Translating Center (TC) FAQ's

Revised June 15, 2016

- Q: Are applications confidential.
  - A: Yes, CIRM keeps all applications confidential and the peer review process is also confidential with all reviewers signing contracts that prohibit disclosure of any proprietary information.
- Q: Are the clients mainly academic investigators / physicians or industry sponsors?
  - A: A list of the current CIRM Grants may be found here: https://www.cirm.ca.gov/grants. The TC will support both academic investigators and industry sponsors.
- Q: Will the TC have to bid on CIRM-sponsored projects?
  - Yes. CIRM-sponsored projects will not be required to use the TC. The TC will need to offer a competitive rate.
- Q: Is the $15 million Translating Center award the sole source of funds available to support CIRM-funded projects.
  - A: The $15M is to fund personnel and operations and a portion of the $15M can be used to offset the reduced rate the TC may offer to CIRM funded projects. Note: The TC will contract directly with CIRM-funded project teams, not CIRM.
- Q: Will funds be provided for upfront startup related costs?
  - A: Yes, as part of TC awarding process, CIRM will work with the successful applicant to develop a budget that include eligible start up costs.
- Q: Is there a co-funding requirement to be eligible for the TC award?
  - A: No, there is no co-funding requirement (this section in the online application may be ignored).
- Q: What are the requirements for California operations? Can work be performed outside CA?
  - The Translating Center must perform operations from a facility located within California. The Center Director and a majority of the Center's dedicated staff must work out of the California facility and any effort for which salary is claimed must be expended in California. The Center Director must commit 100 percent effort to the Center for the first three years of CIRM-funding and no less than 80 percent effort thereafter for the duration of the award.
  - Awardees may use CIRM funds for Allowable Project Activities conducted both in California and outside of California. "Allowable Project Activities" means those activities that are conducted in California and those activities conducted outside of California, provided that: (a) the Awardee exercises direction, supervision and control over the activities and (b) if a separate out-of-state organization performs project activities, that organization does not retain intellectual property or publication rights in any intellectual property (e.g., invention, technology, data) arising out of the CIRM funded project.
- Q: Is the RFA focused on a single source CRO?
  - A: No, a CRO with specialized services may apply assuming they meet the requirements outlined in the RFA. A specialized CRO may also partner with other organizations to provide a competitive proposal.

- Q: Does the Translating Center need to perform all activities listed in the RFA in-house?
    - A: No, the Translating Center may contract out to service providers highly specialized in tasks that the Translating Center core site does not have capability or capacity to do on its own. However, the Translating Center should oversee the work and is ultimately accountable for the service provided. Any proposed consultants or sub-contractors for highly specialized services should be identified in the "Consultants / Sub-contracts / Service Contracts" section of the application.
- Q: Does CIRM own any of the IP of the sponsors that will be conducting the trials?
    - A: No, CIRM does not own any IP. All of the IP resides at the entity or institute which receives CIRM funding.
- Q: Can the TC work with non CIRM-funded clients, or is it limited to working only with CIRM-funded trials?
    - A: The TC may not use CIRM funds to subsidize the direct costs of services provided to non-CIRM funded projects. However, the Translating Center may charge commercially reasonable fees to support other non-CIRM funded projects. As part of the TC's overall and long-term sustainability, the TC is encouraged to work with non CIRM-funded clients in addition CIRM-funded clients.
- Q: Will there be an in-person 'pitch' component to the application process?
    - A: Yes. Eligible applicants will have the opportunity to make an oral presentation at the time of application review. Presentation guidelines will be provided to eligible applicants after receipt of a completed application.
- Q: What CIRM polices / regulations apply to this grant.
    - A. CIRM policies are described in its Grants Administration Policy (GAP). The Clinical GAP broadly represents the terms and conditions of the Award: https://www.cirm.ca.gov/sites/default/files/files/funding_page/Policy_Incorporated_by_100503_010616.pdf
    - A. However, there are specific sections that are not applicable to the Translating Center award, including (1) Application Tiered Scoring and the (2) Loan Conversion.
- Q: If we propose to utilize company employees outside CA to support our operations and we are not creating contracts for this work, are we required to identify these employees as consultants? The Consultants / Subcontracts / Service Contracts grant section requires us to list the use of consultants.
    - A. Consultants are external to the parent organization. Employees from your organization supporting the award outside CA can be identified as organizational assets.
- Q: Are there any restrictions on compensation for TC employees in CA?
    - A. The maximum salary (including bonuses) that can be charged to the CIRM award for a 100% effort is $230k per year. See: https://www.cirm.ca.gov/sites/default/files/files/funding_page/Policy_Incorporated_by_100503_010616.pdf
    - A. In addition, fringe benefits can be charged to the CIRM award in proportion to the salary requested.

- Q. Are there any restrictions on how grant funds can be used (e.g. travel)? Is there a list of approved / non-approved uses?
    - A. Please reference the CIRM Grants Administration Policy

      https://www.cirm.ca.gov/sites/default/files/files/funding_page/Policy_Incorporated_by_100503_010616.pdf

- Q. Where can I find additional information about the services provided by the Accelerating Center to help clarify the coordination efforts with Translating Center?
    - A. You can find additional information about CIRM's Accelerating Center, which was awarded to Quintiles at the following links:
        - Quintiles' presentation to the ICOC: https://www.cirm.ca.gov/sites/default/files/files/agenda/160615_Agenda_Item_%237_Quintiles_CIRM%20AC%20ICOC%20Presentation%20061516.pdf
        - ICOC meeting transcript (starting on p.54): https://www.cirm.ca.gov/sites/default/files/files/agenda/transcripts/ICOC-6-15-16%20Transcript.pdf
    - The scope of services of the Accelerating Center, as outlined in the RFA (which you can find here) include:
        - **Regulatory management services**. Regulatory support, including planning and consultative services necessary to develop supportive preclinical packages; compile and submit successful regulatory applications; design clinical protocols that support clinical development of stem cell treatments, and manage regulatory requirements and interactions necessary to conduct those trials.
        - **Clinical trial operations and management services**. Services that include site selection; patient recruitment and management; logistical support across multiple sites, and coordination of vendors and third party organizations necessary for the efficient conduct of high quality stem cell clinical trials.
        - **Data management, biostatical and analytical services.** Data management (EDC) systems, biostatistics and analytics to enable the generation of high quality, reliable, and statistically sound data from clinical trials. Make available aggregated knowledge to inform researchers and the stem cell community of the best path forward for delivering stem cell treatments to patients.