support clinical research or other CCCE activities, including the location of key processes and workflows between capabilities. Discuss how the design addressed key program needs. Describe potential risks and associated mitigation measures in the design and renovation.

Plans and/or Graphics: Provide scaled diagrams of existing and proposed CCCE facility floor plans and any other diagrams that describe the proposed improvements. The information provided should include adequate information to describe the scope of work.

Renovation Cost: List items and their costs, and provide a high-level description of cost drivers, including compliance with prevailing wage requirements.

Facility Project Schedule: Provide a Gantt schedule consistent with the overall timeline. Include milestones and tasks such as design, permitting, construction, equipment and commissioning necessary to complete the proposed renovation/facilities improvement project and activate the proposed facility.

Key Collaborators

Key Collaborators include any proposed individual or organization conducting activities integral to the program plan, including Alpha Clinics. Key Collaborators may be paid or unpaid with award funds, but such funding should **not** be allocated from the $562,500 Community-Based Partnerships budget.

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 for research funded by CIRM are detailed in the applicable sections of the Grants Administration Policy for Facilities and Equipment Grants and for research and training funds are detailed in the Grants Administration Policy for Clinical Stage Projects. Generally, project costs for personnel, supplies, travel, equipment, and subcontracts may be claimed. Limits for specific cost categories must be observed.

Change in Status

Applicants are required to notify CIRM of any material change in status while the application is pending review, e.g., a change in PD or any changes that could compromise the applicant organization's status as a California organization per CIRM's definition.

Application Review Information

What is the process for evaluating an application?

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.

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 or nurse 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: https://www.cirm.ca.gov/about-cirm/working-groups/. The composition of the ICOC can be viewed at https://www.cirm.ca.gov/about-cirm/about-board/.

The fifteen participating scientists on the GWG will evaluate the applications and score them on a scale of 1-100 according to scientific and technical merit, applying the review criteria described below. For purposes of making funding recommendations to CIRM's board, each application shall be assigned to one of two categories based on the median score as follows:

- **Median score 85 or above:** The application has exceptional merit and warrants funding, if funds are available; or
- **Median score below 85:** The application is not recommended for funding.

The Application Review Subcommittee of the ICOC makes final funding decisions.

Facilities Review

The merit of renovation and capital equipment plans described in the application will be assessed by the Facilities Working Group (FWG), which is composed of six patient advocates from the CIRM Governing Board (ICOC), four real estate specialists, and the Chair of the ICOC. The FWG makes recommendations regarding funding for buildings and capital equipment to the Application Review Subcommittee.

The members of the FWG will evaluate the renovation and capital equipment sections of the applications and score them applying the review criteria described below for facilities components. For purposes of making funding recommendations to CIRM's board, each application shall be assigned to one of two categories based on the median score as follows:

- **Median score 85 or above:** The application has exceptional merit and warrants funding, if funds are available; or
- **Median score below 85:** The application is not recommended for funding.

The Application Review Subcommittee of the ICOC makes final funding decisions.

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 PD served as the PD/PI, a co-PD/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?

Members of the GWG will evaluate and score applications based on the following criteria:

1. Value Proposition

- To what extent does the proposed center offer an impactful and practical value proposition for patients, trial sponsors and/or health care providers?
- How well will the proposed CCCE expand geographic access to regenerative medicine treatments and clinical trials?
- How well will the proposed center expand the value of CIRM's Clinical Infrastructure Network; for example, broadening the Network's reach, providing new expertise, offering new or unique career development opportunities, or contributing to trust building, respect and new capacities / benefits to proposed partners?

2. Plan and Design

- Are the clinical operations appropriately planned and designed to expand the accessibility of regenerative medicine treatments?
- Does the applicant have an effective plan to manage investigational or approved regenerative medicine products within the project timeline?
- To what extent do the proposed career development activities serve to develop the workforce integral to the delivery of regenerative medicine treatments?
- How well will the proposed outreach and engagement activities meaningfully increase referrals of California patients to regenerative medicine treatment opportunities?
- How well could the proposed community-based partnerships address informational, economic, or other determinants impacting access to regenerative medicine treatments?
- To what extent does the applicant propose meaningful collaboration with the CIRM Alpha Clinics to assist patients in accessing clinical trials and approved treatments?
- Is the evaluation plan and schedule appropriate to collect and synthesize operational information, optimize center operations and enable effective knowledge sharing?

3. Feasibility

- How feasible is the project plan, and how likely is it to be implemented within the proposed timeline?
- To what extent does the applicant have appropriate experience conducting clinical trials?
- Is the applicant team appropriate to successfully develop and operate the proposed CCCE?
- To what extent does the proposed team have access to all the necessary resources to develop and operate the CCCE, support patients, career development, outreach and engagement programs and community-based partnerships?

4. Serving the Needs of California Patients and Affected Communities

- To what extent do the proposed activities hold the potential to increase referrals or patient access (e.g. enrollment) to clinical trials or approved treatments?
- How effective are the tools and resources that the applicant team will offer to engage and recruit patient cohorts that encompass all affected populations?
- Does or will the project team bring perspectives and experience from patients and affected populations to the implementation of proposed activities?

How will the merit of the facilities components be evaluated?

Members of the FWG will evaluate and score applications based on the following criteria:

1. Appropriateness of the renovation and facilities improvement project to support the proposed CCCE activities

- To what extent does the scope of work, as defined by the facilities design narrative, plans, and other relevant information, describe a facility that best supports the goals of the proposed CCCE?
- Is the proposed location and layout of the facility appropriate for its goals?

2. Feasibility of the proposed renovations/facility improvements

- To what extent is the proposed construction timeline, including key milestones and activity timelines, feasible and appropriate for the project?
- How well is the project staffed with appropriate levels of renovation/construction expertise?

3. Appropriateness of the renovation/facility improvement costs

- To what extent do the proposed costs adequately account for design, construction, equipment, contingencies, and any other anticipated costs?
- Is the project appropriately budgeted to adhere to prevailing wage requirements?

Award Administration

Issuance of Award

A CIRM award is issued via a Notice of Award (NOA), which is the formal contract that defines the terms and conditions of an award and documents the commitment of funds from CIRM. CIRM reserves the right to modify or establish funded project activities and the associated budget prior to issuance of the NOA. CIRM also establishes project milestones, success criteria and timelines at its sole discretion after consultation with the PD and based on information provided in the application. CIRM may also review key contracts/agreements that are critical to the success of the project for compliance with CIRM's policies and regulations.

Milestones and Payment

Upon execution of the NOA, CIRM will issue an initial payment; subsequent disbursements will be made as outlined in the NOA. Continued CIRM funding is contingent upon timely progress against specific aims or milestones and timelines established under the NOA. Where project milestones are not timely met, CIRM reserves the right to either redirect resources to maximize the project outcome or, at its sole discretion, to suspend payment and/or terminate the project. Five percent (5%) of the award budget will be withheld pending completion of all remaining milestones and reporting requirements.

Reporting

Awardees will be required to provide periodic written progress and financial reports to CIRM. CIRM will partner with the Awardee to foster the success of the project. Awardees will have ongoing communication with the CIRM Science Officer throughout the duration of the award, typically meeting by teleconference and periodically in person.

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.

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

Resources

CIRM's Clinical Infrastructure and Research Programs

CIRM's Clinical Infrastructure and Research Programs consist of the following:

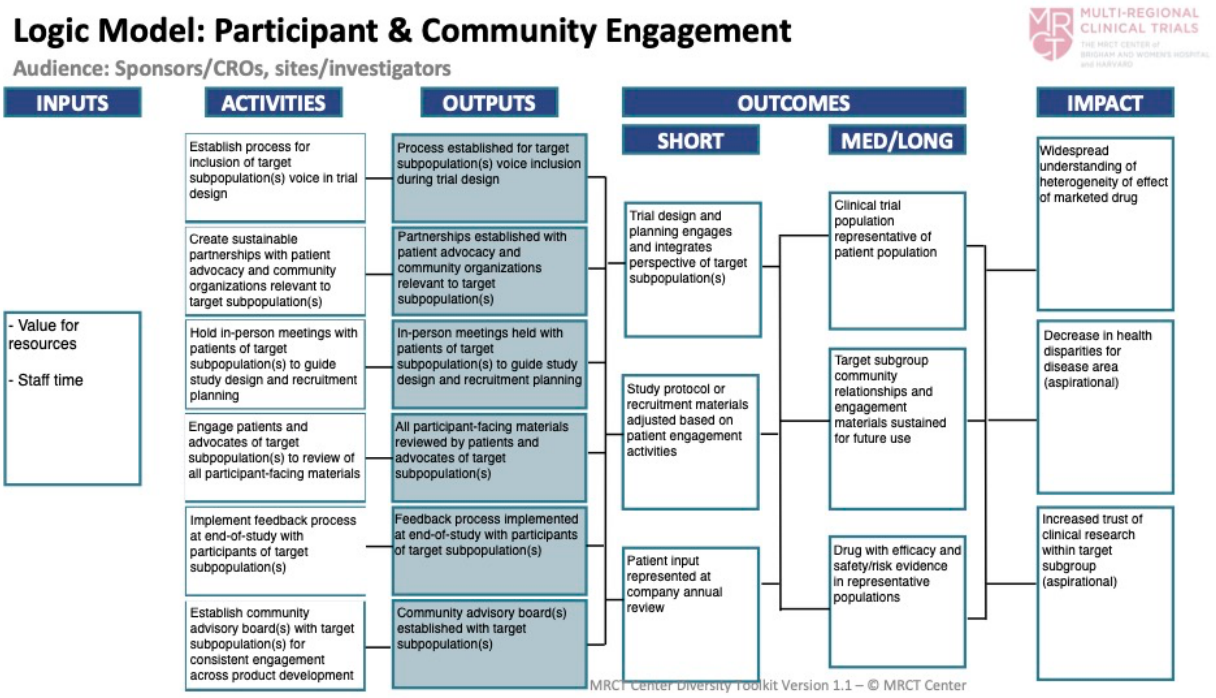
PROGRAM	PILLAR	OBJECTIVE	ACTIVITIES OR SCOPE	ADDITIONAL INFORMATION
CLIN2	Ongoing Clinical Research Funding Opportunity	Conduct eligible, FDA regulated regenerative medicine clinical trials	Funding supports investigators to conduct all activities necessary for completion of a Phase 1, 2, or 3 trial, studies to understand mechanism of action and potency assay development, patient support activities (engagement, enrollment, retention), and data sharing.	https://www.cirm.ca.gov/researchers/funding-opportunities-clinical-trial-stage-research/
Patient Support Program (PSP)	Infrastructure	Provide logistical and financial support to California patients enrolled in CIRM-funded clinical trials	Travel assistance and coordination, lodging support throughout clinical visits, meals and other nutritional assistance. Eligible patients are referred to the program by the clinical research coordinators or other members of the clinical trial team.	In development
Alpha Stem Cell Clinics (INFR4)	Infrastructure	Streamline and accelerate delivery of cell and gene therapies across the state of California	Nine clinics housed at major CA medical centers with expertise in delivering FDA approved regenerative medicine therapies and conducting FDA regulated clinical trials.	https://www.cirm.ca.gov/alpha-clinic-network/

Accreditation

For information on recommended accreditations related to regenerative medicine products, consult the Foundation for the Accreditation of Cell Therapy (FACT) by visiting https://www.factglobal.org/.

Logic Models

The Multi-Regional Clinical Trials center at Brigham and Women's Hospital and Harvard (https://mrctcenter.org/) has developed resources for clinical trial sites implementing community engagement programs. A recommended logic model is below.



Bierer B.E., White S.A., Meloney L.G., Ahmed H.R., Strauss D.H., Clark L.T., (2021)
Cambridge and Boston, MA: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center).

Requirements and Definitions

Terms used here are defined in CIRM Funding Opportunities: Common Requirements and Definitions.

Contact Information

For programmatic questions that are not addressed in the above resources, send email correspondence to ccce@cirm.ca.gov.

For questions related to application review, send email correspondence to review@cirm.ca.gov.

For questions related to budgets or allowable project costs, please consult the Grants Management FAQ on CIRM's website under "For Researchers > Grants > Managing your Grant." For more information on budgets or allowable costs that are not addressed in the above resources, send email correspondence to grantsmanagement@cirm.ca.gov.