

Memorandum

To: Members of the ICOC

From: Rosa Canet-Avilés, Ph.D. Chief Science Officer & Interim Lead, Patient Access and
Geoffrey Lomax, Associate Director Patient Access

Re: Revised Concept Plan, Community Care Centers of Excellence

Date: March 27, 2025

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 promote access across the state, to clinical trials, treatments and cures arising from CIRM-funded research.

In April 2024, CIRM issued the INFR8: CIRM Community Care Centers of Excellence Request for Applications (RFA). After receiving nine completed applications, the results of the GWG/FWG review yielded only one Tier 1 recommendation, and this application focused solely on supporting clinical trials rather than delivery. **As a consequence, and in order to optimize our resources available for the CCCE program, the team has determined a new RFA should be issued to focus solely on treatment delivery to align with Proposition 14's objectives.** This strategic realignment aims to ensure that future investments enhance the geographic distribution of clinical trial sites in CA delivering regenerative medicine while providing a separate funding mechanism for support-focused initiatives.

Concept Plan Proposal:

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.

The program would invite applications from organizations that:

1. Have a demonstrated capacity to conduct clinical trials;
2. Are proposing to conduct regenerative medicine clinical trials and delivery of approved products within the award period;
3. Are located in geographically diverse areas serving underrepresented populations.

CIRM is recommending an allocation of \$36 million for funding of up to four CCCE awards.

Request for Board Action:

We request that the ICOC withdraw the current INFR8 (CCCE) concept plan and adopt the current proposed funding opportunity.