

Frequently Asked Questions

Request for Application Community Care Centers of Excellence

- 1. Are there specific dollar amounts or limits that should be allocated to each of the core functions and activities, i.e. outreach, facilities, patient care, education?**

Specific limits or amounts for the required core activities are not prescribed other than the \$625k for Community Based Partnerships (CBO). The remaining budget may be distributed across these program areas as appropriate to support the proposed activities.

- 2. For the budget allocation \$7.5M vs \$10.054M does this mean only \$3M for facilities or infrastructure or if one is applying to the \$10M category it can be allocated outside the \$3M range?**

Specific limits or amounts for the required core activities or facilities or infrastructure are not prescribed other than the \$625k for Community Based Partnerships (CBO). The remaining budget may be distributed across these program areas as appropriate to support the proposed activities.

- 3. How might an applicant work with an Alpha Clinic that provides services to the CCCE site? Can a CCCE subcontract with an Alpha Clinic?**

Applicants are encouraged to partner with CIRM Clinical Infrastructure Programs. CCCE applicants may subcontract with Alpha Clinics. For example, the Alpha Clinics have developed educational curriculum, patient education tools and other resources that may be applied by the CCCE to support the objectives of this program.

- 4. Can facility improvement be used for future transitioning from a Support to a Support and Delivery Site in the next RFA?**

CIRM's board has only approved the CCCE funding opportunity. Facility improvements must be to support activities and services that take place during the award period. Facilities may continue to be used for this purpose beyond the award period.

- 5. Can an Alpha Clinic support more than one CCCE?**

Yes, CCCE applicants are encouraged to develop collaborations with Alpha Clinic sites. There are no limitations with regard to the number of CCCE applicants an Alpha Clinic can collaborate with. We recommend that the CCCE applicant clearly outline the collaborative initiatives or projects, specifying how they are responsive to the program objectives.

- 6. Can Alpha Clinics personnel dedicate a percentage of their time to support/train CCCEs with community engagement activities?**

Yes, provided such activities are consistent with your existing milestones or within the scope of the Alpha Clinics RFA and you may propose to revise your milestone(s) to

provide such support or training. We recommend you consult with your program officer, as we encourage collaboration, and can work with you to accommodate.

7. Who can be the applicant organization?

The applicant organization should be located in the proposed service area and administer the operations essential for providing clinical trial support and/or delivery. If the applicant organization is proposing to use multiple locations or partners in the service area, the applicant should designate a lead site to coordinate clinical operations. Program Director must be an employee of the applicant organization and maintain an appointment at the lead site. Please note, that the program director cannot have an existing CIRM award that is substantially similar or has overlapping activities pending review or approval under any CIRM opportunity.

8. Can Co-Program Directors arrangement be established? Is it possible for the effort allocation to be shared between Co-Program Directors?

CIRM policy does not allow effort allocation for Program Directors to be shared.

9. Will data need to be shared (uploaded) to CIRM via some sort of portal or reporting mechanism?

All CIRM Clinical Infrastructure Programs are required to capture and report general metrics associated with the recruitment and accrual of patients in clinical trials. Any reporting required by CIRM pursuant to award implementation will be performed via our Grants Management Portal. In addition, applicants should consider strategies or approaches for data or knowledge sharing that can be made available to collaborators and the broader community including returning results to participants, community partners, policy makers and the public.

10. For the training and education component: Does this include lab based training or clinical training (e.g. MD training for cell therapy and regenerative medicine)?

Career development opportunities should advance the knowledge or experience of physicians, nurses, research coordinators, community health workers or other health care professionals that are integral to the education, navigation or delivery of regenerative medicine clinical trials or treatments. Lab-based training should be integral to the delivery of treatments.

11. In terms of the career development and training, would it be acceptable for CCCEs to team up with and share resources with already existing training program for example within CIRM Alpha Clinics?

Applicants are encouraged to collaborate with the Alpha Clinics or CIRM Education programs to adapt, expand, or otherwise utilize established training opportunities.

12. Is there an advantage for our application if there are placements of CIRM scholars and trainees?

Applicants should propose programs for the placement of trainees participating in CIRM-funded education programs. However, trainees should also be appropriate for the type of

career development your institution is best positioned to support regardless of their prior training. Applications proposing to place CIRM Scholars will not be advantaged over other proposals.

13. The RFA allows for a pre-submission consultation. How far in advance must we ask for this prior to the deadline?

You may request a consultation with the CIRM Patient Access Team anytime before application submission. Contact: ccce@cirm.ca.gov

14. Since it is a 5-year grant, will funds be allocated in equal amounts or can funds be granted/allocated at different amounts (depending on actual needs and costs)?

Funds may be allocated at different amounts. The budget proposed in the application should be justified based on actual needs and costs.

15. Can partnerships be with private entities, or must all partnerships be with non-profits?

Community-based organizations designated to be recipients of Community Based Partnership funding (e.g \$625k funding) should be designated as “Community-Based Partners.” A “community-based organization” means a public or private nonprofit organization of demonstrated effectiveness that— (A) is representative of a community or significant segments of a community; and (B) 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.

This requirement does not preclude the applicant from utilizing other award funds towards entering into a partnership agreement with private entities.

16. What sort of accountability and/or reporting will be required for the \$625K partnerships with CBO's?

The RFA references a logic model that includes activities, outputs, outcomes and impacts. Partnership proposals should be well defined utilizing these logic model parameters and consider measures and/or metrics to ensure accountability. Applicants may consider conditioning disbursement of partnership funds on the attainment of milestones consistent with the logic model parameters. Funds will be released by CIRM on receipt of a partnership agreement between the applicant organization and the community- based partner(s) and/or their fiscal agent. These funds can be distributed at the discretion of the applicant organization over the life of the award, and specific partnership agreement do not need to be in place at the time of application.

17. When navigating patients, are referrals limited to CIRM-funded clinical trials being supported by the CIRM Alpha Clinics Network?

A major aim of the RFA is to provide patients access (referrals) to FDA-authorized clinical trials involving cell, gene and/or approved regenerative medicine treatments available within CIRM's Clinical Infrastructure Network and elsewhere.

- Not all CIRM-funded trials are conducted at Alpha Clinic sites so referrals to any site where a CIRM-funded trial is open are encouraged.
- The Alpha Clinics support CIRM-funded and non-CIRM-funded trials. Patients can be referred to any Alpha Clinic supported trial.
- Patients may also be referred to cell, gene or regenerative medicine treatments at an Alpha Clinic host institution that is not being directly supported by the Alpha Clinic (e.g. support may be provided by an NCI-designated Cancer Center). Referrals may be made provided the (1) clinical trial or treatment is FDA-authorized or approved and (2) the treatment includes a cell, gene or regenerative medicine product.

18. Can the center be solely focused on workforce development?

Applicants must propose performance of all the core program activities under this award: clinical trial support, career development and outreach and engagement.

19. Can you please provide more information about the letters of support and the licenses and material transfer agreements?

Letters of support can serve to substantiate the feasibility of your application. Letters from your organization may serve to demonstrate access to all the necessary resources to support the proposal. Letters from proposed partners should demonstrate their commitment to the proposed activities described in the application. Letters from current or previous partners may address your ability to successfully conduct activities described in the application.

Licenses and material transfer agreements document that you can access tools, technologies or other resources integral to the success of your proposed activities.

20. Is there a minimum amount of matching support to receive priority review status (RFP p. 8)? Is a match required for each budget year?

Matching funds are not required but if offered may help demonstrate institutional commitment to this project and potential for sustaining the program beyond the CIRM funding period.

21. Will this equally apply to underserved communities in both rural and urban centers?

The objective of the RFA is to establish geographically diverse and culturally responsive centers to expand equitable access to communities and populations that would otherwise have more limited opportunities in the absence of these centers. The RFA does not distinguish between rural and urban centers.

If you have any questions, email ccce@cirm.ca.gov