CALIFORNIA'S STEM CELL AGENCY

MEMORANDUM

TO: MEMBERS OF THE ICOC
FROM: GEOFFREY LOMAX, ASSOCIATE DIRECTOR MEDICAL AFFAIRS
SUBJECT: DRAFT CONCEPT PLAN: COMMUNITY CARE CENTERS OF EXCELLENCE
DATE: JANUARY 12, 2024

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*. 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 be operational in the first five years, 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 concept plan development. The needs assessment included three regional listening sessions, 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 stakeholder's integral to health care access. Participants included regional and community health centers, community health workers, elected officials, and community-based organizations. 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 varies geographically.

Concept Plan Development:

The draft concept plan is intended to be responsive to the diversity of social determinants and operational capacities identified in the needs assessment. Further, the current draft has been drafted to be responsive to recommendations from the Access and Affordability Working Group; Scientific, Medical and Ethical Standards Working Group and the Science Subcommittee (please see attachment 1).

The program 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, (2) provide career development opportunities, and (3) conduct health education, research, and engagement activities in collaboration with community-based organizations.

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

CIRM is recommending an allocation of $60.12 million for funding of the CCCE awards.

The awards will include specified budget categories including:

- **Core Operations**: Funds for operation of a licensed and certified healthcare facility[1] with the aim of (1) supporting regenerative medicine clinical-trials or the delivery of approved products (support sites), or (2) have or be in the process of developing capacity to deliver investigational or regenerative medicine products during the award period (delivery sites).
- **Community Partnerships:** Create partnerships with community-based organizations 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.

[1] https://data.chhs.ca.gov/dataset/healthcare-facility-locations

- **Indirect Costs**: The indirect cost rate will be set at 20% for non-profit applicant organizations.

Requested Actions:

CIRM requests approval of the draft CCCE Concept Plan by the ICOC.

Attachment 1: Working Group and Subcommittee Considerations

1. **The CCCE program represents an expansion of CIRM activities. What assurances do we have that these activities will be conducted in accordance with CIRM's scientific, ethical standards and practice-based standards?**

   CIRM proposes multiple layers of assurance to support concurrence with CIRM standards including:

   Eligibility / Public Policy Requirements: The concept plan cites several objective public policy requirements that will be verified as a condition of determining applicant eligibility. For example, the applicant must:

   - Have licensed and certified healthcare facility.[2]
   - Have a demonstrated capacity to support human subjects' protocols[3] consistent with FDA guidelines[4] in a health research context.
   - Not provide direct to consumer fee for service interventions involving "stem cell therapies"[5] subject to the notice requirements of CA Bus & Prof Code § 684 (2018).

   Training and Certification: Numerous key informants and members of the Scientific Medical and Ethical Standards Working Group cited the value of training and certification programs. Such programs have been utilized to support good clinical practice and the conduct of research. CIRM will incorporate appropriate training and certification into program milestones and associated costs will be allowable in the awards. CIRM Infrastructure and Education programs may complement existing certificate program, particularly those for Community Health Workers and Patient Navigators, with cell and gene therapy specific content.

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[2] https://data.chhs.ca.gov/dataset/healthcare-facility-locations
[3] https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trials-guidance-documents
[5] "Stem cell therapy" means a therapy involving the use of human cells, tissues, or cellular or tissue-based products, but shall not include a therapy involving human cells, tissues, or cellular or tissue-based products that meets the criteria set out in Section 1271.10 of Title 21 of the Code of Federal Regulations, as amended May 25, 2004, as published in the Federal Register (69 Fed. Reg. 29829), or that qualifies for any of the exceptions described in Section 1271.15 of Title 21 of the Code of Federal Regulations, as amended May 25, 2004, as published in the Federal Register (69 Fed. Reg. 29829).

2. **Community-based partnerships are important so what assurances do we have that such partnerships will occur with CBOs?**

   CBO partnerships or a partnering plan will be required as a condition of application and subject to GWG review. CIRM proposes a separate budged line-item dedicated to supporting partnerships with CBOs, so such funds are dedicated to this purpose.

3. **There are a lot of "moving pieces"; how will CIRM coordinate program operations?**

   CIRM is developing information platforms to coordinate various program operations. For example, CIRM's Education Program Portal will serve as a hub for facilitating access to and implementation of training and career development opportunities. Similar CIRM resources will be developed to support engagement efforts. The Alpha Clinics has developed an intranet for providing visibility to service offerings. CIRM will aim to make utilization of these platforms a condition for achieving program milestones.

   In addition, the Medical Affairs Team proposes an award management approach that includes collaboration across CIRM units. For example, we will include CIRM Education Team and Communication Team in our management plan. We are also recommending additional staffing with expertise in health education and outreach and program planning and evaluation.