CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INFR 8: CIRM Community Care Centers of Excellence (CCCE) FAQs

1. *We are a certified health care organization where clinical trials can be conducted, but they have not been conducted here yet. Do we meet the eligibility criteria?*
   - A: No. For eligibility purposes, the applicant organization must have clinical care sites where clinical trials have been conducted. By extension, these sites would be conducting FDA-authorized clinical trials involving stem cell-based or genetic regenerative medicine therapies over the award period.

2. *We plan to collaborate with a member of an Alpha Clinic in a consulting/advising capacity, and they will not be compensated. Do they need to be mentioned in our application?*
   - A: Individuals who are considered Key Personnel, as defined in the CIRM Common Requirements and Definitions, must be named even if they receive no compensation. Planned collaborators from a community-based organization or CIRM's Alpha Clinics, who do not meet the definition of Key Personnel, can be mentioned in the optional "Information for Review" section of the application. Do not add names to the proposal document that are not listed in the Key Personnel or Information for Review sections.

3. *Does a certain amount of the award need to go towards renovation activities and equipment?*
   - A: No, applicants should request funds for what is needed to operationalize the CCCE. This may include both equipment and renovations, one or the other, or neither.

4. *Our facility needs renovation to deliver cell and gene therapies. Will we still be eligible if we can't deliver on day one?*
   - A: Yes. The award is designed to facilitate the centers in developing those capacities necessary for delivery. Any intended renovations or facility improvements must be detailed using the appropriate template on the application.

5. *The RFA allows for a pre-submission consultation. How far in advance must we ask for this prior to the deadline?*
   - A: You may request a consultation with the CIRM Patient Access Team any time before application submission. Contact: ccce@cirm.ca.gov

6. *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)?*
   - A: 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.

7. *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)?*
   - A: Funds may be allocated at different amounts. The budget proposed in the application should be justified based on actual needs and costs.

8. *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?*
   - A: Applicants are encouraged to collaborate with the Alpha Clinics or CIRM Education programs to adapt, expand, or otherwise utilize established training opportunities.

9. *Can Community Based Partnership funds (e.g. $562,500 budget set aside) be used for contracts with for-profit organizations?*
   - A: No, partnerships can be with public or private entities that are a non-profit organization with a 501(c)(3) status or a fiscally sponsored entity of a 501(c)(3) non-profit organization. See page 7 of the RFA for details.

10. *Do specific Community Based Partnerships need to be proposed at time of application?*
    - A: No, partnerships may be developed over the course of the award, but Community Based Partnership funding must be set aside for this purpose.

11. *If our AOO was verified as part of the initial INFR8 grant application, will they need to go through the verification process again?*
    - A: No, if the AOO is the same individual who was previously verified then they do not need to go through that process again.

12. *For equipment purchases associated with building capacity to launch treatment of cell and gene therapy, does the piece of equipment need to be 100% dedicated to the CIRM INFR8 grant program? What about spaces renovated using INFR8 funding?*
    - A: The equipment or facility should be deployed consistent with the objectives and scope of the RFA. For example, delivery of CGT treatments. In addition, CIRM-related activities (such as a CIRM-funded trial) should be prioritized for equipment or facility utilization.

13. *Are applicants required to build a GMP manufacturing facility for cell and gene therapies as part of this award?*
    - A: No, applicants are not required to develop GMP facilities. In the Scientific Proposal, applicants are asked to describe how they would receive, process and deliver regenerative medicine investigational products or treatments at their proposed site.

14. *Are multiple Program Directors allowed on INFR8 applications?*
    - A: No, for INFR8 there can be only a single Program Director. Additional team members who meet the definition of "Key Personnel" (refer to CIRM Common Requirements & Definitions) can be listed as such, with their role on the team described in that section.

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