

## INFRA4 Alpha Clinic Expansion Award FAQ's

Revised April 4, 2017

- **Q: Are applications confidential?**
  - A: Yes, CIRM keeps all applications confidential and the peer review process is also confidential with all reviewers signing contract that prohibit disclosure of any proprietary information.
  
- **Q: Are the Alpha Clinic trial sponsors mainly academic investigators / physicians or industry sponsors?**
  - A: Both, a list of the current Alpha Clinic trials may be found here: <https://www.cirm.ca.gov/patients/alpha-clinics-network/alpha-clinics-trials>.
  
- **Q: Are there any specific requirements for the trials conducted at the Alpha Clinic?**
  - A: Yes. Trials sponsors must hold an IND, and the trial must meet the eligibility criteria for a CIRM [Clinical Trial Stage Projects](#).
  
- **Q: Is there a co-funding requirement?**
  - A: No, there is no co-funding requirement.
  
- **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 our funding.
  
- **Q: Can the Alpha Clinic work with non CIRM-funded trials, or is the Alpha Clinic limited to working only with CIRM-funded trials?**
  - A: As part of the Alpha Clinic's overall and long-term sustainability, it is encouraged to work with non CIRM-funded trials in addition CIRM-funded trials.
  
- **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 policies / 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](https://www.cirm.ca.gov/sites/default/files/files/funding_page/Policy_Incorporated_by_100503_010616.pdf)

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- **Q: When the Alpha Network Sites are at capacity, are they required to provide priority services to CIRM grantees?**
  - A: The Alpha Clinics are expected to maintain a high standard of care that is applied to any trial in the Network regardless of sponsor / funding organization. CIRM does not require the Alpha Clinics to prioritize CIRM grants.
  
- **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](https://www.cirm.ca.gov/sites/default/files/files/funding_page/Policy_Incorporated_by_100503_010616.pdf)
  
- **Q: Academic medical centers may have several hospitals and sites of operation to optimally implement the aims of this RfA. Can we propose a distributed model where several sites constitute the Alpha Clinic?**
  - A: Yes, please describe all assets and infrastructure that can be leveraged into an operation plan for the Alpha Clinic.
  
- **Q. Are there specific requirements for the Training Program such as offer a scholarship to individuals?**
  - A. There are no specific requirements but the program should offer a combination of coursework and practical experience. The applicant should propose a program and structure that would offer training and exposure to physicians and physician scientists in stem cell/cell therapy clinical trials. This should include training in the regulatory process and regulatory requirements, clinical trial design and implementation, quality systems including product release, patient informed consent, safety monitoring and follow-up. Other relevant components could also be added that leverage institutional assets and unique offerings.
  
- **Q. Where in the application should we document our ability to perform stem cell clinical trials?**
  - The Organizational Capacity, Assets and Resources section.