



MEMORANDUM

TO: Members of the Science Subcommittee of the ICOC
FROM: Geoffrey Lomax Associate Director Medical Affairs and Policy
SUBJECT: Concept Plan: Community Care Centers of Excellence
DATE: November 20, 2023

Background

The mission of the California Institute for Regenerative Medicine (CIRM) is to *accelerate world-class science to deliver transformative regenerative medicine treatments equitably to a diverse California and world*. 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.

CIRM initiated a statewide needs assessment in October 2022 to inform the concept plan development. The needs assessment included three regional listening sessions, and a statewide workshop (in person and virtual), engaging key informants and stakeholders. CIRM has provided the AAWG with needs assessment updates and has [compiled findings](#) to inform public deliberations.

Needs assessment participants included numerous stakeholders integral to health care access. Participants included regional and community health centers, community health workers, elected officials, and Community-Based Organizations (CBOs). Stakeholders expressed enthusiasm for the opportunity to partner with CIRM to expand access to regenerative medicine. Participants suggested that making treatments widely available to California patients will require approaches attuned to social determinants that vary both geographically and within defined sub-populations. Further, operational capacities and readiness to support clinical research and make treatments broadly available to California patients also vary geographically.

Concept Plan Development:

The draft concept plan is intended to be responsive to the diversity of social determinants and operational readiness identified in the needs assessment. The aim is to establish geographically diverse and culturally responsive centers of excellence to (1) support clinical research in collaboration with the Alpha Clinics Network, Patient Support Program, California CGT Manufacturing Network, and other CIRM initiatives,



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(2) provide career development opportunities, and (3) conduct health education, research, and engagement activities in collaboration with Community-Based Organizations (CBOs).

Award amounts will vary depending on whether an applicant organization is proposing to (1) support clinical research protocols or (2) support clinical research protocols and deliver investigational or regenerative medicine products during the award period. More detailed delineations of these objectives are described in the draft concept plan.

CIRM is recommending an allocation of \$60.2 million for funding the CCCE awards. The awards will include specified budget categories including:

- **Core Operations:** CIRM will fund clinical operations that provide one of two core functions under an award:
 1. **Support Site Only:** A Support Site will offer patients access to FDA-regulated regenerative medicine clinical trials or approved products available at partnering institutions such as an Alpha Clinic site.
 2. **Support and Delivery Site:** In addition to offering access to regenerative medicine clinical trials or approved products, these sites will deliver onsite treatments to patients under an FDA-regulated clinical trial or for an approved regenerative medicine product.
- **Community Partnerships:** Create partnerships with Community-Based Organizations (CBOs) to support clinical research or care, career development, and community engagement.
- **Facilities Funding:** Acquisition or deployment of equipment or renovation of facilities necessary to navigate, screen, treat, or follow up with patients participating in regenerative medicine clinical trials or delivering approved products.
- **Indirect Costs:** The indirect cost rate will be set at 20% for non-profit applicant organizations.

Ethics and Policy Considerations:

The concept plan includes provisions intended to ensure implementation is consistent with CIRM's policies for the protection of human research participants. This award would be subject to CIRM's [Medical and Ethical Standards Regulations](#), and in addition, the concept plan includes the following:

- **Licensing and Common Rule Compliance:** The applicant must be a licensed and certified healthcare facility¹ with a demonstrated capacity to support human

¹ <https://data.chhs.ca.gov/dataset/healthcare-facility-locations>



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- subjects protocols² consistent with FDA guidelines³ in a health research context.
- Prohibition on Unauthorized “Stem Cell” Treatments: The applicant organization 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 \(2018\)](#).
 - Research Ethics Training: Program implementation will include research ethics training for community partners consistent with requirements for clinical and social science research.

Requested Actions:

CIRM requests a recommendation from the Science Subcommittee to approve the CCCE concept plan draft for ICOC consideration.

² <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trials-guidance-documents>