

California Institute for Regenerative Medicine

Community Care Centers of Excellence Concept Plan

Geoffrey Lomax DrPH
May 14, 2024
CIRM Access and Affordability Working Group





Mission Statement



OUR MISSION

Accelerating world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world



CIRM AAWG 5/14/24



CCCE Program Development Timeline



Board Review Application Phase Needs Assessment Phase Listening Sessions Statewide and Interviews **Public Workshop Deliver** Real World Real Central Valley Sacramento Draft Concept Posting Inland Empire and Virtual Consult Science Webinar 5/15 Engage Applicants Coachella Valley Subcommittee AAWG and Applications Due **ICOC** 8/15 Oct 22 – Mar 23 June 2023 Q3-Q4 2023 March 2024

CIRM AAWG 5/14/24

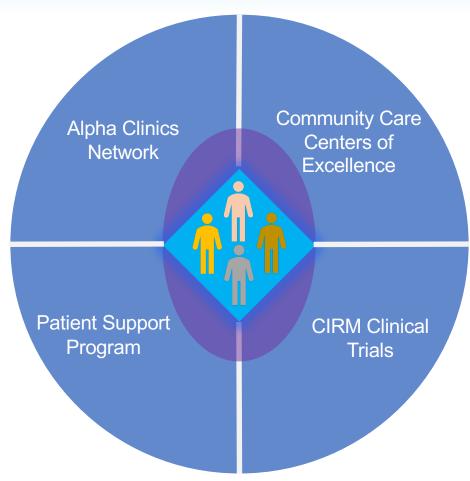


CIRM's Clinical Infrastructure Network



- Nine Awards
- Supporting CIRM-Funded Clinical Trails
- Status: Active

- Address Financial and Logistical Barriers
- Improve Patient and Research Outcomes
- Status: Launching



- Bring CGT Clinical Capacity to Communities
- Address Social Determinants Impacting Participation
- Status: RFA open

- CIRM-Funded Clinical Trials (100+ funded to date)
- Optimal Care for Unmet Medical Needs
- Status: Active and ongoing

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Activities Supported by CCCE Award



• Clinical Operations:

- **1. Support Site**: Supporting access to regenerative medicine clinical trials or approved products .
- 2. Support and Delivery Site: Develop the capacity to deliver investigational or regenerative medicine products during the award period, and do not administer unauthorized stem cell treatments.
- <u>Career Development:</u> Adapt, apply or otherwise utilize EDUC and other CIRM Training resources. Serve as a placement site for CIRM scholars and trainees. Integrate regenerative medicine into navigator and community health worker certification programs.



Activities Supported by CCCE Award



- Outreach and Engagement: Applicants must develop outreach and engagement programs to enable awareness and informed access to clinical trials, regenerative medicine treatments and career development opportunities.
 Programs should be adapted to the needs of different populations and serve to support the successful attainment of DEI objectives.
- <u>Community-Based Partnerships</u>: Applicants must allocate a minimum of \$625,000 in the award budget for community-based partnerships. Applicants should propose at least one partnership with a community-based organization or organizations to support clinical research, career development and/or outreach and engagement. Emphasis should be placed on supporting activities that reduce disparities and support broad representation in clinical research.

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Partnership Aims Examples



- Targeted interventions aimed at reducing disparities in referrals to clinical trials with the overall aim of increasing the referral or participation rates of medically underserved patients and vulnerable populations.
- Efficacious partnerships should serve to produce trust, respect and capacity building (benefit). Emphasis on Community Health Workers and Patient Navigation.
- Applicants are encouraged to propose holistic and integrated approaches for satisfying the objective of this program. Specifically, consider how your clinical, career development, community-based partnership and network development initiatives can work in tandem or synergistically to enhance the capacity of CIRM's Clinical Infrastructure Network to treat patients and address barriers or conditions that contribute to disparate access.

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The CIRM Governing Board has allocated \$60.2 million for funding of the CCCE program to support the (1) core operations, (2) community-based partnerships (\$625,000), (3) building renovation, and equipping facilities for a five-year duration.

This opportunity provides two categories of award based on whether the proposed site will offer clinical trial support only or both support and deliver as shown below.

- A Clinical Trial Support Site may request a total award amount of up to \$7.5 million per award.
- A Clinical Trial Support and Delivery Site may request a total award amount of up to \$10.054 million per award.



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