



# Grants Working Group Public Review Summary

*Alpha Stem Cell Clinic for Northern and Central California*

Application Number: INFR4-10314

Review Date: July 25, 2017

Partnering Opportunity to Create a CIRM Alpha Stem Cell Clinic (INFR4)



REVIEW SUMMARY

08.23.17

INFRASTRUCTURE



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## Alpha Stem Cell Clinic for Northern and Central California

**APPLICATION NUMBER: INFR4-10314**

**REVIEW DATE: July 25, 2017**

**REQUEST FOR APPLICATIONS: INFR4 Partnering Opportunity to Create a CIRM Alpha Stem Cell Clinic**

### Application Summary

The Alpha Clinic will provide pivotal resources to assist in the approval & conducting of stem cell/regenerative medicine clinical trials. A centralized space & personnel to administer the therapies to patients in the 33-county catchment region (~6 million people in Northern/Central CA).

Thanks to infrastructure & funding provided by CIRM, stem cell/regenerative medicine clinical trials at our institution are ongoing or recently completed for: HIV, osteopenia, swallowing disorders, retinopathy, disc repair, spine pain, critical limb ischemia, heart disease, non-healing ulcers, burn injuries, cartilage repair & traumatic brain injury. Our outstanding telemedicine program will help other Alpha Clinic sites extend coverage for trials to the northern and central regions of California.

### Funds Requested

\$7,905,671

### Recommendation

Score: 1

Votes for Score 1 = 13 GWG members

Votes for Score 2 = 0 GWG members

Votes for Score 3 = 0 GWG members

- A score of "1" means that the application has exceptional merit and warrants funding;
- A score of "2" means that the application needs improvement and does not warrant funding at this time but could be resubmitted to address areas for improvement if the Application Review Subcommittee has not approved an application for funding following the Grants Working Group's Review;
- A score of "3" means that the application is sufficiently flawed that it does not warrant funding.

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## Review Overview

Reviewers thought that the proposed alpha clinic had several strengths that would enhance the value of the Network. They noted that the clinic would expand geographic reach into northern and central California. The applicant's telemedicine capabilities were a particular strength and would expand patient access to stem cell clinical trials. Reviewers noted that the GMP manufacturing facility is well established and already provides significant value to trial sponsors. Reviewers expressed minor concerns about the Program Director's administrative experience and the application's lack of a detailed contingency plan. Reviewers thought this was a strong application and unanimously recommended it for funding.

## Review Summary

**Will the proposed Alpha Clinic accelerate completion of stem cell therapy clinical trials, enhance the value of the Alpha Stem Cell Clinic Network, and be positioned to be sustainable?**

- a) **Would the proposed clinic accelerate and/or expand patient access to stem cell clinical trials?**
- The proposed clinic's catchment region and excellent telemedicine capabilities will expand patient access to stem cell clinical trials in central and northern California.
  - Centralized clinical trial agreements and fast-tracking IRB processes could modestly accelerate stem cell trials.
- b) **Would the proposed clinic expand the value of the Network, for example, broadening the Network's geographic reach, providing expertise in new disease areas, providing new/unique technical capability, or other elements that accelerate/support stem cell clinical trials. Does the proposed center offer a sufficient, impactful, and practical value proposition for patients, trial sponsors and/or health care providers?**
- The proposed clinic will expand the Network's geographic reach into northern and central California.
  - The applicant runs a well-respected telemedicine program and the utilization of this program for stem cell clinical trials is a particular strength of the proposed clinic.
  - The well-established GMP manufacturing facility will provide significant value to the Network.
- c) **Is the proposed clinic positioned to be sustainable beyond four years?**
- The clinic is positioned to be sustainable beyond four years.
  - The applicant has good business plans to generate revenue from its core facilities.

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**Has the applicant developed a plan designed to successfully establish and operationalize the Alpha Clinic?**

**a) Does the project plan and timeline for establishing the center, conducting clinical trials, and implementing the pipeline development plan demonstrate an urgency that is commensurate with CIRM's mission?**

- The project plan and timeline demonstrate an urgency that is commensurate with CIRM's mission.

**b) Does the application propose all required core activities (including the Fellows Program) and are they appropriately designed to meaningfully enhance the value of the Network?**

- The application proposed all required core activities.
- The fellows program will provide comprehensive training in stem cell therapy clinical trials.

**c) Is the operation of the clinic appropriately planned and designed to provide meaningful, accelerating, and impactful resources dedicated to stem cell clinical trials?**

- The applicant has extensive experience in navigating IND pathways and operationalizing clinical trials.
- The applicant provided sufficient short-term and long-term plans to expand the capacity of the GMP manufacturing facility.

**Is the proposal feasible?**

**a) Is the proposed plan, including the fellows program and pipeline development plan, feasible and likely to be implemented within the proposed timeline?**

- The proposed plan is feasible and likely to be implemented within the proposed timeline.

**b) Is the proposed team appropriately qualified and staffed and have access to all the necessary resources to establish, operate, and maintain the clinic?**

- There were concerns about the Center Director's lack of deep administrative experience but reviewers noted that the breadth of experience provided by the rest of the team was especially strong.

**c) Will the clinic have the capability and resources to provide the required core services to support stem cell clinical trials?**

- The infrastructure for the proposed clinic is already operational and the clinic will be co-located with the applicant's well-respected Clinical and Translational Science Center.

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**d) Does the team have a viable contingency plan to manage risks and delays?**

- The team did not provide a comprehensive contingency plan to manage potential risks and delays but did indicate that the applicant institution would provide funding.